
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 20-F

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2019

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____.

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report _____

For the transition period from _____ to _____.

Commission file number: 001-38452

MEREO BIOPHARMA GROUP PLC

(Exact name of Registrant as specified in its charter)

England and Wales
(Jurisdiction of incorporation or organization)

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(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
American Depositary Shares, each representing five ordinary shares, nominal value of £0.003 per share	MREO	The Nasdaq Stock Market LLC
Ordinary Shares, nominal value of £0.003 per share		The Nasdaq Stock Market LLC*

* Not for trading, but only in connection with the registration of American Depositary Shares representing such Ordinary Shares pursuant to the requirements of the U.S. Securities and Exchange Commission.

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

The number of outstanding shares as of December 31, 2019 was:

<u>Title of each class</u>	<u>Number of Shares Outstanding at December 31, 2019</u>
Ordinary shares, nominal value of £0.003 per share	97,959,622

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes No

Note – Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or an emerging growth company (as defined in Rule 12b-2 of the Act).

Large Accelerated Filer Accelerated Filer Non-accelerated Filer
Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act.

† The term “new or revised financial accounting standard” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP International Financial Reporting Standards as issued by the International Accounting Standards Board Other

If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

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RELIANCE ON SEC ORDER

Mereo BioPharma Group plc, or the Company, is filing its Annual Report on Form 20-F for the fiscal year ended December 31, 2019, or the 2019 Annual Report, pursuant to the Securities and Exchange Commission's, or SEC, Order under Section 36 of the Securities Exchange Act of 1934 Modifying Exemptions from the Reporting and Proxy Delivery Requirements for Public Companies dated March 25, 2020 (Release No. 34-88465).

As set forth in the Company's Form 6-K furnished to the SEC on April 28, 2020, the Company was unable to file the 2019 Annual Report within the prescribed time period because, as a result of the outbreak of the novel coronavirus, or COVID-19, the Company experienced disruptions to operations in terms of travel and limited access to the Company's facilities resulting in an impact to staff's ability to carry out some of their usual work. Potential investors and business partners also faced increased challenges resulting from COVID-19 which affected their ability to complete the processes necessary to move ahead with an investment or partnership decision because of COVID-19's impact on their business. As a result of these factors, the 2019 Annual Report was not completed by the filing deadline.

CERTAIN DEFINITIONS

Unless otherwise indicated and except where the context otherwise requires, references in this annual report on Form 20-F to:

- "ADSs" are to our American Depositary Shares, each of which represents five ordinary shares of Mereo BioPharma Group plc;
- "ADRs" are to the American Depositary Receipts that evidence our ADSs;
- "Exchange Act" are to the United States Securities Exchange Act of 1934, as amended;
- "FDA" are to the United States Food and Drug Administration;
- "Mereo," the "Company," "we," "our," "ours," "us" or similar terms are to Mereo BioPharma Group plc, together with its subsidiaries;
- the "Merger" are to the merger of Mereo MergerCo One Inc. and OncoMed Pharmaceuticals, Inc., with OncoMed Pharmaceuticals, Inc. surviving as a wholly-owned subsidiary of Mereo US Holdings Inc., and as an indirect wholly-owned subsidiary of Mereo BioPharma Group plc;
- the "Merger Agreement" are to the Agreement and Plan of Merger and Reorganization, dated December 5, 2018, by and among Mereo BioPharma Group plc, Mereo US Holdings Inc., Mereo MergerCo One Inc. and OncoMed Pharmaceuticals, Inc.;
- "ordinary shares" are to our ordinary shares, each of £0.003 nominal value;
- "SEC" are to the United States Securities and Exchange Commission;
- "Securities Act" are to the Securities Act of 1933, as amended;
- "\$," "USD," "US\$" and "U.S. dollar" are to the United States dollar; and
- "£," "GBP," "pound sterling," "pence" and "p" are to the British pound sterling (or units thereof).

PRESENTATION OF FINANCIAL INFORMATION

This annual report contains our audited consolidated financial statements as of December 2018 and 2019 and for the years ended December 31, 2017, 2018 and 2019 (our "audited consolidated financial statements"), prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"). Our financial information is presented in pound sterling. None of our financial statements were prepared in accordance with generally accepted accounting principles in the United States.

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This annual report contains translations of certain pound sterling amounts into U.S. dollars at specified rates solely for the convenience of the reader. These translations should not be construed as representations that the pound sterling amounts actually represent such U.S. dollar amounts or could be converted into U.S. dollars at the rate indicated. Unless otherwise indicated, such U.S. dollar amounts have been translated from pound sterling at an exchange rate of £0.7692 to US\$1.00, the exchange rate for pound sterling on December 31, 2019.

USE OF TRADEMARKS, SERVICE MARKS AND TRADENAMES

“Mereo,” the Mereo logo and other trademarks, trade names or service marks of Mereo appearing in this annual report are the property of Mereo. This Form 20-F also contains trade names, trademarks and service marks of others, which are the property of their respective owners. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

This annual report contains additional trademarks, service marks, and trade names of others, which are the property of their respective owners. All trademarks, service marks, and trade names appearing in this annual report are, to Mereo’s knowledge, the property of their respective owners. Mereo does not intend its use or display of other companies’ trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of Mereo by, any other companies.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains statements that constitute forward-looking statements (including within the meaning of the U.S. Private Securities Litigation Reform Act of 1995). Many of the forward-looking statements contained in this annual report can be identified by the use of forward-looking words such as “anticipate,” “believe,” “could,” “expect,” “foresee,” “should,” “plan,” “intend,” “estimate,” “would,” “may,” “outlook,” and “potential,” among others. The absence of these words, however, does not mean that the statements are not forward-looking.

Forward-looking statements appear in a number of places in this annual report and include, but are not limited to, statements regarding intent, belief or current expectations. Forward-looking statements are based on the current beliefs and assumptions of the management of Mereo and on information currently available to such management. While the management of Mereo believes that these forward-looking statements are reasonable as and when made, there can be no assurance that future developments will be as anticipated. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to of various factors, including, but not limited to, those identified under the section “Item 3. Key Information—D. Risk Factors” in this annual report. These risks and uncertainties include factors relating to:

- the development of our product candidates, including statements regarding the expected initiation, timing, progress, and availability of data from our clinical trials;
- the potential attributes and benefits of our product candidates and their competitive position;
- our ability to successfully commercialize, or enter into strategic relationships with third parties to commercialize, our product candidates, if approved;
- our estimates regarding expenses, future revenues, capital requirements, and our need for additional financing;
- our being subject to ongoing regulatory obligations if our products secure regulatory approval;
- our reliance on third parties to conduct our clinical trials and on third-party suppliers to supply or produce our product candidates;
- the patient market size of any diseases and market adoption of our products by physicians and patients;

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- our ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights;
- the duration of our patent portfolio;
- the COVID-19 pandemic and the associated disruptions that could materially impact our business including planned clinical developments;
- the United Kingdom’s withdrawal from the European Union could lead to increased market volatility, make it more difficult for us to do business in Europe or have other adverse effects on our business;
- our ability to retain key personnel and recruit additional qualified personnel;
- our ability to manage growth;
- our ability to successfully integrate and realize the benefits of our past or future strategic acquisitions or investments; and
- other risk factors discussed under “Item 3. Key Information—D. Risk Factors”.

Our actual results or performance could differ materially from those expressed in, or implied by, any forward-looking statements relating to those matters. Accordingly, no assurances can be given that any of the events anticipated by the forward-looking statements will transpire or occur, or if any of them do so, what impact they will have on our results of operations, cash flows or financial condition. Except as required by law, we are under no obligation, and expressly disclaim any obligation, to update, alter or otherwise revise any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future events or otherwise.

PART ONE

Item 1. Identity of Directors, Senior Management And Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

3.A. Selected Financial Data

The selected historical consolidated financial information for the years ended December 31, 2016, 2017, 2018 and 2019 and the selected statements of financial position data as of December 31, 2016, 2017, 2018 and 2019 have been derived from, and should be read in conjunction with, the audited consolidated financial statements of Mereo BioPharma Group plc and notes thereto appearing elsewhere in this annual report.

The information presented below is qualified by the more detailed historical consolidated financial statements set forth in this annual report, and should be read in conjunction with those consolidated financial statements, the notes thereto and the discussion under “Item 5. Operating and Financial Review and Prospects” included elsewhere in this annual report.

We have not included selected historical consolidated financial data for the years ended December 31, 2015 in the table below as we qualify as an emerging growth company (an “Emerging Growth Company”) as defined in Section 2(a)(19) of the Securities Act, we make use of an accommodation for reduced reporting.

Consolidated Statements of Comprehensive Loss Data

	Year Ended December 31,			
	2016	2017	2018	2019
	(in thousands of pounds, except per ordinary share data)			
Consolidated Statement of Comprehensive Loss Data:				
Research and development expenses	(24,563)	(34,607)	(22,703)	(23,608)
General and administrative expenses	(11,617)	(10,697)	(11,775)	(15,909)
Operating loss	(36,180)	(45,304)	(34,478)	(39,517)
Net income recognized on acquisition of subsidiary	—	—	—	1,035
Finance income	375	827	307	377
Finance charge	(180)	(1,090)	(3,091)	(3,496)
Net foreign exchange gain/(loss)	2,263	(1,384)	(44)	483
Net loss before tax	(33,722)	(46,951)	(37,306)	(41,118)
Taxation	5,331	8,152	5,277	6,274
Loss attributable to equity holders of the parent	(28,391)	(38,799)	(32,029)	(34,844)
<i>Other comprehensive income – items that may be reclassified to profit or loss</i>				
Net fair value gain / (loss) on investments in debt instruments held at fair value	—	—	—	—
Exchange differences on translation of foreign operations	—	—	—	(499)
Other comprehensive income, net of tax	—	—	—	(499)
Total, comprehensive income attributable to equity holders of the parent	(28,391)	(38,799)	(32,029)	(35,343)
Basic and diluted loss per share	(0.63)	(0.56)	(0.45)	(0.39)

Consolidated Statements of Financial Position Data

	As of December 31,			
	2016	2017	2018	2019
	(in thousands of pounds)			
Consolidated Balance Sheets Data:				
Cash and short-term deposits and short-term investments	53,578	52,545	27,542	16,347
Total assets	86,765	96,335	67,276	86,449
Issued capital	193	213	214	294
Share premium	99,975	118,227	118,492	121,684
Accumulated loss	(40,579)	(79,316)	(111,221)	(146,065)
Total equity	79,257	62,483	32,771	40,256
Total liabilities	7,508(1)	33,852(2)	34,505(3)	46,193
Total equity and liabilities	86,765	96,335	67,276	86,449

- (1) Includes £3.1 million aggregate principal amount of, and accrued interest on, the Novartis Notes. See “Item 5. Operating and Financial Review and Prospects—B. Liquidity and Capital Resources—Indebtedness—Novartis Notes.”
- (2) Includes £2.0 million aggregate principal amount of, and accrued interest on, the Novartis Notes. See “Item 5. Operating and Financial Review and Prospects—B. Liquidity and Capital Resources—Indebtedness—Novartis Notes.”
- (3) Includes £2.0 million aggregate principal amount of, and accrued interest on, the Novartis Notes. See “Item 5. Operating and Financial Review and Prospects—B. Liquidity and Capital Resources—Indebtedness—Novartis Notes.”

3.B. Capitalization and Indebtedness

Not applicable.

3.C. Reasons For the Offer and Use of Proceeds

Not applicable.

3.D. Risk Factors

You should carefully consider the risks and uncertainties described below, together with the other information contained in this annual report, before making any investment decision. Any of the following risks and uncertainties could have a material adverse effect on our business, prospects, results of operations and financial condition. The market price of our ordinary shares and ADSs could decline due to any of these risks and uncertainties, and you could lose all or part of your investment. The risks described below are those that we currently believe may materially affect us. We may face additional risks and uncertainties not currently known to us or that we currently deem to be immaterial.

Risks Related to Our Business and Industry

We have a limited operating history and have never generated any product revenue.

We are a multi-asset, clinical-stage biopharmaceutical company with a limited operating history, and have incurred significant operating losses since our formation. We had net losses of £34.8 million, £32.0 million and £38.8 million, in the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated net loss of £146.1 million (£111.2 million as of December 31, 2018). Our losses have resulted principally from expenses incurred from the research and development of our product candidates and from general and administrative costs that we have incurred while building our business infrastructure. We expect to continue to incur significant operating losses for the foreseeable future as we expand our research and development efforts, and seek to obtain regulatory approval and potentially commercialize our product candidates. We anticipate that our expenses will increase substantially as we:

- prepare to conduct our Phase 1b trial of etigilimab in oncology indications;
- continue to conduct our ongoing Phase 2 clinical trial of alvelestat for the treatment of severe AATD;
- continue to conduct our ongoing Phase 2b clinical trial of setrusumab for the treatment of OI, which currently involves a 12-month period during which the off-effects of setrusumab will be examined following the top-line data read out in 2019;
- plan for a strategic partnership for the development of setrusumab prior to a pivotal trial of setrusumab in the United States, Europe and Canada in children with severe OI in 2020, with fracture rate as the primary endpoint;
- seek regulatory approvals for our product candidates;
- potentially establish a commercial infrastructure and work with contract manufacturing organizations (“CMOs”) to scale up manufacturing processes to commercialize or co-commercialize selected product candidates, if approved;
- maintain, expand, and protect our intellectual property portfolio;
- secure, maintain, or obtain freedom to operate for our technologies and product candidates;
- add clinical, scientific, operational, financial, and management personnel, including personnel to support the development of our product candidates and potential future commercialization or co-commercialization efforts;
- expand our operations in the United Kingdom and potentially hire additional employees in the United States and in Europe, territories where we anticipate direct commercialization or commercialization with a partner; and
- seek to acquire additional novel product candidates to treat oncology and rare diseases;

Our expenses may also increase substantially if we experience any delays or encounter any issues with any of the above, including, but not limited to, failed clinical trials, complex results, safety issues, or unforeseen regulatory challenges.

We have devoted substantially all of our financial resources and efforts to the acquisition and clinical development of our product candidates. We have not completed the clinical development of any product through approval and have never generated any product revenue.

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To become and remain profitable, we must succeed in developing and commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials of our current or any future product candidates, obtaining regulatory approval for our product candidates that successfully complete clinical trials, establishing manufacturing supplies and marketing capabilities, and ultimately commercializing or entering into strategic relationships for our current and future product candidates, if approved. We are only in the preliminary stages of many of these activities. We may never succeed in these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. We may be subject to different or contradictory regulatory requirements in different countries, and different regulatory authorities may not be aligned on the clinical trials necessary to support approval of our product candidates. If we are required by the FDA, the EMA, or other regulatory authorities to perform studies in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of our current product candidates, our expenses could increase and our ability to generate revenue could be further delayed. In addition, we may not be able to acquire new product candidates or may encounter unexpected difficulties or delays in such acquisitions, which would impair our business.

Furthermore, adoption by the medical community of our product candidates, if approved, may be limited if third-party payors offer inadequate reimbursement coverage. Cost control initiatives may decrease coverage and payment levels for our product candidates, which in turn would negatively affect the price that we will be able to charge for such product candidates. We are unable to predict the coverage that will be provided by private or government payors for any product we have in development. Any denial of private or government payor coverage, inadequate reimbursement for our product candidates, or delay in receipt of reimbursement payments could harm our business and, even if we do generate product royalties or product sales, we may never achieve or sustain profitability. Our failure to sustain profitability would depress the market price of our ADSs and ordinary shares and could impair our ability to raise capital, acquire new product candidates, expand our business, or continue our operations. A decline in the market price of our ADSs or ordinary shares also could cause you to lose all or a part of your investment.

We will need additional funding to complete the development of our current product candidates; to license, acquire, and develop future product candidates; and to commercialize our product candidates, if approved. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate research and development programs, any future commercialization efforts or acquisitions of potential product candidates.

While we raised \$81 million in private placement transactions in 2020, we expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue to advance our oncology and rare disease portfolio. In addition, if we obtain marketing approval for product candidates where we retain commercial rights, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Furthermore, we expect to incur additional costs associated with operating as a public company in the United Kingdom and the United States and maintaining a quotation and listing, respectively, on the AIM and Nasdaq. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We believe that our existing cash and cash equivalents will be sufficient to enable us to fund our operating expenses, capital expenditure requirements and debt repayment requirements to the start of 2022 at which point we will require additional capital. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition.

We have based our liquidity and capital resources estimates on assumptions that may prove to be wrong. As a result, we could use our capital resources sooner than we currently expect, or our operating plan may change as a result of many factors unknown to us. These factors, among others, may necessitate that we seek additional capital sooner than currently planned.

Our future capital requirements will depend on many factors, including:

- the costs, timing, and results of our planned Phase 1b trial for etigilimab, our ongoing Phase2b extension trial for setrusumab and our ongoing Phase 2 clinical trial for alvelestat;
- the costs and timing of manufacturing clinical supplies of our product candidates;
- the costs, timing, and outcome of regulatory review of our product candidates, including post-marketing studies that could be required by regulatory authorities;
- the costs, timing, and outcome of potential future commercialization activities, including manufacturing, marketing, sales, and distribution, for our product candidates that we commercialize directly;
- the timing and amount of revenue, if any, received from commercial sales of our product candidates;
- the costs and timing of preparing, filing, and prosecuting patent applications; maintaining and enforcing our intellectual property rights; and defending any intellectual property-related claims, including any claims by third parties that we are infringing, misappropriating or otherwise violating the third party's intellectual property rights;
- the sales price and availability of adequate third-party coverage and reimbursement for our product candidates;
- the effect of competitors and market developments;
- the extent to which we are able to acquire new product candidates or enter into licensing or collaboration arrangements for our product candidates, although we currently have no commitments or agreements to complete any such transactions;
- milestone and deferred payments under our license and option agreement with AstraZeneca; and
- our ability to satisfy HMRC's enquiries with respect to claims in respect of fiscal year 2019 and future years.

Fundraising and business development efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect our business, the holdings or the rights of our shareholders, or the value of our ADSs and ordinary shares.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay, or discontinue our research and development programs or any commercialization efforts; be unable to expand our operations or acquire product candidates; or be unable to otherwise capitalize on our business opportunities, as desired, which could harm our business.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Since our formation, we have devoted substantially all of our resources to acquiring our product candidates and developing setrusumab, alvelestat, acumapimod, leflutroazole; building our intellectual property portfolio; developing our supply chain; planning our business; raising capital; and providing general and administrative support for these operations. Additionally, prior to our acquisition of etigilimab and navicixizumab in the merger with OncoMed, OncoMed had invested significant resources to developing both product candidates. We have not yet demonstrated our ability to successfully complete any Phase 3 or other pivotal clinical trials, obtain regulatory approval, arrange for third parties to manufacture commercial-scale product candidates, or conduct or partner with others to conduct sales and marketing activities necessary for successful product commercialization. Additionally, although we have acquired product candidates from two large pharmaceutical companies, we have not demonstrated the sustainability of our business model of acquiring and developing product candidates from, and becoming a partner of choice for, large pharmaceutical companies, nor have we demonstrated our ability to obtain approvals for or to commercialize or co-commercialize these product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We may not be successful in our efforts to identify and acquire additional product candidates.

Part of our strategy involves identifying and acquiring novel product candidates that have received significant investment from large pharmaceutical and biotechnology companies and that have substantial pre-clinical, clinical,

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and manufacturing data packages. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- any product candidates we acquire that have generated positive clinical data for our target indication or in diseases other than our target indications may not prove to be effective in treating our target indications;
- potential product candidates may, with further studies, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be product candidates that will receive marketing approval and achieve market acceptance;
- the regulatory pathway for a potential product may be too complex and difficult to navigate successfully or economically; and
- there may be competitive bids for potential product candidates which we do not seek to or are unable to match.

In addition, we may choose to focus our efforts and resources on a potential product that ultimately proves to be unsuccessful. Further, time and resources spent searching for, identifying, acquiring, and developing potential product candidates may distract our management's attention from our primary business or other development programs. If we are unable to identify and acquire additional suitable product candidates for clinical development, this would adversely impact our business strategy and our financial position and share price.

Raising additional capital may cause dilution to, or adversely affect the rights of, our security holders, restrict our operations; or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we may seek to finance our cash needs through securities offerings, debt financings, license and collaboration agreements, or other capital raising transactions. If we raise capital through securities offerings, your ownership interest will be diluted, and the terms of the securities we issue in such transaction may include liquidation or other preferences that adversely affect your rights as a holder of our ADSs. Debt financing, if available, could result in fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, to acquire, sell or license intellectual property rights, to make capital expenditures, to declare dividends, or other operating restrictions. For example, our credit facility with Silicon Valley Bank and Kreos Capital V (UK) Limited (the "credit facility") requires us to seek consent for certain corporate transactions, dispositions, or incurrences of certain debt. In addition, the credit facility is secured by substantially all of our assets, including intellectual property rights owned or controlled by us. In addition, if the resolutions relating to the June 2020 Private Placement (as described below) are not passed on or before August 7, 2020 the convertible notes will not convert into ordinary shares, the warrants will not become capable of exercise and the holders of the convertible notes and warrants will become entitled to certain amounts (up to \$137.1 million) that will represent material liabilities for the Company. If we raise additional funds through collaboration or licensing agreements, we may have to relinquish valuable rights to our technologies, future revenue streams, or product candidates or grant licenses on terms that may not be favorable to us. In addition, we could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our security holders, and may cause the market price of our ADSs and ordinary shares to decline.

We depend heavily on the success of etigilimab, setrusumab, alvelestat, acumapimod, leflutrolole and navicixizumab. We cannot give any assurance that any of these product candidates or therapeutic candidates will receive regulatory approval, which is necessary before they can be commercialized. If we are unable to commercialize, whether on our own or through agreements with third parties, etigilimab, setrusumab, alvelestat, acumapimod and leflutrolole or experience significant delays in doing so, our ability to generate revenue and our financial condition will be adversely affected.

We do not currently generate any revenue from sales of any product candidates, and we may never be able to develop or commercialize a marketable product. We have invested substantially all of our efforts and financial resources in the acquisition and development of etigilimab, setrusumab, alvelestat, acumapimod, leflutrolole and navicixizumab. Our ability to generate royalty and product revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of our current product candidates, if approved, which may never occur. Our current product candidates will require additional clinical development, management of clinical and manufacturing activities, regulatory approval in multiple jurisdictions, procurement of manufacturing supply, commercialization, substantial additional investment, and significant marketing efforts before we generate any revenue from product sales.

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We are not permitted to market or promote any product candidates in the United States, Europe, or other countries before we receive regulatory approval from the FDA, the EMA, or comparable foreign regulatory authorities, and we may never receive such regulatory approval for our current product candidates. We have not submitted a BLA or a New Drug Application (“NDA”) to the FDA, an MAA or CMA to the EMA, or comparable applications to other regulatory authorities, and do not expect to be in a position to do so in the foreseeable future. The success of our current product candidates will depend on many factors, including the following:

- we may not be able to demonstrate that any of our current product candidates is safe and effective as a treatment for the targeted indications to the satisfaction of the applicable regulatory authorities;
- the applicable regulatory authorities may require additional clinical trials of our current product candidates, which would increase our costs and prolong development;
- the results of clinical trials of our current product candidates may not meet the level of statistical or clinical significance required by the applicable regulatory authorities for marketing approval;
- the applicable regulatory authorities may disagree with the number, design, size, conduct, or implementation of our planned and future clinical trials for our current product candidates;
- the contract research organizations (“CROs”), that we retain to conduct clinical trials may take actions outside of our control that materially adversely impact clinical trials for our current product candidates;
- the applicable regulatory authorities may not find the data from clinical trials sufficient to demonstrate that the clinical and other benefits of our current product candidates outweigh their safety risks;
- the applicable regulatory authorities may disagree with our interpretation of data from our clinical trials or may require that we conduct additional trials;
- the applicable regulatory authorities may not accept data generated at our clinical trial sites;
- if we submit a BLA or NDA to the FDA, and it is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling, or distribution and use restrictions;
- the applicable regulatory authorities may require development of a risk evaluation and mitigation strategy (a “REMS”) as a condition of approval;
- the applicable regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers;
- the applicable regulatory authorities may change their approval policies or adopt new regulations;
- through our clinical trials, we may discover factors that limit the commercial viability of our current product candidates or make the commercialization of any of our current product candidates unfeasible; and
- if approved, acceptance of our current product candidates by patients, the medical community, and third-party payors; our ability to compete with other therapies to treat certain oncology indications, OI, AATD, AECOPD or HH; continued acceptable safety profiles following approval of our current product candidates; and our ability to qualify for, maintain, enforce, and defend our intellectual property rights and claims.

If we do not successfully manage one or more of these factors in a timely manner or at all, we could experience significant delays or may not be able to successfully commercialize our current product candidates.

We cannot be certain that our current product candidates will be successful in clinical trials or receive regulatory approval. Further, our current product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our current product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to manufacture and market our current product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such product candidates, if approved.

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We plan to seek regulatory approval to commercialize, or co-commercialize, our current rare disease product candidates both in the United States and the European Union (“EU”), and potentially in additional foreign countries. While the scope of regulatory approval is similar in many countries, to obtain separate regulatory approval in multiple countries requires us to comply with the numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution, and we cannot predict success in these jurisdictions.

Our business is subject to economic, political, regulatory and other risks associated with international operations.

Our business is subject to risks associated with conducting business internationally. We source research and development, manufacturing, consulting, and other services from companies based throughout the United States, the EU, and Switzerland, and we conduct our clinical trials in the United States, Canada, certain European countries, and other countries. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.K. economies and markets;
- differing regulatory requirements for drug approvals in non-U.K. countries;
- differing jurisdictions could present different issues for securing, maintaining, or obtaining freedom to operate for our intellectual property in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with non-U.K. laws and regulations;
- changes in non-U.K. regulations and customs, tariffs, and trade barriers;
- changes in non-U.K. currency exchange rates of the pound sterling and currency controls;
- changes in a specific country’s or region’s political or economic environment, including the implications of the United Kingdom’s withdrawal from the EU;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.K. or non-U.K. governments;
- differing reimbursement regimes and price controls in certain non-U.K. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling outside of the United Kingdom;
- workforce uncertainty in countries where labor unrest is more common than in the United Kingdom;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- business interruptions resulting from geo-political actions, including war and terrorism, health epidemics and other widespread outbreaks of contagious disease, or natural disasters, including earthquakes, typhoons, hurricanes, floods, and fires; and
- business interruptions resulting from the COVID-19 pandemic or any other similar pandemic.

Exchange rate fluctuations may materially affect our results of operations and financial condition.

Owing to the international scope of our operations, fluctuations in exchange rates, particularly between the pound sterling and the U.S. dollar, the euro, or the Swiss Franc, may adversely affect us. Further, potential future revenue may be derived from multiple jurisdictions and in multiple currencies. As a result, our business and the price of our ADSs and ordinary shares may be affected by fluctuations in foreign exchange rates not only between the pound sterling and the U.S. dollar, but also the currencies of other countries, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

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The COVID-19 pandemic or any other similar pandemic may materially impact our business including planned clinical developments and our ongoing clinical studies.

The outbreak of COVID-19 has developed into a global pandemic, spreading to most regions of the world including the United States and the United Kingdom and to locations where we have facilities or ongoing clinical trials. The pandemic has resulted in impacts both direct and indirect to businesses including disruptions to resources, inability of workers to carry out their jobs effectively, disruptions to supply chains, inability to travel and increased pressure on health systems required to treat COVID-19.

As a result of government and local regulation we have been required to introduce a work from home policy for the large majority of our work force and our facilities remain open only for business critical activities. The requirement by governments to stay at home or to “social distance” limits normal communications and may also increase cyber security risk or create data accessibility concerns. It also significantly curtails the numbers of individuals who can work in our offices.

COVID-19 has created an unprecedented burden on health systems in impacted countries around the world. As a result, clinical centers have diverted resources away from the performance of clinical trials and because of that and the vulnerability of patients in the Company’s etigilimab development program for selected solid tumors, setrusumab clinical development program for osteogenesis imperfecta (OI) and its Phase 2 alvelestat program for patients with severe alpha-1 antitrypsin deficiency (AATD), the Company’s clinical activities will face some delays. AATD patients, in particular, are at greater risk from COVID-19 given that the condition is a respiratory and lung condition, for this reason, our Phase 2 alvelestat trial will be delayed with topline data now expected in the second half of 2021. Subject to a partnership, we are also currently planning to initiate a Phase 3 study in children with OI in late 2020, however, the initiation of the study may also be delayed.

As a result of the COVID-19 pandemic and depending on the length of such pandemic, we may experience disruptions that would significantly impact our business including:

- A delay or interruption in our ability to enroll and treat patients and to obtain data from ongoing clinical trials;
- A delay in our timelines for the initiation of new clinical trials;
- A delay in our ability to further recruit patients to our clinical trials and to screen patients for eligibility for our clinical trials;
- Interruption to key clinical trial activities including monitoring of clinical sites, patient visits, inability to follow patients after they have received treatment and patient assessments;
- A delay in our ability to close and negotiate third party partnerships or collaborations or to progress third party collaborations already in place;
- Limitations on employee resources as a result of increased sickness, requirement for employees to care for family members or requirement for employees to self-isolate themselves;
- Interruptions and delays in our development programs as a result of the government required “stay at home” guidelines;
- Delay in responses from regulatory authorities in relation to approvals, amendments or other regulatory engagements required for our ongoing development activities; or
- Supply chain interruptions.

The COVID-19 pandemic continues to rapidly evolve and the extent to which it may impact our future business is highly uncertain and difficult to predict. In particular it is not currently known how long travel restrictions and social distancing/isolation requirements will continue to apply in the countries in which we operate and the impact on global health systems, financial markets or the economy as a whole is not yet known.

The United Kingdom's withdrawal from the European Union could lead to increased market volatility, which could adversely impact the market price of our ADSs and make it more difficult for us to do business in Europe or have other adverse effects on our business.

The United Kingdom formally exited the European Union, commonly referred to as Brexit, on January 31, 2020. Under the terms of its departure, the United Kingdom will enter a transition period during which it will continue to follow all European Union rules and the trading relationship will remain the same. The transition period is scheduled to end on December 31, 2020. The long term effects of Brexit will depend on the agreements and arrangements the United Kingdom negotiates with the European Union, including whether and to what extent it will retain access to the European Union markets following the transition period. There will be a period of considerable uncertainty particularly in relation to United Kingdom financial and banking markets as well as on the regulatory process in Europe as these negotiations continue to unfold. As a result of this uncertainty, financial markets could experience volatility which could adversely affect the market price of our ADSs. Depending on the final terms of any agreements and arrangements negotiated with the European Union, we may also face new regulatory costs and challenges that could have a material adverse effect on our operations, including the potential for a delay in our clinical progress and approvals in Europe. Depending on the terms of any agreements and arrangements negotiated with the European Union, the United Kingdom could lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers that could make our doing business worldwide more difficult. In addition, currency exchange rates in the pound sterling and the euro with respect to each other and the U.S. dollar have already been adversely affected by Brexit. Should this foreign exchange volatility continue it could cause volatility in our financial results.

Following the Licensing Agreement for Navi, and if we sell or out-license our non-oncology/non-rare disease product candidates or out-license any of our oncology or rare disease product candidates for any territories, we could be exposed to future liabilities.

Having recently completed the out-license of Navi, we plan to partner or sell or out-license our non-oncology/non-rare disease product candidates, which include acumapimod for the treatment of AECOPD and leflutrolole for the treatment of infertility and HH in obese men, recognizing the need for a larger sales infrastructure and greater resources to take these product candidates to market. We also plan to form a strategic partnership for setrusumab prior to initiation of the pivotal study in children with OI.

We may be exposed to future liabilities and/or obligations with respect to any such sale or out-licensing arrangements or partnerships. We may be required to set aside provisions for warranty claims or contingent liabilities in respect of such sales or out-licensing arrangements. We may be required to pay damages (including, but not limited to, litigation costs) to a purchaser or licensee to the extent that any representations or warranties that we had given to that purchaser or licensee prove to be inaccurate or to the extent that we have breached any of our covenants or obligations contained in the disposal documentation. In certain circumstances, it is possible that any incorrect representations and warranties could give rise to a right by the purchaser or licensee to unwind the contract in addition to receiving damages. Furthermore, we may become involved in disputes or litigation in connection with such product candidates. Certain obligations and liabilities associated with our prior management of the development of any disposed product candidate can also continue to exist notwithstanding any sale, such as liabilities arising from the infringement of intellectual property rights of others.

As a result of the above, the total amount of costs and expenses that may be incurred with respect to liabilities associated with a sale or out-license may exceed our expectations, and we may experience other unanticipated adverse effects, all of which could adversely affect our business, financial condition, results of operations, and prospects.

Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval

Etigilimab, setrusumab, alvelestat, acumapimod and leflutrolole are in clinical development. Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results. If clinical trials of our product candidates are prolonged or delayed, or if our product candidates fail to show the desired safety and efficacy in later stage clinical trials, we may be unable to obtain required regulatory approvals and be unable to commercialize, or co-commercialize, our product candidates on a timely basis, or at all.

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To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive clinical trials that such product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful.

We may experience delays in our ongoing clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Our clinical trials can be delayed, suspended, or terminated for a variety of reasons, including the following:

- delays in or failure to obtain regulatory or ethics committee approval to commence a trial, for example, if we are unable to submit our proposed protocol to the FDA for the Phase 1b for etigilimab;
- delays in or failure to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure of our CROs to execute our trials in accordance with the clinical trial protocol; good laboratory, clinical, and manufacturing practices (“GxP”); or other regulatory or contractual obligations;
- delays in or failure to obtain institutional review board (“IRB”) approval, centrally or at each site;
- delays in or failure to recruit suitable patients to participate in a trial;
- failure to have patients complete a trial or return for post-treatment follow-up;
- for our rare disease product candidates, failure to enroll a sufficient number of patients with the rare disease and clinical trial design challenges such as, but not limited to, the off-label use of drugs to treat rare disease or where the most common treatment method has not been clinically tested or has been approved on the basis of a different endpoint and not directly tied to a clinical outcome study, for example, augmentation therapy for AATD;
- clinical sites deviating from trial protocol or dropping out of a trial or committing gross misconduct or fraud;
- adding new clinical trial sites;
- unexpected technical issues during manufacture, storage, or transport of our product candidates and the corresponding drug product;
- inability to manufacture sufficient quantities of our product candidates for use in clinical trials;
- business interruptions resulting from the COVID-19 pandemic or any other similar pandemic;
- third-party actions claiming infringement by our product candidates in clinical trials inside or outside of the United States and obtaining injunctions interfering with our progress;
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, hurricanes, floods, and fires;
- safety or tolerability concerns causing us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks;
- changes in regulatory requirements, policies, and guidelines;
- lower than anticipated retention rates of patients and healthy volunteers in clinical trials;
- unexpected technical issues with the equipment used to conduct clinical trials or analyze the results;
- our third-party research contractors failing to comply with regulatory requirements or to meet their contractual obligations to us in a timely manner, or at all;
- delays in establishing the appropriate dosage levels or frequency of dosing or treatment in clinical trials;
- difficulty in identifying the populations that we are trying to treat in a particular trial, which may delay enrollment and reduce the power of a clinical trial to detect statistically significant results;

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- the quality or stability of our product candidates falling below acceptable standards for either safety or efficacy; and
- discoveries that may reduce the commercial viability of our product candidates.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs, centrally or at the institutions in which such trials are being conducted, by the data monitoring committee or data safety monitoring board for such trial or by the FDA, the EMA, or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols; inspection of the clinical trial operations or trial site by the FDA, the EMA, or other regulatory authorities resulting in the imposition of a clinical hold; unforeseen safety issues or adverse side effects; failure to demonstrate a benefit from using a drug; failure of our clinical trials to demonstrate adequate efficacy and safety; changes in governmental regulations or administrative actions; or lack of adequate or timely funding to continue the clinical trial.

A number of academic institutions are currently conducting and sponsoring clinical trials relating to our product candidate, alvelestat, including a clinical trial in patients with BOS. We do not control the design or administration of investigator-sponsored trials, and such investigator-sponsored trials could identify significant concerns with respect to alvelestat that could impact our findings from our own clinical trials, and adversely affect our ability to obtain marketing approval from the FDA or other applicable authorities. To the extent the results of these or other investigator-sponsored trials are inconsistent with, or different from, the results of our company-sponsored trials or raise concerns regarding alvelestat, the FDA or a foreign regulatory authority may question the results of a company-sponsored trial, or subject such results to greater scrutiny than it otherwise would. In these circumstances, the FDA or such foreign regulatory authorities may require us to conduct additional clinical studies or submit additional clinical data, which could delay clinical development or marketing approval of alvelestat.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA, the EMA, or another regulatory authority. The FDA, the EMA, or such other regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA, the EMA, or such other regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA, the EMA, or the other regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of our product candidates.

If we experience delays in the completion of any clinical trial of our product candidates or any clinical trial of our product candidates is terminated, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from our product candidates, if any, will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down the development and approval process of our product candidates, and jeopardize our ability to commence product sales and generate revenue, if any. Significant clinical trial delays could also allow our competitors to bring product candidates to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and could impair our ability to commercialize our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Clinical trials must be conducted in accordance with the laws and regulations of the FDA, EU rules and regulations and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs, centrally or at the institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced in compliance with the requirements of current good manufacturing practice ("cGMP") and other regulations. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing the CROs' committed activities, we have limited influence over the CROs' actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice ("GCP") requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards, or are delayed for a

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significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays, or both. In addition, clinical trials that are conducted in countries outside the EU and the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements, and the engagement of non-EU and non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA or the EMA, and different standards of diagnosis, screening, and medical care.

Prior to our acquisition of etigilimab, navicixizumab, setrusumab, alvelestat, acumapimod and leflutrozone, we were not involved in the development of these product candidates and, as a result, we are dependent on Novartis, AstraZeneca and OncoMed having accurately reported the results and correctly collected and interpreted the data from all clinical trials conducted prior to our acquisition.

We were not involved in the development of our current product candidates prior to our acquisition of such product candidates from Novartis, AstraZeneca and OncoMed. For all of our current product candidates, we have had no involvement with or control over their manufacturing or pre-clinical and clinical development prior to our acquisition of them. We are dependent on Novartis, AstraZeneca and OncoMed having conducted their research and development in accordance with the applicable protocols and legal, regulatory, and scientific standards; having accurately reported the results of all clinical trials conducted prior to our acquisition; and having correctly collected and interpreted the data from these trials. To the extent Novartis, AstraZeneca or OncoMed has not done this, the clinical development, regulatory approval, or commercialization of our product candidates may be adversely affected.

Interim “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim “top-line” or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or “top-line” data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Our product candidates may have serious adverse, undesirable, or unacceptable side effects which may delay or prevent marketing approval or lead to the withdrawal of approval after it has been granted. If such side effects are identified during the development of these product candidates or following approval, if any, we may need to abandon our development of these product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.

Undesirable side effects that may be caused by etigilimab, setrusumab, alvelestat, acumapimod and leflutrozone could cause us or regulatory authorities to interrupt, delay or halt clinical trials, and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA, or other comparable foreign authorities. Each of our product candidates has completed one or more clinical trials. In the trials conducted prior to our ownership and following our ownership, the most common adverse events observed have been the following:

- for etigilimab, rash, fatigue, nausea, pruritus, cough and autoimmune hepatitis;
- for setrusumab, headache, influenza, arthralgia, and fatigue;
- for alvelestat, headache, nasopharyngitis, and elevated levels of the liver enzymes aspartate aminotransferase and alanine aminotransferase;
- for acumapimod, a mild acne-like rash, tachycardia, dizziness, and headache; and
- for leflutrozone, headache, increased hematocrit, and small increases in blood pressure.

Clinical development for all of these product candidates is ongoing. Results of our ongoing and future clinical trials, or results from clinical trials for other similar product candidates, could reveal a high and unacceptable

severity and prevalence of adverse side effects. In such an event, our trials could be suspended or terminated and the FDA, EMA, or other comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications.

For example, the FDA approved the first sclerostin inhibitor for treatment of osteoporosis, Amgen Inc. (“Amgen”) and UCB S.A.’s (“UCB”) anti-sclerostin antibody, romosozumab (Evenity), in April 2019 following an 18-1 favorable advisory committee vote. However, Evenity received a Black Box warning that there may be an increase in risk of myocardial infarction (“MI”), stroke or cardiovascular death and it should not be initiated in patients who have had an MI or stroke in the last year. This was over a year after the FDA rejected our request for a Type C meeting to discuss the initiation of a pediatric Phase 3 study for setrusumab for the treatment of patients with severe OI. Based on these events and with our setrusumab Phase 2b efficacy and safety data in adult OI patients, we re-engaged with the FDA at the end of 2019 to discuss the expansion of the pivotal trial of setrusumab for the treatment of patients with severe OI to include sites in the United States. In February 2020, we announced the successful completion of a Type B End-of-phase 2 meeting with the FDA to discuss the expansion of the pediatric Phase 3 study for setrusumab for the treatment of children and adolescents with OI in the United States. In June 2019, the EMA’s CHMP adopted a negative opinion recommending the refusal of a marketing authorization for Evenity. However, Amgen and UCB announced in October 2019 that following a re-examination procedure the CHMP has adopted a positive opinion recommending marketing authorization for Evenity. In December 2019, the European Commission approved the MAA for Evenity.

Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential product liability claims. Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by these product candidates, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of any such product and require us to take it off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication, or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a REMS plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the way a product is administered, conduct additional clinical trials, or change the labeling of a product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- third-party private or government payors may not offer, or may offer inadequate, reimbursement coverage for, our product candidates, or reimbursement payments may be delayed or impossible to recover;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or any collaborators from achieving or maintaining market acceptance of our product candidates or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates.

Manufacturing tests of setrusumab have shown that it may cause an opalescence appearance to the liquid antibody formulation.

Our product candidate for treating OI, setrusumab, is of the IgG2 type subclass monoclonal antibody. The IgG2 subclass is known for having a tendency to reversibly self-associate and this can cause an opalescence appearance to the liquid antibody formulation that can be mediated by protein concentration, pH and temperature. The presence of an opalescence solution does not have an impact on product potency and effectiveness and does not generally correlate with the formation of aggregates or particles. Whilst we have recently conducted several large scale manufacturing runs of drug substance and drug product at third-party CMO’s without observing any opalescence and formulation studies are being conducted to in order to minimize any risk of significant opalescence or of aggregate formation, there can be no assurances that this opalescence will not occur in future manufacturing runs.

We depend on enrollment of patients in our clinical trials for our product candidates. If we are unable to enroll patients in our clinical trials, or enrollment is slower than anticipated, in particular for our product candidates with rare disease indications, our research and development efforts could be adversely affected.

Successful and timely completion of clinical trials for our product candidates will require that we enroll a sufficient number of patient candidates. Trials may be subject to delays as a result of the limited number of patients with the diseases that these product candidates target, patient enrollment taking longer than anticipated, or patient withdrawal. We will compete with other companies in enrolling the same limited population of patients, which may further challenge our ability to timely enroll patients in our clinical trials as there are a significant number of studies ongoing in oncology in the United States and Europe. Due to the small number of patients for any rare disease, it may be difficult for us to enroll a sufficient number of patients in our clinical trials for our product candidates with indications in rare diseases or enrollment for these product candidates may take significantly longer than we anticipate. It is estimated that OI, the target indication for setrusumab, affects a minimum of 20,000 people in the United States and approximately 32,000 people in Germany, Spain, France, Italy, and the United Kingdom, collectively. There are an estimated 50,000 and 60,000 persons in North America and Europe, respectively, with the genotypes that we intend to enroll in our clinical trials for AATD, the target indication for alvelestat. Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs or biologics approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. For example, our Phase 2 alvelestat trial recruits individuals with alpha-1 antitrypsin deficiency-related lung disease, who are potentially at greater risk from COVID-19 exposure. As a consequence of the COVID-19 pandemic, recruitment into our Phase 2 alpha-1 antitrypsin deficiency study will be delayed, with topline data now expected in the second half of 2021. Subject to a partnership, we are also currently planning to initiate a Phase 3 study in children with OI in late 2020, however, the initiation of the study may also be delayed. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our development and approval of our product candidates, and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the development, manufacturing, marketing, and use of pharmaceutical product candidates. Currently, we have no product candidates that have been approved for commercial sale; however, the current and future use of our product candidates by us and any collaborators, in clinical trials, and the sale of these product candidates, if approved, in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, our collaborators, or others selling these product candidates. Any claims against us, regardless of their merit, could be difficult and costly to defend and could adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. In addition, regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;

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- regulatory investigation, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize, co-commercialize, or promote our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

Although we maintain product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our coverage to include the sale of commercial product candidates if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

The regulatory approval processes of the FDA, the EMA, and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable as they rely on third party decisions outside of our control, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA, the EMA, and comparable foreign authorities is unpredictable and relies on third party decisions outside of our control, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any of our product candidates and it is possible that none of our product candidates will obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA, or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA, or comparable foreign regulatory authorities that a product is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA, or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA, or comparable foreign regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials or may find the data to be unacceptable;
- the data collected from clinical trials may not be sufficient to support the submission of a BLA or NDA in the United States, an MAA or CMA in the EU, or other comparable submission to obtain regulatory approval in other countries;
- the FDA, the EMA, or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, the EMA, or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any product candidates. The FDA, the EMA, and other regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for a product. Even if we believe the data collected from clinical trials are promising, such data may not be sufficient to support approval by the FDA, the EMA, or any other regulatory authority.

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In addition, even if we were to obtain approval for any jurisdiction, regulatory authorities may approve our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product with a label that does not include the labeling claims necessary or desirable for the successful commercialization of such product. Any of the foregoing scenarios could materially harm our commercial prospects and business.

Even if any of our product candidates obtains regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, any of our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with such product.

If the FDA, the EMA, or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, and recordkeeping for such product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, facility registration, and drug listing, as well as continued compliance with cGMP requirements for manufacturing, good distribution practice, requirements for product distribution, and GCP requirements for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize, or co-commercialize, a product. We and our contract manufacturers will also be subject to user fees and periodic inspection by the FDA, the EMA, and other regulatory authorities to monitor compliance with these requirements and the terms of any product approval we may obtain. In addition, any regulatory approvals that we receive for a product may also be subject to limitations on the approved indicated uses for which such product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of such product.

If there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or the manufacture of a product, or if we or one of our distributors, licensees, or co-marketers fails to comply with regulatory requirements, the regulatory authorities could take various actions. These include imposing fines on us, imposing restrictions on our product or its manufacture, and requiring us to recall or remove a product from the market. The regulatory authorities could also suspend or withdraw our marketing authorizations, or require us to conduct additional clinical trials, change our product labeling, or submit additional MAAs. If any of these events occurs, our ability to sell our product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements.

The policies of the FDA, the EMA, and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States, the United Kingdom, Europe, or other jurisdictions. For example, the current U.S. presidential administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, in January 2017, an Executive Order was issued directing all executive agencies, including the FDA, that, for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and Regulatory Affairs in February 2017, the administration indicated that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents, and in September 2017, the FDA published notices in the Federal Register soliciting broad public comment to identify regulations that could be modified in compliance with these Executive Orders. It is difficult to predict how these requirements will be implemented, and the extent to which they will

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impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Even if we obtain marketing approval of any of our product candidates in a major pharmaceutical market such as the United States or the EU, we may not be able to obtain approval or commercialize that product in other markets, which would limit our ability to realize our full market potential.

In order to market any product candidates in a country or territory, we must establish and comply with numerous and varying regulatory requirements of such country or territory regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals in multiple markets may require additional pre-clinical studies or clinical trials, which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain, and may be subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We currently do not have any product candidates approved for sale in the United States, the EU, or any other markets, and our management team does not have experience in obtaining regulatory approval in markets outside of the United States and the EU. If we seek regulatory approval in other markets and fail to obtain marketing approval in those markets or, if our product candidates are approved in such markets but we fail to maintain such approvals, our ability to realize the full market potential of our product candidates will be compromised.

Our employees and independent contractors, including principal investigators, CROs, CMOs, consultants, vendors, and any other third parties we may engage in connection with the development and commercialization of our product candidates may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could adversely affect our business.

Misconduct by our employees and independent contractors, including principal investigators, CROs, CMOs, consultants, vendors, and any other third parties we may engage in connection with the development and commercialization of our product candidates, could include intentional, reckless, or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, the EMA and other similar regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, fraud and abuse, and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete, and accurate financial information and data. Specifically, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in pre-clinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations. We are also subject to the data privacy regime in the EU, which imposes obligations and restrictions on the collection and use of personal

data relating to individuals located in the EU and includes the General Data Protection Regulation (the “GDPR”) and any national laws implementing or supplementing the GDPR. If we do not comply with our obligations under the EU privacy regime, we could be exposed to significant fines and may be the subject of litigation and/or adverse publicity, which could have a material adverse effect on our reputation and business.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

In the United States, EU and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (as so amended, the “ACA”) was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting “transfers of value” made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price (“AMP”) of branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the AMP;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted, or injected;
- extension of a manufacturer’s Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer’s Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board, which, once empaneled, would have the authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law unless overruled by a supermajority vote of Congress. The Bipartisan Budget Act of 2018 repealed the creation of the Independent Payment Advisory Board before it could take effect;
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services (“CMS”), to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;
- expansion of the entities eligible for discounts under the Public Health Service program; and
- a licensure framework for follow on biologic product candidates.

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Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. The Trump administration has also announced that it will discontinue the payment of cost-sharing reduction (“C-SR”) payments to insurance companies until Congress approves the appropriation of funds for the C-SR payments. The loss of the C-SR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. A bipartisan bill to appropriate funds for C-SR payments has been introduced in the Senate, but the future of that bill is uncertain. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, each chamber of Congress has put forth multiple bills this year designed to repeal or repeal and replace portions of the ACA. Although none of these measures have been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. Congress will likely consider other legislation to replace elements of the ACA. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business. It is uncertain the extent to which any such changes may impact our business or financial condition.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our future customers and accordingly, our financial operations.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to non-rare drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare product candidates and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition, and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical product candidates and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize, or co-commercialize, our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in

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the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of product candidates in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market product candidates, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize, or co-commercialize, our product candidates, if approved.

In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product candidates and therapies.

We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States, the EU, or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

There have been, and likely will continue to be, additional legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop product candidates.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item, or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The U.S. federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other hand;
- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act (“FCA”) which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the federal government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false

or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”) and its respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as its business associates that perform certain services involving the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- the U.S. federal Food, Drug and Cosmetic Act (“FDCA”), which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices;
- the U.S. Public Health Service Act (“PHSA”), which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;
- the U.S. federal legislation commonly referred to as the “Physician Payments Sunshine Act,” enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring that our current and future internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in government funded healthcare programs (including Medicare, Medicaid and other federal healthcare programs in the United States),

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individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

We are subject to governmental regulation and other legal obligations related to privacy, data protection and data security. Our actual or perceived failure to comply with such obligations could harm our business.

We are subject to diverse laws and regulations relating to data privacy and security in the EU, including the GDPR. New global privacy rules are being enacted and existing ones are being updated and strengthened. We are likely to be required to expend capital and other resources to ensure ongoing compliance with these laws and regulations.

The GDPR applies extraterritorially and implements stringent operational requirements for controllers and processors of personal data. For example, the GDPR: (i) requires detailed disclosures to data subjects; (ii) requires disclosure of the legal basis on which personal data is processed; (iii) makes it harder to obtain valid consent for processing; (iv) requires the appointment of a data protection officer where sensitive personal data (i.e. health data) is processed on a large scale; (v) provides more robust rights for data subjects; (vi) introduces mandatory data breach notification through the EU; (vii) imposes additional obligations when contracting with service providers; and (viii) requires an appropriate privacy governance framework to be implemented including policies, procedures, training and data audit. The GDPR permits member state derogations for certain issues and, accordingly, we are also subject to EU national laws relating to the processing of certain data such as genetic data, biometric data and data concerning health. Complying with these numerous, complex and often changing regulations is expensive and difficult. Failure by us, or our partners or service providers, to comply with the GDPR could result in regulatory investigations, enforcement notices and/or fines of up to the higher of 20 million euros or up to 4% of our total worldwide annual turnover. In addition to the foregoing, any breach of privacy laws or data security laws, particularly those resulting in any security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential patient or consumer information, could have a material adverse effect on our business, reputation and financial condition.

As a data controller, we are accountable for any third-party data service providers we engage to process personal data on our behalf. We attempt to address the associated risks by performing security assessments, detailed due diligence and regularly performing privacy and security reviews of our vendors and requiring all such third-party providers with data access to sign agreements, including business associate agreements, and where required under EU law, obligating them to only process data according to our instructions and to take sufficient security measures to protect such data. There is no assurance that these contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information. Any violation of data or security laws by our third-party processors could have a material adverse effect on our business and result in the fines and penalties outlined above.

We are also subject to evolving European privacy laws on electronic marketing and cookies. The EU is in the process of replacing the e-Privacy Directive (2002/58/EC) (the “e-Privacy Directive”) with a new set of rules taking the form of a regulation, which will be directly applicable to the laws of each European member state, without need for further implementation. The draft e-Privacy Regulation (the “e-Privacy Regulation”) imposes strict opt-in marketing rules with limited exceptions for business-to-business communications, alters rules on third-party cookies, web beacons and similar technology and significantly increases fining powers to the same levels as GDPR (i.e. the greater of 20 million euros or 4% of total global annual revenue). While the e-Privacy Regulation was originally intended to be adopted on May 25, 2018 (alongside the GDPR), it is still going through the European legislative process and commentators now expect it to be adopted during the second half of 2020 or during 2021 following a transition period.

Due to our international operations, we are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010 (the “Bribery Act”); the U.S. Foreign Corrupt Practices Act (the “FCPA”); and other anti-corruption laws that apply in countries where we do business and may do business in the future. The Bribery Act, FCPA, and these other laws generally prohibit us, our officers and our employees and intermediaries from bribing, being bribed by, or providing prohibited payments or anything else of value to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA, or local anti-corruption laws. In addition, we cannot predict the nature, scope, or effect of future regulatory requirements to which any of our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing any international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations (collectively, the “Trade Control Laws”).

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA, or other legal requirements, including Trade Control Laws. If we are not in compliance with the Bribery Act, the FCPA, and other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement, and other sanctions and remedial measures and legal expenses. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws, or Trade Control Laws by U.K., U.S., or other authorities, even if it is ultimately determined that we did not violate such laws, could be costly and time-consuming, require significant personnel resources, and harm our reputation.

We will seek to build and continuously improve our systems of internal controls and to remedy any weaknesses identified. There can be no assurance, however, that the policies and procedures will be followed at all times or effectively detect and prevent violations of the applicable laws by one or more of our employees, consultants, agents, or collaborators and, as a result, we could be subject to fines, penalties, or prosecution.

Risks Related to Commercialization

We operate in a highly competitive and rapidly changing industry, which may result in others acquiring, developing, or commercializing competing product candidates before or more successfully than we do.

The biopharmaceutical and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to acquire, develop, and obtain marketing approval for new product candidates on a cost-effective basis and to market them successfully. If etigilimab, setrusumab, alvelestat, acumapimod or leflutroazole is approved, we will face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, non-rare pharmaceutical companies, and biopharmaceutical companies in the United States, Europe, and other jurisdictions. These organizations may have significantly greater resources than we have and conduct similar research; seek patent protection; and establish collaborative arrangements for research, development, manufacturing, and marketing of product candidates that may compete with our product candidates.

We expect to face competition for each of our current product candidates, including specifically:

- We consider etigilimab’s current closest potential competitors to be existing cancer treatments such as the commercially available immuno-oncology agents (e.g., Yervoy, Keytruda, and Opdivo), chemotherapeutic agents, and antibody based therapeutics such as Avastin and Erbitux. In addition, other potential competitors include several other anti-TIGIT agents (e.g., those currently being developed by Genentech (Roche), Merck, Bristol-Myers Squibb or BMS, Arcus Biosciences, iTeos Therapeutics, Compugen and BeiGene) and investigational immuno-oncologic agents against other targets. There are established pharmaceutical and biotechnology companies that are known to be involved in oncology research.

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- We consider setrusumab's current closest potential competitors in development for the treatment of OI to be Amgen denosumab (Prolia) an anti-resorptive agent, and Amgen and UCB's anti-sclerostin antibody, romosozumab (Evenity), which was approved in the United States in April 2019 for osteoporosis. In June 2019, the EMA's CHMP adopted a negative opinion recommending the refusal of a marketing authorization for Evenity. However, Amgen and UCB announced in October 2019 that following a re-examination procedure the CHMP has adopted a positive opinion recommending marketing authorization for Evenity. In December 2019, the European Commission approved the MAA for romosozumab (Evenity). In addition, Jiangsu Hengrui has commenced Phase 1 development of an anti-sclerostin antibody for osteoporosis, and Transcena Holding has licensed the anti-sclerostin antibody blosozumab from Eli Lilly and Company ("Lilly") and plans to develop it for osteoporosis. Additionally, Bone Therapeutics S.A. ("Bone Therapeutics") is developing osteoblastic cell therapy product candidates. Baylor College of Medicine is also conducting a Phase 1 open label trial of fresolimumab, a TGF-B inhibitor, in adult OI patients.
- We consider alvelestat's current closest potential competitors for the treatment of severe AATD to be alpha1-proteinase inhibitors that are administered intravenously in AAT augmentation therapy. Currently, there are four inhibitors on the market in the United States and the EU: Prolastin-C from Grifols, S.A. ("Grifols"), Aralast from Shire plc, now a subsidiary of Takeda Pharmaceutical Company Ltd ("Shire"), Zemaira from CSL Limited ("CSL"), and Glassia from Kamada Ltd. ("Kamada"). Kamada is also investigating an inhaled version of augmentation therapy, InhibRx, Inc. ("InhibRx") is in Phase 1 development of INBRX-101, a recombinant human alpha-1 antitrypsin Fc fusion protein (rhAAT-Fc) for replacement therapy, and Apic Bio, Inc. ("Apic Bio") is in the early stages of developing gene-therapy approaches for AATD. Vertex Pharmaceuticals Inc. ("Vertex") has a small molecule corrector program for AATD with VX-814 in Phase 2 development and VX-864 in Phase 1 development. Santhera Pharmaceuticals ("Santhera"), has in-licensed an inhaled NE inhibitor and is planning a multiple ascending dose study, with the initial indication targeted being CF; and CHF-6333 is an inhaled human NE inhibitor in Phase 1 development by Chiesi Farmaceutici S.p.A. ("Chiesi") for the treatment of non-cystic fibrosis bronchiectasis and CF.
- For acumapimod, although we are not aware of any approved therapies for the treatment of AECOPD, there are a wide range of established therapies available for COPD as well as a number of product candidates in development, with Verona Pharma plc ("Verona Pharma"), GlaxoSmithKline plc. ("GlaxoSmithKline"), and AstraZeneca each conducting Phase 2 trials on drugs for the treatment of COPD. In addition, Pulmatrix, Inc. ("Pulmatrix") has PUR1800, a narrow-spectrum kinase inhibitor (NSKI) expected to begin a Phase 1b for AECOPD in 2020. We consider acumapimod's current closest potential competitor in development for the treatment of AECOPD to be Verona Pharma's RPL554, a PDE3 / PDE4 dual inhibitor that is currently being developed as a bronchodilator and anti-inflammatory agent for COPD and asthma patients.
- We consider leflutrolole's current closest potential competitors for the treatment of HH to be testosterone replacement therapies ("TRT"). These include Androgel from AbbVie Inc. ("AbbVie"), and Lilly's Axiron, both administered transdermally by applying a gel formulation, which are approved in the United States and Europe, Andriol from Merck & Co., Inc. ("Merck"), an oral testosterone therapy, which is approved in Europe but not in the United States and Jatenzo from Clarus Therapeutics, Inc. ("Clarus") approved in the United States in March 2019. There are also other approved TRT product candidates that are administered via injection and other oral TRTs that are still in the development or registration stages, such as Tlando from Lipocine, Inc. ("Lipocine"). The FDA held advisory committee meetings in January 2018 for Tlando. On May 9, 2018, Lipocine announced that it had received a complete response letter from the FDA and on May 14, 2019, Lipocine announced the acceptance of the NDA for Tlando. Lipocine has also announced an injunction against Clarus for its product Jatenzo.

We also anticipate that new companies will enter these markets in the future. If we successfully develop and commercialize any of etigilimab, setrusumab, alvelestat, acumapimod or leflutrolole, they will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and

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rapid technological changes in the biopharmaceutical and pharmaceutical industries could render our product candidates obsolete, less competitive, or uneconomical. Our competitors may, among other things:

- have significantly greater name recognition, financial, manufacturing, marketing, drug development, technical, and human resources than we do, and future mergers and acquisitions in the biopharmaceutical and pharmaceutical industries may result in even more resources being concentrated in our competitors;
- develop and commercialize product candidates that are safer, more effective, less expensive, more convenient, or easier to administer, or have fewer or less severe effects, or in certain cases could be curative for the condition;
- obtain quicker regulatory approval;
- establish superior proprietary positions covering our product candidates and technologies;
- implement more effective approaches to sales and marketing; or
- form more advantageous strategic alliances.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel; establishing clinical trial sites and patient registration; and in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than our product candidates. Our competitors may also obtain FDA, EMA, or other regulatory approval for their product candidates more rapidly than we may obtain approval for our own product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, existing products approved for other indications could be used off-label and may compete with our products. For example, the only treatments available to OI patients are drugs such as bisphosphonates, which are not approved for this indication but are commonly used off-label in children.

We have obtained orphan drug designation for setrusumab for the treatment of OI in the United States and EU, but we may be unable to obtain orphan drug designation for alvelestat or any future product candidates, and we may be unable to obtain or maintain the benefits associated with orphan drug designation, including the potential for orphan drug exclusivity, for setrusumab or any other product for which we obtain orphan drug designation.

Under the Orphan Drug Act of 1983 (the “Orphan Drug Act”), the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the EMA’s Committee for Orphan Medicinal Products (“COMP”) recommends to the European Commission the granting of orphan designation to promote the development of medicinal products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. Additionally, designation is granted for medicinal products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating, or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, where the medicine can demonstrate that it is of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax credits for qualified clinical testing, and user-fee waivers. In addition, if a product receives the first FDA approval of that drug for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the rare disease or condition. Under the FDA’s regulations, the FDA will deny orphan drug exclusivity to a designated drug upon

approval if the FDA has already approved another drug with the same active ingredient for the same indication, unless the drug is demonstrated to be clinically superior to the previously approved drug. In the EU, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following approval. This period can be extended by two years if studies in children are performed in accordance with a PIP. In addition, this period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the drug is sufficiently profitable not to justify maintenance of market exclusivity or where the manufacturer is unable to supply the treatment. In the EU, a marketing authorization for an orphan designated product will not be granted if a similar drug has been approved in the EU for the same therapeutic indication, unless the applicant can establish that its product is safer, more effective or otherwise clinically superior. A similar drug is a product containing a similar active substance or substances as those contained in an already authorized product. Similar active substance is defined as an identical active substance, or an active substance with the same principal molecular structural features (but not necessarily all of the same molecular features) and which acts via the same mechanism.

We have obtained orphan drug designation from the FDA and EMA for setrusumab for the treatment of OI, and we plan to seek orphan drug designation for alvelestat and future rare disease product candidates. Even with orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical product candidates, which could prevent us from marketing our product candidates if another company is able to obtain orphan drug exclusivity before we do. In addition, exclusive marketing rights in the United States may be unavailable if we seek approval for an indication broader than the orphan-designated indication or may be lost in the United States if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the drug to meet the needs of patients with the rare disease or condition following approval. Further, even if we obtain orphan drug exclusivity, that exclusivity may not effectively protect our product candidates from competition because different drugs with different active moieties can be approved for the same condition. In addition, the FDA and the EMA can subsequently approve product candidates with the same active moiety for the same condition if the FDA or the EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, while we intend to seek orphan drug designation for other existing and future product candidates, including alvelestat, we may never receive such designations.

There have been legal challenges to aspects of the FDA's regulations and policies concerning the exclusivity provisions of the Orphan Drug Act, and future challenges could lead to changes that affect the protections afforded to our product candidates in ways that are difficult to predict. In 2014, a U.S. district court invalidated the FDA's denial of orphan exclusivity to an orphan designated drug, which the FDA had based on its determination that the drug was not proven to be clinically superior to a previously approved "same drug." In response to the decision, the FDA released a policy statement stating that the court's decision is limited to the facts of that particular case and that the FDA will continue to deny orphan drug exclusivity to a designated drug upon approval if the drug is the "same" as a previously approved drug, unless the drug is demonstrated to be clinically superior to that previously approved drug. Since then, similar legal challenges have been initiated against the FDA for its denial of orphan drug exclusivity to other designated drugs, and in 2017, Congress amended the Orphan Drug Act to require a demonstration of clinical superiority upon approval as a condition of receiving orphan drug exclusivity when another "same drug" has already been approved for the same indication. In the future, there is the potential for additional legal challenges to the FDA's orphan drug regulations and policies, and it is uncertain how ongoing and future challenges might affect our business.

We may seek and fail to obtain breakthrough therapy designation by the FDA for etigilimab, setrusumab or alvelestat, or any future product candidates or access to the PRIME scheme by the EMA for etigilimab, alvelestat or any future product candidates. Even if we obtain such designation or access, the designation or access may not lead to faster development or regulatory review or approval, and it does not increase the likelihood that our product candidates will receive marketing approval.

In 2012, the FDA established a breakthrough therapy designation which is intended to expedite the development and review of product candidates that treat serious or life-threatening diseases where preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically-significant endpoints, such as substantial treatment effects observed early in clinical development.

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The designation of a product as a breakthrough therapy provides potential benefits that include but are not limited to more frequent meetings with the FDA to discuss the development plan for the product and ensure collection of appropriate data needed to support approval; more frequent written correspondence from the FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient drug development program, beginning as early as Phase 1; organizational commitment involving senior managers; and eligibility for rolling review and priority review. Drugs and biologics designated as breakthrough therapies by the FDA are also eligible for accelerated approval. Similarly, the EMA has established the PRIME scheme to expedite the development and review of product candidates that show a potential to address to a significant extent an unmet medical need, based on early clinical data. In November 2017, setrusumab was admitted to the PRIME scheme of the EMA. Additionally, in relation to navicixizumab, we conducted a Phase 1b clinical trial in ovarian cancer, in combination with paclitaxel, in platinum-resistant ovarian cancer. A successful FDA Type B meeting was held in July 2019 and the potential for accelerated approval was discussed.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. We cannot be sure that our evaluation of our product candidates as qualifying for breakthrough therapy designation will meet the FDA's expectations. In any event, the receipt of a breakthrough therapy designation for a product may not result in a faster development process, review, or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Similarly, access to the PRIME scheme is at the discretion of the EMA, and we cannot be sure that alvelestat or any future product candidates will be granted access to the scheme; that participation in the scheme will result in expedited regulatory review or approval of our product candidates; or that access to the scheme, once granted, will not be revoked.

We plan to develop our product candidates for oncology and rare diseases through the next key clinical milestone and then partner or in select cases to develop through regulatory approval and potentially commercialization. If we are unable to develop our own sales, marketing, and distribution capabilities or enter into business arrangements, we may not be successful in commercializing our product candidates.

We have no marketing, sales, or distribution capabilities and we currently have no experience with marketing, selling or distributing pharmaceutical product candidates. We also currently have no strategic relationships in place for the commercialization of our product candidates. We intend to form a strategic partnership for setrusumab prior to initiation of the pivotal study in children with OI. This partnership may include co-commercialization rights or regional arrangements. We may seek to partner etigilimab and alvelestat following further clinical development or regulatory approval.

We currently intend to enter into strategic relationships with pharmaceutical, biopharmaceutical or other partners for the continued development of our non-oncology/non-rare disease product candidates, acumapimod and leflutrolole, and we may take the same approach for other product candidates. These arrangements would also likely include the commercialization of a product. Alternatively, we may seek to sell or out-license one or more of our non-oncology/non-rare disease product candidates. See “—Risks Related to Our Business and Industry—Following the Licensing Agreement for Navi, and if we sell or out-license other of our non-oncology/non-rare disease product candidates or out-license any of our oncology or rare disease product candidates for any territories, we could be exposed to future liabilities.”

As a result of the entering into any such planned partnerships or arrangements, our revenue from product sales may be lower than if we directly marketed or sold these product candidates on our own. In addition, any revenue we receive will depend upon the terms of such partnership or arrangement, which may not be as favorable to us as possible, and the efforts of the other party, which may not be adequate or successful and are likely to be beyond our control. We may not be successful in identifying a suitable partner or partners, and we may not be able to reach agreement with them at all. If we are unable to enter into these partnerships or arrangements on acceptable terms or at all, we may not be able to successfully commercialize these product candidates.

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These commercialization approaches are expensive and time consuming, and some or all of the costs associated with such efforts may be incurred in advance of any approval of our product candidates. If we are not successful in commercializing our product candidates, either on our own or through strategic relationships with third parties, our future product revenue will suffer and we may incur significant losses.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those product candidates and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers, and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, assuming approval. Our ability to achieve acceptable levels of coverage and reimbursement for product candidates by governmental authorities, private health insurers, and other organizations will have an effect on our ability to successfully commercialize our product candidates. Assuming we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Third party payors may also elect to restrict coverage to a subset of patients that could potentially be treated with our products, if approved. We cannot be sure that coverage and reimbursement in the United States, the EU, or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical product candidates and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar, or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed product candidates at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved product candidates. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for product candidates exists among third-party payors in the United States. Therefore, coverage and reimbursement for product candidates can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Our operations are also subject to extensive governmental price controls and other market regulations in the United Kingdom and other countries outside of the United States, and we believe the increasing emphasis on cost-containment initiatives in European and other countries will put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical product candidates are subject to varying price control mechanisms as part of national health systems. To obtain reimbursement or pricing approval, some of these countries might compare the new product to an existing standard of care, including other treatments aimed at the

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same disease, if they exist. Health technology assessments, including cost-effectiveness evaluations, may be conducted in order to assess the medical value or added clinical benefit of a therapy. Countries may also conduct budget-impact assessments for a new therapy. In some cases, tendering is used to decide which therapy will be reimbursed and made available for a group of patients where more than one treatment exists. Countries might also require further studies or in-use evidence to be developed, or create coverage with evidence generation under some form of so-called managed access agreements. Some countries allow for a company to set the price, which is then agreed in negotiation with the country authorities, who might then monitor sales for that product and re-assess or re-evaluate when a certain statutory health insurance expenditure threshold is reached. Other countries might set their price based on prices in a selected country or group of countries under international or external reference pricing systems. If an agreement cannot be reached, confidential discounts might be negotiated between the manufacturer and the healthcare system authorities. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved product candidates and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new product candidates.

Our existing and future product candidates may not gain market acceptance, in which case our ability to generate product revenues will be compromised.

Even if the FDA, the EMA, or any other regulatory authority approves the marketing of our product candidates, whether developed on our own or with a collaborator, physicians, healthcare providers, patients, or the medical community may not accept or use our product candidates. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue or any profits from operations. The degree of market acceptance of our product candidates will depend on a variety of factors, including:

- the timing of market introduction;
- the number and clinical profile of competing product candidates;
- the clinical indications for which our product candidates are approved;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- relative convenience and ease of administration;
- cost-effectiveness;
- marketing and distribution support;
- availability of adequate coverage, reimbursement, and adequate payment from health maintenance organizations and other insurers, both public and private; and
- other potential advantages over alternative treatment methods.

If our product candidates fail to gain market acceptance, our ability to generate revenues will be adversely affected. Even if our product candidates achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

Any product candidates for which we intend to seek approval as biologic product candidates in the United States may face competition sooner than anticipated.

In the United States, the Biologics Price Competition and Innovation Act of 2009 (the “BPCIA”) created an abbreviated approval pathway for biological product candidates that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In

addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of its product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could adversely affect the future commercial prospects for any biological product candidates.

We believe that if any product is approved as a biological product under a BLA, it should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference product candidates for competing product candidates, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for a reference product in a way that is similar to traditional generic substitution for non-biological product candidates is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In the EU, MAAs for product candidates that are biosimilar to an already authorized biological product, the so-called reference product, can rely on the safety and efficacy data contained in the dossier of the reference product. To qualify as a biosimilar product the marketing authorization applicant must demonstrate, through comprehensive comparability studies with the reference product, that its product is: (i) highly similar to the reference product notwithstanding the natural variability inherent to all biological medicines, and (ii) that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety, quality, and efficacy. Biosimilars can only be authorized for use after the period of exclusivity of the reference biological medicine has expired. In general, this means that the biological reference product must have been authorized for at least 10 years before a biosimilar can be made available by another company.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties, including independent investigators and CROs, to conduct our clinical trials. If these CROs do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon independent clinical investigators and CROs to conduct our clinical trials and to monitor and manage data for our ongoing clinical programs. We rely on these parties for the execution of our clinical trials and control only certain aspects of these parties' activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our independent investigators and CROs are required to comply with GxP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GxP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we fail to exercise adequate oversight over any of our independent investigators or CROs or if we or any of our independent investigators or CROs fail to comply with applicable GxP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon a regulatory inspection of us or our independent investigators or CROs, such regulatory authority will determine that any of our clinical trials complies with GxP requirements. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, these independent investigators and CROs are not our employees and we are not able to control, other than by contract, the amount of resources, including time, which they devote to our clinical trials. If our independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their

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performance is substandard, it may delay or compromise the prospects for approval and commercialization of our product candidates. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information is misappropriated.

If any of our relationships with our independent investigators or CROs terminate, we may not be able to enter into arrangements with alternative independent investigators or CROs or to do so on commercially reasonable terms. Switching or adding additional investigators or CROs involves additional cost and potential delays and requires our management's time and focus. In addition, there is a natural transition period when a new independent investigator or CRO commences work. As a result, delays could occur, which could materially impact our ability to meet our desired clinical development timelines.

If our independent investigators or CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to a failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We currently rely on third-party CMOs for the production of clinical supply of our product candidates and intend to rely on CMOs for the production of commercial supply of our product candidates, if approved. Our dependence on CMOs may impair the development of our product candidates and may impair the commercialization of our product candidates, which would adversely impact our business and financial position.

We have limited personnel with experience in manufacturing, and we do not own facilities for manufacturing our product candidates. Instead, we rely on and expect to continue to rely on CMOs for the supply of cGMP grade clinical trial materials and commercial quantities of our product candidates, if approved. Reliance on CMOs may expose us to more risk than if we were to manufacture our product candidates ourselves. Novartis previously provided clinical supplies for setrusumab, acumapimod, and leflutrolole and certain transitional services. We have moved the clinical supply manufacture for these product candidates to CMOs. We also intend to contract with CMOs for the clinical supply of etigilimab and alvelestat.

The facilities used to manufacture our product candidates must be approved by the FDA, the EMA, and comparable foreign authorities pursuant to inspections. While we provide oversight of manufacturing activities, we do not and will not control the execution of our manufacturing activities by, and are or will be essentially dependent on, our CMOs for compliance with cGMP requirements for the manufacture of our product candidates. As a result, we are subject to the risk that our product candidates may have manufacturing defects that we have limited ability to prevent. If a CMO cannot successfully manufacture material that conforms to our specifications and the regulatory requirements, we will not be able to secure or maintain regulatory approval for the use of our investigational medicinal product candidates in clinical trials, or for commercial distribution of our product candidates, if approved. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, the EMA or comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would delay our development program and significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidates or that obtained approvals could be revoked. Furthermore, CMOs may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement at a time that is costly or otherwise inconvenient for us. In addition, the manufacture of biologics involves expensive and complex processes and worldwide capacity at CMOs for the manufacture of biologics is currently limited. In addition, Novartis has a contractual right to approve or reject any additional CMO we wish to engage for the manufacture of setrusumab, other than those CMOs that we and Novartis have already agreed upon. If we were unable to find an adequate CMO or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed.

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We rely on and will continue to rely on CMOs to purchase from third-party suppliers the raw materials necessary to produce our product candidates. We do not and will not have control over the process or timing of the acquisition of these raw materials by our CMOs. Moreover, we currently do not have any agreements for the production of these raw materials. Supplies of raw material could be interrupted from time to time and we cannot be certain that alternative supplies could be obtained within a reasonable timeframe, at an acceptable cost, or at all. In addition, a disruption in the supply of raw materials could delay the commercial launch of our product candidates, if approved, or result in a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. Growth in the costs and expenses of raw materials may also impair our ability to cost effectively manufacture our product candidates. There are a limited number of suppliers for the raw materials that we may use to manufacture our product candidates and we may need to assess alternate suppliers to prevent a possible disruption of the manufacture of our product candidates.

Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we generally do not begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates.

As part of their manufacture of our product candidates, our CMOs and third-party suppliers are expected to comply with and respect the proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes the proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved.

We intend to enter into strategic relationships with third parties, based on a product-by-product assessment, for the development of some of our product candidates. If we fail to enter into these arrangements, our business, development and commercialization prospects could be adversely affected.

Our development program for our product candidates, particularly as we enter late-stage development for some of our product candidates, will require substantial additional funds. We currently intend to enter into strategic relationships with pharmaceutical, biopharmaceutical or other partners for the continued development of our non-oncology/non-rare disease product candidates, acumapimod and leflutrolole, and we may take the same approach for other product candidates. Alternatively, we may seek to sell or out-license one or more of our non-oncology/non-rare disease product candidates. See “—Risks Related to Our Business and Industry—Following the Licensing Agreement for Navi, and if we sell or out-license other of our non-oncology/non-rare disease product candidates or out-license any of our oncology or rare disease product candidates for any territories, we could be exposed to future liabilities.”

The types of development arrangements referred to above are complex and time-consuming to negotiate and document, and we may not be able to enter into these arrangements on favorable terms or at all. In addition, we face significant competition from other companies in seeking out these types of development arrangements. If we are successful in entering into such an arrangement, we will be subject to other risks, including our inability to control the amount of time and resources the third party will dedicate to our product candidates, financial or other difficulties experienced by such third party, relinquishing important rights to such third party, and the arrangement failing to be profitable to us.

If we are unable to enter into an appropriate arrangement for the development of our non-oncology/non-rare disease product candidates, we may have to reduce, delay, or terminate the development of such product candidates. We could also seek to sell or out-license one or more of our non-oncology/non-rare disease product candidates. If we, instead, decide to increase our expenditures to fund development activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms or at all. As a result, our business may be substantially harmed.

See also “—Risks Related to Commercialization—We intend to directly commercialize or co-commercialize our product candidates for rare diseases and to seek strategic relationships with third parties for the development and/or commercialization of our product candidates for non-oncology/non-rare diseases. If we are unable to develop our own sales, marketing, and distribution capabilities or enter into business arrangements, we may not be successful in commercializing our product candidates.”

Risks Related to Intellectual Property

We rely on patents and other intellectual property rights to protect our product candidates, the obtainment, enforcement, defense and maintenance of which may be challenging and costly. Failure to enforce or protect these rights adequately could harm our ability to compete and impair our business.

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property protection, for example, for compositions-of-matter of our product candidates, formulations of our product candidates, polymorphs, salts and analogs of our product candidates, methods used to manufacture our product candidates, methods for manufacturing of the final drug product candidates, and methods of using our product candidates for the treatment of the indications we are developing or plan to develop, or on in-licensing such rights. Our patent portfolio comprises patents and patent applications which cover Navi (which was licensed to Oncologie, Inc. in January 2020) and our etigilimab product candidate (solely owned by OncoMed), patents and patent applications which cover our setrusumab, acumapimod, and leflutrolole product candidates acquired or exclusively licensed from Novartis and patents and patent applications which cover our alvelestat product candidate exclusively licensed (with the option to purchase) from AstraZeneca. The assignments of those patents and patent applications which we acquired from Novartis have been registered with the relevant authorities in key territories and the exclusive licenses from AstraZeneca have also been registered with the relevant authorities in key territories. There is no assurance that our pending patent applications will result in issued patents, or if issued as patents, will include claims with sufficient scope of coverage to protect our product candidates, or that any pending patent applications will be issued as patents in a timely manner. Failure to obtain, maintain or extend adequate patent and other intellectual property rights could adversely affect our ability to develop and market our product candidates, resulting in harm to our business.

The patent prosecution process is expensive and time-consuming. We or our licensors may not be able to prepare, file and prosecute all necessary or desirable patent applications for a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we or our licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Moreover, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Further, the issuance, scope, validity, enforceability, and commercial value of our and our current or future licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in issued patents that protect our technology or product candidates, in whole or in part, or that effectively prevent others from commercializing competitive technologies and product candidates. The patent examination process may require us or our licensors to narrow the scope of the claims of our or our licensors' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being issued as a patent. Even if patent applications do successfully issue as patents and even if such patents cover our product candidates, third parties may initiate an opposition, interference, reexamination, post grant review, inter partes review, nullification or derivation action in courts or before patent offices, or similar proceedings challenging the validity, enforceability, or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such patent applications, and then only to the extent the issued claims cover the technology.

Because patent applications are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates. Furthermore, in the United States, if third parties have filed such patent applications on or before March 15, 2013, the date on which the United States changed from a first to invent to a first to file patent system, an interference proceeding can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after

March 15, 2013, a derivation proceeding can be initiated by such third parties to determine whether our invention was derived from such third parties' product candidates. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

We enjoy only limited geographical protection with respect to certain patents and may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and maintaining and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their competitor's own product candidates and, further, may export otherwise infringing product candidates to territories where we and our licensors have patent protection, but enforcement rights are not as strong as that in the United States or Europe. These product candidates may compete with our product candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before grant. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions, such as in China, which has different requirements for patentability, including a stringent requirement for a detailed description of medical uses of a claimed drug. It is also quite common that depending on the country, the scope of patent protection may vary for the same product or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing product candidates in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

Our patents and other proprietary rights may not adequately protect our technologies and product candidates, and may not necessarily address all potential threats to our competitive advantage.

The degree of protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- the patents of third parties may impair our ability to develop or commercialize our product candidates;
- the patents of third parties may be extended beyond the expected patent term and thus may impair our ability to develop or commercialize our product candidates;
- we or our licensors or any future strategic collaborators might not have been the first to conceive or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensors or any future strategic collaborators might not have been the first to file patent applications covering our inventions, our product candidates, or uses of the product candidates in the indications under our development or to be developed;
- it is possible that the pending patent applications that we own or have exclusively licensed may not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- issued patents that we own or have exclusively licensed may not provide coverage for all aspects of our product candidates in all countries, such as for uses of our product candidates in the indications under our development or to be developed;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive product candidates for sale in our major commercial markets;
- others performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license;
- our or our licensors' inventions or technologies may be found to be not patentable; and
- we may not develop additional technologies that are patentable.

We may become subject to third parties' claims alleging infringement of third-party patents and proprietary rights, or we may be involved in lawsuits to protect or enforce our patents and other proprietary rights, which could be costly and time consuming, delay or prevent the development and commercialization of our product candidates, or put our patents and other proprietary rights at risk.

Our commercial success depends, in part, upon our ability to develop, manufacture, market, and sell our product candidates without alleged or actual infringement, misappropriation, or other violation of the patents and proprietary rights of third parties. Litigation relating to patents and other intellectual property rights in the biopharmaceutical and pharmaceutical industries is common, including patent infringement lawsuits and interferences, oppositions, and reexamination proceedings before the U.S. Patent and Trademark Office (the "USPTO"), and foreign patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including in the biopharmaceutical and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous U.S., European, and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. Some claimants may have substantially greater resources than we have and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biopharmaceutical and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

We may be subject to third-party claims including infringement, interference or derivation proceedings, post-grant review and inter partes review before the USPTO, or similar adversarial proceedings or litigation in the U.S. and other jurisdictions. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention, or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In addition, defending such claims would cause us to incur substantial expenses and could cause us to pay substantial damages, if we are found to be infringing a third party's patent rights. These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully. As an example of the foregoing risks, we are aware of a third-party patent family which currently includes a patent granted by the European Patent Office ("EPO"), containing claims that appear to cover the use of setrusumab in the treatment of OI. The patent owner could assert such patent against us, which could present the foregoing risks and impose limitations in our ability to develop, manufacture or sell setrusumab for such use in the EU, unless we obtain a license under such patent, such patent is determined to be invalid or unenforceable by the EPO or a national court in one or more relevant territories, or such patent is revoked or otherwise limited by the EPO. This patent is currently the subject of ongoing opposition proceedings before the EPO, but there can be no assurance as to the outcome of such proceedings.

Any of our patents may be challenged, narrowed, circumvented, or invalidated by third parties. The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party preissuance submission of prior art to the USPTO or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from us, even if the eventual outcome is favorable to us.

Further, if a patent infringement suit is brought against us or our third-party service providers, our development, manufacturing or sales activities relating to the product or product that is the subject of the suit may be delayed or terminated. As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which would be likely to include a requirement to pay license fees or royalties or both. These licenses may not be available on acceptable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or more of our product candidates, or forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly. We might, if possible, also be forced to redesign our product candidates so that we no longer infringe the third-party intellectual property rights, which may result in significant cost and delay to us, or which redesign could be technically infeasible. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness, or non-enablement. Third parties might allege unenforceability of our patents because someone connected with prosecution of the patent withheld relevant information, or made a misleading statement, during prosecution. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. There is a risk that in connection with such proceedings, a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competing product candidates. In addition, if the breadth or strength of protection provided by our patents is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize our current or future product candidates.

Furthermore, our patents and other intellectual property rights also will not protect our technology if competitors and other third parties design around our protected technology without infringing our patents or other intellectual property rights. For example, a third party may develop a competitive product that provides benefits similar to our product candidates but that uses a technology that falls outside the scope of our patent protection. Our competitors may also seek approval to market generic versions of any approved products and in connection with seeking such approval may claim that our patents are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors view these announcements in a negative light, the price of our ADSs could be adversely affected.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop, manufacture and market our product candidates.

We cannot guarantee that any of our, our licensors', or the previous owners' patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims, or the expiration of relevant patent applications or patents, are complete or thorough, nor can we be certain that we have identified each

and every third-party patent and patent application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, in the United States, patent applications filed before November 29, 2000 and, upon request, certain patent applications filed after that date that will not be filed outside the United States, remain confidential until those patent applications issue as patents. Patent applications in the United States, EU, and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by others without our knowledge, including any such patent applications that may claim priority from patent applications for patents that we have determined will expire before we commercialize our product candidates. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. Moreover, as we study our product candidates during development, we may learn new information regarding their structure, composition, properties, or functions that may render third-party patent applications or patents that we had not identified as being, or that we had not believed to be, relevant to our product candidates instead to be relevant to or necessary for the commercialization of our product candidates in a jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in the patent, and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date or the possibility of an extension of patent term of any patent in the United States, Europe, or elsewhere that we consider relevant also may be incorrect. Any of the foregoing circumstances, failures, or errors may negatively impact our ability to develop and market our product candidates.

If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business, and our business may be substantially harmed as a result.

We are party to agreements with Novartis and AstraZeneca, under which we in-license certain intellectual property and were assigned, in the case of Novartis, or granted an option to acquire, in the case of AstraZeneca, certain patents and patent applications related to our business. In addition, we are party to an agreement with Oncologie, Inc. ("Oncologie") pursuant to which we have out-licensed certain intellectual property. We may enter into additional license agreements in the future. Our existing license agreements impose and any future license agreements are likely to impose various diligence, milestone payment, royalty, insurance and other obligations on us. Any uncured, material breach under these license agreements could result in the loss of our rights to practice such in-licensed intellectual property, and could compromise our development and commercialization efforts for any current or future product candidates.

We may not be successful in maintaining necessary rights to our product candidates or obtaining patent or other intellectual property rights important to our business through acquisitions and in-licenses.

We currently own and have in-licensed rights to intellectual property, including patents, patent applications and know-how, relating to our product candidates, and our success will likely depend on maintaining these rights. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to continue to acquire, in-license, maintain, or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and the rights to those formulations or methods of making those formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights that we identify as necessary for the development and commercialization of our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies also are pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We may also be unable to license or acquire third-party intellectual property rights on a timely basis, on terms that would allow us to make an appropriate return on our investment, or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the

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same rights and compete with us. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for the development of our product candidates or a development program on acceptable terms, we may have to abandon development of our product candidates or that development program.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies over the lifetime of a patent. In addition, the USPTO and other foreign patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such non-compliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, and non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our product candidates in any indication for which they are approved.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims challenging the inventorship of our patents and patent applications or ownership of our intellectual property. In particular, we may be subject to claims that former employees or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. For example, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, or we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical and pharmaceutical industries involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharmaceutical and pharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the America Invents Act (the “AIA”), which was passed in September, 2011, resulted in significant changes to the U.S. patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

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Among some of the other changes introduced by the AIA are changes to the limitation where a patent may be challenged, thus providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO proceedings to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Similarly, the complexity and uncertainty of European patent laws have also increased in recent years. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

If we do not obtain protection under the Hatch-Waxman Amendments and similar non-U.S. legislation for extending the term of patents covering our product candidates, our ability to compete effectively could be impaired.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the "Hatch-Waxman Amendments." The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product or method of use as compensation for patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Similar patent term extensions may be available in other jurisdictions. For example, a supplementary protection certificate in Europe may be applied for approval to recover some of the time lost between the patent application filing date and the date of first marketing authorization. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing product candidates sooner. As a result, our revenue from applicable product candidates could be reduced, possibly materially.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our competitive position may be adversely affected.

We currently own registered trademarks. We may not be able to obtain trademark protection in territories that we consider of significant importance to us. In addition, any of our trademarks or trade names, whether registered or unregistered, may be challenged, opposed, infringed, cancelled, circumvented or declared generic, or determined to be infringing on other marks, as applicable. We may not be able to maintain and protect our rights to these trademarks and trade names, which we will need to build name recognition by potential collaborators or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

If we are unable to protect the confidentiality of our trade secrets and know-how, our business and competitive position would be harmed.

We consider proprietary trade secrets and confidential know-how and unpatented know-how to be important to our business. In addition to seeking patents for some of our technology and product candidates, we also may rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed to be of limited value. However, trade secrets and confidential know-how are difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements with us. We also seek to preserve the integrity and confidentiality of our data, trade secrets, and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we cannot know whether the steps we have taken to protect our proprietary technologies will be effective. In addition, current or former employees, consultants, contractors, and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. We therefore cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming, and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Furthermore, if a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Failure to protect or maintain trade secrets and confidential know-how could adversely affect our business and our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our own trade secrets or confidential know-how.

We may be subject to claims by third parties asserting that we or our employees have misappropriated third-party intellectual property, or claiming ownership of what we regard as our own intellectual property. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and lose valuable intellectual property rights or personnel.

Some of our employees, including our senior management, were previously employed at other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the know-how, trade secrets, or other proprietary information of others in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including know-how, trade secrets, or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or undermine our ability to develop and commercialize our product candidates, which would severely harm our business. In addition, if such intellectual property rights were to be awarded to a third party, we could be required to obtain a license from such third party to commercialize our technology or product candidates. Such a license may not be available on commercially reasonable terms or at all, which could hamper or undermine our ability to develop and commercialize our product candidates, which would severely harm our business. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management from the development and commercialization of our product candidates.

Our proprietary information may be lost or we may suffer security breaches.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our

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clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure and those of our CROs or other contractors or consultants may be vulnerable to attacks by hackers or breached due to employee error, malfeasance, or other disruptions. The loss of clinical trial data from completed, ongoing, or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost, or stolen. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and significant regulatory penalties; disrupt our operations; damage our reputation; and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates.

Risks Related to Employee Matters and Managing Growth

Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management, including all of our senior management team, and scientific and technical personnel, many of whom have been instrumental for us and have substantial experience with rare and non-rare diseases and the biopharmaceutical and pharmaceutical industries. The loss of key managers and senior physicians or scientists could delay our acquisition and development activities. In addition, the competition for qualified personnel in the biopharmaceutical and pharmaceutical fields is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical, and managerial employees. We face competition for personnel from other companies and organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to achieve our development objectives, raise additional capital, and implement our business strategy.

We aim to expand our development, regulatory, and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our planned growth, which could disrupt our operations.

To manage our planned future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities or acquire new facilities, and continue to retain, recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such planned growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Risks Related to our ADSs

The market price for ADSs and the underlying ordinary shares may be volatile and may decline regardless of our operating performance, and the value of your investment could materially decline.

The trading price of ADSs may fluctuate, and the trading price of ordinary shares on AIM is likely to continue to fluctuate, substantially.

The market price of ADSs and ordinary shares may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- positive or negative results from, or delays in, testing or clinical trials conducted by our or our competitors;
- delays in entering into strategic relationships with respect to development or commercialization of our product candidates or entry into strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations or commercial product introductions by us or competitors;

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- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- the impact of public health epidemics, such as the ongoing COVID-19 pandemic, and government efforts to slow their spread;
- economic, public health, financial or geopolitical events that affect us or the financial markets generally, including the duration and severity of the impact of the ongoing COVID-19 pandemic;
- public concern relating to the commercial value or safety of our product candidates;
- financing or other corporate transactions;
- publication of research reports or comments by securities or industry analysts, and variances in our periodic results of operations from securities analysts' estimates;
- general market conditions in the biopharmaceutical and pharmaceutical industries or in the economy as a whole;
- the loss of any of our key scientific or senior management personnel;
- sales of our ADSs or ordinary shares by us, our senior management and board members, holders of ADSs or our other security holders in the future;
- actions by institutional shareholders;
- speculation in the press or the investment community; or
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling ADSs or ordinary shares and may otherwise negatively affect the liquidity of ADSs and ordinary shares. In addition, the stock market in general, and emerging companies in particular, have experienced significant price and volume fluctuations that often have been unrelated to the operating performance of the companies affected by these fluctuations. These broad market fluctuations may adversely affect the trading price of ADSs and ordinary shares, regardless of our operating performance. Furthermore, the trading prices for our ADSs and the underlying ordinary shares as well as the ordinary shares of our competitors have been highly volatile as a result of the COVID-19 pandemic. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the market price of our ADSs and ordinary shares.

In the past in the United States, when the market price of a security has been volatile, holders of that security have often instituted securities class action litigation against the issuer of such securities. If any of the holders of ADSs or ordinary shares were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our senior management would be diverted from the operation of our business. Any adverse determination in litigation could also subject us to significant liabilities.

Future sales of ordinary shares or ADSs could depress the market price of ADSs.

If holders of ordinary shares or ADSs sell, or indicate an intent to sell, substantial amounts of ordinary shares or ADSs in the public markets, the trading price of ADSs or ordinary shares could decline significantly. These sales might also make it more difficult for us to sell equity or equity-related securities at a time and price that we otherwise would deem appropriate.

The dual listing of ordinary shares and ADSs is costly to maintain and may adversely affect the liquidity and value of ordinary shares and ADSs.

Our ADSs are listed for trading on Nasdaq and our ordinary shares trade on AIM. Since April 24, 2019 we have maintained a dual listing, which has generated and will continue to generate additional costs, including significant legal, accounting, investor relations, and other expenses that we did not incur prior to April 24, 2019, in addition to the costs associated with the additional reporting requirements described elsewhere in this annual report. We cannot predict the effect of this dual listing on the value of our ADSs and ordinary shares. However, the dual listing of ADSs and ordinary shares may dilute the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for our ADSs. The price of our ADSs could also be adversely affected by trading in ordinary shares on AIM. In addition, the dual listing of ordinary shares and ADSs

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may cause the market price for ADSs and the underlying ordinary shares to fluctuate and decline regardless of our operating performance. See “—The market price for ADSs and the underlying ordinary shares may be volatile and may decline regardless of our operating performance, and the value of your investment could materially decline.”

Fluctuations in the exchange rate between the U.S. dollar and the pound sterling may increase the risk of holding ADSs.

The share price of ordinary shares is quoted on AIM in pence sterling, while our ADSs trade on Nasdaq in U.S. dollars. Fluctuations in the exchange rate between the U.S. dollar and the pound sterling may result in differences between the value of our ADSs and the value of ordinary shares, which may result in heavy trading by investors seeking to exploit such differences. In addition, as a result of fluctuations in the exchange rate between the U.S. dollar and the pound sterling, the U.S. dollar equivalent of the proceeds that a holder of our ADSs would receive upon the sale in the United Kingdom of any ordinary shares withdrawn from the depository, and the U.S. dollar equivalent of any cash dividends paid in pound sterling on ordinary shares represented by our ADSs, could also decline.

You may be subject to limitations on the transfer of ADSs and the withdrawal of the underlying ordinary shares.

ADSs are transferable on the books of the depository. However, the depository may close its books at any time or from time to time when the depository, in good faith, determines such action is necessary or advisable pursuant to the deposit agreement. The depository may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depository are closed, or at any time if we or the depository thinks it is necessary or advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason, subject to your right to cancel your ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying ordinary shares may arise because the depository has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or because we are paying a dividend on our ordinary shares.

In addition, you may not be able to cancel your ADSs and withdraw the underlying ordinary shares when you owe money for fees, taxes and similar charges to the depository and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to our ADSs or to the withdrawal of our ordinary shares or other deposited securities.

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

We are incorporated under English law. The rights of holders of ordinary shares and, therefore, certain of the rights of holders of ADSs, are governed by English law, including the provisions of the U.K. Companies Act 2006, and by our Articles of Association (our “Articles”). These rights differ in certain respects from the rights of shareholders in typical U.S. corporations.

The depository for ADSs is entitled to charge holders fees for various services, including annual service fees.

The depository for ADSs is entitled to charge holders fees for various services including for the issuance of ADSs upon deposit of ordinary shares, cancellation of ADSs, distributions of cash dividends or other cash distributions, distributions of ADSs pursuant to share dividends or other free share distributions, distributions of securities other than ADSs and annual service fees. In the case of ADSs issued by the depository into The Depository Trust Company (“DTC”), the fees will be charged by the DTC participant to the account of the applicable beneficial owner in accordance with the procedures and practices of the DTC participant as in effect at the time. The depository for ADSs will not be responsible for any United Kingdom stamp duty or stamp duty reserve tax arising upon the issuance or transfer of ADSs. For a discussion of the United Kingdom stamp duty and stamp duty reserve tax consequences of the issuance and transfer of ADSs, see “Item 10. Additional Information—E. Taxation.”

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If securities or industry analysts do not publish research or publish inaccurate research or unfavorable research about our business, the price and trading volume of ordinary shares and ADSs could decline.

The trading market for our ordinary shares and ADSs depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our ordinary shares or ADSs or publishes incorrect or unfavorable research about our business, the price of our ordinary shares and/or ADSs would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, or downgrades our ordinary shares or ADSs, demand for ADSs or ordinary shares could decrease, which could cause the price of ADSs and/or ordinary shares and/or trading volume to decline.

Our ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable results to the plaintiff(s) in any such action.

The deposit agreement governing our ADSs provides that holders and beneficial owners of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement or our ADSs, including claims under U.S. federal securities laws, against us or the depository to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. Although we are not aware of a specific federal decision that addresses the enforceability of a jury trial waiver in the context of U.S. federal securities laws, it is our understanding that jury trial waivers are generally enforceable. Moreover, insofar as the deposit agreement is governed by the laws of the State of New York, New York laws similarly recognize the validity of jury trial waivers in appropriate circumstances. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement and our ADSs.

In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim sounding in fraud or one which is based upon a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute). No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depository of compliance with any provision of U.S. federal securities laws and the rules and regulations promulgated thereunder.

If any holder or beneficial owner of ADSs brings a claim against us or the depository in connection with matters arising under the deposit agreement or our ADSs, including claims under U.S. federal securities laws, such holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us or the depository. If a lawsuit is brought against us or the depository under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different results than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

You may not receive distributions on ordinary shares represented by ADSs or any value for them if it is unlawful or impractical to make them available to holders of ADSs.

Pursuant to the terms of the deposit agreement, the depository for ADSs will distribute the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. This means that you may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have a material adverse effect on the value of ADSs.

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It may be difficult for you to bring any action or enforce any judgment obtained in the United States against us or members of our Board, which may limit the remedies otherwise available to us.

We are incorporated as a public limited company in England and Wales, and the majority of our assets are located outside the United States. In addition, the majority of the members of our board of directors (our “Board”) are nationals and residents of countries, including the United Kingdom, outside of the United States. Most or all of the assets of these individuals are located outside the United States. As a result, it may be difficult or impossible for you to bring an action against us or against these individuals in the United States if you believe your rights have been infringed under the securities laws or otherwise. In addition, a United Kingdom court may prevent you from enforcing a judgment of a U.S. court against us or these individuals based on the securities laws of the United States or any state thereof. A United Kingdom court may not allow you to bring an action against us or our directors based on the securities laws of the United States or any state thereof.

Shareholders in countries other than the United Kingdom will suffer dilution if they are unable to participate in future pre-emptive equity offerings.

Under English law, shareholders (being those shareholders that are included in a company’s register of members as holders of the legal title to that company’s shares) usually have pre-emptive rights to subscribe on a pro rata basis in the issuance of new shares for cash. The exercise of those pre-emptive rights by certain shareholders not resident in the United Kingdom may be restricted by applicable law or practice in the United Kingdom and overseas jurisdictions. In particular, the exercise of pre-emptive rights by United States shareholders would be prohibited unless an offering is registered under the Securities Act or an exemption from the registration requirements of the Securities Act applies. Furthermore, under the deposit agreement for our ADSs, the depository generally will not make available those pre-emptive rights to holders of ADSs unless certain conditions are met, including that the provision of such pre-emptive rights to the ADS holders is reasonably practicable. If no exemption applies and we determine not to register such offering, shareholders in the United States may not be able or permitted to exercise their pre-emptive rights. We are also permitted under English law to disapply pre-emptive rights (subject to the approval of our shareholders by special resolution or the inclusion in the articles of a power to disapply such rights) either generally or in relation to a specific allotment and thereby exclude certain shareholders, such as overseas shareholders, from participating in a rights offering (usually to avoid a breach of local securities laws).

Holders of ADSs may not have the same voting rights as holders of ordinary shares and may not receive voting materials in time to be able to exercise their right to vote.

Holders of ADSs are not able to exercise voting rights attaching to ordinary shares underlying our ADSs on an individual basis. Each holder of ADSs has appointed the depository or its nominee as the holder’s representative to exercise, pursuant to the instructions of the holder, the voting rights attaching to our ordinary shares underlying our ADSs. Holders of ADSs may not receive voting materials in time to instruct the depository to vote, and it is possible that they, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

Because we do not anticipate paying any cash dividends on ADSs or ordinary shares in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

Under English law, a company’s accumulated realized profits must exceed its accumulated realized losses on a non-consolidated basis before dividends can be paid. Therefore, we must have distributable profits before issuing a dividend. We have not paid dividends in the past on our ordinary shares. Further, we intend to retain future earnings, if any, for use in our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, our credit facility prohibits us from paying dividends on our equity securities without Kreos’s consent, and any future debt agreements may likewise preclude us from paying dividends. As a result, capital appreciation, if any, on ADSs or ordinary shares will be your sole source of gains for the foreseeable future.

We are currently a “foreign private issuer” under the rules and regulations of the SEC and, as a result, are exempt from a number of rules under the Exchange Act and are permitted to file less information with the SEC than a company incorporated in the United States.

We are incorporated as a public limited company in England and Wales and are deemed to be a “foreign private issuer” under the rules and regulations of the SEC. As a foreign private issuer, we are exempt from certain

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rules under the Exchange Act that would otherwise apply if we were a company incorporated in the United States, including:

- the requirement to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies with securities registered under the Exchange Act;
- the requirement to file financial statements prepared in accordance with U.S. GAAP;
- the proxy rules, which impose certain disclosure and procedural requirements for proxy solicitations; and
- the requirement to comply with Regulation Fair Disclosure (“Regulation FD”), which imposes certain restrictions on the selective disclosure of material information.

In addition, our officers, directors and principal shareholders are exempt from the reporting and “short-swing” profit recovery provisions of Section 16 of the Exchange Act and the related rules with respect to their purchases and sales of our ADSs and ordinary shares.

As a foreign private issuer, we are not required to comply with some of the corporate governance standards of Nasdaq applicable to companies incorporated in the United States.

Our Board is required to meet certain corporate governance standards under Nasdaq Listing Rules, including the requirement to maintain an audit committee comprised of three or more directors satisfying the independence standards of Nasdaq applicable to audit committee members. While foreign private issuers are not required to comply with most of the other corporate governance rules of Nasdaq, we believe we currently comply with, and intend to continue to comply with, the majority of such requirements, including the requirements to maintain a majority of independent directors and nominating and compensation committees of our Board comprised solely of independent directors. We follow UK requirements with respect to shareholder meetings including shareholder meetings required to disapply preemption rights and issue ordinary shares to investors in connection with private placements of our securities and follow the AIM rules and Corporate Governance Code published by the Quoted Companies Alliance for other corporate governance matters. As a result, holders of our ADSs may not be afforded the benefits of the corporate governance standards of Nasdaq to the same extent applicable to companies incorporated in the United States. See “Item 16G. Corporate governance—Foreign Private Issuer Exemption” elsewhere in this annual report.

Additional reporting requirements may apply if we lose our status as a foreign private issuer.

If we lose our status as a “foreign private issuer” under the rules and regulations of the SEC at some future time, then we will no longer be exempt from such rules and, among other things, will be required to file periodic reports and financial statements as if we were a company incorporated in the United States. The costs incurred in fulfilling these additional regulatory requirements could be substantial.

Although our reporting obligations as a foreign private issuer are fewer than those of a public company incorporated in the United States, our costs of complying with our SEC reporting requirements are significant, and our management is required to devote substantial time to complying with SEC regulations.

As a company with securities listed in the United States, and particularly after we no longer qualify as an emerging growth company, we will incur significant legal, accounting, and other expenses that we did not incur previously. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on non-U.S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our Board. In addition, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make the ADSs less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible to, and intend to, take advantage, for up to five years, of certain exemptions from various reporting requirements applicable to other public companies that are not Emerging Growth Companies, such as not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We expect to continue to take advantage of some or all of the available exemptions. We cannot predict whether investors will find the ADSs less attractive if we rely on these exemptions. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs and the market price of the ADSs may be more volatile.

In addition, the JOBS Act also provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Failure to establish and maintain effective internal controls could have a material adverse effect on our business and stock price.

Pursuant to Section 404, we are required to furnish a report by our senior management on our internal control over financial reporting beginning with this annual report. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404, we have been engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

The executive officers, Board and certain of our existing shareholders own a majority or a significant portion of our outstanding ordinary shares and, as a result, have control or significant influence over us and our interests may conflict with the interests of these shareholders.

Our executive officers, Board and significant shareholders and their respective affiliates, in the aggregate, beneficially own a majority of our outstanding ordinary shares (including ordinary shares in the form of our ADSs). Depending on the level of attendance at our general meetings of shareholders, these shareholders either alone or

voting together as a group may be in a position to control or significantly influence the outcome of decisions taken at any such general meeting. Any shareholder or group of shareholders controlling more than 50% of the share capital present and voting at our general meetings of shareholders may control any shareholder resolution requiring a simple majority, including the appointment of board members, certain decisions relating to our capital structure and the approval of certain significant corporate transactions. Any shareholder or group of shareholders controlling more than 75% of the share capital present and voting at our general meetings of shareholders may control any shareholder resolution amending our Articles. These shareholders may have interests that differ from ours and may vote in a way with which we disagree and which may be adverse to your interests. Among other consequences, this concentration of ownership may have the effect of delaying or preventing a change in control and might therefore negatively affect the market price of our ADSs and ordinary shares.

We may be a passive foreign investment company (“PFIC”) for any taxable year, which could result in material adverse U.S. federal income tax consequences if you are a U.S. investor.

In general, a non-U.S. corporation will be a PFIC for any taxable year in which (i) 75% or more of its gross income consists of passive income (the “income test”) or (ii) 50% or more of the value of its assets consists of assets (generally determined on a quarterly average basis) that produce, or are held for the production of, passive income (the “asset test”). For purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes interest, dividends, gains from certain property transactions, rents and royalties (other than certain rents or royalties derived in the active conduct of a trade or business). Cash is a passive asset for PFIC purposes. Goodwill (the value of which may be determined by reference to the company’s market capitalization) is treated as an active asset to the extent attributable to activities intended to produce active income.

Based on our gross income, the average value of our assets, including goodwill, and the nature of the current state of our business, we believe we were a PFIC for the year ended December 31, 2019. There can be no assurance regarding our PFIC status for the current taxable year or any particular year in the future because PFIC status is factual in nature, depends upon factors not wholly within our control, generally cannot be determined until the close of the taxable year in question and is determined annually. Accordingly, U.S. investors should invest in our ADSs only if they are willing to bear the U.S. federal income tax consequences associated with investments in PFICs.

If we were a PFIC for any taxable year during which a U.S. investor owns ADSs or ordinary shares, certain adverse U.S. federal income tax consequences could apply to such U.S. investor. We provide the information necessary for a U.S. investor to make a qualifying electing fund election with respect to us. See “Item 10. Additional Information—E. Taxation” for further information. U.S. investors should consult their tax advisers regarding our PFIC status for any taxable year and the potential application of the PFIC rules to an investment in our ADSs.

Risks Related to the Merger

We may have failed to discover undisclosed liabilities of OncoMed.

Our investigations and due diligence review of OncoMed may have failed to discover undisclosed liabilities of OncoMed. If OncoMed has undisclosed liabilities, we as a successor owner may be responsible for such undisclosed liabilities. Such undisclosed liabilities could have an adverse effect on the business and results of operations of us and our subsidiaries and may adversely affect the value of our ADSs and ordinary shares.

Our intangible assets may become impaired, which could result in material non-cash charges to our results of operations.

In April 2019, we acquired a substantial quantity of intangible assets in the Merger. At least annually, or whenever events or changes in circumstances indicate a potential impairment in the carrying value as defined by IFRS as issued by the IASB, we will evaluate such intangible assets for impairment based on the recoverable value for such intangible assets, being the higher of fair value less costs to sell and value in use, of such intangible assets. Estimated fair values could change if there are changes in our capital structure, cost of debt, interest rates, capital expenditure levels, operating cash flows or market capitalization. Impairments of intangible assets could require material non-cash charges to our results of operations.

OncoMed's ability to utilize its net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws.

As the Merger counted as an "ownership change", it impacted OncoMed's ability to fully realize the benefit of its net operating loss carryforwards.

At December 31, 2019, OncoMed had U.S. federal tax losses to be carried forward of approximately £47.5 million, of which £40.9 million can be carried forward indefinitely and £6.6 million which will begin to expire in 2023, if not utilized. At December 31, 2019, OncoMed had U.S. state tax losses to be carried forward of approximately £3.2 million which begin to expire in 2028, if not utilized.

A U.S. federal tax refund in respect of the AMT carryforward of approximately \$1.3 million was subsequently received in August 2019, following closing of the Merger. As at December 31, 2019, it is anticipated that a further \$1.3 million will be received in 2020 relating to AMT.

Item 4. Information On The Company

4.A. History and Development of the Company

Our legal and commercial name is Mereo BioPharma Group plc. Our company was incorporated on March 10, 2015, and was registered as a private limited company under the laws of England and Wales with the company number 09481161. On June 3, 2016, we were re-registered as a public limited company under the laws of England and Wales. Our principal executive offices are located at 4th Floor, 1 Cavendish Place, London, W1G 0QF, United Kingdom and our telephone number is +44 333 023 7300. Our website is www.mereobiopharma.com. Information on Mereo's website is not incorporated by reference into or otherwise part of this annual report. We have included our website address in this annual report solely for informational purposes. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The address of this website is <http://www.sec.gov>.

Mereo's portfolio consists of six clinical-stage product candidates, four of which were acquired from large pharmaceutical companies and two oncology anti-cancer product candidates which we acquired in the Merger. Mereo does not have any approved products and, as a result, has not generated any revenue from product sales aside from the license of navicixizumab by the Group to Oncologie in January 2020 pursuant to the terms of a global licensing agreement under which, the Company received an upfront payment of \$4 million with an additional payment of \$2 million conditional on a Chemistry, Manufacturing and Controls ("CMC") milestone. On April 23, 2019, we completed the Merger with OncoMed. Mereo MergerCo One Inc., a Delaware corporation and direct, wholly-owned subsidiary of Mereo US Holdings Inc., a Delaware corporation and direct, wholly-owned subsidiary of Mereo, was merged with and into OncoMed. OncoMed now operates as an indirect, wholly-owned subsidiary of Mereo.

Since June 9, 2016, Mereo ordinary shares have traded on AIM under the symbol "MPH." On April 24, 2019, our ADSs commenced trading on Nasdaq under the symbol "MREO."

We are an Emerging Growth Company. As such, we are eligible to, and intend to, take advantage, for up to five years, of certain exemptions from various reporting requirements applicable to other public companies that are not Emerging Growth Companies, such as not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

We will remain an Emerging Growth Company until the earliest of: (i) the last day of our fiscal year during which we have total annual gross revenues of at least \$1.07 billion; (ii) the last day of our fiscal year following the fifth anniversary of the closing of our initial public offering; (iii) the date on which we have, during the previous three-year period, issued more than \$1.0 billion in non-convertible debt; (iv) the date on which we are deemed to be a Large Accelerated Filer under the Exchange Act, with at least \$700 million of equity securities held by non-affiliates.

For information regarding our capital expenditures, see "Item 5. Operating and Financial Review and Prospects—B. Liquidity and Capital Resources."

4.B. Business Overview

We are a biopharmaceutical company focused on the development and commercialization of innovative therapeutics that aim to improve outcomes for oncology and rare diseases. Our existing portfolio consists of six clinical stage product candidates. Our lead oncology product candidate, etigilimab (an “Anti-TIGIT”), has completed a Phase 1a dose escalation clinical trial in patients with advanced solid tumors and has been evaluated in a Phase 1b study in combination with nivolumab in select tumor types. Our second oncology product, navicixizumab, for the treatment of late line ovarian cancer, has completed a Phase 1 study and has been partnered with Oncologie. Our rare disease product candidates are setrusumab for the treatment of OI and alvelestat for the treatment of severe AATD which is being investigated in an ongoing Phase 2 proof-of-concept study in the U.S. and Europe and expect to report top line data from this study in the second half of 2021. We plan to form a strategic partnership for the development of setrusumab in adults and children following the completion of the Phase 2b study and alignment with the FDA and EMA on the pivotal study design for children with OI.

We plan to develop our product candidates for oncology and rare diseases through the next key clinical milestone and then partner or in selected cases to develop through regulatory approval and potentially commercialization.

We plan to partner or sell our other two product candidates (which do not target oncology or rare diseases), acumapimod for the treatment of AECOPD and leflutrolole for the treatment of infertility and HH in obese men, recognizing the need for greater resources to take these product candidates to market.

Our strategy is selectively to acquire and develop product candidates for oncology and rare diseases that have already received significant investment from large pharmaceutical and biotechnology companies and that have substantial pre-clinical, clinical and manufacturing data packages. Since our formation in March 2015, we have successfully executed on this strategy by acquiring six clinical-stage product candidates of which four were in oncology and rare diseases. Four of these six clinical-stage product candidates were acquired from large pharmaceutical companies and two were acquired in the Merger. We aim to efficiently to develop our product candidates through the clinic and have commenced or completed large, randomized Phase 2 clinical trials for four of our product candidates.

Oncology and rare diseases represent an attractive development and in some cases commercialization opportunity for us since they typically have high unmet medical need and can utilize regulatory pathways that facilitate acceleration to approval and to the potential market. Development of products for oncology and rare diseases both involve close collaboration with key opinion leaders and investigators. Development of rare disease products generally involves close coordination with the patient organizations and patients are treated at a limited number of specialized sites which helps identification of the patient population and enables a small targeted sales infrastructure to commercialize the products in key markets.

Our team has extensive experience in the pharmaceutical and biotechnology sector in the identification, acquisition, development, manufacturing and commercialization of product candidates in multiple therapeutic areas. Our senior management has long-standing relationships with senior executives of large pharmaceutical and biotechnology companies which we believe enhances our ability to form strategic partnerships on our product candidates and to identify and acquire additional product candidates.

Our Pipeline

The following tables summarize our pipeline for our oncology and rare disease product candidates and our other product candidates for partnering. We have global commercial rights to etigilimab, setrusumab, alvelestat, acumapimod and leflutrolole.

ONCOLOGY AND RARE DISEASE PORTFOLIO

Product Candidate / Indication	Phase 1a	Phase 1b	Phase 2	Phase 3
Etigilimab Solid tumors	[Progressed]			
Navicixizumab* Ovarian Cancer	[Progressed]			
Setrusumab Osteogenesis imperfecta	[Progressed]			
Alvelestat Alpha-1 anti-trypsin deficiency	[Progressed]			

* Partnered with Oncologie, Inc.

OTHER CANDIDATES FOR PARTNERING

Product Candidate / Indication	Phase 1	Phase 2	Phase 3
Acumapimod Acute exacerbations of COPD	[Progressed]		
Leflutrozoole HH Infertility	[Progressed]		

Oncology Disease Product Candidates

- Etigilimab (OMP-313M32):** Etigilimab is an antibody against TIGIT (T-cell immunoreceptor with Ig and ITIM domains). TIGIT is a next generation checkpoint receptor shown to block T-cell activation and the body’s natural anti-cancer immune response. Etigilimab is an IgG1 monoclonal antibody which binds to the human TIGIT receptor on immune cells with a goal of improving the activation and effectiveness of T-cell and NK cell anti-tumor activity. Mereo completed a Phase 1a dose escalation clinical trial with etigilimab in patients with advanced solid tumors and enrolled patients in a Phase 1b study in combination with nivolumab in selected tumor types.

23 patients were treated in the Phase 1a dose escalation study with doses up to 20mg/kg Q2W. Tumor types included colorectal cancer, endometrial cancer, pancreatic cancer and other tumor types. No dose limiting toxicities were observed. In the Phase 1b combination study, a total of ten patients, nine of whom had progressed on prior anti-PD1/PD-L1 therapies were enrolled at doses of 3, 10, and 20 mg/kg. Tumor types included gastric cancer and six other tumor types. Eight patients were evaluable for tumor growth assessment, and all of these patients had progressed on PD1/PD-L1 therapies with best responses including two patients with a partial response and stable disease. Patients remained on study for up to 224 days. No dose limiting toxicities (DLTs) were observed.

The only treatment-related adverse event in the Phase 1a portion of the study with an incidence rate greater than 20 percent was rash (35 percent), and the most common treatment-related adverse events in the Phase 1b portion of the study were rash (40 percent), fatigue (30 percent) and pruritus (20 percent).

There was only one treatment-related serious adverse event in the Phase 1a portion (autoimmune hepatitis) and there were no treatment-related serious adverse events in the Phase 1b portion of the study. The Phase 1b study has now completed.

The etigilimab program was previously subject to an exclusive license option with Celgene Corporation (“Celgene”) as part of the Collaboration Agreement. See “—Material Agreements—Collaboration Agreement with Celgene.” In June 2019, we announced that Celgene had notified OncoMed that Celgene had decided, in light of strategic product portfolio considerations, not to exercise its option to license etigilimab. The Collaboration Agreement was terminated with respect to etigilimab effective on October 11, 2019. As a result, we have worldwide rights to the etigilimab program. See “—Material Agreements—Novartis Agreements” and “—Material Agreements—AstraZeneca Agreement” for important information regarding our license agreements with Novartis and AstraZeneca.

- **Navicixizumab (OMP-305B83):** Navi is a bispecific antibody that inhibits delta-like ligand 4 (DLL4) and vascular endothelial growth factor VEGF). We acquired this therapeutic product in the merger with OncoMed. Navi was licensed by the Group to Oncologie in January 2020 pursuant to the terms of a global licensing agreement. Holders of contingent value rights are entitled to receive the benefit of certain cash milestone payments made to Mereo under the license agreement. In a Phase 1a clinical trial, Navi demonstrated single agent activity. Following this we conducted a Phase 1b clinical trial in ovarian cancer, in combination with paclitaxel, in platinum-resistant ovarian cancer. A successful FDA Type B meeting was held in July 2019 and the potential for accelerated approval was discussed. Navicixizumab has also been granted Fast Track Approval by the FDA. In January 2020 we completed a global license agreement for the further development and commercialization of Navi to Oncologie.

Rare Disease Product Candidates

Our portfolio consists of the following rare disease product candidates:

- **Setrusumab (BPS-804):** Setrusumab is a novel antibody we are developing as a treatment for OI, a rare genetic disease that results in bones that can break easily and is commonly known as brittle bone disease. OI is a debilitating orphan disease for which there are no treatments approved by the FDA or EMA. It is estimated that OI affects a minimum of 25,000 people in the United States and approximately an aggregate of 32,000 people in Germany, Spain, France, Italy, and the United Kingdom. Setrusumab is designed to inhibit sclerostin, a protein that inhibits the activity of bone-forming cells. We believe setrusumab's mechanism of action is well suited for the treatment of OI and has the potential to become a novel treatment option for patients that could reduce fractures and improve patient quality of life.

In 2016, we obtained orphan drug designation in OI for setrusumab in the United States and the EU and, in November 2017, it was accepted into the Priority Medicines scheme ("PRIME") of the EMA. Prior to our acquisition of setrusumab, Novartis conducted four clinical trials in 106 patients and healthy volunteers. A Phase 2 clinical trial of setrusumab in OI showed statistically significant improvements in bone formation biomarkers and bone mineral density. In April 2017, we initiated a Phase 2b clinical trial for setrusumab in adults in the United States, Europe and Canada. The trial is randomized with three blinded arms at high, medium and low doses to establish the dose response curve and an open label arm at the top dose. We reported top-line data on the three blinded dose ranging arms in November 2019 with the results supporting progression of setrusumab into a pediatric pivotal study in OI.

Following the completion of the dosing part of the study, patients are continuing to be followed for a further twelve months to examine the off-effects of setrusumab. We have also agreed on a PIP for setrusumab with the EMA and in February 2020, we announced the successful completion of a Type B End-of-Phase 2 meeting with the FDA to discuss the development of setrusumab for the treatment of children and adolescents with OI in the United States. We intend to partner setrusumab prior to conducting a pivotal trial of setrusumab in children with severe OI to begin in late 2020, with fracture rate as the primary endpoint. We believe that the results from this trial, if favorable, will be sufficient to support the submission of an MAA to the EMA for setrusumab for the treatment of children with severe OI and a CMA for the treatment of OI in adults in the EU.

- **Alvelestat (MPH-966):** Alvelestat is a novel, oral small molecule we are developing for the treatment of severe AATD, a potentially life-threatening, rare, genetic condition caused by a lack of effective alpha-1 antitrypsin ("AAT"), a protein that protects the lungs from enzymatic degradation. This degradation leads to severe debilitating diseases, including early-onset pulmonary emphysema, a disease that irreversibly destroys the tissues that support lung function. There are an estimated 50,000 patients in North America and 60,000 patients in Europe with severe AATD. Alvelestat is designed to inhibit NE, a neutrophil protease, which is a key enzyme involved in the destruction of lung tissue. We believe the inhibition of NE has the potential to protect AATD patients from further lung damage.

Prior to our license of alvelestat, AstraZeneca conducted 12 clinical trials involving 1,776 subjects, including trials in bronchiectasis and CF. Although these trials were conducted in diseases other than AATD, we believe the data demonstrated potential clinical benefit and biomarker evidence of treatment effect for AATD patients. We have initiated a Phase 2 proof-of-concept clinical trial in patients with severe AATD in the United States and the EU and as previously announced, expect to report top-line data from this trial in the second half of 2021.

Other Product Candidates for Partnering

Our portfolio of other disease products consists of the following product candidates:

- **Acumapimod (BCT-197):** Acumapimod is a p38 MAP kinase inhibitor we are developing as an oral first-line acute therapy for patients with AECOPD. COPD is a non-fully-reversible, progressive lung disease in which inflammation plays a central role. There are an estimated 16 million people in the United States diagnosed with COPD. Of all hospital admissions in the United States related to COPD, approximately 63 percent are for AECOPD patients. We believe acumapimod offers a potential new treatment for controlling inflammation by targeting pathways that drive the pathological mechanism behind AECOPD.

Since there are currently no approved therapies in the United States or the EU to treat AECOPD, we believe that there is significant medical need for a drug which is disease-modifying. We believe acumapimod could potentially prevent AECOPD instead of just treating the symptoms and has the potential to improve quality of life, slow the progression of the disease, and significantly reduce direct healthcare costs.

Prior to our acquisition of acumapimod, Novartis conducted five clinical trials in 459 patients and healthy volunteers, including a Phase 2a trial in AECOPD patients that showed a clinically meaningful improvement in lung function at the highest dose.

We conducted a Phase 2 dose-ranging clinical trial for acumapimod in 282 patients with AECOPD to explore two different dosing regimens on top of standard of care, which included steroids, antibiotics, and bronchodilators. Both dosing regimens showed a statistically significant change in FEV1 from baseline to Day 7, meeting the trial's primary endpoint on an intent-to-treat patient population basis. In addition, dose-dependent, statistically significant reductions in hsCRP and fibrinogen were shown with treatment with acumapimod, with hsCRP remaining suppressed through the 26-week observation period. Treatment with acumapimod also showed a statistically significant reduction in the number of COPD exacerbations that required hospitalization. Consistent with these results, there was a significant reduction in the use of corticosteroid and antibiotics in the follow-up portion of the study. In addition, acumapimod was reported to be safe and well tolerated. Based on these results, we intend to explore strategic options with third parties for the further development of acumapimod.

In addition, in April 2019, we announced a successful end of Phase 2 meeting with the FDA regarding acumapimod. In the meeting, we and the FDA agreed on a development plan for acumapimod. In September 2019, we had a positive SAWP meeting with the EMA.

- **Leflutrozoole (BGS-649):** Leflutrozoole is a once-weekly oral therapy we are developing for the treatment of infertility and HH in obese men. HH is a clinical syndrome that results from inadequate levels of testosterone. Based on WHO estimates and scientific data, we estimate there are approximately seven million cases of HH in obese men in the United States. In these men, a decline in testosterone is exacerbated by high levels of the aromatase enzyme, which is present in fat tissue and leads to a reduction in testosterone. Leflutrozoole is designed to inhibit the aromatase enzyme and is being developed to restore normal levels of testosterone without causing excessively high testosterone levels or reducing the levels of LH or FSH. Both LH and FSH play key roles in sperm formation and LH plays a key role in endogenous testosterone formation. In contrast to current therapies for HH, which involve the exogenous administration of testosterone and lead to further down regulation of LH and FSH, we believe that leflutrozoole, by preserving sperm formation through LH and FSH production, may present a benefit to patients.

Prior to our acquisition of leflutrolole, Novartis conducted seven clinical trials exposing 131 patients and healthy volunteers to leflutrolole, including a Phase 2 proof-of-concept trial for HH in obese men in which leflutrolole normalized testosterone levels in all patients and demonstrated an increase in LH and FSH levels.

In March 2018, we reported top-line data from our completed Phase 2b dose-ranging clinical trial of leflutrolole for the treatment of HH in obese men. The trial enrolled 271 patients who were administered placebo or one of three doses of leflutrolole. The trial met our primary endpoint of normalizing testosterone levels in at least 75 percent of subjects after 24 weeks of treatment and all of the secondary endpoints, including normalizing testosterone in at least 90 percent of patients after 24 weeks of treatment at the two highest doses and improvement in LH and FSH levels at all three doses. Leflutrolole was reported to be well-tolerated in the trial. A subset of 143 patients entered into a six-month safety extension study. Following the positive result of the safety extension study for leflutrolole, we convened an advisory board meeting and concluded that the future development of leflutrolole should focus on male infertility. We intend to explore strategic options with third parties for the further development of leflutrolole.

Our Strategy

We intend to become a leading biopharmaceutical company developing innovative therapeutics that aim to improve outcomes for patients with rare and select oncology indications. The key elements of our strategy to achieve this goal include:

- **Rapidly develop our oncology and rare disease product candidates.** Etigilimab, our lead oncology program, has completed a Phase 1a dose escalating monotherapy study and has been evaluated in a Phase 1b combination study with nivolumab in a range of tumor types. We plan to initiate a Phase 1b study of etigilimab in combination with a PDL-1/PD-1 in Q4 2020. Our second oncology product, Navicixizumab, for the treatment of late line ovarian cancer, has completed a Phase 1 study and has been partnered with Oncologie, Inc. We have completed and announced top-line data on a Phase 2b clinical trial of setrusumab for the treatment of OI in adults in the United States, Europe and Canada. We reported top-line data on the three blinded dose ranging arms in November 2019 with the results supporting progression of setrusumab into a pediatric pivotal study in OI. Following the completion of the dosing part of the study, patients will continue to be followed for a further twelve months to examine the off-effects of setrusumab. We have agreed on a PIP for setrusumab with the EMA and following our end of Phase 2 Type B meeting with the FDA in February 2020, and following a strategic partnership, we expect to initiate a pivotal trial in children with severe OI in late 2020, with fracture as the primary end point. We plan to form a strategic partnership for setrusumab prior to initiation of the pivotal study in children with OI and believe the results from this trial, if favorable, will be sufficient to support the submission of a BLA in the United States and MAA in the EU for setrusumab for the treatment of children with severe OI and a CMA for the treatment of adults with OI. We have commenced a Phase 2 proof-of-concept clinical trial of alvelestat for the treatment of severe AATD and as previously announced expect to report top-line data from this trial in the second half of 2021. If the results are favorable and pending regulatory feedback, we will determine the optimum path forward for development of alvelestat towards approval and commercialization.
- **Efficiently advance our other product candidates (non-oncology/non-rare diseases) and explore strategic relationships with third parties for further clinical development and/or commercialization or strategic sales or out-licensing.** Based on the results from our Phase 2 clinical trial of acumapimod, we plan to enter into one or more strategic relationships with third parties for acumapimod to undertake the next phase of clinical development and, if approved, commercialization. In March 2018, we reported top-line Phase 2b data for leflutrolole for the treatment of HH and in December 2018, we reported positive results from the safety extension study for leflutrolole. We intend to explore strategic relationships with third parties for the further development and commercialization of leflutrolole.
- **Continue to be a partner of choice for large pharmaceutical and biotechnology companies.** We believe that we are a preferred partner for large pharmaceutical and biotechnology companies as they seek to unlock the potential in their development pipelines and deliver therapeutics to patients in areas of high unmet medical need. We have strong relationships with these companies, as evidenced by our agreements with Novartis and AstraZeneca, as well as by the Merger, and a track record of structuring transactions that enable us to leverage our core capabilities while creating value for all stakeholders. We intend to continue to enter into strategic relationships that align our interests with those of large pharmaceutical and biotechnology companies and that we believe to be mutually beneficial.

- **Leverage our expertise in business development.** Our senior management team has extensive relationships with large pharmaceutical and biotechnology companies. Our senior management team has extensive relationships with large pharmaceutical and biotechnology companies. These relationships are important to us as we seek to form strategic partnerships on our product candidates and as appropriate, to grow our pipeline of product candidates in oncology and rare diseases.

Therapeutic Candidates

Etigilimab (OMP-313M32) for the Treatment of Advanced Solid Tumors

We acquired etigilimab in the Merger with OncoMed in 2019. TIGIT (T-cell immunoreceptor with Ig and ITIM domains) is an inhibitory receptor and via interactions with its ligands may block T-cells from attacking tumor cells. The anti-TIGIT therapeutic candidate, etigilimab, is intended to activate the immune system, through multiple mechanisms, and enable anti-tumor activity. Etigilimab completed the single-agent Phase 1a portion of a Phase 1a/b clinical trial, which enrolled patients with advanced or metastatic solid tumors, and also completed enrollment of the Phase 1b portion of the clinical trial, which combined etigilimab with anti-PD1 (nivolumab).

The Phase 1a/b clinical trial enrolled patients with advanced solid tumors into either a Phase 1a single-agent portion (dose escalation in all patients and expansion in selected tumor types) or Phase 1b combination portion in selected tumor types with nivolumab (dose escalation). 23 patients were treated in the Phase 1a dose escalation portion of the study with doses up to 20mg/kg every two weeks and 10 patients were treated in the Phase 1b combination portion of the study at doses up to 20 mg/kg every two weeks in combination with nivolumab. Tumor types in the Phase 1a portion of the study were colorectal cancer (6 patients), endometrial cancer (4 patients), head & neck cancer (4 patients), pancreatic cancer (2 patients), triple negative breast cancer (2 patients) and five other tumor types and those included in the Phase 1b portion of the study included gastric cancer (3 patients) and seven other tumor types. No dose limiting toxicities were observed in the Phase 1a or 1b portions of the study and the recommended Phase 2 dose in the Phase 1a monotherapy arm was the top dose of 20mg/kg biweekly. The only treatment-related adverse event with an incidence rate greater than 20% in the Phase 1a portion of the study was skin disorders (35%), and the most common treatment-related adverse events in the Phase 1b portion of the study were skin disorders (50%) and fatigue (30%) . There was only one treatment-related serious adverse event in the Phase 1a portion (autoimmune hepatitis) and there were no treatment-related serious adverse events in the Phase 1b portion of the study. None of the patients in the Phase 1a portion had an objective response and 30% had stable disease. One of the ten patients in the Phase 1b portion had an objective response and one additional patient had stable disease. The study has now completed enrollment.

In preclinical studies with anti-TIGIT antibodies, immune activation and robust anti-tumor activity have been observed—both as a single agent and in combination with other cancer immunotherapeutics including anti-PD1. At the 2017 American Association of Cancer Research (“AACR”) meeting, preclinical data demonstrating the capacity of an anti-TIGIT antibody to induce long-term immune memory and durable anti-tumor response was presented. Also, at the 2018 AACR meeting data that showed that anti-TIGIT treatment reduced the abundance of regulatory T-cells (Tregs) within tumors in animal models, and mechanistic studies that demonstrated an important contribution of effector function for anti-tumor efficacy in animal models was presented.

The etigilimab program was previously subject to an exclusive license option with Celgene as part of the Collaboration Agreement. See “Business—Material Agreements—Collaboration Agreement with Celgene.” In June 2019, we announced that Celgene had notified OncoMed that Celgene had decided, in light of strategic product portfolio considerations, not to exercise its option to license etigilimab. The Collaboration Agreement was terminated with respect to etigilimab effective on October 11, 2019. See “—Material Agreements—Collaboration Agreement with Celgene.” As a result, we have worldwide rights to the etigilimab program.

Navicixizumab (OMP-305B83) for Treatment of Ovarian Cancer and Taxol

We acquired Navicixizumab (“Navi”) in the Merger with OncoMed in 2019. Subsequently in January 2020, we out-licensed Navi to Oncologie. See “—Material Agreements—Licensing Agreement for Navicixizumab.” In addition, Navi is the subject of the CVR Agreement which sets forth certain rights and obligations of us with respect to Navi. See “—Material Agreements—CVR Agreement Between Us and Computershare—The NAVI Milestones.”

Setrusumab (BPS-804) for the Treatment of Osteogenesis Imperfecta

Overview

We are developing setrusumab for the treatment of OI. Setrusumab is a novel, intravenously administered antibody that is designed to inhibit sclerostin, a protein that inhibits the activity of bone-forming cells, known as osteoblasts. We believe that by blocking sclerostin, setrusumab has the potential to induce or increase osteoblast function and maturation of these cells, increasing overall bone mass and thereby reducing fractures in OI patients.

Background of Osteogenesis Imperfecta

OI is a genetic disorder characterized by fragile bones and reduced bone mass, resulting in bones that break easily, loose joints and weakened teeth. In severe cases, patients may experience hundreds of fractures in a lifetime. In addition, people with OI often suffer from muscle weakness, early hearing loss, fatigue, curved bones, scoliosis (curved spine), brittle teeth, respiratory problems and short stature. The disease can be extremely debilitating and even fatal in newborn infants with a severe form of the disease. OI is a rare condition that affects a minimum of 25,000 people, an incidence rate of 6.2 out of 100,000, in the United States, according to estimates by the Osteogenesis Imperfecta Foundation, and approximately 32,000 people, an incidence rate of 10 out of 100,000, in Germany, Spain, France, Italy, and the United Kingdom, according to estimates by Orphanet. OI occurs across the globe without any currently described discernable higher prevalence in one population specifically.

There are eight recognized forms of OI, designated type I through type VIII. Type I is the least severe form, although it still has a significant impact on patients' lives, including fractures and other physical manifestations, while type II is the most severe and frequently causes death at or shortly after birth. The most prevalent form of OI is type I, which is estimated to occur in approximately 50% to 60% of OI patients. The less severe forms of OI, such as type I and type IV, are still serious conditions and are characterized by broken bones, often as a result of minor trauma. Patients typically have a blue or gray tint to the sclera, the part of the eye that is usually white, and there is a risk of early hearing loss in adults.

The most severe forms of OI, particularly type II, may be characterized by an extremely small, fragile rib cage, and underdeveloped lungs. Infants with these abnormalities have life-threatening problems related to breathing and often die shortly after birth.

Current Treatment Landscape for Osteogenesis Imperfecta

There are no therapies approved by the FDA or EMA for the treatment of OI. The only treatments available to OI patients are the acute management of fractures as they occur and drugs such as bisphosphonates, which are not approved for this indication but are commonly used off-label in children.

Current treatment of OI is directed towards management of fractures with casting or surgical fixation. Following either of these, physical therapy will often be required. Preventative surgeries, such as intramedullary, or in-bone, nailing fixation are also undertaken. Supportive care for the disease involves surgery to correct deformities, internal splinting of bones with metal rods, bracing to support weak limbs and decrease pain, physical therapy, and muscle strengthening and aerobic conditioning to improve bone mass and strength.

Some OI patients are treated off-label with drugs indicated for osteoporosis. Bisphosphonate drugs slow down the rate at which osteoclasts, which are cells which resorb or take away bone, reduce the bones' mass. These include Aredia (pamidronate), Fosamax (alendronate) and Reclast (zoledronic acid). However, bisphosphonate drugs are not approved by the FDA or the EMA for use in OI. We are not aware of any long-term clinical studies demonstrating an improvement in fractures in adults and the effect of long-term therapy with these drugs remains unclear. Therefore, we believe the effect of bisphosphonate drugs on fractures, growth, bone deformity, mobility, and pain remains unclear in both adults and children.

Our Approach

Our product for treating OI is setrusumab, a fully human monoclonal antibody that is designed to inhibit sclerostin. Sclerostin is produced in osteocytes, which are mature bone cells that are thought to be the mechanoreceptor cells that regulate the activity of bone-building osteoblasts and bone-resorbing osteoclasts.

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Sclerostin inhibits the activity of osteoblasts. We believe that by blocking sclerostin, setrusumab has the potential to induce or increase osteoblast activity and maturation of these cells, increasing overall bone mass and, thereby reducing fractures in OI patients.

Clinical Development of Setrusumab

The following table summarizes the historical, current and planned clinical trials of setrusumab:

Historical Trials			Current Trials			Planned Trials			
Phase	Population	Subjects Treated with Setrusumab	Phase	Population	Enrollment	Phase	Population	Planned Enrollment	Target Start
Phase 1	Healthy Volunteers (postmenopausal women)	30	Phase 2b	OI(adult)	112	Phase 3	OI (pediatrics)	~160	Phase 3 ready in EU
Phase 2	Hypophosphatasia	8							
Phase 2	Women with Low Bone Mineral Density	36							
Phase 2	OI	9							

Current and Planned Clinical Trials in Osteogenesis Imperfecta

In April 2017, we commenced a Phase 2b clinical trial of setrusumab in adults in the United States, Europe and Canada. The Phase 2b clinical trial is a multi-center, randomized trial with three blinded arms at a high, medium and low doses to establish the dose response curve and an open label arm at the top dose. The trial completed enrollment of 112 patients and we reported 12-month top-line data from the trial in November 2019. Following the 12-month dosing part of the trial, patients will be followed for a further twelve months to examine the off-effects of setrusumab. Similar to the Phase 2 clinical trial conducted by Novartis, we enrolled patients with type I, III and IV OI.

12 month Top-line Data From Setrusumab Phase 2b Dose-ranging Study in Adult Patients

On November 11, 2019, we reported 12-month top-line data from our Phase 2b dose-ranging clinical trial for setrusumab in adults with Type I, III or IV OI.

The primary endpoint of the trial was change in trabecular volumetric bone mineral density (“Tr vBMD”) of the radius (wrist) over baseline after 12 months of treatment as measured by high resolution peripheral quantitative computerized tomography (“HRpQCT”). As a result of the unexpected high heterogeneity of the trial patients’ trabecular bone baseline values at the wrist (including both very low and very high trabecular bone at baseline as compared to the literature available), the primary endpoint was not met at any of the three setrusumab dose levels. HRpQCT is a relatively new imaging technique that has not been used widely in clinical studies and was chosen in order to improve the understanding of the effect of setrusumab on the bone biology in OI patients, given it can measure both trabecular and cortical volumetric BMD separately.

Importantly, when the percentage change in trabecular and cortical volumetric bone mineral density (“BMD”) at the wrist were combined (the total volumetric BMD as measured by HRpQCT, a secondary endpoint of the study), an increase in total volumetric BMD was observed and reached statistical significance in the medium and high dose cohorts. Mean increases in total volumetric BMD were 4.11% (p=0.004), 4.5% (p=0.028), and 0.58% (p=0.97) in the high, medium, and low dose cohorts (post hoc analysis), respectively. This suggests total volumetric BMD increases were driven by the ability of setrusumab to increase cortical volumetric BMD.

The study achieved its important secondary endpoint of increase in areal BMD at the lumbar spine at six and 12 months over baseline using dual energy x-ray absorptiometry (“DXA”), a well-established measurement tool of BMD (cortical and trabecular bone), reaching statistical significance in the high and medium doses cohorts at both six and 12 months, with a clear dose-dependent response. Mean increases in areal BMD at the lumbar spine were 8.8% (p<0.001), 6.8 % (p<0.001), and 2.6% (p=0.057) in the high, medium, and low dose cohorts at 12 months, respectively. Moreover, increases in areal BMD were consistent across all OI subtypes (I, III and IV) represented in the study and improved with duration of treatment. Statistically significant changes in areal BMD were also observed by DXA at the femoral neck and total hip with mean increases of 3.1% (p=0.022) and 2.2% (P=0.011), respectively, at 12 months in the high dose cohort.

On January 14, 2020, we reported additional data to the above from our Phase 2b does-ranging clinical trial for setrusumab. This additional data demonstrated a dose dependent increase in bone strength (stiffness and failure load) as measured by Finite Element Analysis (“FEA”). This was a second prespecified primary end point and reached statistical significance in the high dose cohort. FEA is a technique that, based on the HRpQCT, allows for the estimation of physical properties of bone.

We also reported on the end point of Trabecular Bone Score (TBS) at the lumbar spine. Setrusumab demonstrated a statistically significant increase in TBS at both the high (p<0.001) and medium dose cohorts (p<0.001). TBS is a gray-level texture index determined from patient lumbar spine DXA scans that correlates with 3D parameters of trabecular bone architecture thought to help predict fracture.

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Although the Phase 2b trial was not powered to show a difference in fracture rates, a trend of reduction in fractures was observed in the high-dose cohort. Setrusumab was safe and well-tolerated in the study. There were no cardiac-related safety concerns observed in the study.

The study enrolled 112 adults (69 with type I, 28 with type IV and 15 with type III OI) at 27 clinical sites across the United States and Europe and randomized patients originally to one of four different blinded monthly dosing regimens of setrusumab: high, medium, low and placebo. The study was subsequently revised to convert the placebo arm into an open-label arm where patients received the high dose regimen of setrusumab. Six-month results from this open-label arm were reported in May 2019 and presented at the American Society of Bone Mineral Research (ASBMR) Annual Meeting in September 2019. Patients in the open-label arm of the study have not yet completed 12 months of treatment with setrusumab, therefore the top-line 12-month results reported on November 11, 2019 and on January 14, 2020 are from the three-arm blinded portion of the study.

Phase 2b (ASTEROID) Study Design

The Phase 2b dose-ranging (ASTEROID) study was a 12-month, randomized, double-blind, Phase 2b dose-finding study in 112 adults diagnosed with type I, III or IV OI and a confirmed COL1A1/COL1A2 mutation who have fractured over the previous five years. The primary endpoint of the study was the change over baseline in Tr vBMD of the wrist at 12 months, assessed using HRpQCT. Change from baseline at six and 12 months for areal BMD at the lumbar spine, as measured by DXA, was an important secondary endpoint. Additional secondary endpoints included HRpQCT parameters (such as total volumetric BMD), bone biomarkers, patient reported outcomes (PRO) and quality of life measures. Fracture data were also collected throughout the duration of the study, although the trial was not statistically powered for fractures.

Patient Baseline Demographics

The study enrolled 112 adults (69 with type I, 28 with type IV and 15 with type III OI) at 27 clinical sites across the U.S. and Europe and randomized patients originally to one of four different blinded monthly dosing regimens of setrusumab: high, medium, low and placebo. The study was subsequently revised to convert the placebo arm into an open-label arm where patients received the high dose regimen of setrusumab. Six-month results from this open-label arm were reported in May 2019 and presented at the ASBMR annual meeting in September 2019. Patients in the open-label arm of the study have not yet completed 12 months of treatment with setrusumab, therefore the top-line 12-month results reported in November 2019 are from the three-arm blinded portion of the study.

Patients in the trial had not been treated with bisphosphonates in the previous three months or other anabolic or anti-resorptive medications in the previous six months. Ten patients discontinued treatment with setrusumab in the blinded portion of the study.

Efficacy Endpoint Results

Patient baseline Tr vBMD HRpQCT values ranged widely from 18.2 to 279 and changes did not show a dose response. As such, the study demonstrated mean changes in Tr vBMD of the wrist over baseline of 0.7% (± 5.1), -0.8% (± 4.2), and 0.61% (± 2.8) in the high (n=27), medium (n=20), and low dose (n=22) cohorts, respectively. Bone strength (Failure Load and Bone Stiffness) measured by FEA, derived from HRpQCT, was a second prespecified primary end point and showed a dose dependent response, reaching statistical significance in the high dose cohort. High dose change from baseline was 2.0% (P=0.037), Medium dose 1.1% (NS) and Low Dose -0.06% (NS).

The study achieved its important secondary endpoint of increase in areal BMD at the lumbar spine at six and 12 months over baseline using two-dimensional DXA measurement, reaching statistical significance in the high and medium doses cohorts at both six and 12 months, with a clear dose-dependent response. The magnitude of areal BMD changes over baseline at the lumbar spine at six months in the blinded high-dose cohort was consistent with the previously reported six-month data from the open-label arm of the study.

Table 1: Increase in areal BMD at the lumbar spine as measured by DXA by dose cohort

Dose Cohort	Mean % Change in Areal BMD at Six Months	P Value at Six Months	Mean % Change in Areal BMD at 12 Months	P Value at 12 Months
High (n=23)	+4.2%	p<0.001	+8.8%	p<0.001
Medium (n=17)	+3.61%	p=0.003	+6.8%	p<0.001
Low (n=21)	+1.52%	p=0.153	+2.6%	P=0.057

Increases in areal BMD as measured by DXA were also consistent across all OI subtypes represented in the study (types I, III and IV).

Table 2: Increase in areal BMD at the lumbar spine as measured by DXA by OI subtype in high dose group

OI Type in High Dose Cohort	Mean % Change in Areal BMD at Six Months	Mean % Change in Areal BMD at 12 months
Type I (n=17)	+4.1%	+8.6%
Type III & IV (n=6)	+5.4%	+9.8%

Statistically significant changes in areal BMD were also observed by DXA at the femoral neck and total hip with mean increases of 3.2% (p=0.022) and 2.3% (P=0.009), respectively, at 12 months in the high dose cohort.

Although the study was not statistically powered to show a difference in fracture rates, a trend of reduction in fractures was observed in the high dose cohort. Fractures in the study included both X-ray confirmed as well as those confirmed by a local radiologist dependent on the nature of the fracture.

Table 3: Percentage of patients with at least one fracture and occurrence rate per patient year

Dose Cohort	Percentage of Patients	
	Experience <input type="checkbox"/> 1 New Fracture	Fractures per Subject Year
High (n=27)	15%	0.16
Medium (n=20)	35%	0.49
Low (n=22)	23%	0.39

Summary of Top-line Safety Results

Top-line 12-month safety results suggest setrusumab was safe and well tolerated in the study. The adverse event profile was balanced across the arms. There were five, eight and four serious treatment emergent adverse events in the high, medium and low dose groups, three of which were initially recorded as treatment related. Two events occurred in one patient, these were headache and hydrocephalus. The patient had a history of basilar invagination, subdural haematoma and subdural haemorrhage; the Neurologist and Data Monitoring Committee (“DMC”) concluded that the events were unlikely related to the study drug. There was a temporary interruption to the study drug but the patient restarted treatment and continued the study with no complications. The other serious adverse event that was initially recorded as related was of anaphylactic reaction, which occurred two days following setrusumab infusion. This was the patient’s sixth infusion. As the reaction was two days following the infusion and the patient previously had five doses, it was determined that it was unlikely to be a drug reaction and the patient continued therapy, without symptoms or signs with repeat infusions. All of the nine adverse events that were reported as potentially cardiac related were discussed at the DMC (including cardiology review), and none were concluded to represent a cardiovascular safety concern.

Next Steps

Patients who have completed 12-months of treatment in the ASTEROID study continue into a 12-month extension “off therapy” portion to examine the off effect of setrusumab. Patients who continue in the extension portion have the option to receive 12 months of treatment with the bisphosphonate zoledronic acid (given at months six and/or 12). Such patients will receive both DXA and HRpQCT scans at six and 12 months after entering the extension portion.

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In addition, we have agreed on a PIP for setrusumab with the EMA and in February 2020, we announced the successful completion of a Type B End-of-Phase 2 meeting with the FDA to discuss the development of setrusumab for the treatment of children and adolescents. Following completion of a strategic partnership, we intend to initiate a pivotal trial of setrusumab in the United States, Europe and Canada in children with severe OI in late 2020, with fracture rate as the primary endpoint. We intend to enroll approximately 165 children aged 2 to <18 years old in this trial.

In Europe, the EMA has an adaptive pathways program which allows for early and progressive patient access to medicine. In July 2016, the EMA launched the PRIME scheme, a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. In February 2017 setrusumab was accepted into the adaptive pathways program and in November 2017, the EMA granted PRIME designation for setrusumab for the treatment of OI. See “—Government Regulation—Foreign Government Regulation.”

Positive Feedback from Type B End-of-Phase 2 Meeting with the FDA

On February 28, 2020, we announced the successful completion of a Type B End-of-Phase 2 meeting with the FDA to discuss the development of setrusumab for the treatment of children and adolescents with OI. Following the review of the data from the our Phase 2b (ASTEROID) study with setrusumab in adults with OI, the FDA agreed on the design of a Phase 3 pediatric study in OI to be completed prior to the submission of a Biologics License Application (“BLA”) in the United States. This is in line with our proposed pivotal pediatric study design that has already been agreed to in principle with the EMA. The Phase 3 pediatric study will include the following elements:

- a single study with two cohorts in approximately 165 children and adolescents ages 2 to <18 years diagnosed with Type I, II, III or IV OI and a confirmed genetic mutation leading to a collagen defect;
- a safety cohort with a limited number of patients will confirm the dose of setrusumab based on safety and the efficacy cohort will be a two-arm, randomized, double-blind, active control design of 12 months duration;
- in the efficacy cohort, participants will be randomized to one of two double-blinded study arms: in one arm participants will receive setrusumab at a dose equivalent to the high-dose arm utilized in the Phase 2b (ASTEROID) study and in the other arm, participants will receive a standardized bisphosphonate;
- primary endpoint of fracture rate versus active control following 12 months of treatment; and
- secondary endpoint of BMD at the lumbar spine at 12 months over baseline measured using two-dimensional DAX, bone biomarkers, patient reported outcomes (PRO) and quality of life measures.

Alvelestat (MPH-966) for the Treatment of Severe Alpha-1-Antitrypsin Deficiency (“AATD”)

Overview

We are developing alvelestat for the treatment of severe AATD, a potentially life-threatening rare, genetic condition that results in severe debilitating diseases, including early-onset pulmonary emphysema. Alvelestat is a novel, oral small molecule designed to inhibit NE. Scientific data indicate that the increased risk of lung tissue injury in AATD patients may be due to inadequately controlled NE caused by insufficient AAT. We believe that by inhibiting NE, alvelestat has the potential to reduce the destruction of lung tissue and stabilize clinical deterioration in severe AATD patients.

Background of Alpha-1-Antitrypsin Deficiency

AATD is a genetic disease. There are estimated to be 50,000 people in North America and 60,000 in Europe with severe AATD, which we define as AATD in patients with either a PiZZ genotype or Null/Null genotype. The major function of AAT in the lungs is to protect the connective tissue from NE released from triggered neutrophils. In the majority of people, the lungs are defended from NE attack by AAT, which is a highly effective inhibitor of NE. Severe AATD patients produce ineffective or no AAT and are, therefore, unable to defend against NE attack. As a result, severe AATD patients commonly experience degeneration of lung function, such as early-onset pulmonary emphysema, which significantly affects quality of life and life expectancy. They may require oxygen therapy in order to continue their daily lives and the most severe patients may require lung transplantation.

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AATD is the result of a mutation of the SERPINA1 gene. Most people with severe AATD inherit two copies of the defective PiZ allele, or gene variant, of the SERPINA1 gene, resulting in a PiZZ genotype. Patients with a PiZZ genotype have approximately 15% of normal AAT levels. Individuals who inherit two copies of the Null allele, resulting in a Null/Null genotype, do not produce any AAT. These two groups are at very high risk of developing lung disease. AATD patients with the PiZZ genotype experience a decline in FEV1, a standard measure of exhalation. The annual mortality rate in this genotype estimated to be 4%. Given that individuals with the Null/Null genotype do not produce any AAT, we believe that they are likely to experience an even greater annual decline in FEV1.

Current Treatment Landscape for Alpha-1-Antitrypsin Deficiency

AATD patients are monitored by pulmonary functions tests, including spirometry. Treatment involves bronchodilators and inhaled corticosteroid medications and pulmonary rehabilitation, with increased intensity of therapy guided by disease severity. Surgical options include lung volume reduction surgery and lung transplantation. Both are highly invasive, and transplantation is only an option for a portion of patients with end-stage disease despite optimal therapy.

Augmentation therapy is available for AATD, using a partially purified plasma preparation highly enriched for AAT that is administered weekly by intravenous infusion. This therapy was first approved by the FDA in the 1980s based on its biochemical efficacy, meaning its ability to raise blood levels of AAT, but not based on clinical outcome data. Several observational studies have suggested that AAT augmentation therapy may slow the rate of decline in lung function in a subgroup of AATD patients with moderate-to-severe airflow obstruction. In a randomized, controlled trial of augmentation therapy, patients had some reduction in the progression of emphysema, as assessed by measuring lung density using computed tomography. The study did not show significant slowing in the decline in FEV1.

We believe that current therapies for AATD are inadequate. Surgical options are limited to a few patients, are highly invasive, have variable results, and do not address the underlying pathology of AATD. AAT augmentation therapy, while FDA approved, was not approved on the basis of clinical outcome data. Further, AAT augmentation therapy is not reimbursed and thus is not currently available to patients in several jurisdictions, including some key European markets. In addition, AAT augmentation therapy requires potentially inconvenient weekly intravenous infusions.

Our Approach

Our product candidate for treating severe AATD is alvelestat, a potent, specific oral small molecule that is designed to inhibit NE. We believe that by inhibiting NE, alvelestat has the potential to reduce the enzymatic destruction of lung tissue. Furthermore, we believe that convenient oral dosing of alvelestat could provide a significant advantage compared to the current treatments for AATD of surgery or weekly intravenous AAT augmentation therapy. In our clinical development programs, we intend to generate data to allow healthcare authorities to take evidence-based decisions.

Clinical Development of Alvelestat

The following table summarizes the historical and current clinical trials of alvelestat:

Historical Trials				Current Trials			
Phase	# of Studies	Population	Subjects Treated with Alvelestat	Phase	Population	Enrollment	Trial Started
Phase 1	7	Healthy Volunteers / COPD	143	Phase 2	AATD	165	Q4 2018
Phase 2	3	COPD	958				
Phase 2	1	CF	26				
Phase 2	1	Bronchiectasis	22				

Phase 2 Clinical Trials

Although prior clinical trials of alvelestat were in indications other than AATD, we believe that the clinical benefit observed in these trials and the biomarker evidence of treatment effect make alvelestat a promising potential product candidate for treating severe AATD. In particular, we believe the results from the Phase 2 clinical trials in bronchiectasis and CF are most relevant in assessing alvelestat's potential to treat severe AATD.

Phase 2 Clinical Trial in Severe AATD

We are conducting a Phase 2 proof-of-concept clinical trial of alvelestat in 165 patients with severe AATD in the United States and the EU. AATD patients are at greater risk from COVID-19 given that the condition is a respiratory and lung condition, and for this reason, our Phase 2 alvelestat trial will be delayed with topline data now expected in the second half of 2021. The trial is a 12-week, double-blind, placebo-controlled clinical trial examining two doses of alvelestat compared to placebo with primary endpoints of elastin breakdown as measured by the biomarker desmosine. We believe that by inhibiting NE, alvelestat will reduce the breakdown of elastin and therefore the amount of desmosine. Planned secondary endpoints are plasma A□-Val(360), a biomarker of NE activity, NE activity in sputum, and lung function tests, including FEV1.

We plan to enroll only patients with PiZZ or Null/Null genotypes with confirmed emphysema, who have not received AAT augmentation therapy or have undergone a wash-out period following AAT augmentation therapy.

If the results from this trial are favorable, we intend to seek regulatory advice on the design of, and commence, a pivotal trial.

We received an investment from, and are collaborating with, the venture philanthropy arm of the Alpha-1 Foundation, TAP, with respect to our alvelestat development program. TAP is investing in the program subject to our meeting agreed-upon development milestones. We also agreed to issue warrants to TAP to subscribe for shares in us, at certain future dates and subject to TAP making agreed-upon investments in the alvelestat development program. On October 8, 2018, we entered into a funding agreement with TAP, which provided for funding of up to \$0.4 million. On November 1, 2018 the first tranche of \$0.1 million was received and as a result we issued 41,286 warrants to subscribe for our ordinary shares at an exercise price of £0.003 per share.

Acumapimod (BCT-197) for the Treatment of AECOPD

Overview

We are developing acumapimod as a first-line acute therapy in patients with a severe AECOPD to reduce further acute exacerbations of COPD. Acumapimod is a novel, orally active p38 MAP kinase inhibitor designed to inhibit the pathological mechanism behind inflammation, which is a key feature of AECOPD. Currently available treatments only manage the symptoms of severe AECOPD and are comprised primarily of oxygen therapy, corticosteroids, antibiotics, and bronchodilators. We believe acumapimod offers a potential new treatment by targeting the underlying disease and delivering tangible benefits for patients and payors by potentially preventing severe AECOPD, or reducing the frequency of exacerbations and reducing readmissions.

Background of COPD and AECOPD

COPD includes chronic bronchitis, emphysema, refractory (non-reversible) asthma, and some forms of bronchiectasis. COPD is a non-fully-reversible, progressive lung disease that was the third largest cause of death in the world in 2010 according to the Global Burden of Disease Study, and the WHO forecasts that it will remain the third largest cause of death in the world in 2030. The National Heart Lung Blood Institute estimates that 16 million people in the United States have been diagnosed with the disease and the same number likely suffer from the disease without being aware of it. In 2015, according to the WHO, there were over three million deaths from the disease worldwide.

An AECOPD is defined as an acute event characterized by a worsening of the patient's symptoms beyond normal day-to-day variations that requires a change in medication and a severe AECOPD is where a patient requires hospitalization or visits the emergency room. Typical symptoms include an increase in breathlessness and/or increase in sputum production, which lead to an increase in the frequency or dose of bronchodilators or an increase in corticosteroid use, or the need to seek further medical attention. The risk of AECOPD increases with COPD progression and increases following exacerbations. Increased inflammation is a core feature of an AECOPD. This is demonstrated by inflamed airways and the influx of white blood cells that respond to and can propagate inflammation.

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On average, COPD patients suffer one to three AECOPDs per year with an average hospital stay, if admitted, of three to 10 days. Each episode of AECOPD poses significant risk to the patient, including an increased risk of death. Approximately 8% of patients admitted to the hospital for COPD die while in the hospital. The frequency and severity of exacerbations increase with age, disease severity and history of prior AECOPD. The five-year survival rate for those suffering three or more AECOPDs per year is 30%, but those who do not suffer AECOPDs have an 80% survival rate. Moderate to severe cases of AECOPD can also result in greatly diminished quality of life, disability, and serious co-morbidities, including heart disease. After an AECOPD many patients do not return to their pre-AECOPD baseline respiratory function. Furthermore, a patient who has several AECOPDs a year is typically exposed to large quantities of systemic corticosteroids, which can lead to osteoporosis and diabetes.

AECOPDs account for the greatest proportion of COPD costs. Of all COPD-related hospital admissions in the United States, approximately 63% are for AECOPD patients, representing more than 1.5 million emergency room visits in the United States alone. Based on current estimates of U.S. COPD rates, the direct costs of COPD are estimated at \$4,000 per patient per year. Costs increase in correlation with each progressive stage of the disease. In the United States in 2010, mild COPD patients had median direct costs of \$1,681 per patient per year, moderate patients had direct costs of \$5,037 per patient per year and severe patients had direct costs of \$10,812 per patient per year. Hospital stays make up the greatest proportion of the total COPD burden on the healthcare system, accounting for approximately 45% to 50% of the total direct cost generated by COPD patients. The mean length of hospital stays varies but is typically about 4.7 days. In the United States, the average cost of admission is \$7,500 but more than 20% of patients are re-admitted within 30 days with significantly higher cost.

Current Treatment Landscape of AECOPD

We are not aware of any approved therapies for the treatment of AECOPD in the United States or the EU. The management of AECOPD is directed at relieving symptoms and restoring functional capacity of the airways. In its milder forms, an AECOPD can be controlled with inhaled steroids, bronchodilators, and antibiotics. The bronchodilators reduce the patients' breathlessness by opening up the airways, and corticosteroids reduce inflammation. In more severe cases, AECOPD requires hospitalization, where patients are typically treated with oral or intravenous steroids and antibiotics.

The current recommended management for AECOPD includes beta2 agonists, the addition of anticholinergics or an increase in its dosage, the systemic administration of corticosteroids and antibiotics, and the intravenous administration of methylxanthines, such as aminophylline. Additionally, supporting oxygen therapy is used in order to provide the patient with sufficient blood oxygen levels. While AECOPDs are often triggered by bacterial or viral pathogens or pollutants, antibiotics are often used as the precise etiology is often unknown.

We believe that there is a significant medical need for a drug which is disease-modifying and could potentially prevent severe AECOPDs instead of just treating the symptoms. In addition, we believe that a drug that could prevent or reduce severe AECOPDs and also has anti-inflammatory effects would significantly improve the quality of life of COPD patients due to improved lung function, fewer infections and possibly reduced risk of rehospitalization and mortality.

Our Approach

Our product candidate for treating AECOPD is acumapimod, an orally administered small molecule that inhibits p38 MAP kinase. p38 MAP kinase is an enzyme that plays a key role in the cellular response to external stress signals. p38 MAP kinase is activated in COPD and AECOPD. Inhibition of this enzyme has been shown to have anti-inflammatory effects, primarily through the inhibition of the expression of inflammatory mediators or molecules called cytokines. The inflammatory cytokines are key to initiating and escalating the inflammatory response by attracting inflammatory cells and inducing further release of the cytokines by these cells. Key cytokines released in the inflammatory response are tumor necrosis factor alpha ("TNF α ") and interleukin-8, which are released in the blood stream, and interleukin-6, which is released from bronchial epithelial cells, all of which are blocked by inhibiting p38 MAP kinase.

We believe that acumapimod has the following key advantages over current therapies:

- potential to be a rapid-onset treatment targeting inflammatory drivers of AECOPD;

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- designed to target anti-inflammatory response systemically and locally with easier oral administration than inhaled treatments;
- simple oral regimen of three doses over five days that can be conveniently administered in either the hospital or an outpatient setting;
- designed to target pathophysiology of acute exacerbations without generalized immune suppression;
- potential for efficacy in steroid-resistant population; and
- short course treatment that can reduce further acute exacerbations of COPD.

Clinical Development of Acumapimod

The following table summarizes the historical clinical trials of acumapimod. We intend to explore strategic options with third parties for the further development of acumapimod.

Historical Trials			
Phase	# of Studies	Population	Subjects Treated with Acumapimod
Phase 1	5(1)	Healthy Volunteers	168
Phase 2	1	AECOPD	108
Phase 2	1	Acute Kidney Injury	50
Phase 2	1	AECOPD	188

(1) Includes two company-initiated 16-patient drug-drug interaction studies.

Phase 2 Dose-Ranging Clinical Trial in Severe AECOPD

We conducted a dose-ranging Phase 2 clinical trial in the United States and Europe to identify the most effective dosing regimen for severe AECOPD patients. The primary endpoint of the trial was to demonstrate a change in FEV1 from baseline to Day 7. A total of 282 patients enrolled in the trial.

This dose-ranging trial assessed two dosing regimens of acumapimod and placebo, each in combination with standard of care, which included steroids, antibiotics, and bronchodilators. Patients were followed for 26 weeks to explore recurrence rates of AECOPD and number of re-hospitalizations. Secondary and exploratory endpoints included biomarkers hsCRP and fibrinogen, clinical failure rate, number of moderate/severe AECOPDs during the trial, the area under the curve of FEV1 over time and time to normalization of FEV1.

The reduction in clinical failure rate was also observed. Clinical treatment failure is defined as a composite endpoint in which any patient fulfils one of more of the following criteria:

- hospitalization or re-hospitalization due to worsening respiratory symptoms;
- worsening of respiratory symptoms requiring the addition of another antibiotic or substitution of a new antibiotic;
- worsening of respiratory symptoms requiring an increase in dose of oral corticosteroids or initiation of new corticosteroids;

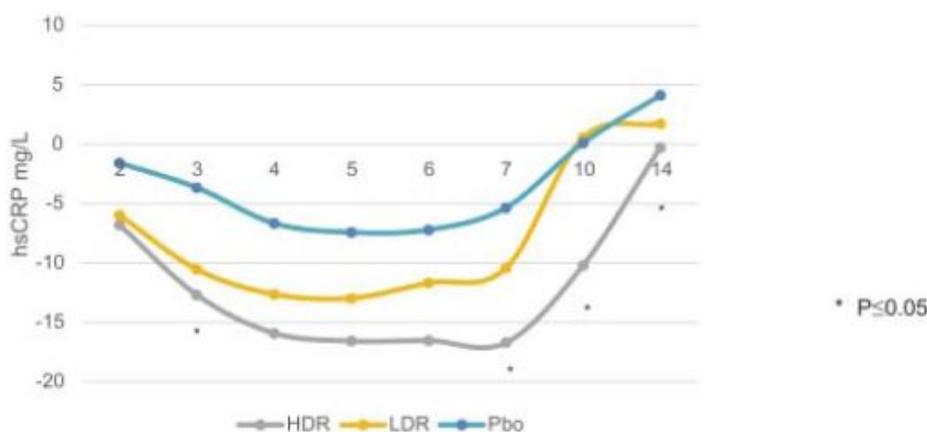
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- worsening of respiratory symptoms requiring an additional treatment regimen of systemic corticosteroids and/or antibiotics, after completion of the first regimen;
- COPD-related death; or
- any new moderate or severe exacerbation after a period of seven days of resolution from the index AECOPD.

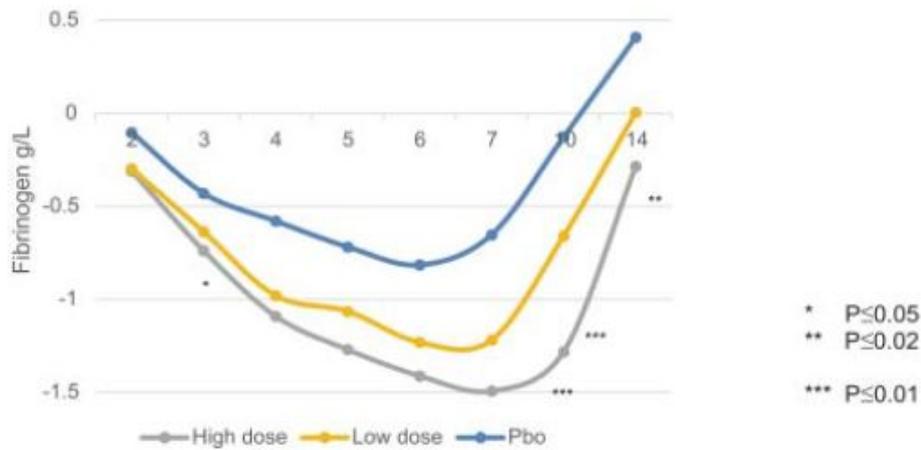
Both dosing regimens of acumapimod showed a statistically significant change in FEV1 from baseline to Day 7 ($p=0.012$ and $p \leq 0.001$), meeting the trial's primary endpoint on an intent-to-treat patient population basis. The standard of care plus placebo group did not show a significant change from baseline ($p=0.102$). The high- and low-dosage acumapimod groups showed a mean improvement in FEV1 of 84 ml and 115 ml, respectively, compared to 57 ml for the standard of care plus placebo group. While the acumapimod groups showed greater improvement when compared to the standard of care plus placebo group, the difference in improvement was not statistically significant.

Dose-dependent, statistically significant reductions in both hsCRP and fibrinogen were shown with treatment with acumapimod, with hsCRP remaining suppressed through the 26-week observation period. The graphs below show these reductions during the period when patients were experiencing their first occurrence of AECOPD, or their index AECOPD.

Absolute Change from Baseline in hsCRP During the First 14 days of the Study While Patients Were Experiencing their Index AECOPD

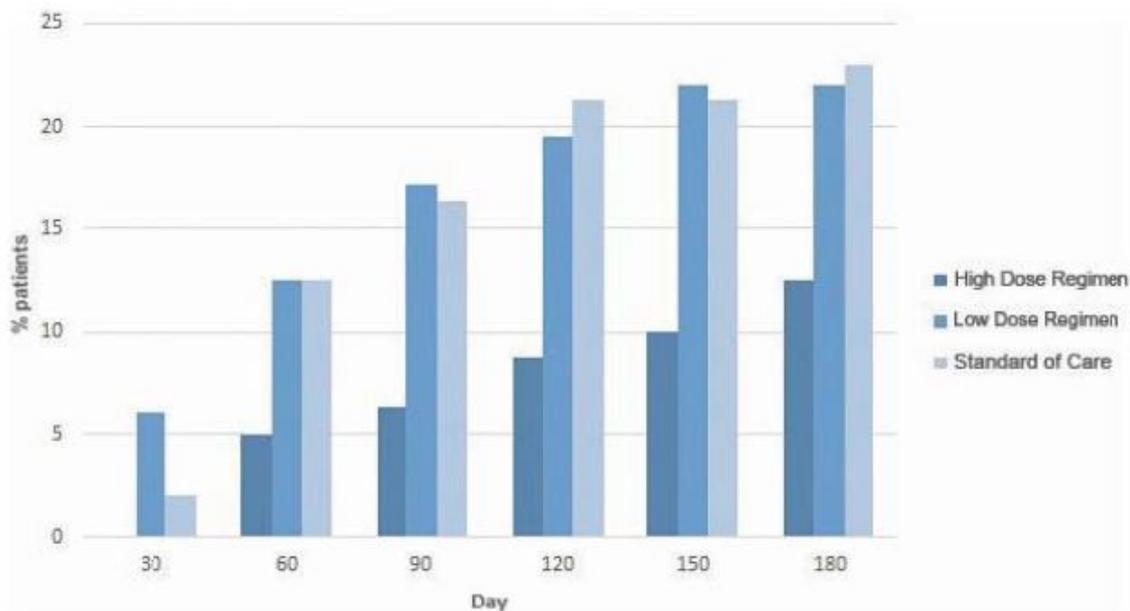


Absolute Change from Baseline in Fibrinogen During First 14 Days of the Study While Patients were Experiencing their Index AECOPD



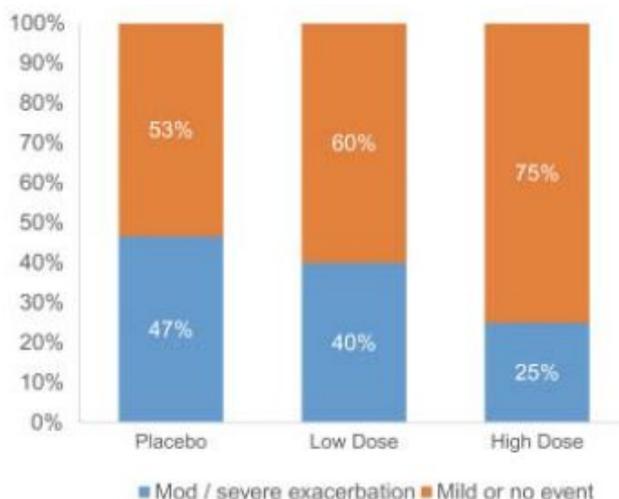
As shown in the chart below, the high-dose acumapimod group showed a statistically significant reduction in clinical treatment failure of more than 50% (p < 0.027 to 0.05) compared to the standard of care plus placebo group, measured by the number of rehospitalizations for the treatment of COPD at Days 90 through 150, with a trend observed as early as Day 30. A trend showing reduced composite clinical treatment failures of 56% to 28% from Day 30 through Day 150 was also observed in the high-dose acumapimod group.

Percentage of Patients Rehospitalized for the Treatment of COPD



Further analysis of the most severe patients, defined as patients who experienced two or more exacerbations in the previous year, showed a 46% reduction in the number of patients who suffered a subsequent moderate or severe re-exacerbation. The results from the analysis of these patients with the highest unmet need are shown in the graph below.

Re-Exacerbations of Severe COPD Patients During the Follow-up Phase



Consistent with the results from this trial, there was a reduction in the number of patients receiving antibiotic and systemic steroids in the high-dose group versus placebo of 46% observed in the long-term follow-up portion of the trial.

In this trial, acumapimod was observed to be well tolerated. Adverse events included two cases of acneiform rash, which were resolved. No induced liver injuries were observed. In addition, in April 2019, we announced a successful end of Phase 2 meeting with the FDA regarding acumapimod. In the meeting, we and the FDA agreed on a development plan for acumapimod. In September 2019, we had a positive SAWP meeting with the EMA.

Leflutrolole (BGS-649) for the Treatment of Hypogonadotropic Hypogonadism

Overview

We are developing leflutrolole for the treatment of infertility and HH in obese men. In obese men, a decline in testosterone is exacerbated by high levels of the aromatase enzyme in the fat tissue. The aromatase enzyme converts testosterone to estradiol, thereby reducing testosterone levels. Leflutrolole is a novel once-weekly oral aromatase inhibitor designed to normalize testosterone levels and improve HH without causing the excessively high testosterone levels and impaired fertility that may result from TRT, the primary treatment for HH. Following the positive result of a safety extension study for leflutrolole, we convened an advisory board meeting and concluded that the future development of leflutrolole should focus on male infertility. We intend to develop a clinical and regulatory path accordingly. We intend to explore strategic options with third parties for the further development of leflutrolole.

Background of Hypogonadotropic Hypogonadism

HH is a clinical syndrome that results from the failure of the testes to produce adequate levels of testosterone. Low testosterone or male hypogonadism is classified in two different types: primary hypogonadism and HH. Primary hypogonadism generally results from the failure of the testes to produce sufficient levels of testosterone, due to testicular trauma, disease (such as mumps), or genetic defects. HH also results from the failure of the testes to produce sufficient levels of testosterone, in this case due to the disruption of the hypothalamic-pituitary-testicular (“HPT”) axis, an endocrine pathway, and is typically associated with obesity, aging, stress, or as a side effect of medications. The symptoms of testosterone deficiency are non-specific, which can make the diagnosis difficult. Symptoms that are most commonly associated with testosterone deficiency include reduced or loss of libido, the absence of morning erections and erectile dysfunction. Other common symptoms include fatigue, impaired physical endurance, loss of vitality, lack of motivation and mood disturbance. In physician assessments of the symptoms of HH, patients rate decreased energy levels and impaired sexual function as having the greatest negative impact on quality of life.

The largest group affected by HH is comprised of men over the age of 40 who suffer from chronic diseases, such as obesity or type 2 diabetes. Based on WHO estimates and scientific data, we believe that there are approximately seven million cases of HH in obese men, generally defined as men with a body mass index (“BMI”) of 30 kilograms per meter squared or more, in the United States. Over 85% of men with HH are untreated despite access to care. Obesity rates continue to increase in the United States and in other developed and developing countries around the world. In 2016, the WHO estimated that 35.5% and 21.9% of males in the United States and the EU, respectively, were obese. A recent study in obese men, published in the Netherlands Journal of Medicine, showed that HH increased linearly with an increase in BMI.

Current Treatment Landscape of Hypogonadotropic Hypogonadism

The primary treatment for HH is TRT, in which testosterone is administered to normalize testosterone levels. There are several available routes of administering TRT, including intramuscular injections, scrotal patches, transdermal patches, transdermal gel, and implants. The direct replacement of testosterone exposes the patient to significant side effects. The FDA has concluded that there is a possible increased cardiovascular risk associated with TRT. One of the most common and serious side effects associated with TRT is impaired sperm formation. Additional complications caused by excessive testosterone include prostate enlargement, sleep apnea and worsening heart failure, gynecomastia, or breast development in males, and mood swings. Besides these side effects, each of these delivery methods also has considerable drawbacks. For example, intramuscular injections can be painful, gels and patches run the risk of testosterone transmission to other people, and patches can cause skin irritation.

The leading testosterone replacement product candidates on the market are AbbVie’s AndroGel and Lilly’s Axiron, both of which carry a black box warning. Both product candidates are administered transdermally by applying a gel formulation. Allergan, Inc.’s Androderm is the leading transdermal patch on the market. The most frequently prescribed intramuscular injections are Bayer AG’s Nebido and Endo Pharmaceutical Inc.’s (“Endo”) Aved. The leading implant on the market is Endo’s Testopel.

Our Approach

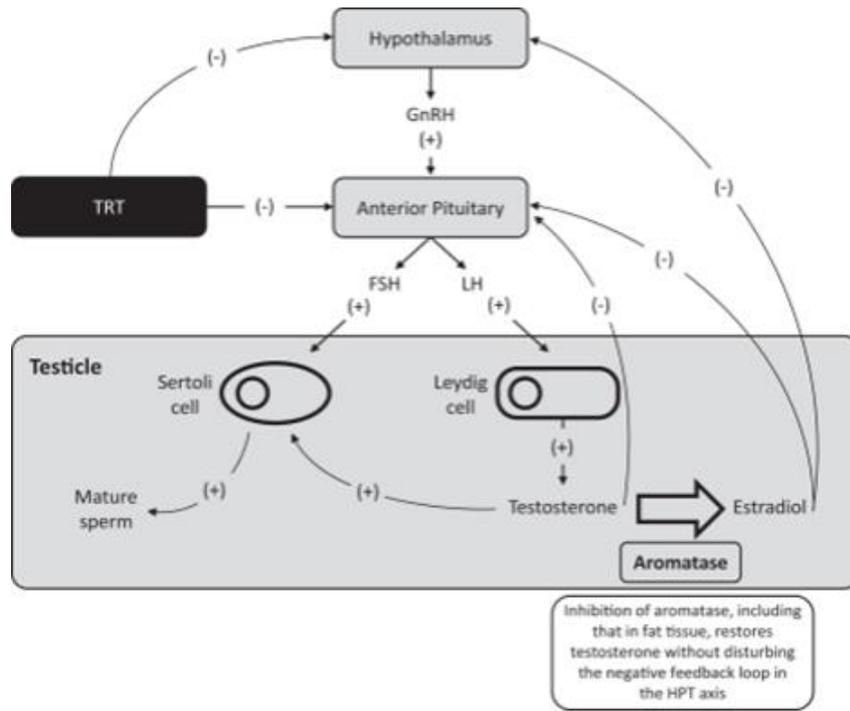
Our product candidate for treating infertility and HH in obese men is leflutrolole, which is intended for once-weekly oral administration and is designed to inhibit the aromatase enzyme, instead of directly replacing testosterone. The aromatase enzyme converts testosterone to estradiol, thereby reducing testosterone levels. Aromatase is expressed at high levels in fat tissue, and therefore obese men are potentially more prone to HH. Leflutrolole is intended to restore normal levels of testosterone without causing the excessively high testosterone levels that may result from TRT. In addition, we believe that the long half-life of leflutrolole of 22 days may allow for convenient weekly dosing.

Testosterone is a hormone that is regulated by three organs in the body, the hypothalamus, anterior pituitary glands and testes, which comprise the HPT axis. The initial stimulus for hormone formation begins in the hypothalamus with the formation of hormones, such as gonadotropin-releasing hormone (“GnRH”), that stimulate the pituitary gland to release LH and FSH. LH, in turn, stimulates the testicular production of testosterone, while FSH stimulates sperm formation. As testosterone levels rise, they feedback directly to the hypothalamus and indirectly through estradiol to the hypothalamus and anterior pituitary gland, which reduces the stimulation to produce more hormones, thereby creating a negative feedback loop that maintains normal testosterone levels. In obese men with HH, excessive aromatase enzyme in fat tissue convert testosterone into estradiol, which inhibits the HPT axis by the negative feedback loop.

The administration of exogenous testosterone, such as with TRT, which is not controlled by the HPT feedback loop, rapidly leads to suppression of LH and FSH. Furthermore, as exogenous testosterone is not controlled by the HPT feedback loop, supraphysiological, or excessively high, levels of testosterone can be reached, which have been associated with cardiovascular disease. In contrast to exogenous TRT, leflutrolole is designed to inhibit aromatase and restore testosterone without disturbing the physiological feedback in the HPT axis, thereby maintaining or increasing LH and FSH with minimal risk of reaching supraphysiological levels of testosterone.

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The diagram below illustrates the HPT feedback loop process, including the negative effects of TRT:



Clinical Development of Leflutrozole

The following is a table of the historical and planned clinical trials of leflutrozole:

Phase	Historical Trials			Subjects Treated with Leflutrozole	Planned Trials	
	# of Studies	Population			Phase	Population
Phase 1	5	Healthy Women / Endometriosis		95	Phase 3	HH obese men
Phase 2	1	HH obese men		24		
Phase 2b	1	HH obese men		200		
Phase 2b (ext)	1	HH obese men		143		

Phase 2b Clinical Trial in Hypogonadotropic Hypogonadism

In March 2018, we announced top-line data from our Phase 2b clinical trial of leflutrozone for the treatment of HH in obese men. We enrolled 271 patients in the trial in the United States and Europe. The trial was a multi-center, randomized double-blind, dose-ranging, placebo-controlled trial of leflutrozone in obese males with HH with a BMI of over 30. Subjects were divided into four groups, with 71 receiving placebo and 67, 66 and 67, receiving the low, intermediate or high dose, respectively, of leflutrozone.

The primary endpoint of the trial was to measure the percentage of patients whose testosterone levels normalized. The trial was designed to detect whether at least 75% of patients had normalized testosterone levels at week 24.

The secondary endpoints were:

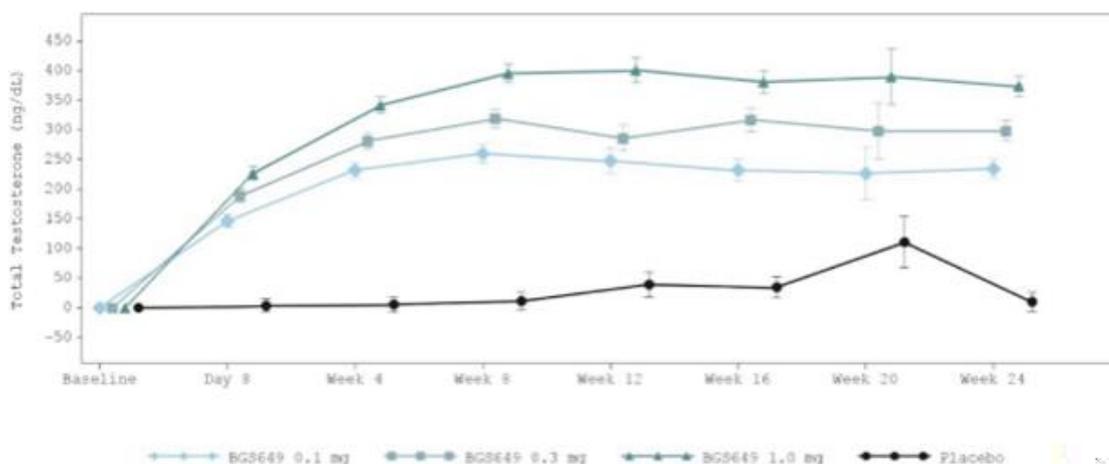
- the ability of leflutrozone to normalize testosterone in at least 90% of patients;
- the effects of leflutrozone on LH and FSH; and
- the proportion of subjects that overshoot testosterone levels at 24 weeks.

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- In addition, the trial was designed:
- to investigate the benefit on patient-reported outcomes (“PROs”), including the Patient-Reported Outcomes Measurement Information System (“PROMIS”), Brief Fatigue Inventory, PROMIS SexSF and International Index of Erectile Function, which examine the most common complaints HH patients present to a doctor, fatigue and sexual dysfunction;
- to assess the effects of leflutrozone on semen analysis (sperm count and motility), in a subset of patients; and
- to evaluate safety and tolerability, which included analysis of lipid profiles, haematocrit bone turnover markers, and bone mineral density measured by DXA score.

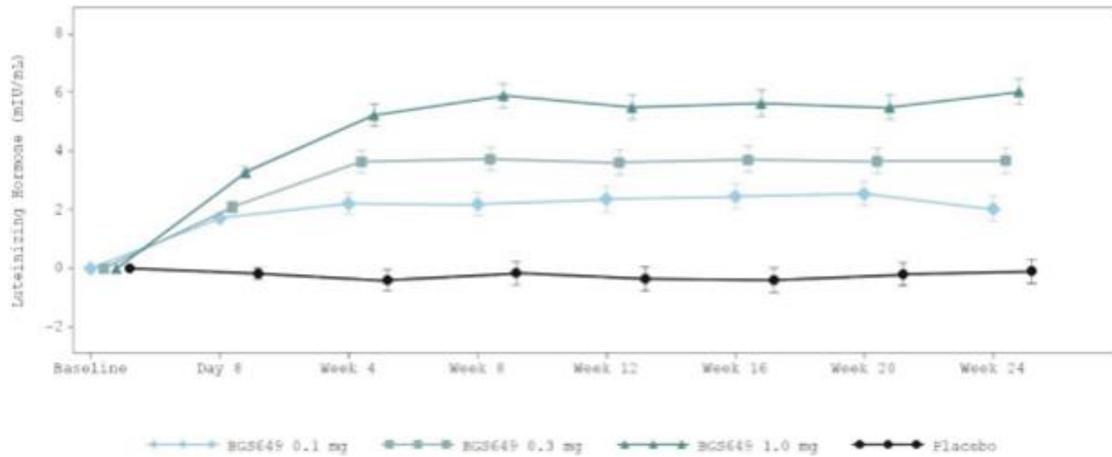
The trial involved a four-week screening phase followed by a 24-week treatment phase and a 12-week follow-up period. All doses of leflutrozone met the primary endpoint, normalizing total testosterone levels in over 75% of subjects after 24 weeks of treatment ($p < 0.001$ versus placebo). Normalization of testosterone was observed at the first measurement following the initial dosing of leflutrozone at day 8 in more than 80% of subjects at all three doses. A dose response was also observed in absolute total testosterone levels and over the dosing period, with mean testosterone reaching 458.0 ng/dl (low dose), 512.5 ng/dl (intermediate dose) and 586.5 ng/dl (high dose). The following graph illustrates the increase in mean total testosterone levels from baseline in patients in each of the three dosing arms of leflutrozone and receiving placebo.

Change from Baseline in Mean Total Testosterone

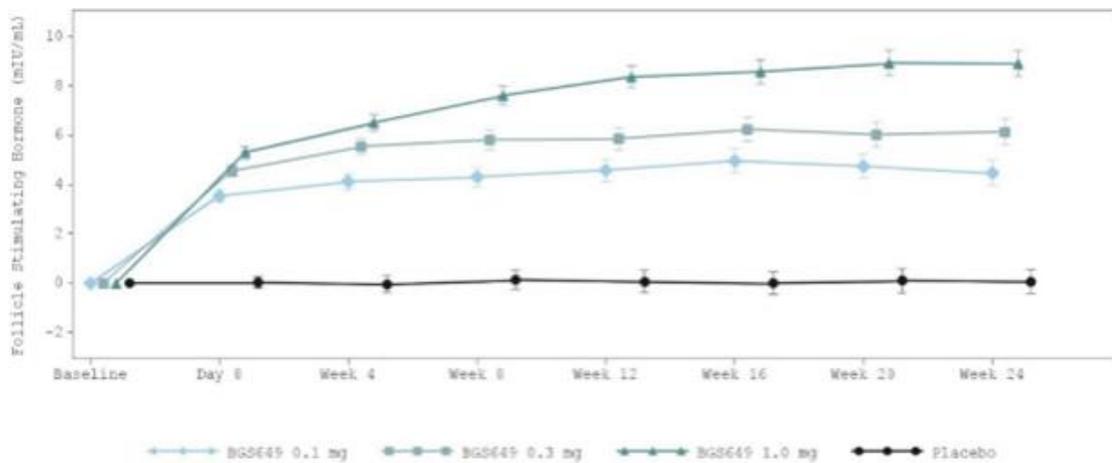


The two highest doses also met the secondary endpoint of normalizing testosterone in 90% of patients at week 24 with the lowest dose normalizing testosterone in 88% of patients at week 24. All three doses of leflutrozone met the remaining secondary endpoints, including the improvement of LH and FSH levels. A statistically significant increase in LH and FSH at all doses at week 24 ($p < 0.001$ for each dose versus placebo) was observed, with an increase following initial dosing at day 8 and an observed dose response. The following graphs illustrate the increase in total LH and total FSH from baseline in patients in each of the three dosing arms of leflutrozone and receiving placebo.

Change from Baseline in Mean Total Luteinising Hormone



Change from Baseline in Mean Total Follicle Stimulating Hormone



The trial also showed an improvement in total motile sperm count across all three doses versus placebo with mean changes at week 20 of 70 million, 14 million and 58 million for the high, intermediate and low doses of leflutrozone, respectively, compared with a decrease of 23 million for placebo. Although the trial was not designed to detect statistical significance for this exploratory endpoint, a statistically significant improvement was shown at the highest dose of leflutrozone (p=0.03). No subjects on leflutrozone had testosterone levels greater than 1500 ng/dl at any time during the study.

In addition, a positive trend of treatment effect was observed at eight to 12 weeks for reduction of fatigue as measured by the PROMIS Brief Fatigue Inventory. The trial was not designed to detect statistical significance for this endpoint.

Leflutrozone was observed to be well tolerated during the trial. An increased incidence of elevated haematocrit levels was observed in each of the treatment arms of the trial, which is consistent with increasing testosterone levels.

Safety Extension Study to the Phase 2b Clinical Trial in Hypogonadotropic Hypogonadism

A subset of 143 patients entered into a six-month extension study to the Phase 2b Clinical Trial for leflutrozone, to gain long-term data on both efficacy and safety. 88 patients completed the additional six months of treatment.

The safety extension study was designed to examine if leflutrozone resulted in a pre-specified reduction in bone mineral density (BMD) at 48 weeks following the initial 24 weeks treatment. The primary end point of this safety extension study was decrease in bone mineral density. In December 2018, we reported positive results from the safety extension study for leflutrozone. The study was successful in demonstrating that none of the doses of leflutrozone met the lower bound (95% confidence interval) of the pre-specified safety criterion of a greater than 3% reduction in lumbar spine bone mineral density after 48 weeks of treatment. Consistent with this finding, none of the doses of leflutrozone met the secondary safety endpoint criterion of a greater than 3% reduction in bone mineral density in the hip (total or femoral neck). In addition, there was no shift into clinical categories of osteopenia or osteoporosis, with no evidence of development of new osteopenia.

Consistent with the top-line data announced by us in March 2018, treatment with leflutrozone resulted in normalization of total testosterone levels in over 75% of subjects at all three doses tested at the end of the six months extension study period (this measure was the primary endpoint in the placebo-controlled portion of the trial). Similarly, normalization of testosterone in at least 90% of patients (a key secondary endpoint of the placebo-controlled portion of the trial) occurred at all three doses (versus at the two highest doses in the initial 6 months). All three doses also continued to meet all other secondary endpoints, including the improvement of testosterone LH and FSH levels. The extension study continued to demonstrate a clear dose-response in both the primary and secondary endpoints. There was an increased incidence of raised haematocrit levels in patients receiving leflutrozone and small increases in blood pressure at the two highest doses consistent with increasing testosterone.

Following the positive result of a safety extension study for leflutrozone, we convened an advisory board meeting and concluded that the future development of leflutrozone should focus on male infertility. We intend to develop a clinical and regulatory path accordingly. We intend to explore strategic options with third parties for the further development of leflutrozone.

Material Agreements

Collaboration Agreement with Celgene

In December 2013, OncoMed entered into the Collaboration Agreement with Celgene pursuant to which OncoMed and Celgene were to collaborate on research and development programs directed to the discovery and development of novel biologic therapeutics, and, if Celgene exercised its option to do so, the discovery, development and commercialization of novel small molecule therapeutics. We acquired OncoMed in the Merger.

OncoMed's etigilimab program was the last remaining biologic therapeutic program that was active under the Collaboration Agreement. Pursuant to the Collaboration Agreement, Celgene had an option to obtain an exclusive license to develop further and commercialize biologic therapeutics in the etigilimab program, which could be exercised during time periods specified in the Collaboration Agreement through the earlier of completion of a certain clinical trial or the twelfth anniversary of the date of the Collaboration Agreement. In turn, OncoMed agreed to lead the development of etigilimab prior to Celgene's exercise of the option for the program and was also responsible for funding all research and development activities for therapeutics in the etigilimab program prior to such exercise. OncoMed was eligible to receive a \$35.0 million opt-in payment upon Celgene's exercise of the option for the etigilimab program. In addition, the Collaboration Agreement also included milestone payments for achievement of specified development, regulatory and commercial milestones which could have totaled up to \$437.5 million (net of past milestone payments) for product candidates in the etigilimab program, including the \$35.0 million opt-in payment. In addition, if the program had been successfully commercialized by Celgene, OncoMed would have been eligible to receive tiered royalties equal to a percentage of net product sales worldwide in the high-single digits to the mid-teens, subject to certain reductions.

In June 2019, we announced that Celgene had notified OncoMed that Celgene had decided, in light of strategic product portfolio considerations, not to exercise its option to license etigilimab. The Collaboration Agreement was terminated with respect to etigilimab effective on October 11, 2019. As a result, we have worldwide rights to the etigilimab program.

Navi was previously a part of the Collaboration Agreement, but the Collaboration Agreement was terminated with respect to Navi effective on January 23, 2019. As a result of this termination, we received worldwide rights to the Navi program, which we subsequently out-licensed to Oncologie. See “—Licensing Agreement for Navicixizumab.”

Licensing Agreement for Navicixizumab

On January 13, 2020, we entered into a global license agreement with Oncologie for the development and commercialization of Navi, an anti-DLL4/VEGF bispecific antibody currently being evaluated in an ongoing Phase 1b study in combination with paclitaxel in patients with advanced heavily pretreated ovarian cancer. Navi previously completed a Phase 1a monotherapy study in patients with various types of refractory solid tumors and is one of two product candidates we acquired through the Merger. In October 2019, the FDA granted Fast Track designation to Navi and has agreed in principle on the design of a study that could potentially support accelerated approval for Navi in a heavily pretreated, platinum-resistant ovarian cancer patient population.

Under the terms of the license agreement, Oncologie will receive an exclusive worldwide license to develop and commercialize Navi. We received an upfront payment of \$4.0 million and will receive an additional payment of \$2.0 million conditional on a CMC (Chemistry, Manufacturing and Controls) milestone. Oncologie will be responsible for all future research, development and commercialization of Navi. Additionally, we will be eligible to receive up to \$300 million in future clinical, regulatory and commercial milestones, tiered royalties ranging from the mid-single-digit to sub-teen percentages on global annual net sales of Navi, as well as a negotiated percentage of sublicensing revenues from certain sublicensees.

As a consequence of the license agreement with Oncologie, and in accordance with the terms and conditions of the CVR Agreement, holders of CVRs pursuant to the CVR Agreement will be entitled to receive certain eligible cash milestone payments made to us under the license agreement relating to the development and commercialization of Navi. See “—CVR Agreement Between Us and Computershare.”

CVR Agreement Between Us and Computershare

Following the closing of the Merger, OncoMed's stockholders received, in exchange for each outstanding share of OncoMed common stock owned immediately prior to the closing of the Merger (except for any dissenting shares): (1) a number of our ADSs determined by reference to an exchange ratio, and (2) one contingent value right (a "CVR"), representing the right to receive contingent payments if specified milestones are achieved within agreed time periods, subject to and in accordance with the terms and conditions of the Contingent Value Rights Agreement (the "CVR Agreement"), dated April 23, 2019 by and among Computershare, as rights agent, and us.

Except in limited circumstances, the CVRs may not be transferred, pledged, hypothecated, encumbered, assigned or otherwise disposed of.

Milestone Events and Payments

The CVR milestones relate to OncoMed's etigilimab and Navi therapeutic candidates, though the milestone relevant to etigilimab can no longer be achieved. The contingent payments would become payable to the rights agent, for subsequent distribution to the holders of the CVRs, upon the achievement of a milestone as follows:

The TIGIT Milestone

A payment, in the form of our ADSs, would have been made to CVR holders if, following April 23, 2019 but prior to December 31, 2019, Celgene had exercised its exclusive option granted by OncoMed to Celgene in relation to reaching a milestone of OncoMed's etigilimab product candidate pursuant to the Collaboration Agreement (the "TIGIT Milestone"), and OncoMed had actually received the cash payment payable by Celgene pursuant to such Celgene option exercise.

In June 2019, we announced that Celgene had notified OncoMed that Celgene had decided, in light of strategic product portfolio considerations, not to exercise its option to license etigilimab. The Collaboration Agreement was terminated with respect to etigilimab effective on October 11, 2019. See "—Collaboration Agreement with Celgene" above. As a result, no payments are expected to become due or payable to CVR holders pursuant to the TIGIT Milestone.

The NAVI Milestones

A cash payment will be made to CVR holders if, (1) within eighteen months following the closing of the Merger, we or any of our subsidiaries enters into a definitive partnership agreement, collaboration agreement, joint venture agreement, profit sharing agreement, license or sublicense agreement, asset sale agreement, stock sale agreement, investment agreement or similar agreement duly approved by our Board with one or more third parties regarding Navi, and (2) within five years of the closing of the Merger, we or any of our subsidiaries actually receives certain eligible cash milestone payments.

NAVI Subsidiary, Inc. ("NAVI Sub"), a wholly-owned subsidiary of OncoMed and an indirect wholly-owned subsidiary of our Company, has been established to hold all of our right, title and interest in and to Navi. For a period of 18 months following the closing of the Merger, we will permit certain individuals associated with NAVI Sub and identified on a confidential schedule to the CVR Agreement (the "NAVI Team") to (i) solicit third party interest with respect to a NAVI Agreement (as defined in the CVR Agreement), such that the NAVI Sub or a third party, as applicable, will advance Navi, and (ii) recommend, by written notice to the chief executive officer of our Company, that we enter into discussions with one or more such third parties that have expressed interest with respect to a NAVI Agreement; provided that, notwithstanding anything to the contrary in the CVR Agreement, we will have no obligation or liability to fund or otherwise support or incur any cost or expense relating to NAVI Sub or Navi in excess of the commitments provided for on a confidential schedule to the CVR Agreement (except in respect of clinical trials commenced prior to the date thereof).

The entry into a NAVI Agreement by us or any of our subsidiaries (including NAVI Sub) shall be subject to, and contingent upon, a determination by our Board, having consulted with outside counsel, that the NAVI Agreement is fair to, advisable and in the best interests of our Company and our shareholders. Without limiting the

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foregoing, neither us nor any of our subsidiaries (including NAVI Sub) shall be compelled to enter into any investment agreement, stock sale agreement, or similar agreement with respect to NAVI Sub or Navi if, immediately following the execution of such agreement, our Company or one or more of our subsidiaries (other than NAVI Sub) would hold less than 19.5% of the issued and outstanding equity interests of NAVI Sub on a fully-diluted basis.

Eligible cash milestone payments will include each cash milestone payment payable to our Company or one or more of our subsidiaries pursuant to a NAVI Agreement (or any agreement contemplated by such NAVI Agreement), except for any (i) royalty or similar sales-based payment that is measured, in whole or in part, by reference to the quantity of Navi that is produced or sold or the revenues (or a formula that makes reference to such revenues) derived therefrom and (ii) for the avoidance of doubt only, any fees for service, research and development funding, reimbursement of intellectual property filing, prosecution, litigation and maintenance-related expenses or reimbursement of manufacturing expenses received from a counterparty pursuant to a NAVI Agreement.

If a NAVI Milestone is achieved, holders of CVRs would be entitled to receive an amount in cash equal to 70% of the aggregate principal amount actually received by us or one or more of our subsidiaries (other than NAVI Sub), net of (A) any tax (including any applicable value added or sales taxes and including any tax which would be payable but for the utilization of a relief), (B) 50% of any expenditure by us or our subsidiaries pursuant to the budget set forth on a confidential schedule to the CVR Agreement, and (C) any other reasonable cost or expense attributable to the receipt of such payment (which, for the avoidance of doubt, shall include (x) any costs, reasonable out-of-pocket fees, expenses or charges incurred by us or our subsidiaries in excess of the commitments provided for in the budget set forth on a confidential schedule to the CVR Agreement, (y) any costs, reasonable out-of-pocket fees, expenses or charges incurred by us or our subsidiaries under the NAVI Agreement, and (z) any costs, reasonable out-of-pocket fees, expenses or charges incurred by us or our subsidiaries, or for which our Company or one or more of our subsidiaries is responsible, in connection with the preparation, negotiation and execution of the relevant NAVI Agreement, in each case to the extent such costs, out-of-pocket fees, expenses or charges have not been previously accounted for in the calculation of a prior NAVI Milestone payment).

The NAVI milestone payments are subject to a cash consideration cap, pursuant to which the aggregate principal amount of all cash payments made to holders of CVRs by us shall in no case exceed \$79.7 million. If the aggregate principal amount to be paid to holders of CVRs by us pursuant to the CVR Agreement would, together with the aggregate principal amount of any prior such cash payments, otherwise exceed \$79.7 million, then the applicable NAVI Milestone payment will be appropriately reduced.

If a NAVI Milestone occurs at any time prior to the fifth anniversary of the closing of the Merger, and on each such occurrence, then, thirty days following the achievement thereof, our Company, or a person nominated by us (with written notice thereof from us to the rights agent), as the case may be, will deliver to the rights agent (i) a certificate certifying the date of satisfaction of the applicable NAVI Milestone and that the holders of CVRs are entitled to receive a NAVI Milestone payment, and (ii) the applicable NAVI Milestone payment, by wire transfer of immediately available funds to an account designated by the rights agent. Upon receipt of the wire transfer referred to in the foregoing sentence, the rights agent will promptly (and in any event, within 10 business days) pay, by check mailed, first-class postage prepaid, to the address of each holder set forth in the CVR Register at such time or by other method of delivery as specified by the applicable holder in writing to the rights agent, an amount in cash equal to the product determined by multiplying (A) the quotient determined by dividing (x) the applicable NAVI Milestone payment by (y) the total number of CVRs registered in the CVR Register at such time, by (B) the number of CVRs registered to such holder in the CVR Register at such time.

The receipt of the upfront milestone payment of \$4.0 million by us under the Navi License Agreement with Oncologie in January 2020 resulted in a payment to CVR holders of approximately 1.2 cents per CVR, a total of approximately \$0.5 million after deductions of costs, charges and expenditures).

CVR Agreement Between OncoMed and Computershare

On March 14, 2019, OncoMed entered into a Contingent Value Rights Agreement, by and between OncoMed and Computershare (the “OncoMed CVR Agreement”). As a result of the Merger, OncoMed became a wholly-owned indirect subsidiary of our Company.

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Pursuant to the OncoMed CVR Agreement, each holder of OncoMed common stock as of the close of business on April 5, 2019, received one contingent value right (each, an “OncoMed CVR”) for each share of OncoMed common stock held by such stockholder as of such date. The OncoMed CVRs each represented the non-transferable contractual right to receive cash payments from OncoMed upon the actual receipt by OncoMed or its affiliates of certain contingent cash payments from Celgene in respect of the achievement of specified approval and sales milestones or the payment of royalties pursuant to the Collaboration Agreement in connection with OncoMed’s etigilimab therapeutic candidate. As stated above, in June 2019, Celgene notified OncoMed, pursuant to the Collaboration Agreement, of Celgene’s decision not to exercise its option to license etigilimab. See “— Collaboration Agreement with Celgene.” As a result, no payments are expected to become due or payable to OncoMed CVR holders pursuant to the TIGIT Milestone.

Novartis Agreements

In July 2015, three of our wholly-owned subsidiaries, Mereo BioPharma 3 Limited, Mereo BioPharma 2 Limited, and Mereo BioPharma 1 Limited (the “Subsidiaries”), entered into asset purchase agreements (the “Purchase Agreements”), to acquire from Novartis rights to setrusumab, acumapimod, and leflutroazole (the “Compounds”), respectively, and certain related assets (together with the Compounds, the “Novartis Assets”).

In connection with the acquisition of the Novartis Assets, we issued 3,849,000 ordinary shares to Novartis pursuant to a subscription agreement. See “Related Party Transactions—Subscription Agreement” for more information. In addition, we paid Novartis \$1.5 million for a payment made by Novartis to a third party in full satisfaction of all monetary obligations of Novartis to such third party with respect to acumapimod. Under the Purchase Agreements, we have agreed to make tiered royalty payments to Novartis based on annual worldwide net sales of product candidates that include the Compounds (the “Acquired Novartis Product Candidates”), at percentages ranging from the high single digits to low double digits. In the event that the parties agree or it is otherwise determined in accordance with the Purchase Agreements that we require third-party intellectual property rights to exploit the Acquired Novartis Product Candidates, we are entitled to offset a specified percentage of amounts paid to such third parties in consideration for such intellectual property rights against the royalties due to Novartis. The royalty payments are payable for a period of ten years after the first commercial sale of an Acquired Novartis Product. We further agreed that in the event of a change in control that involves the transfer, license, assignment, or lease of all or substantially all of a Subsidiary’s assets, including a Compound and related assets, we will pay Novartis a percentage of the proceeds of such transaction, with the majority of the proceeds being retained by us. No payment, however, is required with respect to any transaction of Mereo BioPharma Group plc involving its equity interests, a merger or consolidation of it, or a sale of any of its assets.

We granted Novartis an irrevocable, transferable, royalty-free, worldwide and non-exclusive license to use know-how included within the Novartis Assets for Novartis’ activities unrelated to any Acquired Novartis Product Candidates. We have agreed to use commercially reasonable efforts to develop at least one Acquired Novartis Product. In addition, Novartis agreed to a three-year non-competition restriction in relation to clinical trial activities for the therapeutic treatment of HH in obese men in respect of the leflutroazole Compound and sclerostin in respect of the BGS-804 Compound, subject to exceptions, including where Novartis does not have the ability to control such clinical trial activity and for any of Novartis’ existing contracts or relationships.

We also entered into a sublicense agreement with Novartis (the “Sublicense Agreement”), pursuant to which Novartis granted us an exclusive, worldwide, royalty-bearing sublicense for certain therapeutic antibody product candidates directed against sclerostin (the “Antibody Product Candidates”), including setrusumab. Under the Sublicense Agreement, we have agreed to pay Novartis royalties in the low single digits on worldwide net sales of Antibody Product Candidates. Royalties will be payable on a country-by-country basis until the later of expiration of the last valid claim of the licensed patents covering the Antibody Product Candidates in a country and ten years after the first commercial sale of the Antibody Product Candidates in such country, with a maximum royalty term of 12 years after the first commercial sale of the Antibody Product Candidates in such country. We have also agreed to pay Novartis up to \$3.25 million in development and regulatory milestones, and to use commercially reasonable efforts to develop and commercialize an Antibody Product. The Sublicense Agreement will expire on the earlier of the termination of the agreement under which Novartis is granting us a sublicense (the “Original License Agreement”) and, on a product-by-product and country-by-country basis, the expiration of the royalty term with respect to such Antibody Product Candidate in such country. The Original License Agreement has a perpetual term and may be terminated for breach or upon a change in control of the licensing party. We may terminate the Sublicense Agreement upon written notice to Novartis and either party may terminate the Sublicense Agreement for the other party’s uncured material breach or bankruptcy.

AstraZeneca Agreement

In October 2017, our wholly-owned subsidiary Mereo BioPharma 4 Limited entered into an exclusive license and option agreement (the “License Agreement”), to obtain from AstraZeneca an exclusive worldwide, sub-licensable license under AstraZeneca’s intellectual property rights relating to certain product candidates containing a NE inhibitor, including product candidates that contain alvelestat, with an option to acquire such intellectual property rights following commencement of a pivotal trial and payment of related milestone payments (the “Option”), together with the acquisition of certain related assets.

Upon entering into the License Agreement, we made a payment of \$3.0 million and issued 490,798 ordinary shares to AstraZeneca, for an aggregate upfront payment equal to \$5.0 million. In connection with certain development and regulatory milestones, we have agreed to make payments of up to \$115.5 million in the aggregate and issue additional ordinary shares to AstraZeneca for licensed product candidates containing alvelestat. In addition, we have agreed to make payments to AstraZeneca based on specified commercial milestones of the product candidate. In the event that we sub-license alvelestat, we have also agreed to pay a specified percentage of sublicensing revenue to AstraZeneca. Otherwise, we have agreed to make royalty payments to AstraZeneca equal to ascending specified percentages of tiered annual worldwide net sales by us or our affiliates of licensed product candidates (subject to certain reductions), ranging from the high single digits to low double digits. Royalties will be payable on a licensed product-by-licensed product and country-by-country basis until the later of ten years after the first commercial sale of such licensed product in such country and expiration of the last patent covering such licensed product in such country that would be sufficient to prevent generic entry. Under the License Agreement, we may freely grant sub-licenses to affiliates upon notice to AstraZeneca and we must obtain AstraZeneca's consent, not be unreasonably withheld, to grant sub-licenses to a third party. We have agreed to use commercially reasonable efforts to develop and commercialize at least one licensed product. In addition, we are generally responsible for costs related to the development and commercialization of the licensed products under the License Agreement.

The License Agreement will expire on the expiry of the last-to-expire royalty term with respect to all licensed product candidates. Upon the expiration of the royalty term for a licensed product in a particular country, the licenses to us for such product in such country will become fully-paid and irrevocable. Prior to exercise of the Option, if at all, we may terminate the License Agreement upon prior written notice. Either party may terminate the agreement upon prior written notice for the other party's material breach that remains uncured for a specified period of time or insolvency. AstraZeneca has agreed to a three-year non-competition restriction in relation to the direct or indirect commercialization or development of NE inhibitors for the treatment of AATD. In addition, AstraZeneca agreed not to assert any AstraZeneca intellectual property rights that were included in the scope of the License Agreement against us.

Aspire Capital Transaction

On February 10, 2020, we entered into a Purchase Agreement with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$25.0 million worth of our ordinary shares that are exchangeable for ADSs over the approximately 30-month term of the Purchase Agreement. In addition, pursuant to the Purchase Agreement, Aspire Capital purchased 11,432,925 ordinary shares that are exchangeable for 2,286,585 ADSs for \$3.0 million. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we paid Aspire Capital a commission fee of \$300,000, which was wholly satisfied by the issuance to Aspire Capital of 2,862,595 ordinary shares that are exchangeable for 572,519 ADSs.

Boxer Capital Transaction

On February 19, 2020, we entered into a securities purchase agreement with Boxer Capital. Under the terms of the agreement, Boxer Capital agreed to invest \$3.0 million by purchasing 12,252,715 ordinary shares (equivalent to 2,450,543 ADSs) at a price equivalent to 18.8 pence per ordinary share, which represented a 20% discount to our closing share price of 23.5 pence on AIM on February 18, 2020. We intend to use the net proceeds from this private placement for general corporate purposes, including clinical trial activity and working capital. There are no warrants, derivatives, or other share classes associated with this transaction. Further, there are no restrictions on future financings and there are no financial covenants, participation rights, rights of first refusal, or penalties in the purchase agreement entered into in connection with this transaction.

June 2020 Private Placement

On June 4, 2020, we announced completion of a private placement with net proceeds of approximately \$64.2 million (£51.4 million) with a number of new and existing principally U.S based institutional and accredited investors (the "June 2020 Private Placement"). OrbiMed Private Investments VI, LP (acting through its general partner, OrbiMed Capital GP VI LLC, acting through its managing member, OrbiMed Advisors LLC, collectively referred to herein as "OrbiMed") led the June 2020 Private Placement with participants including Vivo Capital, Surveyor Capital (a Citadel company), Pontifax Venture Capital, Samsara BioCapital, Commodore Capital, and funds managed by Janus Henderson Investors alongside existing investors Boxer Capital of Tavistock Group and Aspire Capital Fund, LLC (collectively, the "Purchasers"). On June 3, 2020, we entered into a securities purchase agreement (the "June 2020 Purchase Agreement") with the Purchasers pursuant to which we received approximately \$64.2 million (£51.4 million) from the Purchasers comprising: the allotment of ordinary shares at a subscription price of approximately \$19.4 million utilizing the existing share authorities of the Company granted by shareholders on June 2, 2016 and June 19, 2019, and the subscription for Tranche 1 Notes in an aggregate principal amount of approximately \$50.6 million. The Purchasers also received conditional warrants entitling the holders to subscribe for an aggregate of 161,048,366 new ordinary shares. The net proceeds from the June 2020 Private Placement will be used primarily to fund clinical development activities of our lead product candidates, reduction of indebtedness and for general corporate purposes.

Arrangements with OrbiMed

In recognition of OrbiMed's participation in, and assistance with, the June 2020 Private Placement, the Company has agreed to grant OrbiMed certain rights. OrbiMed will have the right to nominate two persons to be appointed to the Board of Directors (out of a maximum number of 9 directors), for a period of 180 days from June 3,

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2020 subject to the usual regulatory compliance. OrbiMed has also been granted the right to participate in future financings of the Company, subject, among other things, to the existing pre-emption rights of the Shareholders under the Companies Act 2006 and existing agreements. OrbiMed has been paid a subscription fee by the Company in relation to its participation in the June 2020 Private Placement.

Manufacturing

We do not own or operate manufacturing facilities for the production of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We have entered into manufacturing agreements with a number of drug substance, drug product, and other manufacturers and suppliers for etigilimab, setrusumab, acumapimod, and leflutrolole and we intend to enter into additional manufacturing agreements as necessary. Following our license of alvelestat, we acquired certain clinical trial materials and we plan to outsource production of further clinical supplies to our own manufacturing suppliers. We also intend to outsource certain product formulation trials. We expect that drug product pre-validation and validation batches will be manufactured to satisfy regulatory requirements where we progress product candidates to late stage trials.

We intend to enter into contractual relationships for the manufacture of commercial supplies for setrusumab and alvelestat. Any batches of product candidates for commercialization will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA, the EMA, and the regulatory agencies of other jurisdictions in which we are seeking approval. We employ internal resources to manage our manufacturing contractors and ensure they are compliant with current good manufacturing practices.

Commercialization, Sales and Marketing

We do not have our own marketing, sales, or distribution capabilities. In order to commercialize our rare disease product candidates, if approved for commercial sale, we must either develop a sales and marketing infrastructure or collaborate with third parties that have sales and marketing experience. For setrusumab and alvelestat, if approved, and for any future product candidates for rare diseases, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize or co-commercialize these product candidates in major markets or potentially to outsource aspects of these functions to third parties or partners. We intend to seek to enter into one or more strategic relationships with third parties for our non-oncology/non-rare disease product candidates, acumapimod and leflutrolole to undertake the next phase of clinical development and, if approved, for commercialization.

Competition

We compete directly with other biopharmaceutical and pharmaceutical companies that focus on the treatment of solid tumor cancers and hematologic cancers, OI, AATD, AECOPD or HH. We may also face competition from academic research institutions, governmental agencies and other various public and private research institutions. We expect to face increasingly intense competition as new technologies become available. Any product candidates, including etigilimab, setrusumab, alvelestat, acumapimod and leflutrolole that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

We consider etigilimab's current closest potential competitors to be existing cancer treatments such as the commercially available immuno-oncology agents (e.g., Yervoy, Keytruda, and Opdivo), chemotherapeutic agents, and antibody based therapeutics such as Avastin and Erbitux. In addition, other potential competitors include several other anti-TIGIT agents (e.g., those currently being developed by Genentech (Roche), Merck, Bristol-Myers Squibb or BMS, Arcus Biosciences, iTeos Therapeutics, Compugen and BeiGene) and investigational immuno-oncologic agents against other targets. There are established pharmaceutical and biotechnology companies that are known to be involved in oncology research.

We consider setrusumab's current closest potential competitors in development for the treatment of OI to be Amgen's denosumab (Prolia) an anti-resorptive agent, and Amgen and UCB's anti-sclerostin antibody, romosozumab (Evenity), which was approved in the United States in April 2019 for osteoporosis. The FDA, however, required a Black Box warning that there may be an increase in risk of MI, stroke or cardiovascular death and that Evenity should not be initiated in patients who have had an MI or stroke in the last year. We believe that there is no increased risk of MI or stroke for patients with severe OI and the patient population we are studying is

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younger, with a mean age in the MBPS205 study of 44 years in the adult study and a maximum age of 17 will be allowed in the pediatric study. In the adult study there have been no events of MI or stroke, or other ischaemic pathology. In June 2019, the EMA's CHMP adopted a negative opinion recommending the refusal of a marketing authorization for Evenity. However, Amgen and UCB announced in October 2019 that following a re-examination procedure the CHMP has adopted a positive opinion recommending marketing authorization for Evenity. The CHMP's recommendation was reviewed by the European Commission Evenity was authorized in December 2019. In addition, Jiangsu Hengrui has commenced Phase 1 development of an anti-sclerostin antibody for osteoporosis, and Transcenta Holding has licensed the anti-sclerostin antibody blosozumab from Lilly and plans to develop it for osteoporosis. Additionally, Bone Therapeutics is developing osteoblastic cell therapy product candidates. Baylor College of Medicine is also conducting a Phase 1 open label trial of fresolimumab, a TGF-B inhibitor, in adult OI patients.

We consider alvelestat's current closest potential competitors for the treatment of severe AATD to be alpha1-proteinase inhibitors that are administered intravenously in AAT augmentation therapy.

Currently, there are four inhibitors on the market in the United States and the EU: Grifols' Prolastin-C, Shire's Aralast, CSL's Zemaira and Kamada's Glassia. Kamada is also investigating an inhaled version of augmentation therapy, InhibRx is in Phase 1 development of INBRX-101, a recombinant human alpha-1 antitrypsin Fc fusion protein (rhAAT-Fc) for replacement therapy and Apic Bio is in the early stages of developing gene-therapy approaches for AATD. Vertex has a small molecule corrector program for AATD with VX-814 and VX-864 in Phase 1 development. Santhera has in-licensed an inhaled NE inhibitor and is planning a multiple ascending dose study, with the initial indication targeted being CF; and CHF-6333 is an inhaled human NE inhibitor in Phase 1 development by Chiesi for the treatment of non-cystic fibrosis bronchiectasis and CF.

The current standard of care for AECOPD involves steroids, antibiotics and bronchodilators; however, we are not aware of any drugs specifically approved for the treatment of AECOPD to reduce recurrent AECOPDs. There are a number of product candidates currently in development, with Verona Pharma, GlaxoSmithKline, and AstraZeneca each conducting Phase 2 clinical trials of drugs for the treatment of COPD. In addition, Pulmatrix has PUR1800, a NSKI expected to begin a Phase 1b for AECOPD in 2020. We consider acumapimod's current closest potential competitor in development for the treatment of AECOPD to be Verona Pharma's RPL554, a PDE3 / PDE4 dual inhibitor that is currently being developed as a bronchodilator and anti-inflammatory agent for COPD and asthma patients.

We consider leflutrolole's current closest potential competitors for the treatment of HH to be TRT. These include Androgel from AbbVie, and Lilly's Axiron, both administered transdermally by applying a gel formulation, which are approved in the United States and Europe, Andriol from Merck, an oral testosterone therapy, which is approved in Europe but not in the United States and Jatenzo from Clarus approved in the United States in March 2019. There are also other approved TRT product candidates that are administered via injection and other oral TRTs that are still in the development or registration stages, such as Tlando from Lipocine. The FDA held advisory committee meetings in January 2018 for Tlando. On May 9, 2018, Lipocine announced that it had received a complete response letter from the FDA and on May 14, 2019, Lipocine announced the acceptance of the NDA for Tlando. Lipocine has also announced an injunction against Clarus for its product Jatenzo.

We may face increasing competition for additional new product acquisitions from pharmaceutical companies as new companies emerge with a similar business model and other more established companies focus on acquiring product candidates to develop their pipelines. Many of our competitors have significantly greater name recognition, financial, manufacturing, marketing, drug development, technical and human resources than we do. Mergers and acquisitions in the biopharmaceutical and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining top qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and in acquiring technologies complementary to, or necessary for, our programs.

The key competitive factors affecting the success of etigilimab, setrusumab, alvelestat, acumapimod and leflutrolole, if approved, are likely to be their efficacy, safety, dosing convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

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Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe side effects than any product candidates that we may develop. Our competitors may also obtain FDA, EMA or other regulatory approval for their product candidates more rapidly than we may obtain approval for our own product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if etigilimab, setrusumab, alvelestat, acumapimod or leflutrolole achieve marketing approval, they may be priced at a significant premium over competing product candidates if any have been approved by then.

Intellectual Property

We have acquired or exclusively licensed our intellectual property portfolio from OncoMed, Novartis and AstraZeneca. We strive to protect and enhance the proprietary technologies, inventions and improvements that we believe are important to our business, including seeking, maintaining and defending patent rights, whether developed internally or acquired or licensed from third parties. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, platforms and our product candidates that are important to the development and implementation of our business.

Our intellectual property is held by OncoMed, Mereo BioPharma 1 Limited, Mereo BioPharma 2 Limited, Mereo BioPharma 3 Limited and Mereo BioPharma 4 Limited, each of which is a wholly-owned subsidiary of our Company and holds the intellectual property for our product candidates etigilimab, acumapimod, leflutrolole, setrusumab and alvelestat respectively. As of June 8, 2020 and following the Merger, our patent portfolio comprises approximately 553 issued patents and approximately 184 pending patent applications on a global basis.

Etigilimab (OMP-313M32)

As of June 8, 2020, following the Merger, our patent portfolio relating to our therapeutic candidate etigilimab consisted of two granted U.S. patents and one pending U.S. patent application, as well as corresponding patent applications in major foreign jurisdictions.

The patent portfolio relating to our therapeutic candidate etigilimab contains one core patent family that covers the product per se as well as medical uses thereof. This patent family currently consists of two granted U.S. patents, three granted or allowed foreign patents and 22 pending foreign patent applications. Patents that issue from this core family are generally expected to expire in 2036.

The portfolio also includes a second patent family that relates to specific methods of treatment using etigilimab. This patent family currently consists of one pending U.S. application, and 14 pending foreign patent applications. Any patents that issue from this family are generally expected to expire in 2037.

Navicixizumab (OMP-305B83)

As of June 8, 2020, following the Merger, our patent portfolio relating to Navi consisted of 17 issued U.S. patents and two pending U.S. patent applications, as well as corresponding patents or patent applications in major foreign jurisdictions.

The patent portfolio relating to Navi contains two core patent families, both of which cover the product per se as well as medical uses thereof. Patents and patent applications, if issued, in these core families are expected to expire between 2030 and 2032.

The portfolio also includes several other patent families including issued U.S. and foreign patents and pending applications that relate to specific methods of treatment using Navi. Patents and patent applications, if issued, in these families are expected to expire between 2030 and 2039. Navi was licensed by the Group to Oncologie Inc. in January 2020 pursuant to the terms of a global licensing agreement. See “—Licensing Agreement for Navicixizumab.”

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the USPTO delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically the duration of foreign issued patents is also 20 years from the earliest effective filing date. However, the actual protection afforded by a given patent varies on a product-by-product basis and from country to country, dependent on many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

In addition to patent protection, we also rely upon trademarks, trade secrets and know-how, and continuing technological innovation, to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, employees and consultants and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with our collaborators and selected consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our product candidates or processes, obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our product candidates may have an adverse impact on us. If third parties have prepared and filed patent applications prior to March 16, 2013 in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO, to determine priority of invention. For more information, please see “Risk Factors—Risks Related to Intellectual Property.”

Setrusumab (BPS-804)

As of June 8, 2020, our patent portfolio relating to our product setrusumab consisted of three issued U.S. patents, three pending U.S. patent applications, 86 issued foreign patents, 26 pending foreign patent applications and one pending international patent application filed under the Patent Cooperation Treaty (“PCT”). These issued patents and patent applications, if issued, include claims directed to the setrusumab antibody as well as nucleic acids encoding the antibody and the antibody’s use as a medicament; the use of anti-sclerostin antibodies in the treatment of OI; the use of the setrusumab antibody in the treatment of OI with a specific dosing regimen; and use of a sclerostin antagonist in the treatment of a myopathy with expected expiry dates between 2028 and 2039.

The patent portfolio relating to our product setrusumab includes three patent families:

- The first of these patent families relates to the setrusumab antibody as well as nucleic acids encoding the antibody and the antibody’s use as a medicament. As of June 8, 2020, this patent family included issued patents in Algeria, Argentina, Australia, Canada, China, Colombia, Europe (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom), the Gulf Cooperation Council countries, Hong Kong, India, Indonesia, Israel, Japan, Macau, Mexico, New Zealand, Russia, Singapore, South Africa, South Korea and the United States. We expect issued patents in this family to expire in 2028.

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- The second of these patent families relates to the use of anti-sclerostin antibodies in the treatment of OI and the use of the setrusumab antibody in the treatment of OI at a specific dosing regimen. As of March 1, 2020, this patent family included three pending U.S. patent applications and 22 pending foreign patent applications. We expect patents in this family, if issued, to expire in 2036.
- The third of these patent families relates to the use of an anti-sclerostin antagonist in the treatment of a myopathy. As of June 8, 2020, this patent family included one pending international patent application filed under the PCT. We expect patents in this family, if issued, to expire in 2039.

Alvelestat (MPH-966)

As of June 8, 2020, our patent portfolio relating to our product candidate alvelestat consisted of three issued U.S. patents, no pending U.S. patent applications, 35 issued or allowed foreign patents and three pending foreign patent applications. These patents have all been licensed under our agreement with AstraZeneca. See “Business—Material Agreements—AstraZeneca Agreement.” These issued patents and patent applications, if issued, include claims directed to 2-pyridone derivatives as NE inhibitors and their uses as well as claims to polymorphs of the tosylate salt of a 5-pyrazolyl-2-pyridone derivative, with expected expiry dates between 2024 and 2030. Our patent portfolio relating to our product candidate alvelestat also includes two pending foreign applications which have been filed subsequent to the license agreement with AstraZeneca. These patent applications, if issued, include claims directed to dosage regimens of alvelestat with expected expiry dates in 2041.

Finally, our patent portfolio relating to our product candidate alvelestat includes one pending U.S. patent application which has been filed subsequent to the license agreement with AstraZeneca. This patent application, if issued, includes claims directed to methods of treatment using alvelestat with expected expiry date of 2040.

The patent portfolio relating to our product candidate alvelestat includes four patent families:

- The first of these patent families relates to 2-pyridone derivatives as NE inhibitors and their use. As of June 8, 2020, this patent family included issued patents in Australia, Brazil, Canada, China, Europe (France, Germany, Italy, Netherlands, Spain, Sweden, Switzerland, Turkey and United Kingdom), Hong Kong, India, Japan, Mexico, Russia, South Korea and the United States. We expect issued patents in this family to expire in 2024.
- The second of these patent families relates to polymorphs of the tosylate salt of a 5-pyrazolyl-2-pyridone derivative. As of June 8, 2020, this patent family included issued patents in Australia, Canada, China, Europe (France, Germany, Italy, Netherlands, Spain, Sweden, Switzerland, Turkey and United Kingdom), Hong Kong, Japan, Mexico, Russia and the United States. We expect issued patents in this family to expire in 2030.
- The third of these patent families relates to dosage regimens of alvelestat. As of June 8, 2020, this patent family included two pending U.K. patent applications. We expect patents in this family, if issued, to expire in 2041.
- The fourth of these patent families relates to methods of treatment using alvelestat. As of June 8, 2020, this family included one pending U.S. patent application. We expect patents in this family, if issued, to expire in 2040.

Acumapimod (BCT-197)

As of June 8, 2020, our patent portfolio relating to our product acumapimod consisted of 6 issued U.S. patents, 7 pending U.S. patent applications, 136 issued and allowed foreign patents, 56 pending foreign applications, and three pending international patent applications filed under the PCT. These issued patents and patent applications, if issued, include claims directed to 5-membered heterocycle-based p38 kinase inhibitors, the use of a pyrazole derivative in the treatment of AECOPD, dosage regimens of acumapimod, the use of acumapimod in the treatment of specific patient subpopulations, methods of producing specific polymorphs of acumapimod and synthetic methods of production of acumapimod with expected expiry dates between 2024 and 2038.

The patent portfolio relating to our product acumapimod includes six patent families:

- The first of these patent families relates to the key composition per se and other 5-membered heterocycle-based p38 kinase inhibitors. As of June 8, 2020, this patent family included issued patents

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in Algeria, Australia, Brazil, Canada, China, Colombia, Europe (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Monaco, Netherlands, Poland, Portugal, Romania, Slovenia, Slovakia, Spain, Sweden, Switzerland, Turkey and United Kingdom), Hong Kong, India, Indonesia, Israel, Japan, Malaysia, Mexico, New Zealand, Norway, Russia, Singapore, South Africa, South Korea and the United States. We expect issued patents in this family to expire in 2024.

- The second of these patent families relates to the use of pyrazole derivatives in the treatment of AECOPD. As of June 8, 2020, this patent family included issued patents in Algeria, Australia, Canada, China, Europe (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Germany, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Norway and United Kingdom), Hong Kong, Indonesia, Israel, Japan, Mexico, New Zealand, Philippines, Russia, Singapore, South Africa, South Korea, Taiwan, the United Arab Emirates and the United States. We expect issued patents in this family to expire in 2033.
- The third of these patent families relates to dosage regimens of acumapimod. As of June 8, 2020, this patent family included one granted U.S. patent application, two granted foreign patent applications and 14 pending foreign patent applications. We expect patents in this family, if issued, to expire in 2036.
- The fourth of these patent families relates to specific polymorphs of acumapimod. As of June 8, 2020, this patent family included two pending U.S. patent applications and 26 pending foreign patent applications. We expect patents in this family, if issued, to expire in 2037.
- The fifth of these patent families relates to novel regimes for the prevention of AECOPD and the use of acumapimod in a specific patient subpopulation. As of June 8, 2020, this patent family included two pending U.S. patent applications and 12 pending foreign patent applications. We expect patents in this family, if issued, to expire in 2038.
- The sixth of these patent families relates to synthetic methods for the production of acumapimod. As of June 8, 2020, this patent family included three PCT patent applications. We expect patents in this family, if issued, to expire in 2039.

Leflurozole (BGS-649)

As of June 8, 2020, our patent portfolio relating to our product leflurozole consisted of four issued U.S. patents, one pending U.S. patent application, 90 issued foreign patents, and 9 pending foreign patent applications. These issued patents and patent applications, if issued, include claims directed to leflurozole formulations and the use of leflurozole in treating hypogonadism according to a specific dosing regimen, with expected expiry dates between 2032 and 2040.

The patent portfolio relating to our product leflurozole includes two patent families:

- The first of these patent families relates to leflurozole formulations and to the use of leflurozole in treating hypogonadism according to a specific dosing regimen. As of June 8, 2020, this patent family included issued patents in Algeria, Australia, Brazil, Canada, China, Europe (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Norway, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and United Kingdom), GCC, Hong Kong, Indonesia, Israel, Japan, Mexico, New Zealand, Russia, Singapore, South Africa, South Korea and the United States. We expect issued patents in this family to expire in 2032.
- The second of these patent families relates to the use of leflurozole in treating endometriosis according to a specific dosing regimen. As of June 8, 2020, this patent family included one pending U.S. patent application and three pending foreign patent applications. We expect patents in this family, if issued, to expire in 2037.

Government Regulation

Among others, the FDA, the EMA, U.S. Department of Health and Human Services Office of Inspector General, CMS and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our product candidates.

U.S. Government Regulation

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations, and biological product candidates (“biologics”), under both the FDCA and the PHSA and its implementing regulations.

The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA’s refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of pre-clinical laboratory tests, animal studies and formulation studies in compliance with the FDA’s GLP regulations;
- submission to the FDA of an investigational new drug application (an “IND”), which must become effective before human clinical trials may begin;
- approval by an IRB at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with GCP requirements to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product’s identity, strength, quality and purity;
- satisfactory completion of potential FDA audits of clinical trials sites and the sponsor’s clinical trial records to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees, if applicable, and FDA review and approval of the NDA or BLA; and
- compliance with any post-approval requirements, including the potential requirement to implement a REMS and the potential requirement to conduct post-approval studies.

Pre-clinical Studies

Pre-clinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. The conduct of the pre-clinical tests must comply with federal regulations and requirements, including GLPs. An IND sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some pre-clinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

Clinical trials involve the administration of the investigational new drug or biologic to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives or endpoints of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB must review and approve the plan for a clinical trial. This can be a central or local IRB. In the case of a central IRB a single IRB will be the source of record for all sites in a trial; otherwise, a local IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their website, www.clinicaltrials.gov.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The product is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The product is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: The product is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to patients.

Special FDA Expedited Review and Approval

The FDA has various programs, including fast track designation, breakthrough therapy designation, accelerated approval, and priority review, which are intended to expedite or simplify the process for the development and FDA review of drugs and biologics that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs and biologics to patients earlier than under standard FDA review procedures.

To be eligible for a fast-track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast-track designation provides opportunities for frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the NDA or BLA for a fast-track product on a rolling basis before the complete application is submitted, if the sponsor and FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

In addition, under the provisions of the Food and Drug Administration Safety and Innovation Act passed in July 2012, a sponsor can request designation of a product as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant

endpoints, such as substantial treatment effects observed early in clinical development. Drugs or biologics designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Product candidates studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (“IMM”) that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a product receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to accelerated withdrawal procedures.

Once an NDA or BLA is submitted for a product intended to treat a serious condition, the FDA may assign a priority review designation if the FDA determines that the product, if approved, would provide a significant improvement in safety or effectiveness. Under priority review, the FDA must review an application in six months, compared to 10 months for a standard review. Most product candidates that are eligible for fast-track or breakthrough therapy designation are also likely to be considered appropriate to receive a priority review.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast-track designation, breakthrough-therapy designation, accelerated approval and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

Priority Review Voucher Program

This FDA Priority Review Voucher program is intended to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Under this program, a sponsor who receives an approval for a drug or biologic designated as a “rare pediatric disease” may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. Priority review means that the FDA aims to render a decision in six months. The sponsor receives the priority review voucher upon approval of the rare pediatric disease product application and it can be sold or transferred.

Orphan Product Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic product if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA or BLA. If the request is granted, the FDA will publicly disclose the identity of the therapeutic agent and its potential use. We have been granted orphan product designation by the FDA for our product setrusumab for the treatment of OI. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product is entitled to orphan-product exclusivity. Orphan-product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. If a product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan-product application, it may not be entitled to exclusivity. Orphan exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product

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for the same orphan indication or disease as long as the product candidates contain different active ingredients. Moreover, competitors may receive approval of different product candidates for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA or BLA is subject to a substantial application user fee. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA") for new molecular entity NDAs and original BLAs, the FDA has 10 months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification. This review typically takes 12 months from the date the NDA or BLA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision.

In addition, under the Pediatric Research Equity Act of 2003, as amended and reauthorized, certain NDAs, BLAs or supplements to an NDA or BLA must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA may also require submission of a REMS plan if it determines that a REMS is necessary to ensure that the benefits of the product outweigh its risks. Depending on the specific serious risk(s) to be addressed, the FDA may require that the REMS include a medication guide or patient package insert, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs and BLAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an application to determine, among other things, whether the drug is safe and effective (for biologics, the standard is referred to as safe, pure and potent) and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug or biologic candidate to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an application, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an application, the FDA may inspect the sponsor and one or more clinical trial sites to assure compliance with GCP requirements and the integrity of the clinical data submitted in an NDA.

After evaluating the application and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the

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FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally details specific conditions that must be met in order to secure final approval of the application and may require additional clinical or pre-clinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require additional contraindications, warnings or precautions to be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed product candidates and the establishments at which such product candidates are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, manufacturers and other entities involved in the manufacture and distribution of approved product candidates are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of product candidates;
- injunctions or the imposition of civil or criminal penalties;

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- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information; or
- the FDA or other regulatory authorities may issue safety alerts, “Dear Healthcare Provider” letters, press releases or other communications containing warnings or other safety information about the product.

The FDA strictly regulates marketing, labeling, advertising and promotion of product candidates that are placed on the market. Product candidates may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Foreign Government Regulation

Our product candidates will be subject to similar laws and regulations imposed by jurisdictions outside of the United States, and, in particular, Europe, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

In order to market our future product candidates in the European Economic Area (which is comprised of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein) (the “EEA”), and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EEA, medicinal product candidates can only be commercialized after obtaining a Marketing Authorization (“MA”). There are two types of marketing authorizations:

- the “Community MA,” which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Product candidates for Human Use of the EMA and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of product candidates, such as biotechnology medicinal product candidates, orphan medicinal product candidates and medicinal product candidates indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for product candidates containing a new active substance not yet authorized in the EEA, or for product candidates that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU; and
- “National MAs,” which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for product candidates not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Data and marketing exclusivity. In the EEA, new product candidates authorized for marketing, or reference product candidates, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Pediatric investigation plan. In the EEA, marketing authorization applications for new medicinal product candidates not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan (“PIP”), agreed with the EMA’s Pediatric Committee (“PDCO”). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all Member States of the EU and study results are included in the product information, even when negative, the product is eligible for a six-month supplementary protection certificate extension or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Orphan drug designation. In the EEA, a medicinal product can be designated as an orphan drug if its sponsor can establish that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically-debilitating condition affecting not more than five in 10,000 persons in the EU when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously-debilitating or serious and chronic condition in the European Community and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug will be of significant benefit to those affected by that condition.

In the EEA, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, the EMA or the competent authorities of the Member States, cannot accept another application for a marketing authorization, or grant a marketing authorization, for a similar medicinal product for the same indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP.

This period of orphan market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan drug designation, i.e. the prevalence of the condition has increased above the threshold or it is judged that the product is sufficiently profitable not to justify maintenance of market exclusivity. Granting of an authorization for another similar orphan medicinal product where another product has market exclusivity can happen only in selected cases, such as, for example, demonstration of “clinical superiority” by a similar medicinal product, inability of a manufacturer to supply sufficient quantities of the first product or where the manufacturer itself gives consent. A company may voluntarily remove a product from the orphan register. Medicinal products or medicinal product candidates designated as orphan are eligible for incentives made available by the EU and its Member States to support research into, development and availability of orphan medicinal products. In March 2016, we obtained orphan drug designation for setrusumab for the treatment of OI in the EU. We intend to pursue orphan designation for alvelestat and for future, eligible rare disease programs.

Adaptive pathways. The EMA has an adaptive pathways program which allows for early and progressive patient access to a medicine. The adaptive pathways concept is an approach to medicines approval that aims to improve patients’ access to medicines in cases of high unmet medical need. To achieve this goal, several approaches are envisaged: identifying small populations with severe disease where a medicine’s benefit-risk balance could be favorable; making more use of real-world data where appropriate to support clinical trial data; and involving health technology assessment bodies early in development to increase the chance that medicines will be recommended for payment and ultimately covered by national healthcare systems. The adaptive pathways concept applies primarily to treatments in areas of high medical need where it is difficult to collect data via traditional routes and where large clinical trials would unnecessarily expose patients who are unlikely to benefit from the medicine. The approach

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builds on regulatory processes already in place within the existing EU legal framework. These include: scientific advice; compassionate use; the conditional approval mechanism (for medicines addressing life-threatening conditions); patient registries and other pharmacovigilance tools that allow collection of real-life data and development of a risk-management plan for each medicine.

The adaptive pathways program does not change the standards for the evaluation of benefits and risks or the requirement to demonstrate a positive benefit-risk balance to obtain marketing authorization. In February 2017, setrusumab was accepted into the adaptive pathways program.

PRIME scheme. In July 2016, the EMA launched the PRIME scheme. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is however not guaranteed. The benefits of a PRIME designation includes the appointment of a rapporteur from the Committee for Medicinal Product candidates for Human Use before submission of an MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify product candidates for accelerated review earlier in the application process. In November 2017, the EMA granted PRIME designation for setrusumab for the treatment of OI.

Other U.S. Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical and biologic product candidates, other U.S. federal and state healthcare regulatory laws restrict business practices in the pharmaceutical and biotechnology industry, which include, but are not limited to, state and federal anti-kickback, false claims, data privacy and security and physician payment and pricing transparency laws.

The U.S. federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements, such as those between pharmaceutical manufacturers on the one hand and prescribers, purchasers, formulary managers and beneficiaries on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not meet the requirements of a statutory or regulatory exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the U.S. federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

Additionally, the intent standard under the U.S. federal Anti-Kickback Statute was amended by the ACA to a stricter standard such that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil FCA. The majority of states also have anti-kickback laws, which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers, or to self-pay patients.

The federal false claims and civil monetary penalties laws, including the civil FCA, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. A

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claim includes “any request or demand” for money or property presented to the U.S. government. Actions under the civil FCA may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the civil FCA can result in very significant monetary penalties and treble damages. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of product candidates for unapproved, or off-label, uses. In addition, the civil monetary penalties statute imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Many states also have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

HIPAA created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, the ACA broadened the reach of certain criminal healthcare fraud statutes created under HIPAA by amending the intent requirement such that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

In addition, there has been a trend of increased federal and state regulation of payments made to physicians and certain other healthcare providers. The ACA imposed, among other things, new annual reporting requirements through the Physician Payments Sunshine Act for applicable manufacturers for certain payments and “transfers of value” provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties. Applicable manufacturers must submit reports by the 90th day of each subsequent calendar year. In addition, certain states require implementation of compliance programs and compliance with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, impose restrictions on marketing practices and/or tracking and reporting of gifts, compensation and other remuneration or items of value provided to physicians and other healthcare professionals and entities.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH, and their respective implementing regulations, including the Final HIPAA Omnibus Rule published on January 25, 2013, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH made HIPAA’s security standards directly applicable to “business associates,” defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney’s fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring that internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs.

Violations of any of these laws may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and

Medicaid), disgorgement and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies. Given the significant size of actual and potential settlements, it is expected that the government authorities will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable laws.

Privacy and Data Protection Laws in Europe

We are subject to European laws relating to our and our suppliers', partners' and subcontractors' collection, control, processing and other use of personal data (i.e., any data relating to an identifiable living individual, whether that individual can be identified directly or indirectly). We are subject to the supervision of local data protection authorities in those jurisdictions where we are established, where we offer goods or services to EU residents and where we monitor the behavior of individuals in the EU (i.e., undertaking clinical trials). We and our suppliers, partners and subcontractors process personal data including in relation to our employees, employees of customers, clinical trial patients, healthcare professionals and employees of suppliers including health and medical information. The data privacy regime in the EU includes the GDPR, the e-Privacy Directive and the e-Privacy Regulation (once in force) and the national laws and regulations implementing or supplementing each of them.

The GDPR requires that personal data is only collected for specified, explicit and legal purposes as set out in the GDPR or local laws, and the data may then only be processed in a manner consistent with those purposes. The personal data collected and processed must be adequate, relevant and not excessive in relation to the purposes for which it is collected and processed, it must be held securely, not transferred outside of the EEA (unless certain steps are taken to ensure an adequate level of protection), and must not be retained for longer than necessary for the purposes for which it was collected. In addition, the GDPR requires companies processing personal data to take certain organizational steps to ensure that they have adequate records, policies, security, training and governance frameworks in place to ensure the protection of data subject rights, including as required to respond to complaints and requests from data subjects. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for processing, will require the appointment of a data protection officer where sensitive personal data (i.e., health data) is processed on a large scale, introduces mandatory data breach notification throughout the EU and imposes additional obligations on us when we are contracting with service providers.

In addition, to the extent a company processes, controls or otherwise uses "special category" personal data (including patients' health or medical information, genetic information and biometric information), more stringent rules apply, further limiting the circumstances and the manner in which a company is legally permitted to process that data. Finally, the GDPR provides a broad right for EU member states to create supplemental national laws which may result in divergence across Europe making it harder to maintain a consistent operating model or standard operating procedures. Such laws, for example, may relate to the processing of health, genetic and biometric data, which could further limit our ability to use and share such data or could cause our costs to increase, and harm our business and financial condition.

We depend on a number of third parties in relation to the provision of our services, a number of which process personal data on our behalf. With each such provider we enter into contractual arrangements to ensure that they only process personal data according to our instructions, and that they have sufficient technical and organizational security measures in place. Where we transfer personal data outside the EU, we do so in compliance with the relevant data export requirements from time to time. We take our data protection obligations seriously, as any improper, unlawful or accidental disclosure, loss, alteration or access to, personal data, particularly sensitive personal data (i.e., special category), could negatively impact our business and/or our reputation.

We are also subject to EU laws on personal data export, as we may transfer personal data from the EU to other jurisdictions which are not considered by the European Commission to offer adequate protection of personal data. Such transfers need to be legitimized by a valid transfer mechanism under the GDPR. There is currently ongoing litigation challenging the commonly used transfer mechanisms, the EU Commission approved model clauses. In addition, the EU-U.S. Privacy Shield (the "Privacy Shield") is currently under review by the European Commission. As such, it is uncertain whether the Privacy Shield framework and/or model clauses will be invalidated in the near future. These changes may require us to find alternative bases for the compliant transfer of personal data from the EU to the United States and we are monitoring developments in this area. Invalidation of any mechanism on which we rely could require operational changes and increased costs and may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity that could have an adverse effect on our business.

The EU is in the process of replacing the e-Privacy Directive with a new set of rules taking the form of a regulation, which will be directly applicable to the laws of each European member state, without the need for further implementation. The draft e-Privacy Regulation imposes strict opt-in marketing rules with limited exceptions for business-to-business communications and alters rules on third-party cookies, web beacons and similar technology. Regulation of cookies and web beacons may lead to broader restrictions on online research activities, including efforts to understand users' internet usage. The current draft also significantly increases fining powers to the same levels as GDPR (i.e., the greater of 20 million euros or 4% of total global annual revenue). While no official timeframe has been provided, commentators have stated that the e-Privacy Regulation is likely to be agreed in 2019 and to come into force during the second half of 2020 or during 2021 following a transition period.

There are costs and administrative burdens associated with compliance with the GDPR and the resultant changes in the EU and EEA member states' national laws and the introduction of the e-Privacy Regulation once it takes effect. Any failure or perceived failure to comply with global privacy laws carries with it the risk of significant penalties and sanctions of up to 20 million euros or 4% of global turnover. These laws or new interpretations, enactments or supplementary forms of these laws, could create liability for us, could impose additional operational requirements on our business, could affect the manner in which we use and transmit patient information and could increase our cost of doing business. Claims of violations of privacy rights or contractual breaches, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Sales of any product candidates for which we receive regulatory approval for commercial sale will therefore depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities, managed care plans, private health insurers and other organizations.

In the United States, the process for determining whether a third-party payor will provide coverage for a pharmaceutical or biologic product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific product candidates on an approved list, also known as a formulary, which might not include all of the FDA-approved product candidates for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a third-party payor's decision to provide coverage for a pharmaceutical or biologic product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for product candidates can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage-determination process will require us to provide scientific and clinical support for the use of our product candidates to each payor separately and will be a time-consuming process.

In the EEA, governments set the price of product candidates through their health technology assessment, and reimbursement rules and control of national health care systems that fund a large part of the cost of those product candidates to consumers. Some jurisdictions operate positive and negative list systems under which product candidates may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries might compare the new product to an existing standard of care, including other treatments aimed at the same disease, if they exist. Health technology assessments, including

cost-effectiveness evaluations, may be conducted in order to assess the medical value or added clinical benefit of a therapy. Countries may also conduct budget-impact assessments for a new therapy. In some cases, tendering is used to decide which therapy will be reimbursed and made available for a group of patients where more than one treatment exists. Countries might also require further studies or in-use evidence to be developed, or create coverage with evidence generation under some form of so-called managed access agreements. Some countries allow for a company to set the price, which is then agreed in negotiation with the country authorities, who might then monitor sales for that product and re-assess or re-evaluate when a certain statutory health insurance expenditure threshold is reached. Other countries might set their price based on prices in a selected country or group of countries under international or external reference pricing systems. If an agreement cannot be reached, confidential discounts might be negotiated between the manufacturer and the healthcare system authorities. The downward pressure on health care costs in general, particularly prescription product candidates, has become very intense. As a result, increasingly high barriers are being erected to the entry of new product candidates. In addition, in some countries, legally permissible cross-border imports from low-priced markets within the EU single market exert a commercial pressure on pricing within a country.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of pharmaceutical or biological product candidates have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical product candidates and services, examining the medical necessity and reviewing the cost-effectiveness of pharmaceutical or biological product candidates, medical devices and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our product candidates to be cost effective compared to other available therapies, they may not cover our product candidates after approval, if any, or, if they do, the level of payment may not be sufficient to allow us to sell our product candidates at a profit.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical product candidates. For example, the ACA, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for product candidates that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid-managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjected manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; created the Independent Payment Advisory Board, which, once empaneled, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and biologics; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending. Since its enactment, the U.S. federal government has delayed or suspended implementation of certain provisions of the ACA. In addition, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed product candidates. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Additionally, in August, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of

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2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed product candidates, which have resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical and biologic product candidates.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare product candidates and services, which could result in reduced demand for our product candidates once approved or additional pricing pressures.

Employees

As of December 31, 2019, 2018 and 2017, Mereo had 50, 37 and 31 employees, respectively. As at December 31, 2019, 39 employees are located in the United Kingdom and 11 employees are located in the United States.

All of our employees are engaged in either general and administrative or research and development functions. None of our employees are covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Legal Proceedings

There are no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which we are aware) that may have, or have had in the recent past (covering the 12 months immediately preceding the date of this annual report), significant effects on our financial position or profitability.

4.C. Organizational Structure

Mereo BioPharma Group plc was formed as a private limited company organized under the laws of England and Wales on March 10, 2015 and re-registered as a public limited company on June 3, 2016.

As at December 31, 2019, Mereo BioPharma Group plc has the following wholly-owned direct or indirect subsidiaries:

Legal Name of Subsidiary	Jurisdiction of Organization
Mereo BioPharma 1 Limited	United Kingdom
Mereo BioPharma 2 Limited	United Kingdom
Mereo BioPharma 3 Limited	United Kingdom
Mereo BioPharma 4 Limited	United Kingdom
Mereo BioPharma Ireland Limited	Ireland
Mereo US Holdings Inc.	Delaware
OncoMed Pharmaceuticals, Inc.	Delaware
Navi Subsidiary, Inc.	Delaware

4.D. Property, Plants and Equipment

Mereo's principal office is located at 4th Floor, One Cavendish Place, London W1G 0QF, United Kingdom, where Mereo leases approximately 4,000 square feet of office space. Mereo leases this office space under a lease that terminates on August 16, 2025.

As a result of the Merger, Mereo leases approximately 45,000 square feet in Redwood City, California of which approximately 15,000 square feet is subject to third party sub-leases which expire on June 30, 2020. Mereo intends to seek reduced lease accommodation in California for its US staff and is currently in negotiations with its landlord and third parties.

Item 4A. Unresolved Staff Comments

None.

Item 5. Operating And Financial Review And Prospects

5.A. Operating Results

The following discussion of our financial condition and results of operations should be read in conjunction with Mereo's audited consolidated financial statements and related notes included elsewhere in this annual report. The following discussion is based on Mereo's financial information prepared in accordance with IFRS as issued by the IASB, which may differ in material respects from generally accepted accounting principles in other jurisdictions, including generally accepted accounting principles in the United States. The following discussion includes forward-looking statements that involve risks, uncertainties, and assumptions. Mereo's actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described under "Item 3. Key Information—D. Risk Factors" and elsewhere in this annual report.

Overview

We are a biopharmaceutical company focused on the development and commercialization of innovative therapeutics that aim to improve outcomes for oncology and rare diseases. Our existing portfolio consists of six clinical stage product candidates. Our lead oncology product candidate, etigilimab (an "Anti-TIGIT"), has completed a Phase 1a dose escalation clinical trial in patients with advanced solid tumors and has been evaluated in a Phase 1b study in combination with nivolumab in select tumor types. Our second oncology product, navicixizumab, for the treatment of late line ovarian cancer, has completed a Phase 1 study and has been partnered with Oncologie, Inc. Our rare disease product candidates are setrusumab for the treatment of OI and alvelestat for the treatment of severe AATD which is being investigated in an ongoing Phase 2 proof-of-concept study in the U.S. and Europe and expect to report top line data from this study in the second half of 2021. We plan to form a strategic partnership for the development of setrusumab in adults and children following the completion of the Phase 2b study and alignment with the FDA and EMA on the pivotal study design for children with OI.

We plan to develop our product candidates for oncology and rare diseases through the next key clinical milestone and then partner or in selected cases to develop through regulatory approval and potentially commercialization.

We plan to partner or sell our other two product candidates (which do not target oncology or rare diseases), acumapimod for the treatment of AECOPD and leflutrozoled for the treatment of infertility and HH in obese men, recognizing the need for greater resources to take these product candidates to market.

Our strategy is selectively to acquire and develop product candidates for oncology and rare diseases that have already received significant investment from large pharmaceutical and biotechnology companies and that have substantial pre-clinical, clinical and manufacturing data packages. Since our formation in March 2015, we have successfully executed on this strategy by acquiring six clinical-stage product candidates of which four were in oncology and rare diseases. Four of these six clinical-stage product candidates were acquired from large pharmaceutical companies and two were acquired in the Merger. We aim to efficiently to develop our product candidates through the clinic and have commenced or completed large, randomized Phase 2 clinical trials for four of our product candidates.

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We do not have any approved product candidates and, as a result, have not generated any revenue from product sales. Our ability to generate revenue sufficient to achieve profitability will depend on our successful development and eventual commercialization of our oncology or rare disease product candidates, if approved, and our ability to complete partnering deals in respect of our non-oncology/non-rare disease product candidates. Since our inception, we have incurred significant operating losses. We had net losses of £34.8 million, £32.0 million and £38.8 million, in the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated net loss of £146.1 million (£111.2 million as of December 31, 2018).

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the clinical and manufacturing development of our oncology and rare disease product candidates and seek regulatory approval. If approved, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution.

For our non-oncology/non-rare disease product candidates, we expect to incur further costs in respect of completing development programs, further regulatory and scientific advice and, if approved, manufacturing, as well as costs associated with seeking suitable partnerships or negotiating possible sales.

We also expect to incur expenses in connection with the in-license or acquisition of additional product candidates and the potential clinical development of any such product candidates. Furthermore, we became a U.S. public company listed on the Nasdaq upon closing of the Merger. We expect to incur additional costs associated with operating as a newly public company in the U.S. listed on the Nasdaq in addition to operating as a U.K. public company traded on AIM, including significant legal, accounting, investor relations, and other expenses that we did not previously incur prior to the Merger. Following the Merger, whilst OncoMed had significantly restructured its cost base ahead of the Merger, we expect to incur additional costs in relation to OncoMed, including operating costs relating to the Redwood City site.

As a result of these anticipated expenditures, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales or other commercialization revenues, if ever, in respect of our oncology or rare disease product candidates or through partnering deals in the case of our non-oncology/non-rare disease product candidates, we will seek to finance our operations through a combination of public or private equity or debt financings or other sources. We may also seek to sell or out-license one or more of our non-oncology/non-rare disease product candidates. Adequate additional financing may not be available to us on acceptable terms, or at all. Our inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy and to continue as a going concern. We will need to generate significant revenue to achieve profitability, and we may never do so.

Since our formation to date, we have raised a total of £163.7 million in gross proceeds from private and public placements of our ordinary shares to institutional investors, £0.3 million from a placement of our ordinary shares to retail investors and exercised share options, \$50.8 million from cash and short-term investments acquired in the merger with OncoMed and £7.3 million from the issuance of the Novartis Notes (part of which were converted into ordinary shares in April 2017, and the remainder of which were converted into ordinary shares in June 2019). In August 2017, we also entered into a credit facility in the amount of £20.0 million which was fully drawn as at June 30, 2019 and December 31, 2018. As at December 31, 2019 our aggregate cash, short-term deposits and short-term investments were £16.3 million.

We are organized into a single segment following management's view of the business as a single portfolio of product candidates. Research and development expenses are monitored at a product level; however, decisions over resource allocation are made at an overall portfolio level. Our financing is managed and monitored on a consolidated basis.

Asset Purchase Agreements with Novartis

In July 2015, three of our wholly-owned subsidiaries, Mereo BioPharma 3 Limited, Mereo BioPharma 2 Limited, and Mereo BioPharma 1 Limited (the “Subsidiaries”), entered into asset purchase agreements (the “Purchase Agreements”), to acquire from Novartis rights to setrusumab, acumapimod, and leflutroazole (the “Compounds”), respectively, and certain related assets (together with the Compounds, the “Novartis Assets”).

In connection with the acquisition of the Novartis Assets, we issued 3,849,000 of our ordinary shares to Novartis pursuant to a subscription agreement. See “Related Party Transactions—Subscription Agreement.” In addition, we paid Novartis \$1.5 million for a payment made by Novartis to a third party in full satisfaction of all monetary obligations of Novartis to such third party with respect to acumapimod. Under the Purchase Agreements, we have agreed to make tiered royalty payments to Novartis based on annual worldwide net sales of product candidates that include the Compounds (the “Acquired Novartis Product Candidates”), at percentages ranging from the high single digits to low double digits. In the event that the parties agree or it is otherwise determined in accordance with the Purchase Agreements that we require third-party intellectual property rights to exploit the Acquired Novartis Product Candidates, we are entitled to offset a specified percentage of amounts paid to such third parties in consideration for such intellectual property rights against the royalties due to Novartis. The royalty payments are payable for a period of ten years after the first commercial sale of an Acquired Novartis Product.

We further agreed that in the event of a change in control that involves the transfer, license, assignment, or lease of all or substantially all of a Subsidiary’s assets, including a Compound and related assets, we will pay Novartis a percentage of the proceeds of such transaction, with the majority of the proceeds being retained by us. No payment, however, is required with respect to any transaction of Mereo BioPharma Group plc involving its equity interests, a merger or consolidation of it, or a sale of any of its assets.

We also entered into a sublicense agreement with Novartis (the “Sublicense Agreement”), pursuant to which Novartis granted us an exclusive, worldwide, royalty-bearing sublicense for certain therapeutic antibody product candidates directed against sclerostin (the “Antibody Product Candidates”), including setrusumab. Under the Sublicense Agreement, we have agreed to pay Novartis royalties in the low single digits on worldwide net sales of Antibody Product Candidates. We have also agreed to pay Novartis up to \$3.25 million in development and regulatory milestones, and to use commercially reasonable efforts to develop and commercialize an Antibody Product Candidate.

License Agreement with AstraZeneca

In October 2017, our wholly-owned subsidiary Mereo BioPharma 4 Limited entered into an exclusive license and option agreement (the “License Agreement”), to obtain from AstraZeneca an exclusive worldwide, sub-licensable license under AstraZeneca’s intellectual property rights relating to certain product candidates containing a NE inhibitor, including product candidates that contain alvelestat, with an option to acquire such intellectual property rights, following commencement of a pivotal trial and payment of related milestone payments (the “Option”), together with the acquisition of certain related assets.

Upon entering into the License Agreement, we made an upfront payment of \$3.0 million to AstraZeneca in cash and issued 490,798 new ordinary shares for an aggregate upfront payment equal to \$5.0 million. In connection with certain development and regulatory milestones, we have agreed to make payments of up to \$115.5 million in the aggregate and issue additional ordinary shares to AstraZeneca for licensed product candidates containing alvelestat. In addition, we have agreed to make payments to AstraZeneca based on specified commercial milestones of the product candidate. In the event that we sub-license alvelestat, we have also agreed to pay a specified percentage of

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sublicensing revenue to AstraZeneca. Otherwise, we have agreed to make royalty payments to AstraZeneca equal to ascending specified percentages of tiered annual worldwide net sales by us or our affiliates of licensed product candidates (subject to certain reductions), ranging from the high single digits to low double digits.

Merger Agreement with OncoMed

On April 23, 2019 we closed the Merger, pursuant to which an indirect, wholly-owned subsidiary of ours was merged with and into OncoMed, with OncoMed continuing as the surviving corporation in the Merger and our indirect, wholly-owned subsidiary. Upon the closing of the Merger, we issued 24,783,320 ordinary shares and OncoMed stockholders received, in exchange for each share of OncoMed common stock owned immediately prior to the Merger: (1) 0.127694 ADSs, each representing five of our ordinary shares, and (2) one contingent value right per OncoMed stockholder, each representing the right to receive contingent consideration upon the achievement of certain milestones relating to certain OncoMed product candidates. Immediately following the effective time of the Merger, former OncoMed stockholders owned 25.8% of our issued share capital on an undiluted basis. In connection with the Merger, we also entered into certain agreements for the benefit of former OncoMed stockholders. See “Business—Material Agreements—CVR Agreement Between Us and Computershare.”

The combination of our biopharmaceutical portfolio of four product candidates with OncoMed’s lead product candidate has created a diversified combined portfolio, resulting in an increased number of potential near-term catalysts. In addition, the cash position of the combined company provided us with extended operational possibilities, with the potential for additional opportunities to arise by way of partnering deals with respect to setrusumab for adults and children with OI and our non-oncology/non-rare product candidates. Finally, our Nasdaq listing, obtained in connection with the Merger, in addition to our existing AIM trading, provides a diversified international shareholder base for us following the Merger.

The closing of the Merger on April 23, 2019 affects the comparability of our financial condition and results of operations as of and for the financial periods discussed in this annual report. In particular, our consolidated statement of comprehensive loss for the year ended December 31, 2019 includes the results of OncoMed on a fully consolidated basis. In addition, unless otherwise noted, the discussion and analysis contained below on our operations as of and for the year ended December 31, 2018, excludes the impact of the Merger.

The Merger qualified as a business combination (as defined in IFRS 3) in our consolidated financial statements for the year ended December 31, 2019. Accordingly, in this section we refer to the Merger as a merger and as an acquisition interchangeably.

For a discussion of the risks relating to the Merger, see “Risk Factors—Risks Related to the Merger.”

Licensing Agreement with Oncologie

On January 13, 2020, we entered into a global license agreement with Oncologie for the development and commercialization of Navi, an anti-DLL4/VEGF bispecific antibody currently being evaluated in an ongoing Phase 1b study in combination with paclitaxel in patients with advanced heavily pretreated ovarian cancer. Navi previously completed a Phase 1a monotherapy study in patients with various types of refractory solid tumors and is one of two product candidates we acquired through the Merger. In October 2019, the FDA granted Fast Track designation to Navi and has agreed in principle on the design of a study that could potentially support accelerated approval for Navi in a heavily pretreated, platinum-resistant ovarian cancer patient population.

Under the terms of the license agreement, Oncologie will receive an exclusive worldwide license to develop and commercialize Navi. We received an upfront payment of \$4.0 million and will receive an additional payment of \$2.0 million conditional on a CMC (Chemistry, Manufacturing and Controls) milestone. Oncologie will be responsible for all future research, development and commercialization of Navi. Additionally, we will be eligible to

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receive up to \$300 million in future clinical, regulatory and commercial milestones, tiered royalties ranging from the mid-single-digit to sub-teen percentages on global annual net sales of Navi, as well as a negotiated percentage of sublicensing revenues from certain sublicensees.

As a consequence of the license agreement with Oncologie, and in accordance with the terms and conditions of the CVR Agreement, holders of CVRs pursuant to the CVR Agreement will be entitled to receive certain eligible cash milestone payments made to us under the license agreement relating to the development and commercialization of Navi. See “—CVR Agreement Between Us and Computershare.”

Aspire Capital Transaction

On February 10, 2020, we entered into a Purchase Agreement with Aspire Capital, an Illinois limited liability company, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$25.0 million worth of our ordinary shares that are exchangeable for ADSs over the approximately 30-month term of the Purchase Agreement. In addition, pursuant to the Purchase Agreement, Aspire Capital purchased 11,432,925 ordinary shares that are exchangeable for 2,286,585 ADSs for \$3.0 million. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we paid Aspire Capital a commission fee of \$300,000, which was wholly satisfied by the issuance to Aspire Capital of 2,862,595 ordinary shares that are exchangeable for 572,519 ADSs.

New Novartis Notes

On February 10, 2020, we entered into a £3,841,479 convertible loan note instrument with Novartis pursuant to which we issued Novartis 3,841,479 unsecured convertible loan notes (the “New Novartis Notes”) and warrants to purchase 1,449,614 ordinary shares.

Boxer Capital Transaction

On February 19, 2020, we entered into a securities purchase agreement with Boxer Capital. Under the terms of the agreement, Boxer Capital agreed to invest \$3.0 million by purchasing 12,252,715 ordinary shares (equivalent to 2,450,543 ADSs) at a price equivalent to 18.8 pence per ordinary share, which represented a 20% discount to our closing share price of 23.5 pence on AIM on February 18, 2020. We intend to use the net proceeds from this private placement for general corporate purposes, including clinical trial activity and working capital. There are no warrants, derivatives, or other share classes associated with this transaction. Further, there are no restrictions on future financings and there are no financial covenants, participation rights, rights of first refusal, or penalties in the purchase agreement entered into in connection with this transaction.

June 2020 Private Placement

On June 4, 2020, we announced completion of a private placement with net proceeds of approximately \$64.2 million (£51.4 million) with a number of new and existing principally U.S based institutional and accredited investors (the “June 2020 Private Placement”). OrbiMed Private Investments VI, LP (acting through its general partner, OrbiMed Capital GP VI LLC, acting through its managing member, OrbiMed Advisors LLC, collectively referred to herein as “OrbiMed”) led the June 2020 Private Placement with participants including Vivo Capital, Surveyor Capital (a Citadel company), Pontifax Venture Capital, Samsara BioCapital, Commodore Capital, and funds managed by Janus Henderson Investors alongside existing investors Boxer Capital of Tavistock Group and Aspire Capital Fund, LLC (collectively, the “Purchasers”). On June 3, 2020, we entered into a securities purchase agreement (the “June 2020 Purchase Agreement”) with the Purchasers pursuant to which we received approximately \$64.2 million (£51.4 million) from the Purchasers comprising: the allotment of ordinary shares at a subscription price of approximately \$19.4 million utilizing the existing share authorities of the Company granted by shareholders on June 2, 2016 and June 19, 2019, and the subscription for Tranche 1 Notes in an aggregate principal amount of approximately \$50.6 million. The Purchasers also received conditional warrants entitling the holders to subscribe for an aggregate of 161,048,366 new ordinary shares. The net proceeds from the June 2020 Private Placement will be used primarily to fund clinical development activities of our lead product candidates, reduction of indebtedness and for general corporate purposes.

Arrangements with OrbiMed

In recognition of OrbiMed's participation in, and assistance with, the June 2020 Private Placement, the Company has agreed to grant OrbiMed certain rights. OrbiMed will have the right to nominate two persons to be appointed to the Board of Directors (out of a maximum number of 9 directors), for a period of 180 days from June 3, 2020 subject to the usual regulatory compliance. OrbiMed has also been granted the right to participate in future financings of the Company, subject, among other things, to the existing pre-emption rights of the Shareholders under the Companies Act 2006 and existing agreements. OrbiMed has been paid a subscription fee by the Company in relation to its participation in the June 2020 Private Placement.

Financial Operations Overview

Revenue

We do not currently have any approved products. Accordingly, we have not generated any product related revenue during 2019. In 2020 and in subsequent years, we expect to be able to generate revenues if we are able to obtain regulatory approval and commercialize one or more of our product candidates or through the recognition of milestones and other potential revenues from out-licensing or partnering arrangements for any of our product candidates.

Subsequent to the global licensing agreement for the development and commercialization of navicixizumab signed on January 13, 2020, we anticipate reporting revenue for the first time in the financial year ending December 31, 2020 relating to income from an out-licensing arrangement.

Research and Development Expenses

Research and development expenses include:

- employee-related expenses, such as salaries, share-based compensation, and other benefits, for Mereo's research and development personnel;
- costs for production of drug substance and drug product and development of Mereo's manufacturing processes by CMOs;
- fees and other costs paid to CROs, consultants, and other suppliers to conduct Mereo's clinical trials and pre-clinical and non-clinical studies; and
- costs of facilities, materials, and equipment related to drug production and Mereo's clinical trials and pre-clinical and non-clinical studies.

Our direct research and development expenses are allocated on a product-by-product basis. We allocate employee-related expenses for our research and development personnel and other related expenses to specific product candidate development programs.

Product candidates in a later stage of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials as well as preparation for potential specific post-authorization evidence generation that might be demanded by regulatory authorities. We expect that our research and development expense will increase substantially as we continue to advance the clinical development of our product candidates, including through our ongoing Phase 2b clinical trial of setrusumab and our planned pivotal trial of setrusumab in children, and our ongoing Phase 2 proof-of-concept trial for alvelestat; hire additional clinical, scientific, and commercial personnel; and acquire or in-license future product candidates and technologies. As a result, we expect our research and development expenses will increase for the foreseeable future.

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The successful development, approval, and commercialization of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from any of our product candidates.

Our future expenditure on developing its product candidates is therefore highly uncertain. This is due to numerous risks and uncertainties associated with developing our product candidates, including the uncertainty of:

- the scope, rate of progress, and expense of our research and development activities;
- the progress and results of our clinical trials and our pre-clinical and non-clinical studies;
- the terms and timing of regulatory approvals, if any;
- establishment of arrangements with our third-party manufacturers to obtain manufacturing supply;
- protection of our rights in its intellectual property portfolio;
- launch of commercial sales of any of our product candidates, if approved, whether alone or in collaboration with others;
- third party strategic relationships for clinical development and/or commercialization of our non-rare product candidates and performance of our strategic partners under these arrangements;
- the sale, if any, of one or more of our non-rare disease product candidates;
- acceptance of any of our product candidates, if approved, by patients, the medical community and payors at our desired pricing levels;
- competition with other therapies; and
- continued acceptable safety profile of any of our product candidates following approval.

Any of these variables with respect to the development of our product candidates or any other future candidate that we may develop could result in a significant change in the costs and timing associated with their development. For example, if the FDA, the EMA, or another regulatory authority were to require us to conduct pre-clinical studies and clinical trials beyond those that we currently anticipate will be required for the completion of clinical development or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of our clinical development programs. We may never succeed in obtaining regulatory approval for any of our product candidates.

Administrative Expenses

Our administrative expenses principally consist of salaries and related benefits, including share-based compensation, for personnel in our executive, finance and other administrative functions. Other general and administrative costs include facility-related costs and professional services fees for auditing, tax and general legal services, as well as expenses associated with the Merger with OncoMed, our requirements of being a public company quoted on AIM and listed on Nasdaq and costs incurred relating to the issue of equity to the extent not capitalized, including the costs associated with the cancelled offering of our ADSs and ordinary shares in early 2018.

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We expect that our general and administrative costs will increase in the future as our business expands and we increase our headcount to support the planned growth in our operating activities. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses. In addition, we expect to continue to grant share-based compensation awards to existing and future key management personnel and other employees. Additionally, we anticipate increased costs associated with being a U.S. public company, including expenses related to services associated with maintaining compliance with Nasdaq rules and SEC requirements, director compensation, insurance, and investor relation costs. If any of our product candidates that we intend to directly commercialize or co-commercialize obtains regulatory approval, we expect that we will incur expenses associated with building a sales and marketing team.

Finance Income

Finance income consists of interest earned on short-term cash deposits and short-term investments.

Finance Charge

Finance charge consists of interest on the Novartis Notes (part of which were converted into ordinary shares in April 2017, and the remainder of which were converted into ordinary shares in June 2019), interest on our credit facility, losses on short-term cash deposits and finance charges on lease liabilities following the adoption of IFRS 16 (Leases) on January 1, 2019 and any loan modification gains and losses. For further information on the terms of the Novartis Notes and our credit facility see “—Liquidity and Capital Resources—Indebtedness”.

Net Foreign Exchange Gain/(Loss)

Our functional currency is pound sterling. We initially record transactions in foreign currencies at the rate ruling on the date the transaction first qualifies for recognition. Net foreign exchange gain/(loss) consists of the difference arising on settlement or translation of our foreign currencies, which are primarily held in U.S. dollars.

Net income recognized on acquisition of subsidiary

As OncoMed was acquired for an amount less than the fair market value of the net assets acquired on the date control was obtained, a gain on bargain purchase of £3.7 million was realized (recognized net against the acquisition transaction costs within the consolidated statement of comprehensive loss). Total acquisition transaction costs amounted to £2.7 million which were wholly incurred in connection with the acquisition. Therefore, the net income recognized on acquisition of OncoMed was £1.0 million.

Adoption of IFRS 16 (Leases)

Effective January 1, 2019, the Group has adopted IFRS 16 (Leases). IFRS 16 (Leases) replaces existing guidance, including IAS 17 (Leases), and sets out the principles for the recognition and measurement of leases. The new standard has resulted in an increased volume of disclosure information with the consolidated financial statements included herein.

As at January 1, 2019, right-of-use assets related to a leased property (£1.2 million) and a lease of medical equipment used in ongoing clinical trials (£1.3 million). Following the Merger, the Group acquired an additional right-of-use asset related to a leased property in Redwood City, U.S. (£10.8 million). During the year, the total cash outflow for leases amounted to £2.2 million, an increase of £1.9 million from the prior year, primarily due to the acquired OncoMed lease.

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As at December 31, 2019, the following costs are recognized in the consolidated financial statements which are resultant from the adoption of IFRS 16 (Leases):

	£
Depreciation	1,505
Interest expense	1,314
Foreign exchange gain	29

Contingent consideration

As a consequence of the License Agreement with Oncologie, and in accordance with the terms and conditions of the Contingent Value Rights Agreement for former stockholders of OncoMed, dated April 23, 2019, by and among Mereo and Computershare Inc., as rights agent, (the "CVR Agreement"), holders of contingent value rights ("CVRs") pursuant to the CVR Agreement will be entitled to receive certain eligible cash milestone payments made to Mereo under the License Agreement relating to Navi. The receipt of the upfront milestone payment of \$4.0 million by us in January 2020 resulted in a payment to CVR holders of approximately 1.2 cents per CVR, a total of approximately \$0.5 million (after deductions of costs, charges and expenditures). Future milestone payments are also subject to a cash consideration cap, pursuant to which the aggregate principal amount of all cash payments made to holders of CVRs under the CVR Agreement shall in no case exceed \$79.7 million.

Mereo accounts for the CVR arrangement as contingent consideration at fair value. As at December 31, 2019, the fair value of the contingent consideration is estimated at £0.4 million. The estimated contingent consideration payable is based on a risk-adjusted, probability-based scenario. Under this approach, the likelihood of future payments being made to the former shareholders of OncoMed under the CVR arrangement is considered. The estimate could materially change over time in line with the development plan and subsequent commercialization of the Navi product.

Taxation

As a U.K. resident trading entity, we are subject to U.K. corporate taxation. Due to the nature of our business, we have generated losses since formation. As at December 31, 2019, 2018 and 2017, we had cumulative carry-forward tax losses of £70.2 million, £50.6 million and £36.0 million, respectively. Our cumulative carry-forward tax losses are expected to increase throughout 2020. Subject to any relevant restrictions, we expect these to be available to carry forward and offset against future operating profits. As a company that carries out extensive research and development ("R&D") activities, we benefit from the U.K. R&D small or medium-sized enterprise tax credit regime and are able to surrender some of our trading losses that arise from our research and development activities for a cash rebate of up to 33.35% of eligible R&D expenditure. Qualifying expenditures largely comprise employment costs for research staff, subcontracted CRO and CMO costs, consumables and certain internal overhead cost incurred as part of research projects. Certain subcontracted qualifying research expenditures are eligible for a cash rebate of up to 21.67%. We may not be able to continue to claim payable R&D tax credits in the future because we may no longer qualify as a small or medium-sized company.

In the event we generate revenues in the future, we may benefit from the U.K. "patent box" regime that allows profits attributable to revenues from patents or patented product candidates to be taxed at an effective rate of 10%. This relief applies to profits earned from April 1, 2013. When taken in combination with the enhanced relief available on our R&D expenditures, we expect a long-term lower rate of corporation tax to apply to us. If, however, there are unexpected adverse changes to the U.K. R&D tax credit regime or the "patent box" regime, or for any reason we are unable to qualify for such advantageous tax legislation, or we are unable to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments, our business, results of operations, and financial condition may be adversely affected.

As of December 31, 2019, the Group had U.S. federal tax losses to be carried forward of approximately £47.5 million (2018: £nil), of which £40.9 million can be carried forward indefinitely and £6.6 million which will begin to expire in 2023. As of December 31, 2019, the Group had U.S. state tax losses to be carried forward of approximately £3.2 million which begin to expire in 2028.

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As of the end of 2019, total receivables related to tax credits previously recognized amount to £11.4 million, of which £10.4 million relates to cash rebates for eligible types of research and development activities in the U.K and the remaining £1.0 million relates to AMT refund in the U.S. Included within the £10.4 million cash rebate is £5.3 million from the claim for the financial year ended December 31, 2018 as the amount was not repaid during 2019. In 2020, the Group recovered £1.0 million of the cash rebate from the claim for the financial year ended December 31, 2018 and expects to recover the remaining balance of £4.3 million of the 2018 claim later in the first half of 2020. The R&D claim for the financial year ended December 31, 2019 will be submitted around mid-2020 and the Group expects to receive the estimated claim amount of £5.2 million in the second half of 2020.

Critical Accounting Judgments and Estimates

Our financial statements have been prepared in accordance with IFRS as issued by the IASB. In the application of our accounting policies, we are required to make judgments, estimates, and assumptions about the value of assets and liabilities for which there is no definitive third-party reference. The estimates and associated assumptions are based on historical experience and other factors that we consider to be relevant. Actual results may differ from these estimates. We review our estimates and assumptions on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revisions and future periods if the revision affects both current and future periods.

Further details relating to critical accounting judgments and estimates can be found in the consolidated financial statements, incorporated herein by reference.

Recent Accounting Pronouncements

During the year ended December 31, 2019, Mereo adopted IFRS 16 (Leases). During the year ended December 31, 2018, Mereo adopted IFRS 9 (Financial Instruments). Related consequential amendments to other IFRSs have been adopted where relevant, however they have not had a material impact on the consolidated financial statements.

Further details relating to the adoption of IFRS 16 (Leases) can be found in the consolidated financial statements, incorporated herein by reference.

Results of Operations

The following table sets forth Mereo's results of operations for the years ended December 31, 2018 and 2019.

	Year Ended December 31,	
	2018	2019
	(in thousands of pounds)	
Research and development expenses	(22,703)	(23,608)
Administrative expenses	(11,775)	(15,909)
Operating loss	(34,478)	(39,517)
Net income recognized on acquisition of subsidiary	—	1,035
Finance income	307	377
Finance charge	(3,091)	(3,496)
Net foreign exchange (loss)/gain	(44)	483
Loss before tax	(37,306)	(41,118)
Income tax benefit	5,277	6,274
Loss attributable to equity holders of the parent	(32,029)	(34,844)
Net fair value gain /(loss) on investments in debt instruments held at fair value	—	—
Exchange differences on translation of foreign operations	—	(499)
Total comprehensive loss attributable to equity holders of the parent	(32,029)	(35,343)

Comparison of Years Ended December 31, 2018 and 2019*Research and development ("R&D") Expenses*

The following table sets forth our R&D expenses by product development program for the years ended December 31, 2018 and 2019.

	Year Ended December 31,	
	2018	2019
	(in thousands of pounds)	
Setrusumab (BPS-804)	11,304	13,734
Alvelestat (MPH-966)	3,722	4,976
Leflutrozole (BGS-649)	5,091	1,089
Acumapimod (BCT-197)	2,285	388
Navicixizumab ("Navi")	—	1,721
Etigilimab	—	767
GITR-Fc (1)	—	432
Unallocated costs	301	501
Total R&D expenses	22,703	23,608

(1) Consists of R&D expenses incurred by OncoMed. Development of this candidate ceased during 2019.

Total R&D expenses increased by £0.9 million, or 4%, from £22.7 million in 2018 to £23.6 million in 2019.

R&D expenses relating to setrusumab increased by £2.4 million, or 21%. The increase was driven primarily by the manufacture of additional drug product during 2019 which is planned to be used in upcoming clinical studies together with ongoing costs related to the adult Phase 2b study which reported top-line data in November 2019. R&D expenses relating to alvelestat increased by £1.3 million, or 34% to £5.0 million, reflecting a full year of costs for the Phase 2 proof of concept study which commenced in the fourth quarter of 2018.

In total, £2.9 million of total R&D expenses in the current year is specific to programs acquired through the merger with OncoMed in April 2019 for which there is no relevant prior year comparative (Navi, Etigilimab and GITR-Fc). Of this, £1.7 million relates to Navi, which was subject to a global out-licensing agreement announced in January 2020. The licensee, Oncologie, assumed all future ongoing development costs following an agreed transition period to close out the existing Phase 1b study.

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Largely offsetting the increase, R&D expenses relating to leflutrolole and acumapimod decreased by £5.9 million, or 80%. The decrease in spend was driven by the completion of the Phase 2b clinical study on leflutrolole in early 2019 and limited activity mainly relating to regulatory activity for acumapimod following the completion of the study.

Unallocated costs increased by £0.2 million to £0.5 million in 2019. This increase is attributable to certain R&D expenses incurred by OncoMed that are not allocated to a specific product development program.

Administrative expenses

Administrative expenses increased by £4.1 million, or 35%, from £11.8 million in 2018 to £15.9 million in 2019.

The increase was primarily due to an increase in costs following the acquisition of OncoMed. In particular, payroll costs increased by £1.2 million to £3.4 million in 2019. In addition, following the Company's listing on the Nasdaq Global Market, professional fees, including the significantly increased costs of Directors and Officers ("D&O") insurance, have increased by £1.0 million in 2019.

Following the adoption of IFRS 16 (Leases), right-of-use assets were recognized which are subsequently depreciated over their expected term of use. In 2019 this resulted in depreciation costs of £1.5 million in administrative expenses compared to £0.3 million in 2018 prior to the implementation of IFRS 16 (Leases).

Professional fees increased during the year from £1.5 million to £3.1 million reflecting higher costs associated with the Nasdaq listing and managing a larger business in two jurisdictions.

Transaction costs relating to the acquisition of OncoMed are presented separately and included within net income recognized on acquisition of subsidiary (see below).

Net income recognized on acquisition of subsidiary

As OncoMed was acquired for an amount less than the fair market value of the net assets acquired on the date control was obtained, a gain on bargain purchase of £3.7 million was realized (recognized net against the acquisition transaction costs within the consolidated statement of comprehensive loss). Total acquisition transaction costs amounted to £2.7 million which were wholly incurred in connection with the acquisition. Therefore, the net income recognized on acquisition of OncoMed was £1.0 million.

Finance income and charges

Total finance income was £0.4 million in 2019, up from £0.3 million in 2018. The increase was attributable to an increase in interest income earned on additional short-term investments acquired through the acquisition of OncoMed. All short-term investments were sold by December 31, 2019.

Total finance charges increased from £3.1 million in 2018 to £3.5 million in 2019. Following the adoption of IFRS 16 (Leases), interest costs on recognized lease liabilities of £1.3 million were incurred as an expense during the year. In the prior year, no such interest costs were recognized. In addition, non-cash interest costs on the bank loan increased by £0.8 million following modifications made to the terms of the bank loan following the refinancing in May 2019.

The increase in finance costs attributable to interest costs on lease liabilities and the bank loan was partly offset by fair value movements on outstanding warrants accounted for as a financial liability. The overall movement was a decrease in the value of the liability by £0.9 million, up from £0.7 million in 2018, which is recorded as income. The increase in finance costs was further reduced by a re-classification of the loan modification loss occurring in 2018 as a finance charge resulting the increase in finance charges in 2018 of £0.7 million. In 2019 there was a corresponding loan modification gain of £0.5 million.

Net Foreign Exchange Gain/(Loss)

The net foreign exchange gain for the year was £0.5 million, up by £0.5 million from a £nil million loss in 2018. The net foreign exchange gain consists of a £0.1 million foreign exchange loss on the translation of cash deposits which are primarily held in U.S. dollars throughout the year. The foreign exchange loss has been offset by a foreign exchange gain of approximately £0.6 million relating to the retranslation of U.S. dollar denominated intercompany funds held by an entity in the Group with a British pound functional currency.

Taxation

The tax credit for the year was £6.3 million, up by £1.0 million from 2018.

The tax credit represents eligible cash rebates paid or receivable from the tax authorities in the jurisdictions within which we operate. In the U.K., certain subsidiaries within the Group qualify for cash rebates for eligible types of research and development activities and associated expenditure (the "R&D tax credit") which amounted to a total benefit of £5.1 million for 2019.

Further, in August 2019, OncoMed received a tax refund in respect of Alternative Minimum Tax ("AMT") of £1.1 million from the U.S. Internal Revenue Service ("IRS"), of which approximately £0.2 million has been recognized as income tax benefit during the year. It is currently estimated that an additional £1.0 million of tax refund in respect of AMT will be received in 2020 with respect to the current financial year.

As at December 31, 2019, total receivables related to tax credits previously recognized amount to £11.4 million, of which £10.4 million relates to R&D tax credit in the U.K. Included within the £10.4 million cash rebate is £5.3 million from the claim for the financial year ended December 31, 2018 as the amount was not repaid until early 2020. The claim for the financial year ended December 31, 2019 will be submitted around mid-2020 and the Group expects to receive an estimated claim amount of £5.1 million in the second half of 2020.

Loss per share

After taking account of the £3.3 million increase in loss attributable to equity holders and an increase in weighted average number of shares from 71.1 million to 89.4 million, basic and diluted loss per share for the year was 39 pence, down from 45 pence in 2018.

Adoption of IFRS 16 (Leases)

Effective January 1, 2019, the Group adopted IFRS 16 (Leases). The new standard introduces new or amended requirements with respect to lease accounting. In previous years, the Group's lease portfolio consisted of operating leases which have now been recognized on the balance sheet as a right-of-use asset, offset by a corresponding lease liability.

The total impact on assets on adoption was £2.5 million, offset by a lease liability recognized for the same amount. The lease portfolio on adoption consisted of a property lease and a number of specialist equipment leases for use in clinical trial activities.

Following the acquisition of OncoMed, a right-of-use asset of £10.8 million was recognized, offset by a lease liability of £10.7 million. The OncoMed lease portfolio consisted of a property lease in the U.S.

During the year ended December 31, 2019, total depreciation charges of £1.5 million and interest charges of £1.3 million have been recognized under IFRS 16 (Leases).

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Acquisition of OncoMed Pharmaceuticals, Inc.

On April 23, 2019, we completed the acquisition of OncoMed, a California-based and Nasdaq-listed company, at which time OncoMed became an unlisted U.S. subsidiary of Mereo. At completion, we acquired cash and short-term deposits and short-term investments of £39.1 million. The estimated fair value of the intangible assets acquired was £12.7 million.

In connection with the acquisition, 24,783,320 ordinary shares were issued and listed on AIM. On April 24, 2019, 4,956,664 American Depositary Shares (“ADSs”) were listed on the Nasdaq Global Market, with each ADS representing five ordinary shares. Following completion of the acquisition, former OncoMed shareholders owned 25.8% of the enlarged share capital of the Group.

As a consequence of the license agreement with Oncologie (the “License Agreement”), and in accordance with the terms and conditions of the Contingent Value Rights Agreement (“the CVR Agreement”) for former stockholders of OncoMed, dated April 23, 2019, by and among Mereo and Computershare Inc., as rights agent, holders of contingent value rights (“CVRs”) pursuant to the CVR Agreement will be entitled to receive certain eligible cash milestone payments made to Mereo under the License Agreement.

Mereo accounts for the CVR Agreement as contingent consideration at fair value. As at December 31, 2019, the fair value of the contingent consideration is estimated at £0.4 million. As at acquisition date, the fair value of the contingent consideration was estimated at £nil. The estimated contingent consideration payable is based on a risk-adjusted, probability-based scenario. Under this approach, the likelihood of future payments being made to the former shareholders of OncoMed under the CVR Agreement is considered. The estimate could materially change over time in line with the development plan and subsequent commercialization of the Navi product.

Comparison of the Years Ended December 31, 2017 and 2018

For information relating to the comparison of the years ended December 31, 2017 and 2018, see “Item 5. Operating and Financial Review and Prospects” in our annual report on Form 20-F for the fiscal year ended December 31, 2018 filed with the SEC on April 29, 2019.

5.B. Liquidity and Capital Resources

Overview

Under the current business plan and cash flow forecasts, based on our ongoing research and development efforts which are focused on our etigilimab, our oncology product candidate and on our rare disease product candidates, setrusumab and alvelestat, and also our general corporate funding requirements, including repayment of our existing long term debt, taking into account our recently completed fundraising which raised approximately \$64.2 million (£51.4 million) net funds, we expect that our current on-hand cash resources will extend to the start of 2022. Therefore, we will need additional external funding to complete our development plans and take selected products through to commercialization.

We do not currently have any approved product candidates and have never generated any revenue from product sales or otherwise. As a result, to date, we have financed our operations primarily through the issuances of our equity securities and convertible debt and our credit facility, which we entered into in August 2017.

Since our formation to date, we have raised a total of £163.7 million in gross proceeds from private and public placements of our ordinary shares to institutional investors, £0.3 million from a placement of our ordinary shares to retail investors and exercised share options, \$50.8 million from cash and short-term investments acquired in the

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Merger and £7.3 million from the issuance of the Novartis Notes. In August 2017, we also entered into a credit facility in the amount of £20.0 million which was fully drawn down as at December 31, 2019 and December 31, 2018. As at December 31, 2019 our aggregate cash, short-term deposits and short-term investments were £16.3 million (£27.5 million as of December 31, 2018).

In September 2018, we entered into a revised loan agreement which enabled us to extend the interest only period of the credit facility from September 30, 2018 to April 30, 2019. On April 23, 2019, we agreed a revision to the loan agreement which extended the interest only period of the credit facility through December 31, 2019. In connection with the credit facility, we have issued warrants in respect of an aggregate of 1,243,908 ordinary shares at a weighted average exercise price of £2.95 per ordinary share, which are capable of exercise until October 1, 2028. For additional information, see “—Indebtedness—Credit Facility”.

On October 8, 2018, we entered into a funding agreement with The Alpha-1 Project, Inc. (“TAP”), which provided for funding of up to \$0.4 million as a contribution towards the development of our product candidate alvelestat. On November 1, 2018, the first tranche of \$0.1 million was received and as a result we issued 41,286 warrants to subscribe for our ordinary shares at an exercise price of £0.003 per share.

Aspire Capital Transaction

On February 10, 2020, we entered into a Purchase Agreement with Aspire Capital, an Illinois limited liability company, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$25.0 million worth of our ordinary shares that are exchangeable for ADSs over the approximately 30-month term of the Purchase Agreement. In addition, pursuant to the Purchase Agreement, Aspire Capital purchased 11,432,925 ordinary shares that are exchangeable for 2,286,585 ADSs for \$3.0 million. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we paid Aspire Capital a commission fee of \$300,000, which was wholly satisfied by the issuance to Aspire Capital of 2,862,595 ordinary shares that are exchangeable for 572,519 ADSs.

New Novartis Notes

On February 10, 2020, we entered into a £3,841,479 convertible loan note instrument with Novartis pursuant to which we issued Novartis 3,841,479 unsecured convertible loan notes (the “New Novartis Notes”) and warrants to purchase 1,449,614 ordinary shares.

Boxer Capital Transaction

On February 19, 2020, we entered into a securities purchase agreement with Boxer Capital. Under the terms of the agreement, Boxer Capital agreed to invest \$3.0 million by purchasing 12,252,715 ordinary shares (equivalent to 2,450,543 ADSs) at a price equivalent to 18.8 pence per ordinary share, which represented a 20% discount to our closing share price of 23.5 pence on AIM on February 18, 2020. We intend to use the net proceeds from this private placement for general corporate purposes, including clinical trial activity and working capital. There are no warrants, derivatives, or other share classes associated with this transaction. Further, there are no restrictions on future financings and there are no financial covenants, participation rights, rights of first refusal, or penalties in the purchase agreement entered into in connection with this transaction.

June 2020 Private Placement

On June 4, 2020, we announced completion of a private placement with net proceeds of approximately \$64.2 million (£51.4 million) with a number of new and existing principally U.S based institutional and accredited investors (the “June 2020 Private Placement”). OrbiMed Private Investments VI, LP (acting through its general partner, OrbiMed Capital GP

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VI LLC, acting through its managing member, OrbiMed Advisors LLC, collectively referred to herein as “OrbiMed”) led the June 2020 Private Placement with participants including Vivo Capital, Surveyor Capital (a Citadel company), Pontifax Venture Capital, Samsara BioCapital, Commodore Capital, and funds managed by Janus Henderson Investors alongside existing investors Boxer Capital of Tavistock Group and Aspire Capital Fund, LLC (collectively, the “Purchasers”). On June 3, 2020, we entered into a securities purchase agreement (the “June 2020 Purchase Agreement”) with the Purchasers pursuant to which we received approximately \$64.2 million (£51.4 million) from the Purchasers comprising: the allotment of ordinary shares at a subscription price of approximately \$19.4 million utilizing the existing share authorities of the Company granted by shareholders on June 2, 2016 and June 19, 2019, and the subscription for Tranche 1 Notes in an aggregate principal amount of approximately \$50.6 million. The Purchasers also received conditional warrants entitling the holders to subscribe for an aggregate of 161,048,366 new ordinary shares. The net proceeds from the June 2020 Private Placement will be used primarily to fund clinical development activities of our lead product candidates, reduction of indebtedness and for general corporate purposes.

If the Resolutions relating to the June 2020 Private Placement are not passed on or before August 7, 2020 the convertible notes will not convert into ordinary shares, the warrants will not become capable of exercise and the holders of the convertible notes and warrants will become entitled to certain amounts (up to \$137.1 million) that will represent material liabilities for the Company. The Purchasers, representing in aggregate approximately 42 percent of the Company’s total number of shares and votes have undertaken to vote in favor of the Resolutions relating to the warrants and the convertible notes.

Cash Flows

Comparison of Years Ended December 31, 2018 and 2019

The table below summarizes Mereo’s cash flows for the periods presented.

	Year Ended December 31,	
	2018	2019
	(in thousands of pounds)	
Net cash used in operating activities	(23,139)	(45,931)
Net cash from investing activities	252	43,295
Net cash used in financing activities	(2,075)	(5,710)
Net decrease in cash and cash equivalents	<u>(24,962)</u>	<u>(8,346)</u>

Operating Activities

Net cash used in operating activities for the year ended December 31, 2019 was £45.9 million, an increase of £22.8 from £23.1 million in 2018.

The loss for the year increased from £37.3 million to £41.1 million due to an increase in R&D activity and administrative expenses. This was impacted by a decrease in trade payables of £8.3 million and an increase in trade receivables of £1.7 million in 2019 compared to 2018. There was also a decrease in tax received of £7.1 million in 2019 compared to 2018.

In addition various non-cash items impacted 2019 compared to 2018 including the gain on bargain purchase on the acquisition of OncoMed of £3.7 million, a reduction in share based payment charges (including associated taxes) of £4.1 million, a modification gain of £0.5 million on the bank loan following the refinancing of the debt was recorded compared to a modification loss of £0.7 million recorded in 2018 and an increase in finance charges of £0.9 million. In 2019 this resulted in depreciation costs of £1.5 million in administrative expenses compared to £0.3 million in 2018 prior to the implementation of IFRS 16 (Leases). For the year ended December 31, 2019, we recorded a net foreign exchange gain of £0.5 million, compared to a £0.04 million loss for the year ended December 31, 2018.

Specific to the acquisition of OncoMed in April 2019 we assumed £9.2 million of liabilities. Most of those liabilities were settled by December 31, 2019.

In previous years, the impact of tax credits has offset increase in operational expenditure. For the current year, tax credits received in cash decreased by £7.1 million to £1.1 million. Tax credits of £1.1 million received during the

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current year relate to a refund of Alternative Minimum Tax (“AMT”) in the U.S. following the acquisition of OncoMed. Tax credits received in cash during the current year decreased compared to the prior year as the Group had not yet received repayment of the 2018 R&D tax credit from the U.K. tax authorities. As at December 31, 2019, total receivables related to tax credits previously recognized amount to £11.4 million, of which £10.4 million relates to R&D tax credit from the U.K. tax authorities being the balance due for FY 2018 and the credit recognized for FY 2019.

Investing Activities

Net cash from investing activities was £43.3 million in 2019, up from £0.3 million in 2018. The increase was due to the acquisition of OncoMed which provided a net cash inflow on acquisition of £10.1 million and receipt of £32.9 million of short-term investments in the form of short-dated US treasuries, all of which were sold by December 31, 2019.

Financing Activities

Net cash used in financing activities was £5.7 million in 2019, an increase of £3.6 million from 2018. The increase is attributable to the payment of lease liabilities, now reported as a financing activity following the adoption of IFRS 16 (Leases) and an increase in the value of treasury shares purchased in the current year compared with the prior year. Total payments of lease liabilities amounted to £2.2 million during the year of which £1.3 million relates to the US facility acquired with OncoMed in April 2019. Following the acquisition, we acquired an operating lease over a facility utilized by OncoMed. Treasury shares of £1.0 million were purchased during 2019 compared with £0.3 million in 2018.

On April 23, 2019 the Group agreed an amendment to the terms of its bank loan with the lenders. The new terms extended the interest-only period to December 31, 2019 followed by a 15-month capital and interest repayment period.

Subsequent to the end of the financial year, the Company has entered into certain arrangements which provide additional liquidity and capital resource. Those arrangements include:

- On January 13, 2020, the Company announced a global licensing agreement with Oncologie, Inc. (“Oncologie”) for the development and commercialization of navicixizumab. Under the term of the global licensing agreement, the Company received an upfront payment of \$4 million with an additional payment of \$2 million conditional on a Chemistry, Manufacturing and Controls (“CMC”) milestone. Additionally, the Company will be eligible to receive up to \$300 million in future milestones and royalties.
- On February 10, 2020, the Company entered into a £3.8 million convertible equity financing with Novartis Pharma (AG) (“Novartis”). Under the terms of the convertible equity financing, Novartis purchased £3.8 million in a convertible loan note. The loan note is convertible at any time at a fixed price of £0.265 per ordinary share. In connection with the loan note, the Company issued a warrant instrument to Novartis to purchase up to 1,449,614 of the Company’s ordinary shares.
- On February 10, 2020, the Company entered into a Securities Purchase Agreement to issue up to \$28 million of the Company’s ordinary shares exchangeable for American Depositary Shares, including a \$3 million initial purchase, with Aspire Capital Fund, LLC. In exchange for the \$3 million initial purchase the Company issued 11,423,925 ordinary shares (equivalent to 2,286,585 ADSs).

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- On February 19, 2020, the Company entered into a Securities Purchase Agreement with Boxer Capital, LLC to make an investment of \$3 million to purchase 12,252,715 of the Company's ordinary shares (equivalent to 2,450,543 ADSs).
- On June 3, 2020 the Company completed a private placement with net proceeds of approximately \$64.2 million (£51.4 million) from the issue of equity, loan notes and warrants to new and existing shareholders. See also "Liquidity and Capital Resources —Indebtedness—June 2020 Private Placement".

Operating and Capital Expenditure Requirements

As of December 31, 2019, we had an accumulated loss of £146.1 million. We expect to continue to report significant operating losses for the foreseeable future as it continues its research and development efforts and seek to obtain regulatory approval of our product candidates and any future product we develop. See also "Risk Factors—Risks Related to Our Business and Industry—If we do not obtain adequate and timely funding, we may not be able to continue as a going concern".

We expect our expenses to increase substantially in connection with its ongoing development activities related to its product candidates. In addition, as a result of the Merger, we expect to incur additional costs associated with operating as a U.S. public company listed on Nasdaq in addition to operating as a U.K. public company traded on AIM.

We anticipate that our expenses will increase substantially due to the costs associated with its current and planned clinical trials, our outsourced manufacturing activities and other associated costs including the management of its intellectual property portfolio. These costs will increase further if we:

- seek to develop additional product candidates;
- seek regulatory approvals for any of our product candidates that successfully completes clinical trials;
- potentially establish a sales, marketing, and distribution infrastructure and scale-up manufacturing capabilities to commercialize or co-commercialize any product candidates for which we may obtain regulatory approval and chose to commercialize directly;
- expand our intellectual property portfolio;
- add further central clinical, scientific, operational, financial and management information systems, and personnel, including personnel to support our development and to support our operations as a U.S. public company listed on Nasdaq; or
- experience any delays or encounter any issues from any of the above, including but not limited to failed studies, complex results, safety issues, or other regulatory challenges.

We expect that our existing cash and short-term deposits will enable us to fund our currently committed clinical trials and operating expenses and capital expenditure requirements until early 2022. We have based these estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of our product candidates and any future product candidates and because the extent to which we may enter into collaborations with third parties for development of any of our product candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements will depend on many factors, including:

- the costs, timing, and results of our planned Phase 1b study for etigilimab, our ongoing Phase 2b clinical trial for setrusumab our ongoing Phase 2 proof-of-concept clinical trial for alvelestat;

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- the costs and timing of manufacturing clinical supplies of our product candidates;
- the costs, timing, and outcome of regulatory review of our product candidates, including post-marketing studies that could be required by regulatory authorities;
- the costs, timing, and outcome of potential future commercialization activities, including manufacturing, marketing, sales and distribution, for our product candidates that we commercialize directly;
- the timing and amount of revenue, if any, received from commercial sales of our product candidates;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing, misappropriating or otherwise violating their intellectual property rights;
- the sales price and availability of adequate third-party coverage and reimbursement for our product candidates;
- the effect of competitors and market developments;
- the extent to which we are able to acquire new product candidates or enter into licensing or collaboration arrangements for its product candidates, although we currently have no commitments or agreements to complete any such transactions; and
- milestone and deferred payments under Mereo's license and option agreement with AstraZeneca.

Our revenues, if any, will be derived from sales of any product candidates that we are able to successfully develop, receive regulatory approval for, and commercialize in future years. In the meantime, we will need to obtain substantial additional funds to achieve our business objective.

Adequate additional funds may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Any future debt financing or preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute your ownership interests.

If we raised additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Indebtedness

Credit Facility

On August 7, 2017, we entered into a loan agreement (the “Original Loan Agreement”), with Silicon Valley Bank and Kreos Capital V (UK) Limited, which provided for total borrowings of £20.0 million. Under the Original Loan Agreement, we borrowed £10.0 million on each of August 21, 2017 and December 29, 2017 for general working capital purposes. We were obligated to make interest-only payments on the loan amount until September 30, 2018, and thereafter we were obligated to pay interest and principal in 30 equal monthly installments until March 31, 2021. The loan bore interest at an annual fixed rate equal to 9.0%.

In connection with the borrowings under the Original Loan Agreement, in 2017, we issued to the lenders warrants to subscribe for an aggregate of 363,156 of our ordinary shares at an exercise price of £3.029 per ordinary share and warrants to subscribe for an aggregate of 333,334 of our ordinary shares at an exercise price of £3.30 per ordinary share pursuant to a warrant instrument dated August 21, 2017.

On September 28, 2018, we, Silicon Valley Bank and Kreos Capital V (UK) Limited entered into a new loan agreement (the “New Loan Agreement”), which replaced the Original Loan Agreement in its entirety and (i) increased the total commitments of the lenders to £20,455,000, (ii) extended the interest-only period from September 30, 2018 to April 30, 2019, and (iii) reduced the interest rate from 9.0% to 8.5%. Under the New Loan Agreement, both the interest-only period and the maturity date may be further extended subject to the achievement by us of certain conditions set forth in the New Loan Agreement. The New Loan Agreement is secured by substantially all of our assets, including intellectual property rights owned or controlled by us and the shares of our subsidiaries, with all dividends and all other rights deriving from them. It is also secured by all policies and contracts of insurance issued or entered into for our benefit, and all rights, claims and interests which we may have from time to time in any such policy or contract.

In connection with the New Loan Agreement, in 2018 we issued warrants giving the lenders the right to subscribe for 225,974 ordinary shares at an exercise price of £2.31 per ordinary share pursuant to a warrant instrument dated October 1, 2018. These warrants will be capable of exercise until October 1, 2028.

In addition, the New Loan Agreement requires us to seek consent from Kreos if the Company intends to undertake any (i) dispositions, (ii) changes in business, ownership, management or business locations; (iii) mergers or acquisitions; (iv) creation of indebtedness; (v) commitment of guarantees; (vi) creation of a lien on the amount borrowed under the loan or on certain of our intellectual property, or assignment thereof; (vii) distributions or payment of cash dividends; or (viii) transactions with our affiliates, subject to certain exceptions. In all cases, failure to seek such consent would result in default under the New Loan Agreement.

On April 23, 2019, we agreed on a revision to the New Loan Agreement, which extended the interest-only period to December 31, 2019. Thereafter, we will have to pay interest and principal monthly installments until March 31, 2021. In connection with the revised New Loan Agreement and following the closing of the Merger, on May 3, 2019, we issued warrants giving the lenders the right to subscribe for 321,444 shares at an exercise price of £2.95 per share. These warrants will be capable of exercise until October 1, 2028.

The warrants include an adjustment provision to prevent the dilution of the ordinary shares issuable to Silicon Valley Bank and Kreos under certain circumstances.

June 2020 Private Placement

On June 3, 2020, in connection with the June 2020 Private Placement, the investors party to the June 2020 Purchase Agreement (the “Purchasers”) received Convertible Loan Notes relating to a Note Instrument constituting three potential tranches of loan notes (the “2020 Loan Notes”) which were issued in an aggregate principal amount of \$50.6 million. All the 2020 Loan Notes are unsecured and have been contractually subordinated to our existing senior debt facility with Silicon Valley Bank and Kreos pursuant to the terms of a Subordination Agreement to which all Purchasers have acceded as part of the June 2020 Private Placement. Additionally, in connection with the June 2020 Private Placement, on June 3, 2020, we also entered into a warrant instrument pursuant to which the Purchasers received conditional warrants.

The June 2020 Private Placement had three components including the sale of 89.1 million new ordinary shares at a price of 17.4 pence per share which generated proceeds of \$19.4 million (£15.5 million), the sale of \$50.6 million (£40.5 million) of convertible notes, and the issuance of warrants to investors in the June 2020 Private Placement to subscribe for further ordinary shares.

The ability for the convertible notes to be converted into ordinary shares and for the warrants to be exercised is conditional on the passing of certain Resolutions at the General Meeting of shareholders scheduled for June 30, 2020 (the “Resolutions”).

If the Resolutions are passed, the convertible notes will automatically convert into ordinary shares at 17.4 pence per share, subject to the limitation that the new investors in the Private Placement are generally not permitted to own more than 9.99% of our voting shares. Any convertible notes not so converted will remain outstanding. The convertible notes will not be separately admitted to trading on AIM, but the ordinary shares which will be issued following any valid conversion of the convertible notes will be admitted to trading as part of the Company’s single class of shares admitted to trading on AIM or the relevant exchange on which the Company’s shares are traded at the time of such conversion. We estimate that 21,674,143 Tranche 1 Notes will convert automatically if the Resolutions are passed on June 30, 2020, resulting in the issuance of 124,564,033 ordinary shares being issued, leaving 18,859,528 of convertible notes in issue.

Novartis Notes

On June 3, 2016, as part of the fundraising for our product development programs and for general corporate purposes and in connection with our ordinary shares being admitted to trading on AIM, we issued 3,463,563 unsecured convertible loan notes to Novartis (the “Novartis Notes”), for aggregate proceeds of £3,463,563. The Novartis Notes bore interest at 4% per annum payable annually and accruing daily and ranked senior to any other unsecured obligations. Novartis had the right to convert all or some of the Novartis Notes, together with accrued interest, at any time into our ordinary shares at a conversion price of £2.21 per ordinary share as long as, following such conversion, Novartis held no more than 19.5% of the aggregate voting rights of our company. In addition, upon conversion, Novartis was entitled to receive an additional number of our ordinary shares equal to the number of shares into which such Novartis Notes and accrued interest were converted multiplied by 0.93 (the “Bonus Shares”). At December 31, 2016, Novartis was entitled to receive up to 1,453,520 Bonus Shares.

On April 6, 2017, Novartis delivered to us a notice of conversion with respect to £1,398,552 aggregate principal amount of Novartis Notes. Pursuant to such notice, on April 26, 2017, £1,398,552 aggregate principal amount of Novartis Notes was converted into 632,829 fully paid ordinary shares. Additionally, in connection with such conversion, we issued 588,532 Bonus Shares to Novartis. At December 31, 2018, Novartis was entitled to receive up to 864,998 Bonus Shares.

On June 6, 2019 Novartis delivered to us a notice of conversion with respect to the aggregate principal amount and interest of the Novartis Notes. Pursuant to such notice, on June 21, 2019 the aggregate principal amount and interest of £2,367,004 due under the Novartis Notes was converted into 1,071,042 fully paid ordinary shares at the fixed conversion price of £2.21 per share. Additionally, in connection with such conversion, we issued 864,988 Bonus Shares to Novartis. At December 31, 2019 there was no further liability under the Novartis Notes which were converted in full as at that date.

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On February 10, 2020, we entered into a £3,841,479 convertible loan note instrument relating to the issue of 3,841,479 New Novartis Notes. The New Novartis Notes are convertible at any time at a fixed price of £0.265 per ordinary share. In addition, on February 10, 2020, in connection with the New Novartis Notes, we entered into a warrant instrument with Novartis to issue 1,449,614 ordinary shares at a weighted average exercise price of £0.265 per ordinary share. These warrants will be capable of exercise until February 10, 2025. The New Novartis Notes and the warrants include an adjustment provision to prevent the dilution of the ordinary shares issuable to Novartis under certain circumstances.

Contingent Value Rights (“CVR”) arrangement

As a consequence of the License Agreement with Oncologie, and in accordance with the terms and conditions of the Contingent Value Rights Agreement for former stockholders of OncoMed, dated April 23, 2019, by and among Mereo and Computershare Inc., as rights agent, (the “CVR Agreement”), holders of contingent value rights (“CVRs”) pursuant to the CVR Agreement will be entitled to receive certain eligible cash milestone payments made to Mereo under the License Agreement relating to Navi. The receipt of the upfront milestone payment of \$4.0 million by us in January 2020 resulted in a payment to CVR holders of approximately 1.2 cents per CVR, a total of approximately \$0.5 million (after deductions of costs, charges and expenditures). Future milestone payments are also subject to a cash consideration cap, pursuant to which the aggregate principal amount of all cash payments made to holders of CVRs under the CVR Agreement shall in no case exceed \$79.7 million.

Mereo accounts for the CVR arrangement as contingent consideration at fair value. As at December 31, 2019, the fair value of the contingent consideration is estimated at £0.4 million. The estimated contingent consideration payable is based on a risk-adjusted, probability-based scenario. Under this approach, the likelihood of future payments being made to the former shareholders of OncoMed under the CVR arrangement is considered. The estimate could materially change over time in line with the development plan and subsequent commercialization of the Navi product.

5.C. Research and development, patents and licenses, etc.

For a description of the Company’s research and development policies for the last three years see “Item 5. Operating and Financial Review and Prospects—A. Operating Results—Financial Overview—Research and Development Expenses.” For a description of Mereo’s intellectual property, see “Item 4. Information On the Company—B. Business Overview—Intellectual Property.”

5.D. Trend Information

We are currently in the development stage and we expect to remain in that stage for the upcoming year, and therefore trends relating to production, sales, inventory, backlog and selling prices are not applicable. See “—A. Operating Results.”

5.E. Off-Balance Sheet Arrangements

We did not have during the period presented, and do not currently have, any off-balance sheet arrangements.

5.F. Contractual Obligations

The table below summarizes Mereo’s contractual obligations at December 31, 2019.

	Payments Due by Period				Total
	Up to 1 year(1)	1-3 Years	3-5 Years	Over 5 Years	
Bank loan(2)	17,185	5,484	—	—	22,669
Lease liability(3)	2,634	4,643	4,913	8,105	20,295
Total	19,819	10,127	4,913	8,105	42,964

(1) Excludes contingent considerations of £354,000 as the actual amount payable and timing are uncertain.

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- (2) Includes interest. See “—B. Liquidity and Capital Resources—Indebtedness—Credit Facility.” Does not include the funding received from TAP (which had a carrying value of £44,000 as at December 31, 2019) for which repayment is only due upon regulatory approval, if any, of alvelestat.
- (3) Reflects payments due for our office leases in the UK and the US. The UK lease agreement expires in August 2025 and the US lease agreement, acquired in the Merger on April 23, 2019, expires in May 2028. We may terminate the UK lease agreement in August 2020 and, as such, no amounts due under the agreement after August 2020 are reflected.

As further described above under “—A. Operating Results—Asset Purchase Agreements with Novartis” and “—A. Operating Results—License Agreement with AstraZeneca,” under various agreements with Novartis and AstraZeneca, Mereo has agreed to make milestone payments and pay royalties. Mereo has not included any deferred payment obligations, such as milestones or royalties, in the table above, as the amount, timing, and likelihood of such payments are not known and will remain uncertain for the foreseeable future.

In addition, Mereo enters into contracts in the ordinary course of business with CROs, CMOs, and other vendors to assist in the performance of its research and development activities and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations and commitments.

5.G. Safe Harbor

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See the section titled “Special Note Regarding Forward-Looking Statements” at the beginning of this annual report.

Item 6. Directors, Senior Management And Employees

6.A. Directors, Senior Management and Employees

Executive Officers and Directors

The following table presents information about Mereo’s executive officers and directors, including their ages, as of the date of this annual report:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Executive Officers		
Denise Scots-Knight, Ph.D.	61	Chief Executive Officer and Director
Jill Henrich.	57	Senior Vice President of Regulatory Affairs
Richard Jones	54	Chief Financial Officer and Director
Alastair MacKinnon, MBBS	49	Chief Medical Officer
John Richard	62	Head of Corporate Development
Charles Sermon	51	General Counsel
Alexandra (Wills) Hughes-Wilson	48	Head of Patient Access and Commercial Planning
Non-Executive Directors		
Peter Fellner, Ph.D.	76	Chairman of the Board and Director
Peter Bains	62	Director
Paul Blackburn	65	Director
Anders Ekblom, M.D., Ph.D.	65	Director
Kunal Kashyap	55	Director
Deepika R. Pakianathan, Ph.D.	55	Director
Michael S. Wyzga	65	Director

The current business addresses for Mereo’s executive officers and directors is c/o Mereo BioPharma Group plc, 4th Floor, One Cavendish Place, London, W1G 0QF, United Kingdom.

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The following are brief biographies of Mereo's executive officers and directors:

Denise Scots-Knight, Ph.D. Dr. Scots-Knight has served as our Chief Executive Officer since July 2015 and as a member of our Board since our formation. From 2010 until joining us, Dr. Scots-Knight was the Managing Partner of Phase4 Partners Ltd. ("Phase4"), a global life science venture capital firm. Dr. Scots-Knight is currently a board member of Elanco Animal Health Incorporated (NYSE: ELAN). Dr. Scots-Knight previously served as a member of the board of directors of Idenix Pharmaceuticals, Nabriva, Albireo and OncoMed. Dr. Scots-Knight holds a B.Sc. (Hons.) and a Ph.D. from Birmingham University.

Jill Henrich. Ms. Henrich serves as our U.S. Site Head and Senior Vice President of Regulatory Affairs. Prior to the Merger she was Senior Vice President of Regulatory Affairs and QA at OncoMed Pharmaceuticals Inc. Prior to joining OncoMed, Ms. Henrich was at PDL BioPharma, Inc. (Facet Biotech, acquired by Abbott) as Executive Director of Regulatory Affairs with additional responsibility for Regulatory Operations, Corporate Document Control, Medical Writing and Quality Assurance Compliance. She was Senior Director of Regulatory Affairs at Corixa Corporation (formerly Coulter Pharmaceutical, Inc.), and held various positions in Research (Cell Genetics/Molecular Biology) and Regulatory Affairs at Genentech. Ms. Henrich received her Bachelor of Science degree in Biological Sciences/Microbiology from the University of Connecticut.

Richard Jones. Mr. Jones has served as our Chief Financial Officer and as a member of our Board from January 2017. As a consequence of Mr. Jones serving notice in March 2020 that he will be leaving the Board of the Company and will remain in his position as Chief Financial Officer for a transitional period of up to 5 months, Mr. Jones is not standing for re-election to the Board at the Annual General Meeting to be held on June 29, 2020. From 2011 until joining us, Mr. Jones was the Chief Financial Officer and Company Secretary of Shield Therapeutics plc, where he also served as a Non-Executive Director from 2010 to 2011. Mr. Jones serves as a non-executive director on the board of Alliance Pharma plc. Mr. Jones is a qualified chartered accountant (ACA) with the Institute of Chartered Accountants in England and Wales (ICAEW) and holds a B.Eng. (Hons.) from the University of Newcastle upon Tyne.

Alastair MacKinnon. MBBS. Dr. MacKinnon has served as our Chief Medical Officer since July 2015. From 2010 until joining us, Dr. MacKinnon was a Partner of Phase4. Dr. MacKinnon holds a B.Sc. and a MBBS from King's College London and is a Member of the Royal College of Surgeons in Edinburgh.

John Richard. Mr. Richard has served as our Head of Corporate Development since July 2015.

Prior to joining us, he was a consultant for Nomura, a global investment bank, and Phase4, and previously served as the head of business development for Sequus Pharmaceuticals Inc., VIVUS Inc. and Genome Therapeutics Corporation. Mr. Richard serves on the boards of QUE Oncology, and previously served on the boards of Catalyst Biosciences, Vaxart, Inc., Aviragen Therapeutics, Inc., and Targacept, Inc. Mr. Richard holds a B.S. from Stanford University and an MBA from Harvard Business School.

Charles Sermon. Mr. Sermon has served as our General Counsel and Company Secretary since July 2015. From 2010 until joining us, Mr. Sermon was a Partner of Phase4, where he currently serves as a member of the board of directors. Mr. Sermon trained and qualified as a lawyer with Freshfields after completing the Law Society's Final Examination. Mr. Sermon holds an LL.B. (Hons.) from Hull University.

Alexandra (Wills) Hughes-Wilson. Ms. Hughes-Wilson has served as our Head of Patient Access and Commercial Planning since March 2018. Prior to joining us, Ms. Hughes-Wilson was Senior Vice President, Chief Patient Access Officer at Swedish Orphan Biovitrum (publ.) AB, a biotechnology company, from 2012 to 2018, and prior to that served as Vice President Health & Market Access Policy EMEA at Genzyme (now Sanofi Genzyme), a biotechnology company. Ms. Hughes-Wilson holds a bachelor's degree in Law and Politics (Hons.) from the University of Durham, U.K.

Peter Fellner, Ph.D. Dr. Fellner has been Chairman of our Board since July 2015. He served as Chairman of the board of directors of Consort Medical plc from May 2009 until April 2019 and was Chairman of the board of directors of Ablynx NV from November 2013 until January 2018 and Vernalis plc until October 2018. Dr. Fellner was previously Chairman of the board of directors of Acambis plc from 2006 until its acquisition by Sanofi Pasteur and Optos plc from 2000 until its acquisition by Nikon Corporation, and Vice Chairman of Astex Pharmaceuticals Inc. until its acquisition by Otsuka Pharmaceutical Company. He also served as a Director of UCB S.A. and was CEO and then Chairman of Celltech Group plc. Dr. Fellner holds a B.Sc. (Hons.) from the University of Sheffield and a Ph.D. from the University of Cambridge.

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Peter Bains. Mr. Bains has served on our Board since July 2015. Mr. Bains was a Representative Executive Officer and Chief Executive Officer of Sosei Group Corporation, a Japanese listed biotechnology company until 31 December 2018. Previously, he was Chief Executive Officer and Executive Director of Syngene International Ltd, a BSE listed contract research organization, where he served as a Non-Executive Director until 2016. Mr. Bains also served as Non-Executive Chairman of Fermenta Biotech Ltd, an Indian speciality manufacturing company until April 2018. Mr. Bains currently serves as a Non-Executive Director for MiNA Therapeutics Ltd and Apterna Ltd, both privately held UK biotechnology companies, and Indivior PLC, a FTSE listed speciality pharmaceuticals company. Mr. Bains holds a B.Sc. (Hons.) from Sheffield University.

Paul Blackburn. Mr. Blackburn has served on our Board since October 2015. Mr. Blackburn was Senior Vice President Strategic Finance Projects and Financial Controller at GlaxoSmithKline. Mr. Blackburn currently serves on the Board of Directors of Syngene. Mr. Blackburn is a member of the Chartered Institute of Management Accountants. Mr. Blackburn holds a B.Sc. from Warwick University.

Anders Ekblom, M.D., Ph.D. Dr. Ekblom has served on our Board since July 2015. Dr. Ekblom has held a number of executive positions at AstraZeneca, including Executive Vice President Global Drug Development, Executive Vice President Global Medicines Development, Global Head Clinical Development and Chief Executive Officer of AstraZeneca AB Sweden. He currently serves as Chairman of the Board of Elypta AB, as Vice Chairman of the Board of LEO Pharma A/S, and on the boards of directors of Alligator Bioscience AB and AnaMar AB. Dr. Ekblom is a board-certified medical doctor and an Associate Professor at the Karolinska Institutet. Dr. Ekblom holds a M.D., Ph.D. and a D.D.S. from Karolinska Institutet.

Kunal Kashyap. Mr. Kashyap has served on our Board since July 2015. Mr. Kashyap is Chairman and Managing Director of Allegro Capital Advisors. He had also served as an Independent Director of GlaxoSmithKline Consumer Healthcare Ltd until June 2019. Mr. Kashyap was a partner with Arthur Andersen responsible for establishing and managing their operations in South India. Mr. Kashyap is also the Founder and was the Executive Director of Celstream Technologies Private Limited. Mr. Kashyap is a Chartered Accountant from the Institute of Chartered Accountants of India.

Deepika R. Pakianathan, Ph.D. Dr. Pakianathan has served on our Board since April 2019 following completion of the Merger and served as a director of OncoMed since December 2008 until the closing of the Merger. Since 2001, Dr. Pakianathan has been a Managing Member at Delphi Ventures, a venture capital firm focused on biotechnology and medical device investments. Dr. Pakianathan serves on the boards of directors of Karyopharm Therapeutics, Inc., and Calithera Biosciences, Inc. Dr. Pakianathan previously served on the boards of directors of Alexza Pharmaceuticals, Inc., Alder Biopharmaceuticals, Inc., PTC Therapeutics, Inc. and Relypsa, Inc. Dr. Pakianathan received a B.Sc. from the University of Bombay, India, a M.Sc. from The Cancer Research Institute at the University of Bombay, India, and an M.S. and Ph.D. from Wake Forest University.

Michael S. Wyzga. Mr. Wyzga has served on our Board since April 2019 following completion of the Merger and had served as a director of OncoMed since October 2013 until the closing of the Merger. On May 14, 2020, we entered into the Consulting and Interim Chief Financial Officer Agreement with MSW Consulting Inc. and Michael Wyzga by which Mr. Wyzga will serve as Interim Chief Financial Officer following the departure of Mr. Jones. Mr. Wyzga is currently the President of MSW Consulting Inc., a strategic consulting group focused in the life sciences area. From December 2011 until November 2013, Mr. Wyzga served as President and Chief Executive Officer and a member of the board of directors of Radius Health, Inc. Prior to that, Mr. Wyzga served in various senior management positions at Genzyme Corporation, including as Chief Financial Officer from July 1999 until November 2011. Mr. Wyzga is a member of the boards of directors of Exact Sciences Corporation and LogicBio, and is Chairman of the board of directors of GenSight Biologics S.A. and of X4 Biologics. Mr. Wyzga previously served as a member of the boards of directors of Idenix Pharmaceuticals, Inc. and Altus Pharmaceuticals, Inc., and as a member of the supervisory board of Prosensa Holding B.V. He received an M.B.A. from Providence College and a B.S. from Suffolk University.

Arrangements Concerning Election of Directors; Family Relationships

We are not a party to, and are not aware of, any voting agreements among our shareholders. In addition, there are no family relationships among our executive officers and directors.

6.B. Compensation**Executive Officer Remuneration**

The following table sets forth the approximate remuneration paid during the year ended December 31, 2019.

<u>Name and Principal Position</u>	<u>Salary (£)</u>	<u>Cash Bonus(1) (£)</u>	<u>All Other Compensation(2) (£)</u>	<u>Total(3) (£)</u>
Denise Scots-Knight, Ph.D.	390,988	293,241	67,145	751,374
Jill Henrich(4)	199,800	81,181	5,945	286,926
Richard Jones(5)	291,200	-	37,288	328,488
Alastair MacKinnon, MBBS	290,048	217,536	32,537	540,121
John Richard(6)	295,985	210,227	6,773	512,985
Charles Sermon	290,964	218,223	36,492	545,679
Alexandra Hughes-Wilson	178,551	69,525	17,855	265,931

- (1) Amount shown reflects cash bonuses awarded for achievement of performance goals. In 2019, 30% of the annual cash bonus awarded will be made (after deduction of income tax and the relevant employee's national insurance contributions) to Mereo's current executive officers (with the exception of Jill Henrich and Richard Jones) to acquire Mereo ordinary shares under the 2019 DBP (as defined below). See "—D. Share Ownership—Equity Compensation Arrangements."
- (2) Amount shown represents health benefit payments and pension contributions made by us.
- (3) Total compensation set out in this table does not include any amounts for awards under the DBSP or the value of options to acquire Mereo ordinary shares or awards granted to or held by current senior management, which is described in "—Equity Compensation Arrangements."
- (4) Appointed in 2019.
- (5) Under a settlement agreement dated March 27, 2020, Mr. Jones will not be required to acquire Mereo ordinary shares under the 2019 DBP (as defined below) and no cash bonus was payable in respect of 2019 to Mr. Jones.
- (6) Mr. Richard provided services to us in 2018 and 2019 pursuant to a consultancy agreement and currently provides services to us pursuant to an employment agreement. See "—Executive Officer Employment Agreements—John Richard."

Executive Officer Employment and Consultancy Agreements**Denise Scots-Knight, Ph.D.**

We entered into an employment agreement with Dr. Scots-Knight on July 29, 2015. This agreement entitles Dr. Scots-Knight to receive an initial annual base salary of £275,000 (which was subsequently increased to £379,600 for 2018 and £390,988 for 2019) and an opportunity to earn an annual discretionary performance-based bonus, subject to the achievement of performance goals determined in accordance with our annual bonus plan. We currently contribute to Dr. Scots-Knight's Self-Invested Personal Pension Scheme an amount equal to 15% of Dr. Scots-Knight's annual salary, provided that she contributes 4% or more of her annual salary to that scheme. In lieu of a pension contribution, we may, at Dr. Scots-Knight's request, pay a pro-rata amount equal to 10% of her base salary as additional compensation. Either party may terminate the employment agreement by giving the other party not less than 12 months' written notice, provided that we may terminate Dr. Scots-Knight at any time with immediate effect for cause or by giving written notice to Dr. Scots-Knight that we will instead pay her basic salary for any remaining notice period. Dr. Scots-Knight's employment agreement also contains restrictive covenants pursuant to which she has agreed to refrain from competing with us or soliciting our key employees for a period of six months following her termination of employment or soliciting our customers for a period of nine months following her termination of employment.

Jill Henrich

OncoMed entered into an employment agreement with Ms. Henrich on May 22, 2008, pursuant to which she commenced employment with OncoMed on January 5, 2009. This agreement was subsequently amended on October 27, 2015. Following the acquisition of OncoMed, Ms. Henrich became our Senior Vice President of Regulatory Affairs. On November 1, 2019, we entered into a letter agreement with Ms. Henrich amending all prior employment agreements between Ms. Henrich and OncoMed.

The employment agreement between us and Ms. Henrich entitles Ms. Henrich to receive an annual base salary of \$357,200 per year and an opportunity to earn an annual discretionary performance-based bonus, subject to achievement of corporate goals. Either party may terminate the employment agreement at any time, with or without cause. Ms. Henrich's employment agreement also contains restrictive covenants pursuant to which she has agreed to refrain from soliciting our employees for one year following her termination of employment.

Upon termination of Ms. Henrich's employment prior to or twelve months following a change in control of OncoMed, Ms. Henrich is entitled to (i) severance payments of nine months of her then-current annual base salary, (ii) nine months of her then-current target annual bonus for the year in which the termination occurs, and (iii) reimbursement for healthcare premium payments for nine months. In each case, the nine-month severance package increases to twelve months if Ms. Henrich executes a release of all claims arising out of her employment with OncoMed.

Richard Jones

We entered into an employment agreement with Mr. Jones on November 7, 2016 pursuant to which he commenced employment with us on January 28, 2017. This agreement entitles Mr. Jones to receive an initial annual base salary of £250,000 (which was subsequently increased to £260,000 for 2018 and £291,200 for 2019) and an opportunity to earn an annual discretionary performance-based bonus, subject to the achievement of performance goals determined in accordance with our annual bonus plan. Mr. Jones is also eligible to participate in our group personal pension scheme and we have agreed to contribute to the pension scheme an amount equal to 10% of Mr. Jones's annual salary provided that he contributes 4% or more of his annual salary to that scheme. In lieu of a pension contribution, we may, at Mr. Jones's request, pay a pro-rata amount equal to 10% of his base salary as additional compensation. Either party may terminate the employment agreement by giving the other party not less than six months' written notice, provided that we may terminate Mr. Jones at any time with immediate effect for cause or by giving written notice to Mr. Jones that we will instead pay his basic salary for any remaining notice period. Mr. Jones's employment agreement also contains restrictive covenants pursuant to which he has agreed to refrain from competing with us or soliciting our key employees for a period of six months following his termination of employment or soliciting our customers for a period of nine months following his termination of employment.

On March 27, 2020 we entered into a Settlement Agreement with Richard Jones including the terms whereby Mr. Jones will be leaving the Company. Mr. Jones will remain in his position as CFO with the Company for a transitional period up to 5 months from the end of March 2020.

Alastair MacKinnon, MBBS

We entered into an employment agreement with Dr. MacKinnon on July 29, 2015, and subsequently amended the agreement on November 24, 2017. This agreement entitles Dr. MacKinnon to receive an initial annual base salary of £210,000 (which was subsequently increased to £281,600 for 2018 and £290,048 for 2019) and an opportunity to earn an annual discretionary performance-based bonus, subject to the achievement of performance goals determined in accordance with our annual bonus plan.

Dr. MacKinnon is also eligible to participate in our group personal pension scheme and we have agreed to contribute to the pension scheme an amount equal to 10% of Dr. MacKinnon's annual salary provided that he contributes 4% or more of his annual salary to that scheme. In lieu of a pension contribution, we may, at Dr. MacKinnon's request, pay a pro-rata amount equal to 10% of his base salary as additional compensation. Either party may terminate the employment agreement by giving the other party not less than six months' written notice, provided that we may terminate Dr. MacKinnon at any time with immediate effect for cause or by giving written notice to Dr. MacKinnon that we instead pay his basic salary for any remaining notice period. Dr. MacKinnon's

employment agreement also contains restrictive covenants pursuant to which he has agreed to refrain from competing with us for a period of three months following his termination of employment, soliciting our key employees for a period of six months following his termination of employment, or soliciting our customers for a period of nine months following his termination of employment.

John Richard

We entered into a consultancy agreement with Mr. Richard on January 23, 2019, pursuant to which he provided services to us during 2019 and which terminated on September 1, 2019. Mr. Richard currently provides services to us pursuant to a revised and restated employment agreement dated September 1, 2019 (the “Richard Employment Agreement”).

The Richard Employment Agreement entitles Mr. Richard to receive a base salary of \$370,000 per year, and an opportunity to earn an annual discretionary performance-based bonus, subject to the achievement of performance goals determined in accordance with our annual bonus plan. Either party may terminate the employment agreement by giving the other party not less than three months’ written notice, provided that we may terminate Mr. Richard at any time with immediate effect for cause or by giving written notice to Mr. Richard that we will instead pay his basic salary for any remaining notice period. Mr. Richard’s employment agreement also contains restrictive covenants pursuant to which he has agreed to refrain from competing with us or soliciting our key employees or customers for a period of six months following his termination of employment.

Charles Sermon

We entered into an employment agreement with Mr. Sermon on July 29, 2015. This agreement entitles Mr. Sermon to receive an initial annual base salary of £245,000 (which was subsequently increased to £282,490 for 2018 and £290,964 for 2019) and an opportunity to earn an annual discretionary performance-based bonus, subject to the achievement of performance goals determined in accordance with our annual bonus plan. We have agreed to contribute to Mr. Sermon’s Self-Invested Personal Pension Scheme an amount equal to 10% of Mr. Sermon’s annual salary provided that he contributes 4% or more of his annual salary to that scheme. In lieu of a pension contribution, we may, at Mr. Sermon’s request, pay a pro-rata amount equal to 10% of his base salary as additional compensation. Either party may terminate the employment agreement by giving the other party not less than six months’ written notice, provided that we may terminate Mr. Sermon at any time with immediate effect for cause or by giving written notice to Mr. Sermon that we will instead pay his basic salary for any remaining notice period. Mr. Sermon’s employment agreement also contains restrictive covenants pursuant to which he has agreed to refrain from competing with us or soliciting our key employees for a period of six months following his termination of employment or soliciting our customers for a period of nine months following his termination of employment.

Alexandra (Wills) Hughes-Wilson

Mereo entered into a part-time employment agreement with Ms. Alexandra (Wills) Hughes-Wilson on February 19, 2018, and subsequently amended the agreement on May 29, 2018 and on March 8, 2019. Ms. Hughes-Wilson commenced part-time employment with Mereo as its Head of Patient Access and Commercial Planning on March 5, 2018. The employment agreement entitles Ms. Hughes-Wilson to receive an initial annual base salary of £185,400 and an opportunity to earn an annual discretionary performance-based bonus, subject to the achievement of performance goals determined in accordance with Mereo’s annual bonus plan.

Ms. Hughes-Wilson is also eligible to participate in Mereo’s group personal pension scheme and Mereo has agreed to contribute to the pension scheme an amount equal to 10% of Ms. Hughes-Wilson annual salary provided that she contributes 4% or more of her annual salary to that scheme. In lieu of a pension contribution, Mereo may, at Ms. Hughes-Wilson’s request, pay a pro-rata amount equal to 10% of her base salary as additional compensation. Either party may terminate the employment agreement by giving the other party not less than six months’ written notice, provided that Mereo may terminate Ms. Hughes-Wilson at any time with immediate effect for cause or by giving written notice to Ms. Hughes-Wilson that Mereo instead pay her basic salary for any remaining notice period. Ms. Hughes-Wilson’s employment agreement also contains restrictive covenants pursuant to which she has agreed to refrain from competing with Mereo or soliciting its key employees for a period of six months following her termination of employment or soliciting Mereo customers for a period of nine months following her termination of employment.

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Equity Compensation Awards to Directors and Executive Officers of Mereo

The following table summarizes: (i) the outstanding number of options and awards under the equity incentive plans; and (ii) the number of shares granted to directors, executive officers, and non-executive directors, as of March 1, 2020:

<u>Name</u>	<u>Ordinary Shares (including those represented by ADSs)</u>	<u>Ordinary Shares Underlying Options</u>	<u>Exercise Price Per Ordinary Share (£)</u>	<u>ADSs Underlying Options</u>	<u>Exercise Price Per ADS (\$)</u>	<u>Grant Date</u>	<u>Expiration Date</u>
Denise Scots-Knight, Ph.D.	—	1,544,745	1.29	—	—	September 25, 2015	September 25, 2025
	—	346,154	nil	—	—	June 9, 2016	June 9, 2026
	—	25,319	nil	—	—	April 4, 2017	April 4, 2021
	—	32,205	nil	—	—	April 26, 2018	January 31, 2022
	—	—	—	87,500	5.40	May 20, 2019	May 20, 2029
	—	—	—	87,500	3.00	July 23, 2019	July 23, 2029
	—	—	—	175,000	1.84	February 20, 2020	February 20, 2030
	935,999	—	—	—	—	—	—
Jill Henrich	—	—	—	40,000	5.40	May 20, 2019	May 20, 2029
	10,380	—	—	—	—	—	—
Richard Jones	—	650,000	3.03	—	—	April 4, 2017	April 4, 2027
	—	185,950	nil	—	—	April 4, 2017	June 9, 2026
	—	22,058	nil	—	—	April 26, 2018	January 31, 2022
	—	—	—	27,500	5.40	May 20, 2019	May 20, 2029
	—	—	—	27,500	3.00	July 23, 2019	July 23, 2029
	—	—	—	85,000	1.84	February 20, 2020	February 20, 2030
	66,915	—	—	—	—	—	—
Alastair MacKinnon, MBBS	—	772,371	1.29	—	—	September 25, 2015	September 25, 2025
	—	175,622	nil	—	—	June 9, 2016	June 9, 2026
	—	17,127	nil	—	—	April 4, 2017	April 4, 2021
	—	22,588	nil	—	—	April 26, 2018	January 31, 2022
	—	—	—	27,500	5.40	May 20, 2019	May 20, 2029
	—	—	—	27,500	3.00	July 23, 2019	July 23, 2029
	507,920	—	—	85,000	1.84	February 20, 2020	February 20, 2030
John Richard	—	772,371	1.29	—	—	September 25, 2015	September 25, 2025
	—	50,000	2.21	—	—	June 1, 2016	June 1, 2026
	—	—	—	27,500	5.40	May 20, 2019	May 20, 2029
	—	—	—	27,500	3.00	July 23, 2019	July 23, 2029
	—	—	—	85,000	1.84	February 20, 2020	February 20, 2030
	314,658	—	—	—	—	—	—
Charles Sermon	—	772,371	1.29	—	—	September 25, 2015	September 25, 2025
	—	202,347	nil	—	—	June 9, 2016	June 9, 2026
	—	19,734	nil	—	—	April 4, 2017	April 4, 2021
	—	23,966	nil	—	—	April 26, 2018	January 31, 2022
	—	—	—	27,500	5.40	May 20, 2019	May 20, 2029
	—	—	—	27,500	3.00	July 23, 2019	July 23, 2029
	569,859	—	—	85,000	1.84	February 20, 2020	February 20, 2030
Alexandra (Wills) Hughes-Wilson	—	30,769	3.25	—	—	May 2, 2018	May 2, 2028
	—	9,231	3.25	—	—	May 2, 2018	May 2, 2028
	—	—	—	18,000	5.40	May 20, 2019	May 20, 2029
	—	—	—	18,000	3.00	July 23, 2019	July 23, 2029
	—	—	—	50,000	1.84	February 20, 2020	February 20, 2030
	16,250	—	—	—	—	—	—

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Name	Ordinary Shares (including those represented by ADSs)	Ordinary Shares Underlying Options	Exercise Price Per Ordinary Share (£)	ADSs Underlying Options	Exercise Price Per ADS (\$)	Grant Date	Expiration Date
Peter Fellner	—	1,692,673	1.29	—	—	September 29, 2015	September 29, 2025
	—	—	—	5,500	5.40	May 20, 2019	May 20, 2029
	—	—	—	5,500	3.00	July 23, 2019	July 23, 2029
	—	—	—	11,000	1.84	February 20, 2020	February 20, 2030
	65,500	—	—	—	—	—	—
Peter Bains	—	710,583	1.29	—	—	September 29, 2015	September 29, 2025
	—	—	—	5,500	5.40	May 20, 2019	May 20, 2029
	—	—	—	5,500	3.00	July 23, 2019	July 23, 2029
	—	—	—	11,000	1.84	February 20, 2020	February 20, 2030
	206,796	—	—	—	—	—	—
Paul Blackburn	—	236,974	1.84	—	—	May 11, 2016	May 11, 2026
	—	—	—	5,500	5.40	May 20, 2019	May 20, 2029
	—	—	—	5,500	3.00	July 23, 2019	July 23, 2029
	—	—	—	11,000	1.84	February 20, 2020	February 20, 2030
	22,624	—	—	—	—	—	—
Anders Ekblom	—	216,264	1.29	—	—	September 29, 2015	September 29, 2025
	—	—	—	5,500	5.40	May 20, 2019	May 20, 2029
	—	—	—	5,500	3.00	July 23, 2019	July 23, 2029
	—	—	—	11,000	1.84	February 20, 2020	February 20, 2030
	189,702	—	—	—	—	—	—
Kunal Kashyap	—	216,264	1.29	—	—	September 29, 2015	September 29, 2025
	—	—	—	5,500	5.40	May 20, 2019	May 20, 2029
	—	—	—	5,500	3.00	July 23, 2019	July 23, 2029
	—	—	—	11,000	1.84	February 20, 2020	February 20, 2030
	1,497,735	—	—	—	—	—	—
Deepika R. Pakianathan, Ph.D	—	—	—	5,500	5.40	May 20, 2019	May 20, 2029
	—	—	—	5,500	3.00	July 23, 2019	July 23, 2029
	—	—	—	11,000	1.84	February 20, 2020	February 20, 2030
	1,283,670	—	—	—	—	—	—
Michael S. Wyzga	—	—	—	5,500	5.40	May 20, 2019	May 20, 2029
	—	—	—	5,500	3.00	July 23, 2019	July 23, 2029
	—	—	—	11,000	1.84	February 20, 2020	February 20, 2030

Incentive Award Arrangements

We have no incentive award arrangements in place as of the date of this prospectus.

For a description of the equity incentive plans see “—E. Share Ownership—Equity Compensation Arrangements.”

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Non-Employee Directors Remuneration

The following table sets forth the remuneration paid during 2019 to the current non-employee directors, all of which was in the form of annual fees:

<u>Name</u>	<u>Annual Fees (£)</u>
Peter Bains	46,667
Paul Blackburn	48,000
Anders Ekblom	48,000
Peter Fellner	100,000
Kunal Kashyap	40,000
Michael S. Wyzga	27,590
Deepika R. Pakianathan	30,349

Frank Armstrong served as a non-employee director until his resignation on February 11, 2019. Between January 1, 2019 and February 11, 2019 Frank Armstrong was paid total remuneration of £19,959.

Non-Employee Director Service Contracts

The remuneration of the non-executive directors is determined by the Mereo Board as a whole, based on a review of current practices in other companies. Mereo has entered into service contracts with Mereo's directors for their services, which are subject to a three-month termination period. There are no arrangements under which any non-executive director is entitled to receive compensation upon the early termination of his or her appointment.

On May 14, 2020, we entered into the Consulting and Interim Chief Financial Officer Agreement with MSW Consulting Inc. and Michael Wyzga by which Mr. Wyzga will serve as Interim Chief Financial Officer following the departure of Richard Jones.

Pension, Retirement or Similar Benefits

Mereo operates a defined contribution pension scheme which is available to all employees. Mereo makes payments of up to 10% of basic salary for executives (up to 15% for Mereo's Chief Executive Officer) into any pension scheme or similar arrangement as the participating executive may reasonably request (or a payment in lieu thereof). Such payments are not counted for the purposes of determining bonuses or awards under the LTIP. The total amount set aside or accrued by Mereo to provide pension, retirement or similar benefits to Mereo's current directors and Mereo's senior management with respect to 2019 was £163,748, which represents contributions made by Mereo in 2019 in respect of a defined contribution scheme.

6.C. Board practices

Composition of the Mereo Board

Our Board currently consists of nine members. Our Board has determined that none of our directors have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of director and that each of these directors is "independent" as that term is defined under the rules of Nasdaq. As a foreign private issuer, we are not required to meet the Nasdaq rule that our board be comprised of a majority of independent directors. However, we currently comply and intend to continue to comply with this requirement. There are no family relationships among any of our directors or senior management.

Insurance and Indemnification

To the extent permitted by the U.K. Companies Act 2006, Mereo is empowered to indemnify its directors against any liability they incur by reason of their directorship. Mereo maintains directors' and officers' insurance to ensure such persons against certain liabilities. Mereo has entered into a deed of indemnity with each of its directors.

Insofar as indemnification of liabilities arising under the Securities Act may be permitted to the Mereo Board, executive officers, or persons controlling Mereo pursuant to the forgoing provisions, Mereo has been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Committees of the Mereo Board

The Mereo Board has four standing committees: an audit and risk committee, a remuneration committee, a nomination committee, and a research and development committee.

Audit and Risk Committee

The audit and risk committee, which consists of Paul Blackburn, Kunal Kashyap and Michael S. Wyzga, assists the board in overseeing our accounting and financial reporting processes and the audits of our financial statements. Mr. Blackburn serves as Chairman of the committee. The audit and risk committee consists exclusively of members of our board who are financially literate, and Mr. Blackburn is considered an “audit committee financial expert” as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations. Our board has determined that all of the members of the audit and risk committee satisfy the “independence” requirements set forth in Rule 10A-3 under the Exchange Act. The audit and risk committee is governed by a charter that complies with Nasdaq rules.

The audit and risk committee’s responsibilities include:

- recommending the appointment of the independent auditor to the general meeting of shareholders;
- the appointment, compensation, retention and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services;
- pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services;
- evaluating the independent auditor’s qualifications, performance and independence, and presenting its conclusions to the full board on at least an annual basis;
- reviewing and discussing with the executive officers, the board, and the independent auditor our financial statements and our financial reporting process; and
- approving or ratifying any related person transaction (as defined in our related person transaction policy) in accordance with our related person transaction policy.

The audit and risk committee will meet as often as one or more members of the audit and risk committee deem necessary, but in any event will meet at least four times per year. The audit and risk committee will meet at least once per year with our independent accountant, without our senior management being present.

Remuneration Committee

The remuneration committee, which consists of Peter Bains, Deepika R. Pakianathan and Anders Ekblom, assists the board in determining senior management compensation. Mr. Bains serves as Chairman of the committee. Under SEC and Nasdaq rules, there are heightened independence standards for members of the remuneration committee, including a prohibition against the receipt of any compensation from us other than standard board member fees. However, foreign private issuers are not required to meet this heightened standard. Nonetheless, our board has determined that Mr. Bains, Dr. Pakianathan and Dr. Ekblom meet this heightened standard. The remuneration committee is governed by a charter that complies with Nasdaq rules.

The remuneration committee’s responsibilities include:

- identifying, reviewing, and proposing policies relevant to senior management compensation;
- evaluating each member of senior management’s performance in light of such policies and reporting to the board;
- analyzing the possible outcomes of the variable compensation components and how they may affect the compensation of senior management;
- recommending any equity long-term incentive component of each member of senior management’s compensation in line with any compensation policy and reviewing our senior management compensation and benefits policies generally; and
- reviewing and assessing risks arising from our compensation policies and practices.

Nomination Committee

The nomination committee, which consists of Peter Bains, Anders Ekblom and Peter Fellner, assists our board in identifying individuals qualified to become members of our board and senior management consistent with criteria established by our board and in developing our corporate governance principles. Dr. Fellner serves as Chairman of the nomination committee. The nomination committee is governed by a charter that complies with Nasdaq rules.

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The nomination committee's responsibilities include:

- drawing up selection criteria and appointment procedures for board members;
- reviewing and evaluating the size and composition of our board and making a proposal for a composition profile of the board at least annually;
- recommending nominees for election to our board and its corresponding committees;
- assessing the functioning of individual members of the board and senior management and reporting the results of such assessment to the board; and
- developing and recommending to the board rules governing the board, reviewing and reassessing the adequacy of such rules governing the board, and recommending any proposed changes to the board.

Research and Development Committee

The research and development committee, which consists of Peter Bains, Deepika R. Pakianathan and Anders Ekblom, assists our senior management with oversight and guidance related to strategic research and development matters and provides guidance and makes recommendations to our board regarding strategic research and development matters. Dr. Ekblom serves as Chairman of the research and development committee.

The research and development committee's responsibilities include oversight of:

- our strategic development plans for product candidates, taking into account any regulatory feedback; and
- the acquisition of new product candidates.

In addition, the research and development committee is tasked with keeping informed of strategic issues and commercial changes affecting our development programs and potential product acquisitions.

6.D. Employees

As of December 31, 2019, 2018 and 2017, Mereo had 50, 37 and 31 employees, respectively. As at December 31, 2019, 39 employees are located in the United Kingdom and 11 employees are located in the United States.

All of our employees are engaged in either general and administrative or research and development functions. None of our employees are covered by a collective bargaining agreement.

6.E. Share Ownership

The following table sets forth information relating to the beneficial ownership of Mereo ordinary shares as of June 8, 2020 by each member of the Mereo Board and each of Mereo's other executive officers.

The number of Mereo ordinary shares beneficially owned by each board member or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of June 8, 2020 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all ordinary shares held by that person.

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The percentage of Mereo ordinary shares beneficially owned as of June 8, 2020 is computed on the basis of 213,652,487 ordinary shares outstanding as of June 8, 2020. As of the date of this annual report, Mereo's share capital consists of 213,652,487 fully subscribed and paid up shares. Mereo ordinary shares that a person has the right to acquire within 60 days of June 8, 2020 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all board members and executive officers as a group. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Mereo BioPharma Group plc, 4th Floor, One Cavendish Place, London W1G 0QF, United Kingdom.

<u>Name and address of beneficial owner</u>	<u>Number of Ordinary Shares Beneficially Owned as of June 8, 2020(1)</u>	<u>Percentage of Ordinary Shares Beneficially Owned</u>
Executive Officers and Directors:		
Denise Scots-Knight, Ph.D.	929,699	0.4
Richard Jones	66,915	*
Alastair MacKinnon, MBBS	507,920	0.2
John Richard	314,658	0.1
Charles Sermon	569,859	0.3
Peter Fellner, Ph.D.	65,500	*
Peter Bains	206,796	0.1
Paul Blackburn	22,624	*
Anders Ekblom, M.D., Ph.D.	189,702	*
Kunal Kashyap	1,497,735	0.7
Alexandra (Wills) Hughes-Wilson(2)	8,250	*
Deepika R. Pakianathan, Ph.D (3)	1,283,670	0.6
Michael S. Wyzga	-	*

* Indicates beneficial ownership of less than 0.1% of the total outstanding ordinary shares.

- (1) Ordinary shares figures include ordinary shares represented by ADSs.
- (2) Includes 8,000 ordinary shares held by Ms. Hughes-Wilson's husband.
- (3) Delphi Ventures VIII, L.P. ("Delphi VIII") directly holds 254,327 ADSs. Delphi BioInvestments VIII, L.P. ("DBI VIII") directly holds 2,407 ADSs. Delphi Management Partners VIII, L.L.C. ("DMP VIII") is the general partner of Delphi VIII and DBI VIII (together, the "Delphi VIII Funds"), and may be deemed to have sole voting and dispositive power over the ADSs held by the Delphi VIII Funds. DMP VIII and each of James J. Bochnowski, David L. Douglass, Douglas A. Roeder and Deepika R. Pakianathan, Ph.D., the Managing Members of DMP VIII who may be deemed to share voting and dispositive power over the reported securities, disclaim beneficial ownership of the reported securities held by the Delphi VIII Funds except to the extent of any pecuniary interest therein.

To Mereo's knowledge, and other than changes in percentage ownership as a result of the shares issued in connection with Mereo's initial public offering in the United Kingdom, the Merger, the transactions with Aspire Capital and Boxer Capital and the June 2020 Private Placement, there has been no significant change in the percentage ownership held by the major shareholders listed above in the last three years, except as discussed in "Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions."

Equity Compensation Arrangements

Mereo has granted or may grant or intend to grant share options and awards under the following five equity award plans (the "Mereo Share Plans"): (i) the 2015 Plan; (ii) the Share Option Plan; (iii) the LTIP; (iv) the 2016 DBSP; (v) the Mereo 2019 DBP; (vi) the Mereo 2019 Equity Incentive Plan (the 2019 Plan), (vii) the 2019 NED Equity Incentive Plan (the 2019 NED plan) (each as defined below).

The 2015 Plan

Prior to the admission of Mereo ordinary shares to trading on AIM (“Admission”), Mereo granted options under the 2015 Plan. No further grants have been made under the 2015 Plan since Admission.

Eligibility, Awards and Administration

The 2015 Plan provides for the grant of options to executive directors, non-executive directors, employees and consultants.

Options granted under the 2015 Plan vest in accordance with the vesting schedule set out in each option holder’s option agreement, in normal circumstances, between the first and fourth anniversary (or between the first and third anniversary for non-executive directors) of the vesting start date (typically the date of commencement of employment, appointment as a director, or entering into a consultancy agreement with us).

Admission did not automatically accelerate the vesting of options, and unvested options continue to vest in accordance with their original vesting schedule, subject to the rules of the 2015 Plan. The options are not subject to performance conditions other than continued service.

Options are not automatically exercisable on vesting, but upon Admission became exercisable to the extent vested. Options may generally be exercised until the day immediately preceding the tenth anniversary of the date of grant.

Options have been granted under the 2015 Plan with an exercise price ranging from £1.29 per Mereo ordinary share to £2.21 per Mereo ordinary share.

Plan Leavers

Options held by option holders who leave their office or employment will lapse immediately, unless the option holder is a Good Leaver (as defined in the plan rules). If the option holder is a Good Leaver, the option may be exercised to the extent vested at the date of cessation of services and for such period as the Mereo Board determines and communicates to the option holder at that time (except upon death, in which case, options may be exercised for a period of one year), after which time they will lapse.

Certain Transactions

Under the 2015 Plan, certain corporate events such as a Takeover or a Trade Sale (as defined in the plan rules) will accelerate the vesting of all unvested options upon the occurrence of such event. Options will then be exercisable for a period of 40 days thereafter, after which they will lapse.

Adjustments

In the event of any capitalization, rights issue, consolidation, subdivision, reduction or any other variation of Mereo’s share capital, the number of Mereo ordinary shares subject to an option and the exercise price applying to an option may be varied in such manner as the Mereo Board may determine.

Amendment and Termination

The Mereo Board may, at any time, amend the rules of the 2015 Plan with effect from a current, future or past date by way of a resolution, except that no amendment may be made which would abrogate or adversely affect the subsisting rights of option holders, unless consent from a majority of the affected option holders is obtained (by reference to the number of Mereo ordinary shares subject to options). However, any amendment to benefit the administration of the 2015 Plan, to take account of legislative changes, a Takeover or a Trade Sale (as defined in the plan rules) or to obtain or maintain favorable tax treatment or regulatory treatment may be made by the Mereo Board without the consent of option holders.

The Mereo Share Option Plan (the “Share Option Plan”)

The Mereo Board adopted the Share Option Plan on June 9, 2016, and has subsequently amended it. Except where the context indicates otherwise, references to Mereo ordinary shares shall be deemed to include a number of our ADSs representing the right to receive our ordinary shares.

Eligibility, Awards and Administration

The Share Option Plan provides for the grant of options to acquire Mereo ordinary shares to employees and executive directors. Options may be granted to all eligible employees on commencement of employment and may be granted on a periodic basis after that. The Share Option Plan is administered by the Mereo Board who also set the terms and conditions of all options granted under the Share Option Plan, including any vesting and vesting acceleration conditions. Options are granted under the Share Option Plan at the discretion of the Mereo Board.

Vesting and Exercise

Under the Share Option Plan, the Mereo Board may determine the vesting schedule of an option and whether the vesting of an option will be subject to the satisfaction of a performance condition, although options are not currently granted subject to performance conditions other than continued service with Mereo. Once an option has vested, it may be exercised during the period ending on the tenth anniversary of the date of grant, after which time it will lapse. The exercise price of an option may not be less than the greater of: (i) the market value of a share on the date of grant; or (ii) if the shares are to be subscribed, the nominal value of a share. The Mereo Board may determine that an option be settled in cash or by “net exercise” of the option.

Limitation on Awards

No eligible employee may be granted options that, at the time they are granted, would cause the market value of shares subject to the options granted to the employee in respect of a financial year to exceed 400% of the employee’s salary.

Plan Leavers

If a participant ceases to hold office or employment with Mereo as a result of dismissal for gross misconduct, any option the participant holds, whether vested or unvested, will lapse.

If a participant ceases to hold office or employment with Mereo for any reason other than dismissal for gross misconduct then: (i) if the option is already vested, it may be exercised within six months from the date of cessation of services if such cessation did not occur as a result of the participant’s death, and within 12 months from the date of cessation of services if such cessation occurred as a result of the participant’s death; and (ii) if the option is not already vested, it will vest on the normal vesting date as described above, unless the Mereo Board determines that the option will vest on the date of cessation of services. Where an option vests in these circumstances, any performance condition will be taken into account and, unless the Mereo Board determines otherwise, will be pro-rated for time.

Unless the board determines otherwise, options may not be transferred in any way and will lapse immediately on any attempt to do so, except that options may be transferred to a participant’s personal representative upon death.

Certain Transactions

Under the Share Option Plan, if certain changes are made in, or events occur with respect to, Mereo ordinary shares (including any variation of share capital, demerger, delisting, special dividend, rights issue or any other event, which may, in the opinion of the Mereo Board affect the current or future value of Mereo ordinary shares), the number of shares subject to an option or the exercise price of an option may be adjusted as determined by the Mereo Board. In addition, upon such an event, the Mereo Board will determine: (i) whether and to what extent options which have not yet vested will vest; and (ii) the period of time during which any vested option may be exercised.

In the event of certain corporate transactions, including a scheme of arrangement or general offer, the vesting and exercisability of all options will accelerate to the extent determined by the Mereo Board, after which they will

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be exercisable for one month (or such longer period as determined by the Mereo Board, but not exceeding six months), following which they will lapse. However, if there is an internal reorganization, unless the Mereo Board determines otherwise, an option will generally be exchanged in consideration of the grant of a new option which, as determined by the Mereo Board, is equivalent to the option but relates to shares in a different company (whether the acquiring company or a different company). Any option that does not vest or is not exchanged will lapse immediately.

Amendment and Termination

The Mereo Board may, at any time, amend the rules of the Share Option Plan, except that no amendment may be made: (i) which would be to the material disadvantage of the existing rights of participants unless every participant who may be affected by such amendment has been invited to indicate whether he or she approves the amendment and the amendment is approved by a majority of such participants; or (ii) which would prevent the Share Option Plan from being an employees' share scheme in accordance with the U.K. Companies Act 2006. No options may be granted pursuant to the Share Option Plan after the tenth anniversary of the date of Mereo's Admission.

The Mereo Long Term Incentive Plan (the "LTIP")

In order to further incentivize Mereo's employees and align their interests with shareholders, the Mereo Board adopted the LTIP on June 9, 2016 and has subsequently amended it.

Eligibility, Awards and Administration

The LTIP provides for the grant of nil-cost options, conditional awards, cash conditional awards or cash options (the "LTIP Awards"), to Mereo's employees. The shares used to satisfy the LTIP Awards are currently delivered through the Mereo BioPharma Group plc Employee Benefit Trust, which is based in Jersey.

The Mereo Board may determine that the LTIP Awards are settled in cash.

Vesting and Exercise

The LTIP Awards are subject to a vesting schedule as determined by the Mereo Board. LTIP Awards granted to key executive directors and senior management are subject to: (i) a share price performance condition; and (ii) the achievement of strategic operational targets. If on the date a LTIP Award is due to vest or be exercisable a restriction on share dealing (as may be imposed by Mereo's share dealing code or the AIM rules) applies to the award, then the award will vest on the date on which such dealing restriction lifts. During the year ended December 31, 2019, 241,373 options under the LTIP lapsed as the performance conditions for a tranche were not met. On January 1, 2020, a further 161,870 options under the LTIP lapsed as the performance conditions for a tranche were not met. To date, no options under the LTIP have vested.

Limitation on Awards

No eligible employee may be granted LTIP Awards that, at the time they are granted, would cause the market value of shares subject to the LTIP Awards granted to the employee in respect of a financial year to exceed 300% of the employee's salary.

The LTIP Awards may be: (i) reduced; or (ii) where the underlying shares or cash has already been transferred to the participant following vesting or exercise of the LTIP Award (as applicable), clawed back, where prior to the second anniversary of the end of the relevant performance period there has been a material misstatement of Mereo's accounts, an error in assessing a performance condition such that the LTIP Award vests to a greater extent than it would have vested, or fraudulent or material misconduct on the part of the participant.

Scheme Leavers

The LTIP Awards will usually lapse on the participant's cessation of employment or office, unless the cessation is because of death, ill health, injury or disability, or where the participant is no longer employed by Mereo, or for any other reason at the Mereo Board's discretion, except where the participant is summarily dismissed, in which case any unvested LTIP Awards will usually continue until the normal vesting date, unless the Mereo Board determines otherwise.

Certain Transactions

Under the LTIP, if certain changes are made in or events occur with respect to Mereo ordinary shares (including any variation of share capital, any demerger, delisting, special dividend, rights issue or other event which may, in the opinion of the Mereo Board, affect the current or future value of Mereo ordinary shares), the number of shares subject to a LTIP Award, or any performance condition, may be adjusted as determined by the Mereo Board. In addition, upon such an event, the Mereo Board will determine: (i) whether and to what extent awards which have not yet vested will vest; and (ii) the period of time during which any vested option may be exercised.

In the event of certain corporate transactions, including a general offer or a scheme of arrangement, the vesting and exercisability of all LTIP Awards will accelerate to the extent determined by the Mereo Board (taking into account the extent to which any performance conditions have been satisfied and usually the period of time from the date of grant to the date of the corporate transaction), and any nil-cost options will remain exercisable for one month (or such other period as determined by the Mereo Board), following which they will lapse. However, if there is an internal reorganization, a LTIP Award will be exchanged in consideration of the grant of a new award which, as determined by the Mereo Board, is equivalent to the LTIP Award but relates to shares in a different company (whether the acquiring company or a different company). Any LTIP Award that does not vest or is not exchanged will lapse immediately.

Amendment and Termination

The Mereo Board may, at any time, amend the rules of the LTIP or the terms of any LTIP Award, except that no amendment may be made: (i) which would be to the material disadvantage of the existing rights of participants unless every participant who may be affected by such amendment has been invited to indicate whether he or she approves the amendment and the amendment is approved by a majority of such participants; or (ii) which would prevent the LTIP from being an employees' share scheme in accordance with the U.K. Companies Act 2006. No LTIP Awards may be granted pursuant to the LTIP after the tenth anniversary of the date of Admission.

The Mereo Deferred Bonus Share Plan (the "2016 DBSP")

The Mereo Board adopted the 2016 DBSP on June 9, 2016 and has subsequently amended it. Following the adoption of the 2019 DBP in January 2019, no further grants are expected to be made under the 2016 DBSP.

Eligibility, Awards and Administration

The 2016 DBSP provides for the deferral of a percentage (currently 30%) of the annual bonuses awarded to Mereo's employees into the right to acquire shares equal in value to the amount deferred, free of charge.

Under the 2016 DBSP, conditional awards or nil-cost options (the "2016 DBSP Awards") may only be granted to participants who have earned a bonus, pursuant to Mereo's annual bonus plan, for the financial year immediately preceding the financial year in which the grant date occurs. A 2016 DBSP Award will be granted over such number of shares as have at the grant date a market value, as determined by the Mereo Board, equal to the deferred bonus (the amount of bonus which is to be delivered in the form of a conditional award or a nil-cost option).

Vesting and Exercise

The 2016 DBSP Awards will generally vest three years after the date of grant and have no performance conditions or service condition. The 2016 DBSP Awards may be settled in cash if determined by the Mereo Board. The shares used to satisfy the 2016 DBSP Awards are currently delivered through the Mereo BioPharma Group plc Employee Benefit Trust, which is based in Jersey.

If on the date a 2016 DBSP Award is due to vest or be exercisable a restriction on share dealing (as may be imposed by Mereo's share dealing code or the AIM rules) applies to the award, then the award will vest on the date on which such dealing restriction lifts.

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Once a nil-cost option has vested, it may be exercised during the period ending on the first anniversary of the date on which it vested in such manner as the Mereo Board determines, after which time it will lapse.

Limitation on Awards

No eligible employee may be granted 2016 DBSP Awards that, at the time they are granted, would cause the market value of shares subject to the 2016 DBSP Awards granted to the employee in respect of a financial year to exceed 100% of the employee's salary.

The 2016 DBSP Awards may, prior to the third anniversary of the grant date, be: (i) reduced; or (ii) where the underlying shares or cash have already been transferred to the participant following vesting or exercise of the 2016 DBSP Award (as applicable), clawed back, where there has been a material misstatement of Mereo's accounts, an error in assessing the information on which the bonus was determined such that the bonus was overpaid, or fraudulent or material misconduct on the part of the participant.

Certain Transactions

Under the 2016 DBSP, if certain changes are made in or events occur with respect to Mereo ordinary shares (including any variation of share capital, any demerger, delisting, special dividend, rights issue or other event which may in the opinion of the Mereo Board, affect the current or future value of Mereo ordinary shares), the number of shares subject to a 2016 DBSP Award may be adjusted as determined by the Mereo Board. In addition, upon such an event, the Mereo Board will determine: (i) whether and to what extent 2016 DBSP Awards which have not yet vested will vest; and (ii) the period of time during which any vested option may be exercised.

In the event of certain corporate transactions, including a general offer or a scheme of arrangement, the vesting and exercisability of all 2016 DBSP Awards will accelerate to the extent determined by the Mereo Board, after which, the 2016 DBSP Awards will be exercisable for one month (or such other period as or determined by the Mereo Board), following which they will lapse. However, if there is an internal reorganization, a 2016 DBSP Award will be exchanged in consideration of the grant of a new award which, as determined by the Mereo Board, is equivalent to the 2016 DBSP Award but relates to shares in a different company (whether the acquiring company or a different company).

Scheme Leavers

Except for where a participant is summarily dismissed (in which case the awards will be forfeited), the 2016 DBSP Awards usually will continue upon cessation of office or employment with Mereo and vest in full on the normal vesting date as described above. Options will remain exercisable for a period of 12 months from the date of vesting.

Amendment and Termination

The Mereo Board may, at any time, amend the rules of the 2016 DBSP, except that no amendment may be made: (i) which would be to the material disadvantage of the existing rights of participants unless every participant who may be affected by such amendment has been invited to indicate whether he or she approves of the amendment and the amendment is approved by a majority of such participants; or (ii) which would prevent the 2016 DBSP from being an employees' share scheme in accordance with the U.K. Companies Act 2006.

No 2016 DBSP Awards may be granted pursuant to the 2016 DBSP after the tenth anniversary of the date of Admission.

Mereo's Remuneration Committee has approved awards under the 2016 DBSP in respect of bonuses awarded to certain of Mereo's executive officers for 2017. These awards are in the form of nil-cost option grants under the 2016 DBSP in the following amounts: Dr. Scots-Knight: 32,205 shares subject to the option; Mr. Jones: 22,058 shares subject to the option; Dr. MacKinnon: 22,588 shares subject to the option; and Mr. Sermon: 23,966 shares subject to the option. The options are scheduled to vest on the third anniversary of the date of grant.

The Mereo New Deferred Bonus Plan (the “2019 DBP”)

The Mereo Board adopted Mereo’s the 2019 DBP on January 15, 2019.

Holding of Deferred Shares

Under the 2019 DBP, Mereo ordinary shares may be purchased by participants using an after-tax bonus amount paid to them pursuant to Mereo’s annual bonus plan (“Deferred Shares”).

Restrictions on Deferred Shares

The participants must hold the Deferred Shares for two years (or such other period as the Mereo Board may determine in advance) beginning on the date or dates on which a participant purchases those shares with the bonus. Participants must not transfer, assign, charge, sell or dispose of or encumber any Deferred Shares during this period except as permitted under the 2019 DBP or by the Mereo Board. The 2019 DBP permits participants to transfer Deferred Shares to an immediate family member or nominee to hold for them or as a beneficiary, or to a personal representative in the event of the participant’s death.

Cessation of Employment

If a participant ceases employment with Mereo, he or she must continue to hold the Deferred Shares in accordance with the restrictions under the 2019 DBP unless the Mereo Board disapply some or all of the restrictions in respect of some or all of that participant’s Deferred Shares. The Mereo Board will not have discretion to disapply any of the restrictions in the case of a participant who has been dismissed lawfully without notice or could have been so dismissed if he or she had not resigned.

Certain Transactions

Under the 2019 DBP, if any person obtains control of Mereo (by means of holding shares, the possession of voting power, or as a result of any powers conferred by Mereo’s Articles or other document relating to Mereo), the restrictions on Deferred Shares under the 2019 DBP will cease to apply from that date unless the Mereo Board determines otherwise. The Mereo Board may not extend the restrictions under the 2019 DBP.

If an internal reorganization occurs (whereby immediately after a change of control of Mereo, all or substantially all of the issued share capital of the acquiring company is owned directly or indirectly by the persons who were shareholders in Mereo before the change of control) and the Deferred Shares are exchanged for shares in another company, the rules of the 2019 DBP will apply to those shares as if they were Deferred Shares.

Regulatory Issues

The purchase or transfer of Mereo ordinary shares under the 2019 DBP will be subject to obtaining any approval or consent required by AIM or Nasdaq (or any other relevant authority) and any restrictions imposed by Mereo’s share dealing code, the AIM rules, or any applicable laws or regulations which impose restrictions on share dealing.

Amendment and Termination

The Mereo Board may, at any time, amend the rules of the 2019 DBP or the terms of the Deferred Shares, except that no amendment may be made: (i) which would be to the material disadvantage of the existing rights of participants unless every participant who may be affected by such amendment has been invited to indicate whether he or she approves of the amendment and the amendment is approved by a majority of such participants; or (ii) which would prevent the 2019 DBP from being an employees’ share scheme in accordance with the U.K. Companies Act 2006.

The 2019 DBP will terminate on the tenth anniversary of its adoption by the Mereo Board or at any earlier time by resolution of the Mereo Board. Termination of the 2019 DBP will be without prejudice to the existing rights of participants.

The Mereo 2019 Equity Incentive Plan (The 2019 EIP)

Our Board adopted the 2019 EIP on April 4, 2019. The Remuneration Committee made minor amendments to the rules of the 2019 EIP on May 16, 2019 prior to the first awards noted below.

Eligibility, Awards and Administration

The 2019 EIP provides for the grant of the following types of awards to non-executive directors: (i) market value options; (ii) share appreciation rights; (iii) restricted stock / restricted stock unit awards; (iv) performance awards (awards subject to performance conditions) and (v) other share-based awards.

Subject to the terms of the 2019 EIP awards can be granted in respect of ordinary shares, ADSs, cash or a combination thereof. References in this section to ordinary shares will be deemed references to ADSs, as applicable.

The 2019 EIP is administered by the Remuneration Committee unless the Remuneration Committee designates one or more directors as a subcommittee who may act for the Remuneration Committee if necessary. The Board may also choose to administer the 2019 EIP itself.

Vesting Schedule

Awards vest in accordance with the vesting schedule set for the relevant award in its award agreement.

Awards

On May 20, 2019, the Remuneration Committee of the Board agreed to grant awards in respect of market value options over an aggregate of 255,500 ADSs to executives, at an exercise price of \$5.40 per ADS. On July 23, 2019, the Remuneration Committee of the Board agreed to grant awards in respect of market value options over an additional 215,500 ADSs to executives, at an exercise price of \$3.00 per ADS. On February 20, 2020, the Remuneration Committee of the Board agreed to grant awards in respect of market value options over an additional 565,000 ADSs to executives, at an exercise price of \$1.84 per ADS.

In the normal course of events and subject to the participant's continued employment through each applicable vesting date, one fourth of each such market value option grant shall vest on the first anniversary of the grant date and the remainder shall vest in equal monthly installments over the three year period following the first anniversary. No performance conditions apply to such market value options.

Limitation on Awards

Subject to adjustment, the aggregate number of shares available for issuance under the 2019 EIP and the 2019 NED EIP will not exceed 9,590,180 ordinary shares. Beginning in the 2021 calendar year, the total number of ordinary shares available for issuance under the 2019 EIP and the 2019 NED EIP is increased on January 1st of each year in an amount equal to the lesser of (i) 4.5% of our issued and outstanding ordinary shares (measured as of January 1st of such year) and (ii) such number of ordinary shares as determined by the Remuneration Committee of the Board, or such other committee as may be designated by the Board, in its discretion.

Leavers

Unvested awards will usually lapse on termination of office or service (including voluntary departure) save for potentially different good leaver treatment. The effect of a participant's termination of office or service on outstanding awards, including whether the awards may be exercised, settled, vested, paid or forfeited, will be determined by the Remuneration Committee and may be set forth in the participant's award agreement.

Certain Transactions

In the event of certain corporate transactions, including a change of control, the Remuneration Committee may determine the appropriate treatment of an award which may include (but is not limited to) it vesting in full, being settled in cash or being varied or replaced so as to relate to other assets (including shares in another company).

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The number and type of securities subject to award and any exercise price may also be adjusted for various events that may affect the value of ordinary shares or ADSs and for changes in applicable laws, regulations or accounting principles.

Amendment and Termination

The Board may amend, alter, suspend, discontinue or terminate the 2019 EIP or any portion thereof at any time, subject to shareholder approval where required by applicable law or the rules of the stock market or exchange, if any, on which the shares are principally quoted or traded.

However, no such Board action that would materially adversely affect participants' rights under an outstanding award may be taken without such participants' consent, except to the extent that such action is made to cause the 2019 EIP to comply with applicable law, stock market or exchange rules and regulations or accounting or tax rules and regulations or to impose any recoupment provisions on any awards in accordance with the 2019 EIP.

No Award may be granted under the 2019 EIP after the earliest to occur of: (i) the tenth anniversary of the effective date of the 2019 EIP; provided that to the extent permitted by the listing rules of any stock exchange on which we are listed, such ten-year term may be extended indefinitely so long as the maximum number of shares available for issuance under the 2019 EIP have not been issued; (ii) the maximum number of shares available for issuance under the 2019 EIP have been issued; and (iii) our Board terminates the 2019 EIP.

Beginning in the 2021 calendar year, the total number of ordinary shares available for issuance under the 2019 EIP and the 2019 NED EIP is increased on January 1st of each year in an amount equal to the lesser of (i) 4.5% of our issued and outstanding ordinary shares (measured as of January 1st of such year) and (ii) such number of ordinary shares as determined by the Remuneration Committee of the Board, or such other committee as may be designated by the Board, in its discretion.

The Mereo 2019 NED Equity Incentive Plan (The 2019 NED EIP)

Our Board adopted the 2019 NED EIP on April 4, 2019. The Remuneration Committee made minor amendments to the rules of the 2019 NED EIP on May 16, 2019 prior to the first awards noted below.

Eligibility, Awards and Administration

The 2019 NED EIP provides for the grant of the following types of awards to non-executive directors: (i) market value options; (ii) share appreciation rights; (iii) restricted stock / restricted stock unit awards; (iv) performance awards (awards subject to performance conditions) and (v) other share-based awards.

Subject to the terms of the 2019 NED EIP awards can be granted in respect of ordinary shares, ADSs, cash or a combination thereof. References in this section to ordinary shares will be deemed references to ADSs, as applicable.

The 2019 NED EIP is administered by the Remuneration Committee unless the Remuneration Committee designates one or more directors as a subcommittee who may act for the Remuneration Committee if necessary. The Board may also choose to administer the 2019 NED EIP itself.

Vesting Schedule

Awards vest in accordance with the vesting schedule set for the relevant award in its award agreement.

Awards

Awards were granted under the 2019 NED EIP to non-executive directors on May 20, 2019 in respect of (in aggregate) 38,500 ADSs at a per ADS exercise price of \$5.40. The terms of the awards include that, at our discretion, the awards will be settled either in ADSs (for payment of the exercise price) or in cash (by reference to the growth in value in excess of the reference exercise price). On July 23, 2019, the Remuneration Committee of the Board agreed to grant awards in respect of market value options over an additional 38,500 ADSs to non-executive directors, at an exercise price of \$3.00 per ADS. On February 20, 2020, the Remuneration Committee of the Board agreed to grant awards in respect of market value options over an additional 77,000 ADSs to non-executive directors, at an exercise price of \$1.84 per ADS.

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In the normal course of events and subject to the participant holding the participant's current office (or being otherwise employed) through each applicable vesting date, such awards shall vest in equal monthly installments over the one year period following their grant date. No performance conditions apply to such awards.

Limitation on Awards

Subject to adjustment, the aggregate number of shares available for issuance under the 2019 EIP and the 2019 NED EIP will not exceed 4.5% of our issued and outstanding ordinary shares (such limit will be measured as of the date of grant of an award).

Leavers

Unvested awards will usually lapse on termination of office or service (including voluntary departure) save for potentially different good leaver treatment. The effect of a participant's termination of office or service on outstanding awards, including whether the awards may be exercised, settled, vested, paid or forfeited, will be determined by the Remuneration Committee and may be set forth in the participant's award agreement.

Certain Transactions

In the event of certain corporate transactions, including a change of control, the Remuneration Committee may determine the appropriate treatment of an award which may include (but is not limited to) it vesting in full, being settled in cash or being varied or replaced so as to relate to other assets (including shares in another company).

The number and type of securities subject to award and any exercise price may also be adjusted for various events that may affect the value of ordinary shares or ADSs and for changes in applicable laws, regulations or accounting principles.

Amendment and Termination

The Board may amend, alter, suspend, discontinue or terminate the 2019 NED EIP or any portion thereof at any time, subject to shareholder approval where required by applicable law or the rules of the stock market or exchange, if any, on which the shares are principally quoted or traded.

However, no such Board action that would materially adversely affect participants' rights under an outstanding award may be taken without such participants' consent, except to the extent that such action is made to cause the 2019 NED EIP to comply with applicable law, stock market or exchange rules and regulations or accounting or tax rules and regulations or to impose any recoupment provisions on any awards in accordance with the 2019 NED EIP.

No Award may be granted under the 2019 NED EIP after the earliest to occur of: (i) the tenth anniversary of the effective date of the 2019 NED EIP; provided that to the extent permitted by the listing rules of any stock exchange on which we are listed, such ten-year term may be extended indefinitely so long as the maximum number of shares available for issuance under the 2019 NED EIP have not been issued; (ii) the maximum number of shares available for issuance under the 2019 NED EIP have been issued; and (iii) our Board terminates the 2019 NED EIP.

Item 7. Major Shareholders And Related Party Transactions

7.A. Major Shareholders

The following table sets forth information relating to the beneficial ownership of Mereo ordinary shares as of June 8, 2020 by each person, or group of affiliated persons, known by Mereo to own beneficially 3% or more of the outstanding Mereo ordinary shares.

The number of Mereo ordinary shares beneficially owned by each entity, person, board member, or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of

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beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of June 8, 2020 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all Mereo ordinary shares held by that person.

The percentage of Mereo ordinary shares beneficially owned as of June 8, 2020 is computed on the basis of 213,652,487 ordinary shares outstanding as of June 8, 2020. As of the date of this annual report, Mereo's share capital consists of 213,652,487 fully subscribed and paid up shares. Mereo ordinary shares that a person has the right to acquire within 60 days of June 8, 2020 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all board members and executive officers as a group. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Mereo BioPharma Group plc, 4th Floor, One Cavendish Place, London W1G 0QF, United Kingdom.

<u>Name and address of beneficial owner</u>	<u>Number of Ordinary Shares Beneficially Owned as of June 8, 2020, 2020(1)</u>	<u>Percentage of Ordinary Shares Beneficially Owned</u>
3% or Greater Shareholders:		
Tavistock Group(2)	21,151,595	9.9%
OrbiMed funds (3)	20,061,437	9.4%
Baker Brothers (4)	20,061,437	9.4%
Link Fund Solutions Limited (5)	19,031,915	8.9%
Aspire Capital Fund, LLC (6)	16,970,378	7.9%
Novartis Pharma AG (7)	15,703,871	7.4%
Vivo funds (8)	13,374,291	6.3%
Schroders plc(9)	7,845,873	3.7%
Invesco Ltd. (10)	7,620,000	3.6%

- (1) Ordinary shares figures include ordinary shares represented by ADSs.
- (2) Consists of 20,148,246 ordinary shares held by Boxer Capital, LLC and 1,003,349 ordinary shares held by MVA Investors, LLC. Boxer Capital, LLC is a Delaware company with office address 11682 El Camino Real, Suite 320, San Diego, CA 92130. MVA Investors, LLC is a Delaware company with office address 11682 El Camino Real, Suite 320, San Diego, CA 9213.
- (3) Consists of 10,699,433 ordinary shares held OrbiMed Private Investment VII, LP, 6,687,146 ordinary shares held by OrbiMed Partners Master Fund Limited and 2,674,858 shares held by OrbiMed Genesis Master Fund, LP. OrbiMed Private Investment VII, LP is a Delaware limited partnership with office address at c/o Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808. OrbiMed Partners Master Fund Limited is a Bermuda company with office address at c/o Conyers Corporate Services (Bermuda) Limited, Clarendon House, 2 Church Street, Hamilton, HM 11 Bermuda. OrbiMed Genesis Master Fund is a Cayman Islands limited partnership with office address at c/o Intertrust (Cayman) Ltd., 190 Elgin Avenue, George Town, Grand Cayman KY1-9005, Cayman Islands.
- (4) Consists of 18,605,298 ordinary shares held by Baker Brothers Life Sciences, L.P. and 1,456,139 ordinary shares held by 667, L.P. Baker Brothers Life Sciences, L.P. is a Delaware limited partnership with office address at Baker Brothers Investments, 860 Washington St, 3rd Floor, New York, NY 10014. 667, L.P. is a Delaware limited partnership with office address at Baker Brothers Investments, 860 Washington St, 3rd Floor, New York, NY 10014.

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- (5) Based on information known to Mereo and a Form TR 1 provided to Mereo in February 2020, the share holdings consist of (i) 16,478,248 ordinary shares held by BlackRock Investment Management (Transition) and (ii) 2,553,667 ordinary shares held by Link. The address of Link is 6th Floor, 65 Gresham Street, London, EC2V 7NQ, United Kingdom.
- (6) Consists entirely of ordinary shares held by Aspire Capital, which consists of the Initial Shares and the Commission Shares purchased by Aspire Capital pursuant to the Purchase Agreement and ordinary shares acquired pursuant to the June 2020 Private Placement. See “The Aspire Capital Transaction” and the “June 2020 Private Placement”. Aspire Capital Partners LLC (“Aspire Partners”) is the Managing Member of Aspire Capital. SGM Holdings Corp. (“SGM”) is the managing member of Aspire Partners. Mr. Steven G. Martin is the president and sole shareholder of SGM, as well as a principal of Aspire Partners. Mr. Erik J. Brown is the president and sole shareholder of Red Cedar Capital Corp. (“Red Cedar”) which is a principal of Aspire Partners. Mr. Christos Komissopoulos is president and sole shareholder of Chrisko Investors Inc. (“Chrisko”), which is a principal of Aspire Partners. Mr. William F. Blank, III is president and sole shareholder of WML Ventures Corp. (“WML Ventures”), which is a principal of Aspire Partners. Each of Aspire Partners, SGM, Red Cedar, Chrisko, WML Ventures, Mr. Martin, Mr. Brown, Mr. Komissopoulos and Mr. Blank may be deemed to be a beneficial owner of the ordinary shares held by Aspire Capital. Each of Aspire Partners, SGM, Red Cedar, Chrisko, WML Ventures, Mr. Martin, Mr. Brown, Mr. Komissopoulos and Mr. Blank disclaims beneficial ownership of the ordinary shares held by Aspire Capital. The address of Aspire Capital is 155 North Wacker Dr. Suite 1600, Chicago, IL 60606.
- (7) Consists of 15,703,871 ordinary shares held by Novartis. Beneficial ownership information is based on information known to Mereo. The address of Novartis Pharma AG is Lichtstrasse 35, 4056 Basel, Switzerland.
- (8) Consists of 2,439,885 ordinary shares held by Vivo Capital Fund IX, L.P. and 10,934,406 ordinary shares held by Vivo Opportunity Fund, L.P. Vivo Capital Fund IX, L.P. is a Delaware partnership with office address C/O Vivo Capital LLC, 192 Lytton Avenue, Palo Alto, CA 94301. Vivo Opportunity Fund, L.P. is a Delaware partnership with office address C/O Vivo Capital LLC, 192 Lytton Avenue, Palo Alto, CA 94301.
- (9) Consists entirely of ordinary shares. Beneficial ownership information for Schroder UK Public Private Trust PLC is based on information known to Mereo. Schroder Investment Management is the investment manager for Schroder UK Public Private Trust PLC. The address of Schroder Investment Management Ltd. is 1 London Wall Place, London, EC2Y 5AU, UK.
- (10) Consists entirely of ordinary shares held by Invesco Asset Management. Beneficial ownership information is based on information known to Mereo. The address of Invesco Asset Management Limited is 30 Finsbury Square, London EC2A 1AG, United Kingdom.

To our knowledge, and other than changes in percentage ownership as a result of the shares issued in connection with our initial public offering in the United Kingdom, the Merger and the transactions with Aspire Capital and Boxer Capital, there has been no significant change in the percentage ownership held by the major shareholders listed above in the last three years, except as discussed in “—B. Related Party Transactions”.

7.B. Related Party Transactions

The following is a description of related party transactions we have entered into since January 1, 2019, or currently in effect with any member of our board of directors and executive officers.

Novartis Notes

On June 3, 2016, we issued 3,463,563 Novartis Notes to Novartis, for aggregate proceeds to us of £3.5 million. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Indebtedness—Novartis Notes” for additional information on the terms of the Novartis Notes.

On April 6, 2017, Novartis delivered to us a notice of conversion with respect to £1,398,552 aggregate principal amount of Novartis Notes. Pursuant to such notice, on April 26, 2017, £1,398,552 aggregate principal amount of Novartis Notes was converted into 632,829 fully paid ordinary shares. Additionally, in connection with such conversion, we issued 588,532 Bonus Shares to Novartis.

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On June 6, 2019, Novartis delivered to us a notice of conversion with respect to the aggregate principal amount and interest of the Novartis Notes. Pursuant to such notice, on June 21, 2019, the aggregate principal amount and interest of £2,367,004 due under the Novartis Notes was converted into 1,071,042 fully paid ordinary shares at the fixed conversion price of £2.21 per share. Additionally, in connection with such conversion, we issued 864,988 Bonus Shares to Novartis (for £nil consideration). At December 31, 2019, there was no further liability under the Novartis Notes which were converted in full as at that date.

On February 10, 2020, we entered into a £3,841,479 convertible loan note instrument relating to the issue of 3,841,479 New Novartis Notes. The New Novartis Notes are convertible at any time at a fixed price of £0.265 per ordinary share. In addition, on February 10, 2020, in connection with the New Novartis Notes, we entered into a warrant instrument with Novartis to issue 1,449,614 ordinary shares at a weighted average exercise price of £0.265 per ordinary share. These warrants will be capable of exercise until February 10, 2025. The New Novartis Notes and the warrants include an adjustment provision to prevent the dilution of the ordinary shares issuable to Novartis under certain circumstances.

Aspire Capital

As at June 1, 2020, Aspire Capital Fund, LLC held approximately 11.5 percent of Mereo's issued ordinary share capital and as such is considered to be a related party of the Company as defined by the AIM Rules. The participation by Aspire in the June 2020 Private Placement therefore constituted a related party pursuant to AIM Rule 13. The Directors of Mereo, having consulted with the Company's nominated adviser, Cantor Fitzgerald Europe, consider that the terms of the participation by Aspire are fair and reasonable insofar as the shareholders of the Company are concerned.

Supply Payments

In 2016, we paid Novartis a total of £968,219. In 2017, we paid Novartis a total of £4,610,106 for the manufacture and supply of clinical trial material. No payments were made from Mereo to Novartis in 2018 and 2019.

Transactions with Mereo's Executive Officers and Directors

We have entered into employment agreements or consultancy agreements with our executive officers. See "Item 6. Directors, Senior Management and Employees—B. Compensation—Executive Officer Employment and Consultancy Agreement."

Employee Benefit Trust

In 2016, we established an Employee Benefit Trust ("EBT") for the purposes of buying and selling shares on the employees' behalf.

A total of £1.0 million of funding was paid into the EBT by us during the year ended December 31, 2019 (2018: £0.3 million). A total of 1,074,274 shares were purchased by the EBT during the year ended December 31, 2019 (2018: 163,000).

As at December 31, 2019, the EBT had a cash balance of £21,762 (2018: £21,762).

Indemnity Agreements

We have entered into deeds of indemnity with each of our directors. See "Item 6. Directors, Senior Management and Employees—C. Board practices—Composition of the Mereo Board—Insurance and Indemnification."

Related Person Transaction Policy

Our Board has a written related person transaction policy, which sets forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, any transaction or proposed transactions between us and a related person that are material to us or the related person, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit and risk committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

7.C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

8.A. Consolidated Statements and Other Financial Information

See "Item 18. Financial Statements."

Legal Proceedings

There are no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which Mereo is aware) that may have, or have had in the recent past (covering the 12 months immediately preceding the date of this annual report), significant effects on Mereo's financial position or profitability.

Dividend Policy

Mereo has never paid or declared any cash dividends on its ordinary shares, and does not anticipate paying any cash dividends on its ordinary shares in the foreseeable future. Mereo intends to retain all available funds and any future earnings to fund the development and expansion of its business. Under English law, among other things, Mereo may only pay dividends if it has sufficient distributable reserves (on a non-consolidated basis), which are calculated as Mereo's accumulated realized profits that have not been previously distributed or capitalized less its accumulated realized losses, so far as such losses have not been previously written off in a reduction or reorganization of capital.

In addition, the terms of Mereo's existing loan agreement with Silicon Valley Bank and Kreos Capital V (UK) Limited ("Kreos"), preclude Mereo from paying cash dividends without Kreos's consent.

8.B. Significant changes

Except as disclosed elsewhere in this annual report, there have been no other significant changes since December 31, 2019.

Item 9. The Offer And Listing

9.A.4 Offer and Listing Details

ADSs

Our ADSs, each representing five ordinary shares of ours, with a £0.003 per share nominal value each, have been listed on Nasdaq since April 24, 2019. Our ADSs trade under the symbol "MREO." Prior to that date, there was no public trading market for our ADSs.

Ordinary shares

Our ordinary shares have traded on AIM under the symbol "MPH" since June 9, 2016. No trading market currently exists for our ordinary shares in the United States.

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9.B. Plan of Distribution

Not applicable.

9.C. Markets

Our ordinary shares have traded on AIM under the symbol “MPH” since June 9, 2016 and our ADSs have been listed and traded on the Nasdaq Global Market since April 24, 2019 under the symbol “MREO”.

9.D. Selling Shareholders

Not applicable.

9.E. Dilution

Not applicable.

9.F. Expenses of the Issue

Not applicable.

Item 10. Additional Information

10.A. Share Capital

Not applicable.

10.B. Memorandum and Articles of Association

The information in response to this item is contained under the caption “10.B Memorandum and Articles of Association” in our registration statement filed with the SEC on January 25, 2019 and is incorporated herein by reference.

10.C. Material Contracts

For a description of our material contracts, please see “Item 4. Information on the Company—B. Business Overview—Material Agreements.”

10.D. Exchange Controls

There are no governmental laws, decrees, regulations or other legislation in the United Kingdom that may affect the import or export of capital, including the availability of cash and cash equivalents for use by Mereo, or that may affect the remittance of dividends, interest, or other payments by Mereo to non-resident holders of our ordinary shares or ADSs, other than withholding tax requirements. There is no limitation imposed by English law or in the Articles on the right of non-residents to hold or vote shares.

10.E. Taxation

Material U.S. Federal Income Tax Considerations

The following are material U.S. federal income tax consequences to the U.S. Holders (as defined below) of purchasing, owning and disposing of the ADSs and ordinary shares, but it does not purport to be a comprehensive description of all tax considerations that may be relevant to a particular person’s circumstances. This discussion applies only to a U.S. Holder that holds the ADSs or ordinary shares as capital assets for U.S. federal income tax purposes. In addition, it does not describe all of the tax consequences that may be relevant in light of the U.S. Holder’s particular circumstances, including any estate, gift, alternative minimum or Medicare contribution tax consequences and any tax consequences applicable to U.S. Holders subject to special rules, such as:

- banks, insurance companies and other financial institutions;
- real estate investment trusts or regulated investment companies;
- dealers or traders in securities that use a mark-to-market method of tax accounting;

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- persons holding our ADSs or ordinary shares as part of a straddle, integrated transaction or similar transaction;
- persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- entities or arrangements treated as partnerships for U.S. federal income tax purposes and their partners or investors;
- tax-exempt entities, “individual retirement accounts” or “Roth IRAs”;
- S corporations;
- former citizens or residents of the United States;
- a person that is subject to special tax accounting rules under section 451(b) of the U.S. Internal Revenue Code of 1986, as amended (the “Code”);
- persons that own or are deemed to own 10% or more of our stock by vote or value; or
- persons holding our ADSs or ordinary shares in connection with a trade or business outside the United States.

If a partnership (or other entity that is classified as a partnership for U.S. federal income tax purposes) owns the ADSs or ordinary shares, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partner and the partnership. Partnerships owning the ADSs or ordinary shares and partners in such partnerships should consult their tax advisers as to the particular U.S. federal income tax consequences of owning and disposing of the ADSs or ordinary shares.

Persons that own or are deemed to own 10% or more of our stock by vote or value should consult their tax advisers regarding the application of the “controlled foreign corporation” rules to their ownership of our ADSs or ordinary shares.

This discussion is based on the Code, administrative pronouncements, judicial decisions, and final, temporary and proposed Treasury regulations, all as of the date hereof, any of which is subject to change, possibly with retroactive effect.

As used herein, a “U.S. Holder” is a person that, for U.S. federal income tax purposes, is a beneficial owner of our ADSs or ordinary shares and is:

- a citizen or individual resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust that (i) is subject to the primary supervision of a court within the United States and subject to the control of one or more U.S. persons for all substantial decisions or (ii) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

U.S. Holders should consult their tax advisers concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of our ADSs or ordinary shares in their particular circumstances.

For U.S. federal income tax purposes, a beneficial owner of our ADSs generally will be treated as the owner of the underlying ordinary shares represented by such ADSs. Accordingly, gain or loss will generally not be recognized if a U.S. Holder exchanges our ADSs for the underlying ordinary shares.

Passive Foreign Investment Company Rules

Special U.S. tax rules apply to U.S. Holders of stock in companies that are considered to be PFICs. In general, a non-U.S. corporation will be a passive foreign investment company (“PFIC”) for any taxable year in which (i) 75% or more of its gross income consists of passive income (the “income test”) or (ii) 50% or more of the value of its assets (generally determined on a quarterly average basis) consists of assets that produce, or are held for the production of, passive income (the “asset test”). For purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its

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proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes interest, dividends, gains from certain property transactions, rents and royalties (other than certain rents or royalties derived in the active conduct of a trade or business). Cash is a passive asset for PFIC purposes. Goodwill (the value of which may be determined by reference to the company's market capitalization) is treated as an active asset to the extent attributable to activities intended to produce active income.

Based on our gross income, the average value of our assets, including goodwill, and the nature of the current stage of our business, we believe we were a PFIC for the year ended December 31, 2019. There can be no assurance regarding our PFIC status for the current taxable year or any particular year in the future because PFIC status is factual in nature, depends upon factors not wholly within our control, generally cannot be determined until the close of the taxable year in question and is determined annually. Accordingly, U.S. Holders should invest in our ADSs only if they are willing to bear the U.S. federal income tax consequences associated with investments in PFICs.

We provide the information necessary for a U.S. Holder to make a qualifying electing fund election ("QEF Election") with respect to us and we will also use our best efforts to cause each Lower-tier PFIC (as defined below) that we control to provide such information. We intend to provide this information for any taxable year during which our only income is interest income or income from financial investments and for any other taxable year for which we determine that we were a PFIC. However, no assurance can be given that such QEF information will be available for any Lower-tier PFIC that we do not wholly-own. We will post the information necessary to make QEF Elections on our website. If we are a PFIC for any taxable year, the consequences to any U.S. Holder will depend in part on whether the U.S. Holder makes a valid QEF Election or mark-to-market election as described below.

If we are a PFIC for any taxable year and any of our non-U.S. subsidiaries or other companies in which we own equity interests were also a PFIC (any such entity, a "Lower-tier PFIC"), U.S. Holders would be deemed to own a proportionate amount (by value) of the shares of each Lower-tier PFIC and would be subject to U.S. federal income tax according to the rules described in the subsequent paragraph on (i) certain distributions by a Lower-tier PFIC and (ii) dispositions of shares of Lower-tier PFICs, in each case as if the U.S. Holders held such shares directly, even though the U.S. Holders had not received the proceeds of those distributions or dispositions.

Generally, if we were a PFIC for any taxable year during which a U.S. Holder holds our ADSs or ordinary shares and the U.S. Holder does not make a valid QEF Election or a mark-to-market election (described below), gain recognized upon a disposition (including, under certain circumstances, a pledge) of our ADSs or ordinary shares by the U.S. Holder will be allocated ratably over the U.S. Holder's holding period for such ADSs or ordinary shares. The amounts allocated to the taxable year of disposition and to years before we became a PFIC will be taxed as ordinary income. The amount allocated to each other taxable year will be subject to tax at the highest rate in effect for that taxable year for individuals or corporations, as appropriate, and an interest charge will be imposed on the resulting tax liability for each relevant taxable year. Further, to the extent that any distribution received by a U.S. Holder on our ADSs or ordinary shares exceeds 125% of the average of the annual distributions received on such securities during the preceding three years or the U.S. Holder's holding period, whichever is shorter (an "excess distribution"), such excess distribution will be subject to taxation in the same manner. If we are a PFIC for any taxable year during which a U.S. Holder owns our ADSs or ordinary shares, we will generally continue to be treated as a PFIC with respect to such U.S. Holder for all succeeding years during which such U.S. Holder owns our ADSs or ordinary shares, even if we cease to meet the threshold requirements for PFIC status. If we are a PFIC for any taxable year but cease to be PFIC for subsequent years, U.S. Holders should consult their tax advisers regarding the advisability of making a "deemed sale" election that would allow them to eliminate the continuing PFIC status under certain circumstances.

To avoid the foregoing rules, a U.S. Holder can make a QEF Election to treat us and each Lower-tier PFIC as a qualified electing fund in the first taxable year that the entity is treated as a PFIC with respect to the U.S. Holder. A U.S. Holder must make the QEF Election for each PFIC by attaching a separate properly completed IRS Form 8621 for that PFIC to the U.S. Holder's timely filed U.S. federal income tax return. A U.S. Holder making a QEF election other than for the first taxable year in which it owns (or is treated as owning) an equity interest in a PFIC would continue to be subject to the rules described in the preceding paragraph with respect to such PFIC, unless the U.S. Holder makes a "deemed sale" election with respect to the PFIC and recognizes gain taxed under the general PFIC rules described above with respect to the PFIC stock's appreciation before the year for which the QEF Election is made.

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If a U.S. Holder makes a QEF Election with respect to a PFIC, the U.S. Holder will be taxed on its *pro rata* share of the PFIC's ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is a PFIC. If a U.S. Holder makes a QEF Election with respect to us, any distributions we pay out of our earnings and profits that were previously included in the U.S. Holder's income under the QEF Election would not be taxable to the U.S. Holder. A U.S. Holder will increase its tax basis in its ADSs or ordinary shares by an amount equal to any income included under the QEF Election and will decrease its tax basis by any amount distributed on the ADSs or ordinary shares that is not included in the U.S. Holder's income. In addition, a U.S. Holder will recognize capital gain or loss on the disposition of ADSs or ordinary shares in an amount equal to the difference between the amount realized and the U.S. Holder's adjusted tax basis in the ADSs or ordinary shares, as determined in U.S. dollars. A U.S. Holder will not be taxed on the ordinary income and net capital gain under the QEF rules for any year that we are not a PFIC.

Based on the nature of our expected income, the expected composition of our assets, and our business prospects, we do not currently expect to have significant ordinary earnings or net capital gain in any taxable year in which we may be a PFIC. However, it is difficult to predict the nature and composition of our income and assets and the value of our assets in light of the volatile nature of earnings patterns of emerging pharmaceutical or biotechnology companies such as us. Accordingly, U.S. Holders should note that if they make QEF Elections with respect to us and our subsidiaries, they may be required to pay U.S. federal income tax with respect to their ADSs or ordinary shares for any taxable year in which we have a positive amount of earnings or net capital gains even if we do not make any distributions in such year. U.S. Holders should consult their tax advisers regarding the advisability of making QEF Elections in their particular circumstances.

Alternatively, if we are a PFIC for any taxable year and if our ADSs or ordinary shares are "regularly traded" on a "qualified exchange," a U.S. Holder could make a mark-to-market election that will result in tax treatment different from the general tax treatment described in the two preceding paragraphs. Our ADSs and/or ordinary shares will be treated as "regularly traded" in any calendar year in which more than a *de minimis* quantity of the ADSs and/or ordinary shares are traded on a qualified exchange on at least 15 days during each calendar quarter. NASDAQ, on which the ADSs are listed, is a qualified exchange for this purpose. The Internal Revenue Service has not identified specific non-U.S. exchanges that are "qualified" for this purpose. If a U.S. Holder makes a valid mark-to-market election, the U.S. Holder generally will recognize as ordinary income any excess of the fair market value of its ADSs or ordinary shares at the end of each taxable year over the adjusted tax basis of such ADSs or ordinary shares, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of its ADSs or ordinary shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder's tax basis in our ADSs or ordinary shares will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of our ADSs or ordinary shares in a year in which we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a valid mark-to-market election is made for any year in which we are a PFIC, distributions will be treated as described below under "—Taxation of Distributions" except that the preferential tax rates on dividends paid to non-corporate U.S. Holders will not apply. U.S. Holders will not be able to make a mark-to-market election with respect to Lower-tier PFICs, if any. U.S. Holders should consult their tax advisers as to the availability and desirability of a mark-to-market election in their particular circumstances if we are a PFIC for any taxable year.

If a U.S. Holder owns our ADSs or ordinary shares during any year in which we are a PFIC, the U.S. Holder generally will be required to file annual reports on IRS Form 8621 (or any successor form) with respect to us and any Lower-tier PFIC, generally with the U.S. Holder's U.S. federal income tax return for that year. U.S. Holders should consult their tax advisers regarding our PFIC status for any taxable year and the potential application of the PFIC rules to an investment in our ADSs or ordinary shares.

Taxation of Distributions

This discussion under "—Taxation of Distributions" is subject to the PFIC rules described in "—Passive Foreign Investment Company Rules" above. Distributions paid on ADSs or ordinary shares, other than certain pro

rata distributions of our ordinary shares, will be treated as dividends to the extent paid out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of our current and accumulated earnings and profits will be treated first as a tax-free return of capital to the extent of the U.S. Holder's basis in the ADSs or ordinary shares and then as capital gain. For any taxable year in which we do not maintain calculations of our earnings and profits under U.S. federal income tax principles, it is expected that any distributions generally will be reported to U.S. Holders as dividends. Dividends will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be eligible for taxation at a preferential tax rate provided that we were not a PFIC for the taxable year in which the dividend is paid or the prior taxable year. Non-corporate U.S. Holders should consult their tax advisers regarding the availability of this preferential rate in the light of the discussion in "—Passive Foreign Investment Company Rules" above and in their particular circumstances.

If dividend payments in respect of our ADSs or ordinary shares are made in a currency other than the U.S. dollar, the amount of the dividend distribution that a U.S. Holder must include in income will be the U.S. dollar value of the payments made in such other currency, determined at the spot U.S. dollar exchange rate on the date the dividend distribution is includible in income, regardless of whether the payment is in fact converted into U.S. dollars. Generally, if the foreign currency received as a dividend is not converted into U.S. dollars on the date of receipt, any gain or loss resulting from currency exchange fluctuations during the period from the date the dividend payment is includible in income to the date the payment is actually converted into U.S. dollars will be treated as ordinary income or loss and will not be eligible for the special tax rate applicable to qualified dividend income. The gain or loss generally will be income or loss from sources within the United States for foreign tax credit limitation purposes. U.S. Holders are urged to consult their tax advisers regarding the tax consequences of receiving, converting or disposing of any non-U.S. currency, received or deemed received as dividends on our ADSs or ordinary shares or on the sale or retirement of an ADS or an ordinary share.

Dividends will be included in a U.S. Holder's income on the date of the U.S. Holder's, or in the case of our ADSs, the depositary's, receipt. Dividends generally will be income from non-U.S. sources, which may be relevant in calculating a U.S. Holder's foreign tax credit limitation. Subject to certain conditions and limitations, non-U.S. tax withheld, if any, on dividends may be deducted from such U.S. Holder's taxable income or credited against such U.S. Holder's U.S. federal income tax liability. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends that we distribute generally should constitute "passive category income," or, in the case of certain U.S. Holders, "general category income." A foreign tax credit for foreign taxes imposed on distributions may be denied if a U.S. Holder does not satisfy certain minimum holding period requirements. The rules relating to the determination of the foreign tax credit are complex, and U.S. Holders are urged to consult their tax advisers to determine whether and to what extent such U.S. Holder will be entitled to a foreign tax credit.

Sale or Other Taxable Disposition

Except as described under "—Passive Foreign Investment Company Rules" above, a U.S. Holder will generally recognize capital gain or loss on a sale or other taxable disposition of our ADSs or ordinary shares in an amount equal to the difference between the amount realized on the sale or disposition and the U.S. Holder's tax basis in the ADSs or ordinary shares disposed of, in each case as determined in U.S. dollars. A U.S. Holder's initial tax basis in the ordinary shares or ADSs will generally equal the cost of such ordinary shares or ADSs. If a U.S. Holder used foreign currency to purchase the ordinary shares or ADSs, the cost of the ordinary shares or ADSs will be the U.S. dollar value of the foreign currency purchase price on the date of purchase, translated at the spot rate of exchange on that date. Any such gain or loss will be long-term capital gain or loss if at the time of the sale or disposition the U.S. Holder has owned our ADSs or ordinary shares for more than one year. Long-term capital gains recognized by non-corporate U.S. Holders may be subject to a tax rate that is lower than the rate applicable to ordinary income. The deductibility of capital losses is subject to limitations. Any capital gain or loss recognized upon the sale or disposition of ADSs or ordinary shares will generally be treated as U.S.-source income for foreign tax credit limitation purposes. U.S. Holders that sell the ADSs or ordinary shares for an amount denominated in a currency other than the U.S. dollar should consult their tax advisers regarding any potential foreign currency gain or loss that may have to be recognized.

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Information Reporting and Backup Withholding

In general, payments of dividends and proceeds from the sale or other disposition of our ADSs or ordinary shares that are made within the United States or through certain U.S.-related financial intermediaries may be subject to information reporting and backup withholding, unless (i) in the case of information reporting, the U.S. Holder is a corporation or other “exempt recipient” and (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding. Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the U.S. Holder’s U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

Information with Respect to Foreign Financial Assets

Certain U.S. Holders who are individuals (or certain specified entities) may be required to report information relating to their ownership of our ADSs or ordinary shares, or non-U.S. accounts through which our ADSs or ordinary shares are held, subject to certain exceptions. Penalties and potential other adverse tax consequences may be imposed if a U.S. Holder is required to submit such information to the IRS and fails to do so. U.S. Holders should consult their tax advisers regarding their reporting obligations with respect to our ADSs or ordinary shares.

Material United Kingdom Tax Considerations

The following is a description of the material U.K. tax considerations relating primarily to the ownership and disposal of our ADSs by the U.S. Holders described above. The U.K. tax comments set out below are based on current U.K. tax law as applied in England and Wales, and HMRC practice (which may not be binding on HMRC) as at the date of this summary, both of which are subject to change, possibly with retrospective effect. They are intended as a general guide and, save where otherwise stated, only apply to you if you are not resident in the U.K. for U.K. tax purposes and do not hold our ADSs for the purposes of a trade, profession or vocation that you carry on in the U.K. through a branch, agency or permanent establishment in the U.K. and if you hold our ADSs as an investment for U.K. tax purposes and are not subject to special rules.

This summary does not address all possible tax consequences relating to an investment in our ADSs. In particular it does not cover the U.K. inheritance tax consequences of holding our ADSs. It assumes that DTC has not made an election under section 97A(1) of the Finance Act 1986. It assumes that we do not (and will not at any time) derive 75% or more of our qualifying asset value, directly or indirectly, from U.K. land, and that we are and remain solely resident in the U.K. for tax purposes. This summary is for general information only and is not intended to be, nor should it be considered to be, legal or tax advice to any particular holder. Holders of our ADSs are strongly urged to consult their tax advisers in connection with the U.K. tax consequences of their investment in our ADSs.

U.K. Taxation of Dividends

Mereo will not be required to withhold amounts for or on account of U.K. tax at source when paying a dividend in respect of its ordinary shares.

Holders who hold our ADSs as an investment, who are not resident in the U.K. for U.K. tax purposes and who do not hold their ADSs in connection with any trade, profession or vocation carried on by them in the U.K. through a branch, agency or permanent establishment in the U.K. should not be subject to U.K. tax in respect of any dividends on our ordinary shares.

U.K. Taxation of Capital Gains

An individual holder who is not resident in the U.K. for U.K. tax purposes should not be liable to U.K. capital gains tax on capital gains realized on the disposal of their ADSs unless such holder carries on a trade, profession or vocation in the U.K. through a branch or agency in the U.K. to which ADSs are attributable.

Any such individual holder of our ADSs who is temporarily non-resident for U.K. tax purposes will, in certain circumstances, become liable to U.K. tax on capital gains in respect of gains realized while they were not resident in the U.K.

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A corporate holder of our ADSs which is not resident in the U.K. for U.K. tax purposes should not be liable for U.K. corporation tax on chargeable gains realized on the disposal of our ADSs unless it carries on a trade in the U.K. through a permanent establishment in the U.K. to which our ADSs are attributable.

Stamp Duty and Stamp Duty Reserve Tax

The following statements apply to all holders, regardless of their jurisdiction of tax residence.

It is assumed for the purposes of the following statements that all transfers or, or agreements to transfer, our ordinary shares are only made at times when (i) our ordinary shares are admitted to trading on AIM but are not listed on any market (with the term “listed” being construed in accordance with section 99A of the Finance Act 1986); and (ii) AIM continues to be accepted as a “recognized growth market” (as construed in accordance with section 99A of the Finance Act 1986). Holders of our ADSs who propose to transfer, or agree to transfer, our ordinary shares during such time as these conditions are not met (including during any period between the creation and issue of our ADSs and the admission to trading of our ordinary shares on AIM) are strongly urged to obtain their own advice.

No stamp duty is payable on the issue of our ordinary shares into a depository receipt system (such as, Mereo understands, that operated by Citibank) or a clearance service (such as, Mereo understands, DTC). No stamp duty reserve tax (“SDRT”) should be payable on the issue of our ordinary shares into a depository receipt system or a clearance service. Accordingly, no stamp duty or SDRT should be payable on the creation and issue of our ADSs pursuant to the issue of our ordinary shares to Citibank’s custodian.

No stamp duty or SDRT should be payable on transfers of, or agreements to transfer, our ordinary shares into a depository receipt system or a clearance service.

No SDRT or stamp duty should be payable on paperless transfers of, or agreements to transfer, our ADSs through the facilities of DTC.

No stamp duty should be payable on a written instrument transferring, or a written agreement to transfer, our ADSs provided the instrument or agreement is executed and remains at all times outside the U.K. No SDRT should be payable in respect of agreements to transfer our ADSs.

No stamp duty or SDRT should be payable on transfers of, or agreements to transfer, our ordinary shares outside of a depository receipt system or a clearance service.

10.F. Dividends and Paying Agents

Not applicable.

10.G. Statement by Experts

Not applicable.

10.H. Documents on Display

We are subject to certain of the information reporting requirements of the Exchange Act. As a foreign private issuer, we are exempt from the rules and regulations under the Exchange Act prescribing the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act, with respect to their purchase and sale of our shares. In addition, we are not required to file reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we are required to file with the SEC, within four months after the end of each fiscal year, an annual report on Form 20-F containing financial statements audited by an independent accounting firm. We publish unaudited interim financial information after the end of each quarter. We furnish this quarterly financial information to the SEC under cover of a Form 6-K.

The SEC maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The address of this website is <http://www.sec.gov>. The company’s website is www.mereobiopharma.com.

10.I. Subsidiary Information

Not applicable.

Item 11. Quantitative And Qualitative Disclosures About Market Risk

We are exposed to a variety of financial risks. Our overall risk management program seeks to minimize potential adverse effects of these financial risks on our financial performance. Further information relating to quantitative and qualitative disclosures about market risk can be found within Note 25 (Financial and capital risk management and fair value measurement) of our annual financial statements, incorporated by reference into this document.

Interest Rate Risk

We manage interest rate risk by monitoring short and medium-term interest rates and placing cash on deposit for periods that optimize the amount of interest earned while maintaining access to sufficient funds to meet day-to-day cash requirements. We have a committed borrowing facility in an amount of £20.5 million which was fully drawn as of the date of this annual report. Loans under the credit facility bear interest at a fixed rate of 8.5% per annum. Consequently, there is no material exposure to interest rate risk in respect of interest payable.

Credit Risk

We consider all of our material counterparties to be creditworthy. We consider the credit risk for each of our major counterparties to be low. We are, however, dependent on a number of third parties for the delivery of our programs and, in addition, where appropriate we pay upfront deposits and fees in advance of the delivery of services where required. We continue to assess credit risk as part of its management of these third-party relationships.

Liquidity Risk

We manage our liquidity risk by maintaining adequate cash reserves at banking facilities and invested in short term money market accounts, and by continuously monitoring our cash forecasts, our actual cash flows and by matching the maturity profiles of financial assets and liabilities.

Foreign Currency Risk

Foreign currency risk reflects the risk that the value of a financial commitment or recognized asset or liability will fluctuate due to changes in foreign currency rates. The majority of our operating costs are denominated in pound sterling, Euros, and U.S. dollars. Our financial position, as expressed in pound sterling, is exposed to movements in foreign exchange rates, principally against the Euro and U.S. dollar.

We are exposed to foreign currency risk as a result of operating transactions, translation of foreign currency bank accounts and short-term deposits as well as funding arrangements with our subsidiary.

In addition, the assets and liabilities of our subsidiaries are translated into pound sterling at exchange rates in effect at each balance sheet date and operations accounts are translated using the average exchange rate for the relevant period (where the functional currency of the subsidiary is not pound sterling). Foreign currency translation adjustments are accounted for as a component of comprehensive income and reflected in the foreign exchange translation reserve and in comprehensive income on the statement of changes in equity.

We monitor our exposure to foreign exchange risk. We have not entered into foreign exchange contracts to hedge against foreign exchange fluctuations but maintain cash and investments in U.S. dollars to cover anticipated forward commitments. For the year ended December 31, 2019, we recorded a net foreign exchange gain of £0.5 million, compared to a £0.04 million loss for the year ended December 31, 2018.

Item 12. Description of Securities Other Than Equity Securities

12.A. Debt Securities

Not applicable.

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12.B. Warrants and Rights

Not applicable.

12.C. Other Securities

Not applicable.

12.D. American Depositary Shares

Fees and Charges

As an ADS holder, you will be required to pay the following fees under the terms of the deposit agreement:

<u>Service</u>	<u>Fee</u>
Issuance of ADSs (e.g., an issuance of ADS upon a deposit of ordinary shares or upon a change in the ADS(s)-to-ordinary shares ratio), excluding ADS issuances as a result of distributions of ordinary Shares	Up to \$5.00 per 100 ADSs (or fraction thereof) issued
Cancellation of ADSs (e.g., a cancellation of ADSs for delivery of deposited property or upon a change in the ADS(s)-to-ordinary shares ratio)	Up to \$5.00 per 100 ADSs (or fraction thereof) cancelled
Distribution of cash dividends or other cash distributions (e.g., upon a sale of rights and other entitlements)	Up to \$5.00 per 100 ADSs (or fraction thereof) held
Distribution of ADSs pursuant to (i) stock dividends or other free stock distributions, or (ii) exercise of rights to purchase additional ADSs	Up to \$5.00 per 100 ADSs (or fraction thereof) held
Distribution of securities other than ADSs or rights to purchase additional ADSs (e.g., upon a spin-off)	Up to \$5.00 per 100 ADSs (or fraction thereof) held
ADS Services	Up to \$5.00 per 100 ADSs (or fraction thereof) held on the applicable record date(s) established by the depositary
Registration of ADS Transfers (e.g., upon a registration of the transfer of registered ownership of ADSs, upon a transfer of ADSs into DTC and vice versa, or for any other reason)	Up to \$5.00 per 100 ADSs (or fraction thereof) transferred
Conversion of ADSs of one series for ADSs of another series (e.g., upon conversion of Partial Entitlement ADSs for Full Entitlement ADSs, or upon conversion of Restricted ADSs (each as defined in the Deposit Agreement) into freely transferable ADSs, and vice versa)	Up to \$5.00 per 100 ADSs (or fraction thereof) converted

As an ADS holder you will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary, or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex, and facsimile transmission and delivery expenses;
- the expenses and charges incurred by the depositary in the conversion of foreign currency;
- the fees and expenses incurred by the depositary in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs, and ADRs; and
- the fees, charges, costs and expenses incurred by the depositary, the custodian, or any nominee in connection with the ADR program.

ADS fees and charges payable upon (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person to whom the ADSs are issued (in the case of ADS issuances) and to the person whose ADSs are cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of

the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs. In the case of (i) registration of ADS transfers, the ADS transfer fee will be payable by the holders of ADSs whose ADSs are being transferred or by the person to whom the ADSs are transferred, and (ii) conversion of ADSs of one series for ADSs of another series, the ADS conversion fee will be payable by the holder whose ADSs are converted or by the person to whom the converted ADSs are delivered.

In the event of refusal to pay the depositary fees, the depositary may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees from any distribution to be made to the ADS holder. Certain of the depositary fees and charges (such as the ADS services fee) may become payable shortly after the closing of the ADS offering. Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary. You will receive prior notice of such changes. The depositary may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary agree from time to time.

PART TWO

Item 13. Defaults, Dividend Arrearages And Delinquencies

None.

Item 14. Material Modifications To The Rights Of Security Holders And Use Of Proceeds

A.-D. Material Modifications to the Rights of Security Holders

On April 23, 2019, pursuant to the terms of the Merger Agreement, OncoMed merged with and into an indirect wholly-owned subsidiary of Mereo. Upon completion of the Merger, each OncoMed common stock was cancelled and converted into the right to receive (1) 0.127694 ADSs, representing five ordinary shares in the capital of Mereo, as determined by the exchange ratio set forth in the Merger Agreement, and (2) one contingent value right, representing the right to receive contingent consideration upon the achievement of certain milestones relating to certain OncoMed products or product candidates. Accordingly, the shares became governed by Mereo's Articles. See "Item 10. Additional Information—B. Memorandum and Articles of Association." On April 24, 2019, our ADSs were listed on Nasdaq under the symbol of "MREO".

E. Use of Proceeds

Not applicable.

Item 15. Controls And Procedures

(a) Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act and regulations promulgated thereunder) as of December 31, 2019, or the Evaluation Date. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the Evaluation Date, our disclosure controls and procedures were effective in recording, processing, summarizing and reporting, on a timely basis, information required to be included in periodic filings under the

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Exchange Act and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

(b) Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in “Internal Control – Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on this assessment, our management concluded that, as of December 31, 2019, our internal control over financial reporting was effective.

(c) Attestation Report of the Registered Public Accounting Firm

Not applicable.

(d) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this annual report that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit Committee Financial Expert

Our board has determined that Mr. Paul Blackburn qualifies to serve as an “audit committee financial expert” as defined under the SEC rules, and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations. Mr. Paul Blackburn also qualifies as an independent director under the corporate governance standards of the Nasdaq listing requirements and the audit committee independence requirements of Rule 10A-3 of the Exchange Act. For more information see “Item 6. Directors, Senior Management and Employees—C. Board Practices—Committees of the Mereo Board—Audit and Risk Committee.”

Item 16B. Code of Ethics

Code of Business Conduct and Ethics and Anti-Bribery and Anti-Corruption Policy

We have adopted a Code of Business Conduct and Ethics and an Anti-Bribery and Anti-Corruption Policy applicable to all of our directors, executive officers and employees, including our Chief Executive Officer, Chief Financial Officer, controller or principal accounting officer, or other persons performing similar functions, which is a code of ethics as defined in Item 16B of Form 20-F promulgated by the SEC. The full text of the Code of Business Conduct and Ethics and the Anti-Bribery and Anti-Corruption Policy can be found on our website at www.mereobiopharma.com. Information contained on, or that can be accessed through, our website does not constitute a part of this report and is not incorporated by reference herein. If we make any amendment to the Code of Business Conduct and Ethics or the Anti-Bribery and Anti-Corruption Policy or grant any waivers, including any implicit waiver, from a provision of the code of ethics, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC. Under Item 16B of Form 20-F, if a waiver or amendment of the Code of Business Conduct and Ethics applies to our principal executive officer, principal financial officer, principal accounting officer or controller and relates to standards promoting any of the values described in Item 16B(b) of Form 20-F, we are required to disclose such waiver or amendment on our website in accordance with the requirements of Instruction 4 to such Item 16B.

Item 16C. Principal Accountant Fees and Services

Our consolidated financial statements have been prepared in accordance with IFRS and were audited by Ernst & Young LLP, our independent registered public accounting firm registered with the Public Company Accounting Oversight Board in the United States.

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Ernst & Young LLP, has served as our independent registered public accounting firm for each of the two years ended December 31, 2018 and 2019, for which audited financial statements appear in this annual report.

The following table provides information regarding fees paid by us to Ernst & Young LLP for all services, for the years ended December 31, 2018 and 2019:

	Year Ended December 31,	
	2018	2019
	(in thousands of pounds)	
Audit fees(1)	353	559
Audit related fees(2)	171	311
Other fees	10	—
Total fees	<u>534</u>	<u>870</u>

(1) Includes professional services rendered in connection with the audit of our annual financial statements, review of our interim financial statements and audits of our subsidiary accounts.

(2) Includes professional services rendered in connection with planned equity fundraising and the acquisition of OncoMed.

Audit Committee Pre-Approval Policies and Procedures

Our audit committee's specific responsibilities in carrying out its oversight of the quality and integrity of the accounting, auditing and reporting practices of Mereo include the approval of audit and non-audit services to be provided by the independent auditor before the auditor is engaged to render such services. The audit committee approves in advance the particular services or categories of services to be provided to Mereo during the following yearly period and also sets forth a specific budget for such audit and non-audit services. Additional non-audit services may be pre-approved by the audit committee.

Item 16D. Exemptions From The Listing Standards For Audit Committees

None.

Item 16E. Purchases of Equity Securities By The Issuer And Affiliated Purchasers

In the year ending December 31, 2019, Mereo purchased 1,074,274 ordinary shares into Treasury through an Employee Benefit Trust ("EBT"). As at December 31, 2019 a total balance of £21,762 was held by EBT. Mereo utilizes the EBT to buy shares at nominal value from Mereo in sufficient quantity to fulfill awards made under the Mereo Share Plans.

In the year ending December 31, 2018, Mereo purchased 163,000 ordinary shares into Treasury through an Employee Benefit Trust ("EBT"). As at December 31, 2018 a total balance of £21,762 was held by EBT. Mereo utilizes the EBT to buy shares at nominal value from Mereo in sufficient quantity to fulfill awards made under the Mereo Share Plans.

	Total Number of Ordinary Shares Purchased(1)	Average Price Paid Per Ordinary Share	Total Number of Ordinary Shares Purchased as Part of Publicly Announced Plans or Programs(2)	Maximum Number of Ordinary Shares that May Yet Be Purchased Under the Plans or Programs
Month #1 (October 1, 2018 – October 31, 2018)	131,487	£ 1.90	—	—
Month #2 (December 1, 2018 – December 31, 2018)	31,513	£ 1.80	—	—
Month #3 (May 1, 2019 – May 31, 2019)	1,074,274	£ 0.93	—	—
Total	<u>1,237,274</u>	<u>£ 1.88</u>	<u>—</u>	<u>—</u>

(1) On June 4, 2020, Mereo purchased 7 ordinary shares into Treasury through an EBT.

(2) The ordinary shares were not purchased as part of a publicly announced plan or program

Item 16F. Change In Registrant's Certifying Accountant

None.

Item 16G. Corporate Governance

Foreign Private Issuer Exemption

As a "foreign private issuer," as defined by the SEC, Mereo is permitted to follow home country corporate governance practices, instead of certain corporate governance practices required by Nasdaq for U.S. domestic issuers. While Mereo intends to follow most Nasdaq corporate governance rules, it intends to follow U.K. corporate governance practices in lieu of Nasdaq corporate governance rules as follows:

- Mereo does not intend to follow Nasdaq Rule 5620(c) regarding quorum requirements applicable to meetings of shareholders. Such quorum requirements are not required under English law. In accordance with generally accepted business practice, Mereo's Articles provide alternative quorum requirements that are generally applicable to meetings of shareholders.
- Mereo does not intend to follow Nasdaq Rule 5605(b)(2), which requires that independent directors regularly have scheduled meetings at which only independent directors are present.
- Mereo does not intend to follow Nasdaq Rule 5635, which generally requires an issuer to seek shareholder approval in connection with certain private placements of equity securities. Mereo intends to follow U.K. law with respect to any requirement to obtain shareholder approval prior to any private placements of equity securities.

Although Mereo may rely on certain home country corporate governance practices, Mereo must comply with Nasdaq Rule 5640 Notification of Noncompliance and Rule 5640 Voting Rights. Further, Mereo must have an audit committee that satisfies Rule 5605(c)(3), which addresses audit committee responsibilities and authority, and that consists of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii).

Mereo intends to take all actions necessary for it to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act of 2002, the rules adopted by the SEC and the Nasdaq corporate governance rules and listing standards.

Because Mereo is a foreign private issuer, Mereo's directors and senior management are not subject to short-swing profit and insider trading reporting obligations under Section 16 of the Exchange Act. Mereo will, however, be subject to the obligations to report changes in share ownership under Section 13 of the Exchange Act and related SEC rules.

Compliance with the Quoted Companies Alliance Corporate Governance Code

All companies with securities admitted to trading on AIM are required to include on their website details of a recognized corporate governance code that the board of directors of the company has decided to apply, how the company complies with that code, and where it departs from its chosen corporate governance code an explanation of the reasons for doing so. This information is required to be reviewed annually.

Mereo applies the Corporate Governance Code published by the Quoted Companies Alliance (the “QCA Code”). The QCA Code sets out a standard of minimum best practice for small and midsize quoted companies in the U.K.

Mereo Shareholder Rights Under U.K. Law

The rights of the holders of our ordinary shares are governed by the laws of England and Wales and Mereo’s Articles. The rights of a holder of our ADSs are also be governed by the deposit agreement.

Purchase and Redemption Rights

Under the U.K. Companies Act 2006, a public limited company may issue redeemable shares if authorized by its articles of association, subject to any conditions stated therein. No redeemable shares may be issued at a time when there are no issued shares of the company existing which are not redeemable.

Under the U.K. Companies Act 2006, a company may redeem shares only if the shares are fully paid and, in the case of public limited companies, only out of: (1) distributable profits; or (2) the proceeds of a new issue of shares made for the purpose of such redemption.

Preemptive Rights

Under the U.K. Companies Act 2006, the issuance of “equity securities” (being (1) shares in a company other than shares that, with respect to dividends and capital, carry a right to participate only up to a specified amount in a distribution or (2) rights to subscribe for, or to convert securities into, such shares) that are to be paid for wholly in cash must be offered first to the existing holders of Mereo Shares in proportion to the respective nominal values (i.e., par values) of their holdings on the same or more favorable terms, unless an exception applies or a special resolution to the contrary has been passed or the articles of association otherwise provide, in each case in accordance with the provisions of the U.K. Companies Act 2006 and Mereo’s Articles. An exclusion of pre-emptive rights can be granted for a maximum of five years from the date that Mereo’s directors are granted authority to allot the relevant Mereo ordinary shares, after which shareholders’ approval would be required to renew such exclusion.

Inspection Rights

Under English law, a company must retain and keep available for inspection by shareholders, free of charge, and by any other person on payment of a prescribed fee, its register of members. It must also keep available for inspection by shareholders, free of charge, records of all resolutions passed by and minutes of meetings of shareholders for a period of at least ten years from the date of the relevant resolution or meeting, and for a fee, provide copies of such records to shareholders who request them.

Appraisal Rights

There is no mandatory provision in English law for appraisal rights. Such rights could, in theory, be provided for in the articles of association or in a shareholders’ agreement. Mereo’s Articles do not provide for appraisal/dissenters’ rights. However, English law provides dissenters’ rights which would permit a shareholder to object to a court of England and Wales in the context of the compulsory acquisition of minority shares.

Votes on Certain Transactions

The U.K. Companies Act 2006 provides for schemes of arrangement, which are arrangements or compromises between a company and any class of shareholders or creditors and used in certain types of reconstructions, amalgamations, capital reorganizations or takeovers. These arrangements require: (1) the approval, at a shareholders’ or creditors’ meeting convened by order of a court of England and Wales, of a majority in number representing 75% in value of the creditors or class of creditors or members or class of members (as the case may be) present and voting, either in person or by proxy; and (2) the approval of a court of England and Wales.

Amendment of Corporate Governance Documents

Under the U.K. Companies Act 2006, a company incorporated in England and Wales may amend its articles of association by way of a special resolution.

Shareholder Action by Written Consent

Under the U.K. Companies Act 2006, a resolution of the members (or of a class of members) of a public company must be passed at a general meeting of the members. Written resolutions are not permitted.

Notwithstanding the foregoing: (1) English law currently provides that certain matters could be effected by a company otherwise than by passing a resolution where it can be shown that all shareholders of that company have provided unanimous informed consent to the relevant matter; and (2) under the U.K. Companies Act 2006, rights attached to a class of the company's shares may, where the company's articles contain no provision for the variation of the relevant rights, be carried by consent in writing from the holders of at least three-quarters in nominal value of the issued shares of that class.

Shareholder Meetings

The U.K. Companies Act 2006 requires that a public limited company, such as Mereo, must convene an annual general meeting within six months following its accounting reference date.

Subject to the notice requirements of the U.K. Companies Act 2006 outlined below, a general meeting of the shareholders of Mereo may be called by the Mereo Board whenever and at such times and places as it shall determine.

A general meeting may also be convened by the Mereo Board on the requisition of Mereo shareholders who hold at least 5% of the paid-up capital of Mereo carrying voting rights at a general meeting.

General meetings at which special resolutions are proposed and passed generally involve proposals to change the name of the company, permit the company to issue new shares for cash without the shareholders' pre-emptive right, amend the company's articles of association, or carry out other matters where either the company's articles of association or the U.K. Companies Act 2006 prescribe that a special resolution is required.

Other proposals relating to the ordinary course of the company's business, such as the election of directors, would generally be the subject of an ordinary resolution.

Under the U.K. Companies Act 2006, 21 clear days' notice must be given for an annual general meeting and any resolutions to be proposed at that meeting. At least 14 clear days' notice is required for any other general meeting.

In addition, certain matters, such as the removal of directors or auditors, require special notice, which is 28 clear days' notice.

Shareholder Proposals and Shareholder Nomination of Directors

Under the U.K. Companies Act 2006, shareholders of a company may require the directors to call a general meeting of the company and may specify the text of a resolution to be voted on at that meeting if the request is made by shareholders holding at least 5% of the paid-up capital of Mereo carrying voting rights at a general meeting.

In certain circumstances, shareholders may also require the company to circulate to shareholders that are entitled to receive notice of a general meeting, a statement of not more than 1,000 words with respect to (1) a matter referred to in a proposed resolution to be dealt with at that meeting, or (2) other business to be dealt with at that meeting. A company is required to circulate a statement once it has received requests to do so from (1) shareholders representing at least 5% of the total voting rights of all shareholders who have a relevant right to vote, or (2) by at least 100 shareholders who have a relevant right to vote and hold shares in the company on which there has been paid up an average sum, per shareholder, of at least £100.

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Resolutions to appoint or re-appoint directors to a public limited company such as Mereo must generally be put to shareholders on the basis of one resolution for each nominated director.

Number of Directors

Under the U.K. Companies Act 2006, a public limited company must have at least two directors.

Classification of the Board

Under the U.K. Companies Act 2006, a company may not enter into a service contract with a fixed term of more than two years with a director or (where the director is a director of a holding company) with a member of the group consisting of that company and its subsidiaries unless such contract has been approved by an ordinary resolution of the shareholders of the company or (in the case of a director of a holding company) of the shareholders of the holding company. Such a resolution must not be passed unless a memorandum setting out the proposed contract incorporating the provision is made available to members of the company both (1) at the company's registered office for not less than 15 days ending with the date of the meeting; and (2) at the meeting itself.

Removal of Directors

Under the U.K. Companies Act 2006, a company may remove a director without cause at a general meeting by way of an ordinary resolution of shareholders, irrespective of any provision of any agreement or service contract between the director and the company, provided that 28 clear days' notice of the proposed resolution to remove the director is given and certain other procedural requirements under the U.K. Companies Act 2006 are followed (such as allowing the director to make representations against his or her removal either at the meeting or in writing).

Limitation of Director Liability

Under the U.K. Companies Act 2006, any provision (whether contained in a company's articles of association or any contract or otherwise) that purports to exempt a director of a company (to any extent) from any liability that would otherwise attach to him in connection with any negligence, default, breach of duty or breach of trust in relation to the company is void, and any provision where the company is seeking to indemnify a director for such liability is also void except as allowed by the provision of insurance.

Directors and Officers Indemnity

Any provision by which Mereo directly or indirectly provides an indemnity (to any extent) for a director of the company or of an "associated company" (i.e., a company that is a parent, subsidiary or sister company of Mereo) against any liability attaching to him in connection with any negligence, default, breach of duty or breach of trust in relation to the company of which he or she is a director is void except as permitted by the U.K. Companies Act 2006, which provides exceptions for Mereo to:

- purchase and maintain director and officer insurance insuring its directors or the directors of an associated company against any liability attaching in connection with any negligence, default, breach of duty or breach of trust in relation to the company of which he or she is a director;
- provide a "qualifying third party indemnity," which is an indemnity against liability incurred by Mereo's directors and directors of an associated company to a person other than Mereo or an associated company. Such indemnity must not cover criminal fines, penalties imposed by regulatory bodies, the defense costs of criminal proceedings where the director is found guilty, the defense costs of civil proceedings successfully brought against the director by the company or an associated company, or the costs of unsuccessful applications by the director for relief from liabilities for such matters; and
- provide a "qualifying pension scheme indemnity," which is an indemnity against liability incurred in connection with the company's activities as trustee of an occupational pension plan. Such indemnity must not cover a fine imposed in criminal proceedings, or sum payable to a regulatory authority by way of a penalty in respect of non-compliance with any requirement of a regulatory nature (however arising), or any liability incurred by the director in defending criminal proceedings in which he or she is convicted.

The U.K. Companies Act 2006 also provides that Mereo may lend a director of Mereo funds to meet expenditure incurred by him in defending any criminal or civil proceedings in connection with any alleged negligence, default, breach of duty or breach of trust by him in relation to Mereo or an associated company, or in connection with an application for certain specified relief, subject to the requirement that the loan must be on terms that it is to be repaid if the defense or the application for relief is unsuccessful.

Derivative Suits and Class Action Suits

Under English law, generally, the company, rather than its shareholders, is the proper claimant in an action in respect of a wrong done to the company or where there is an irregularity in the company's internal management. Notwithstanding this general position, the U.K. Companies Act 2006 provides that (1) a court may allow a shareholder to bring a derivative claim (that is, an action in respect of and on behalf of the company) in respect of a cause of action arising from a director's negligence, default, breach of duty or breach of trust and (2) a shareholder may bring a claim for a court order on the ground that the company's affairs have been or are being conducted in a manner that is unfairly prejudicial to the interests of its shareholders generally or of some of its shareholders, or that an actual or proposed act or omission of the company is or would be so prejudicial.

The U.K. Limitation Act 1980 imposes a limitation period, with certain exceptions, of civil claims. The period is six years in respect of actions in contract and tort, and 12 years for "actions on a specialty," such as a breach of any obligation contained in a deed. The limitation period begins to run from the date on which the action accrued. In the case of contract, this is the date on which the breach of contract occurred, and in tort this is the date on which the damage is suffered.

Conflicts of Interest Transactions

Under English law, a director is under a duty to avoid conflicts of interest, and is obliged to declare his or her interest (whether direct or indirect) in a proposed transaction with the company to the other directors. It is an offense to fail to declare an interest (whether direct or indirect) in an existing transaction with the company.

The duty to avoid a conflict of interest is not infringed if the situation cannot reasonably be regarded as likely to give rise to a conflict of interest or if the matter has been authorized by the directors.

Reporting Requirements

According to the AIM Rules, which apply to Mereo due to the quotation of our ordinary shares on AIM, Mereo must publish:

- its annual audited accounts as of the end of each financial year within six months after the end of each financial year at the latest; and
- half-yearly financial statements for the first six months of a financial year within three months after the end of each reporting period at the latest.

Furthermore, according to the EU Market Abuse Regulation (Regulation EU No. 596/2014), Mereo must, as soon as possible, publish all inside information that directly concerns it. In particular, inside information directly concerns an issuer if it relates to developments within the issuer's sphere of activity. Inside information is, broadly, any specific information about circumstances that are not public knowledge relating to Mereo or the Mereo Shares that, if it became publicly known, would have a significant effect on the price of Mereo Shares.

Any Mereo shareholder who holds voting rights in Mereo, directly or indirectly, the percentage of which reaches, exceeds or falls below 3%, 4% and each 1% threshold thereafter up to 100% as a result of an acquisition or disposal of shares or financial instruments, shall, without undue delay, and within two trading days at the latest as from the transaction, notify this to Mereo and simultaneously to the FCA.

Short-Swing Profits

Directors, officers and other persons discharging managerial responsibilities, as well as persons closely related to them, are required to notify certain own account transactions in our ordinary shares to Mereo and the FCA.

Other U.K. Law Considerations

See “Item 10. Additional Information—B. Memorandum and Articles of Association—Other U.K. Law Considerations” for other applicable corporate governance practices.

Item 16H. Mine Safety Disclosure

Not applicable.

PART THREE

Item 17. Financial Statements

We have elected to provide financial statements pursuant to Item 18.

Item 18. Financial Statements

Our audited consolidated financial statements are included in this annual report beginning at Page F-1.

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Audited Financial Statements

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Mereo BioPharma Group plc

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Mereo BioPharma Group plc (the Company) as of December 31, 2019 and 2018, and the related consolidated statements of comprehensive loss, changes in equity, and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Adoption of New Accounting Standard

As discussed in Note 4 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of IFRS 16 (Leases).

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the US federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2015.
Reading, United Kingdom
June 15, 2020

**Consolidated statement of comprehensive loss
for the years ended December 31, 2017, 2018 and 2019**

	Notes	Year ended December 31,		
		2017	2018	2019
		(in £'000)		
Research and development expenses		(34,607)	(22,703)	(23,608)
Administrative expenses		(10,697)	(11,775)	(15,909)
Operating loss		(45,304)	(34,478)	(39,517)
Net income recognized on acquisition of subsidiary	5	—	—	1,035
Finance income	9	827	307	377
Finance charge	9	(1,090)	(3,091)	(3,496)
Net foreign exchange (loss)/gain		(1,384)	(44)	483
Loss before tax	7	(46,951)	(37,306)	(41,118)
Taxation	10	8,152	5,277	6,274
Loss attributable to equity holders of the parent		(38,799)	(32,029)	(34,844)
<i>Other comprehensive income – items that may be reclassified to profit or loss</i>				
Net fair value gain / (loss) on investments in debt instruments held at fair value	25	—	—	—
Exchange differences on translation of foreign operations		—	—	(499)
Other comprehensive income, net of tax		—	—	(499)
Total comprehensive loss attributable to equity holders of the parent		(38,799)	(32,029)	(35,343)
Basic and diluted loss per share	11	(0.56)	(0.45)	(0.39)

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated balance sheet
as at December 31, 2018 and 2019

	<u>Notes</u>	<u>Year Ended December 31,</u>	
		<u>2018</u>	<u>2019</u>
		<u>(in £'000)</u>	
Assets			
Non-current assets			
Property, plant and equipment	12	149	11,558
Intangible assets	13	32,632	44,456
		<u>32,781</u>	<u>56,014</u>
Current assets			
Prepayments		1,067	2,111
R&D tax credits	10	5,277	10,426
Other taxes recoverable	10	—	979
Other receivables	15	609	572
Short-term investments	17	2,500	—
Cash and short-term deposits	16	25,042	16,347
		<u>34,495</u>	<u>30,435</u>
Total assets		<u><u>67,276</u></u>	<u><u>86,449</u></u>
Equity and liabilities			
Equity			
Issued capital	18	214	294
Share premium	18	118,492	121,684
Other capital reserves	18	18,593	59,147
Employee Benefit Trust shares	28	(307)	(1,305)
Other reserves	18	7,000	7,000
Accumulated loss	18	(111,221)	(146,065)
Translation reserve	18	—	(499)
Total equity		32,771	40,256

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	Notes	Year Ended December 31,	
		2018	2019
(in £'000)			
Non-current liabilities			
Provisions	20	2,641	1,449
Interest-bearing loans and borrowings	19	14,647	5,373
Warrant liability	21	1,006	131
Other liabilities	22	34	44
Lease liability	4	—	9,318
		<u>18,328</u>	<u>16,315</u>
Current liabilities			
Trade and other payables	23	4,570	6,352
Accruals	23	4,437	5,138
Provisions	20	332	309
Interest-bearing loans and borrowings	19	6,838	15,139
Contingent consideration liability	25	—	354
Lease liability	4	—	2,586
		<u>16,177</u>	<u>29,878</u>
Total liabilities		<u>34,505</u>	<u>46,193</u>
Total equity and liabilities		<u>67,276</u>	<u>86,449</u>

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated statement of cash flows
for the years ended December 31, 2017, 2018 and 2019

	Notes	Year Ended December 31,		
		2017	2018	2019
(in £'000)				
Operating activities				
Loss before tax		(46,951)	(37,306)	(41,118)
Adjustments to reconcile loss before tax to net cash flows:				
Depreciation of property, plant and equipment	12	36	39	1,577
Share-based payment expense	26	3,652	2,190	1,636
Net foreign exchange loss / (gain)		1,384	44	(483)
Provision for social security contributions on employee share options	20	1,116	(1,446)	(738)
Provision for deferred cash consideration	9.1 & 20	—	443	221
Interest earned	9.1	(827)	(307)	(377)
Finance charges	9,2	1,090	1,916	3,731
Modification gain on bank loan	9.2 & 19	—	—	(456)
Modification loss on bank loan	9.2 & 19	—	730	—
Gain on bargain purchase	5	—	—	(3,681)
Fair value remeasurement on contingent consideration	25	—	—	354
Working capital adjustments:				
(Increase) / decrease in trade and other receivables		(840)	804	(936)
Increase / (decrease) in trade and other payables		3,860	1,602	(6,730)
Tax received	10	5,331	8,152	1,069
Net cash flows (used in) operating activities		(32,149)	(23,139)	(45,931)

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	Notes	Year Ended December 31,		
		2017	2018	2019
(in £'000)				
Investing activities				
Cash acquired from acquisition	5	—	—	10,074
Purchase of property, plant and equipment	12	(16)	(36)	(21)
Disposal of property, plant and equipment	12	—	2	—
Purchase of license	13	(2,280)	—	—
(Investments)/proceeds from sale of short-term investments	17	(2,500)	—	32,865
Interest earned		1,052	286	377
Net cash flows (used in)/from investing activities		<u>(3,744)</u>	<u>252</u>	<u>43,295</u>
Financing activities				
Proceeds from issue of ordinary shares	18	15,000	273	—
Transaction costs on issue of shares	18	(730)	(8)	(761)
Proceeds from issue of bank loan	19	20,000	455	—
Transaction costs on bank loan		(200)	(921)	—
Interest paid on bank loan		(327)	(1,645)	(1,739)
Proceeds from TAP agreement	22	—	78	—
Purchase of treasury shares	28	—	(307)	(998)
Payment of lease liabilities	4	—	—	(2,212)
Net cash flows from/(used in) financing activities		<u>33,743</u>	<u>(2,075)</u>	<u>(5,710)</u>
Net (decrease) in cash and cash equivalents		(2,150)	(24,962)	(8,346)
Cash and cash equivalents at January 1		53,578	50,045	25,042
Effect of exchange rate changes on cash and cash equivalents		(1,383)	(41)	(349)
Cash and cash equivalents at December 31	16	<u>50,045</u>	<u>25,042</u>	<u>16,347</u>

The accompanying notes form an integral part of these consolidated financial statements.

**Consolidated statement of changes in equity
for the years ended December 31, 2017, 2018 and 2019**

	Issued capital	Share premium	Other capital reserves	Employee Benefit Trust	Other reserves	Accumulated losses	Translation reserve	Total equity
	(in £'000)							
At December 31, 2016	193	99,975	12,666	—	7,000	(40,579)	—	79,255
Loss for the year to December 31, 2017	—	—	—	—	—	(38,799)	—	(38,799)
Share-based payments – share options (Note 26)	—	—	3,028	—	—	—	—	3,028
Share-based payments – LTIPs (Note 26)	—	—	298	—	—	—	—	298
Share-based payments – deferred bonus shares (Note 26)	—	—	326	—	—	—	—	326
Share-based payments – deferred equity consideration (Note 26)	—	—	1,331	—	—	—	—	1,331
Issue of share capital on April 4, 2017 (Note 18)	15	14,985	—	—	—	—	—	15,000
Issue of share capital on conversion of loan note (Note 18)	2	1,397	—	—	—	—	—	1,399
Issue of share capital for Novartis bonus shares (Note 18)	2	1,081	(1,083)	—	—	—	—	—
Equity element of convertible loan (Note 19)	—	—	(207)	—	—	—	—	(207)
Conversion of convertible loan (Note 19)	—	—	—	—	—	62	—	62
Issue of share capital on October 31, 2017 (Note 18)	1	1,519	—	—	—	—	—	1,520
Transaction costs on issuance of share capital (Note 18)	—	(730)	—	—	—	—	—	(730)
At December 31, 2017	<u>213</u>	<u>118,227</u>	<u>16,359</u>	<u>—</u>	<u>7,000</u>	<u>(79,316)</u>	<u>—</u>	<u>62,483</u>

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	Issued capital	Share premium	Other capital reserves	Employee Benefit Trust	Other reserves	Accumulated losses	Translation reserve	Total equity
	(in £'000)							
Loss for the year to December 31, 2018	—	—	—	—	—	(32,029)	—	(32,029)
Adoption of IFRS 9 (Note 4)	—	—	—	—	—	124	—	124
Share-based payments – share options (Note 26)	—	—	1,871	—	—	—	—	1,871
Share-based payments – LTIPs (Note 26)	—	—	319	—	—	—	—	319
Issue of share capital on June 1, 2018 (Note 18)	—	150	—	—	—	—	—	150
Issue of share capital on August 3, 2018 on exercise of options (Note 18)	—	13	—	—	—	—	—	13
Issue of share capital on October 22, 2018 on exercise of options (Note 18)	1	110	—	—	—	—	—	111
Issue of warrants for TAP agreement (Note 18)	—	—	44	—	—	—	—	44
Transaction costs on issuance of share capital (Note 18)	—	(8)	—	—	—	—	—	(8)
Purchase of treasury shares (Note 28)	—	—	—	(307)	—	—	—	(307)
At December 31, 2018	214	118,492	18,593	(307)	7,000	(111,221)	—	32,771
Loss for the year to December 31, 2019	—	—	—	—	—	(34,844)	—	(34,844)
Currency translation of foreign operations	—	—	—	—	—	—	(499)	(499)
Net fair value gain / (loss) on investments in debt instruments held at fair value (Note 25)	—	—	—	—	—	—	—	—
Share-based payments – share options (Note 26)	—	—	1,543	—	—	—	—	1,543
Share-based payments – LTIPs (Note 26)	—	—	93	—	—	—	—	93
Issue of share capital on April 23, 2019 (Note 18)	74	—	40,818	—	—	—	—	40,892

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	<u>Issued capital</u>	<u>Share premium</u>	<u>Other capital reserves</u>	<u>Employee Benefit Trust</u>	<u>Other reserves</u>	<u>Accumulated losses</u>	<u>Translation reserve</u>	<u>Total equity</u>
	(in £'000)							
Transaction costs related to issuance of share capital on April 23, 2019 (Note 18)	—	(761)	—	—	—	—	—	(761)
Issue of share capital on conversion of loan note (Note 18)	3	2,366	—	—	—	—	—	2,369
Issue of share capital on Novartis bonus shares (Note 18)	3	1,587	(1,590)	—	—	—	—	—
Equity element of convertible loan note (Note 18)	—	—	(310)	—	—	—	—	(310)
Purchase of treasury shares (Note 28)	—	—	—	(998)	—	—	—	(998)
At December 31, 2019	<u>294</u>	<u>121,684</u>	<u>59,147</u>	<u>(1,305)</u>	<u>7,000</u>	<u>(146,065)</u>	<u>(499)</u>	<u>40,256</u>

Notes to the Consolidated Financial Statements

1. Corporate information

Mereo BioPharma Group plc (the “Company”) is a clinical-stage, U.K.-based biopharmaceutical company focused on oncology and rare diseases.

The Company is a public limited company incorporated and domiciled in the U.K., and registered in England, with our shares publicly traded on the Alternative Investment Market of the London Stock Exchange under the ticker symbol MPH. The Company is also listed on the Nasdaq Global Market via American Depositary Shares (“ADSs”) under the ticker symbol MREO. The Company’s registered office is located at Fourth Floor, 1 Cavendish Place, London, W1G 0QF, United Kingdom.

The consolidated financial statements of Mereo BioPharma Group plc and its subsidiaries (collectively, the “Group”) for the year ended December 31, 2019 were authorized for issue in accordance with a resolution of the Directors on [April] [•], 2020]. The principal activities of the Group is the research and development of novel pharmaceutical products.

On April 23, 2019, the Group completed the acquisition of OncoMed Pharmaceuticals, Inc. (“OncoMed”), a company which is based in California and was previously a public company listed on the Nasdaq Global Market in the U.S.

2. Significant accounting policies

2.1 Basis of preparation

The Group’s consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

The financial statements are presented in pound sterling (“£’000”), which is the functional and presentational currency of the Group. All amounts disclosed in the financial statements and notes have been rounded off to the nearest thousand currency units, unless otherwise stated.

2.2 Revision of previously issued financial statements

During 2019, we identified a classification error in our statement of comprehensive loss for the year ended December 31, 2018 related to loan modification expense. In correcting the error, administrative expenses reduced by £0.7 million and finance charges increased by an equivalent amount. There was no impact on net loss. We evaluated the materiality of the error quantitatively and qualitatively and concluded it was not material to our previously issued Consolidated Financial Statements as a whole for the year ended and as of December 31, 2018. Please refer to Financial statement notes 9 and 19.

2.3 Basis of consolidation

The consolidated financial information comprises the financial statements of Mereo BioPharma Group plc and its subsidiaries as at December 31, 2019. Subsidiaries are all entities over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity.

Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases. Intercompany transactions, balances and unrealized gains on transactions between Group companies are eliminated in preparing the consolidated financial statements. Accounting policies of subsidiaries are consistent with the policies adopted by the Group.

The Company has an employee share trust to facilitate share transactions pursuant to employee share schemes. Although the trust is a separate legal entity from the Group, it is consolidated into the Group’s results in accordance with the IFRS 10 rules on special purpose vehicles. The Company is deemed to control the trust principally because the trust cannot operate without the funding the Group provides.

2.4 Segmental information

Management views the Group as a single portfolio of product candidates. Only research and development expenses are monitored at a product candidate level, however the Chief Operating Decision Maker (“CODM”) makes decisions over resource allocation at an overall portfolio level. The Group’s financing is managed and monitored on a consolidated basis.

Following the acquisition of OncoMed during the year, non-current assets held by the Group are located in the United Kingdom and United States. As at December 31, 2019, approximately £22.4 million of non-current assets are located in the United States.

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The Group's CODM is the executive leadership team which is comprised of several individuals including the Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"). The executive leadership team is responsible for managing the operating results of the business.

The operations of the Group are mostly influenced by the timing of progression on underlying clinical development programmes across product candidates which remain under development.

2.5 Going concern

As at May 31, 2020 the group had total cash resources* £10.1 million. Taken together with the private placement which completed on June 3, 2020 and which raised net proceeds of approximately £51.4 million, the group has current total cash resources of £61.5 million.

The Directors have prepared detailed cashflow forecasts for the 30-month period to December 31, 2022 based on delivering the business plan objectives set out in the strategic report which include:

- Completion of the adult Phase 2b extension study for setrusumab
- Completion of the current Phase 2 study for alvelestat
- Commencement later in 2020 of a new Phase 1b study for etiligimab

These forecasts indicate that the group has a total cash runway into 2022 and will have sufficient funds to meet its liabilities as they fall due for at least the next 12 months.

In preparing these forecasts the directors have considered the impact of COVID-19 and in particular the unprecedented burden on health systems in impacted countries around the world. As a result, clinical centres have diverted resources away from the performance of clinical trials and because of that and the vulnerability of patients in the Company's setrusumab clinical development program for osteogenesis imperfecta (OI) and its Phase 2 alvelestat program for patients with alpha-1 antitrypsin deficiency (AATD), the Company's clinical activities will face some delays. AATD patients, in particular, are at greater risk from COVID-19 given that the condition is a respiratory and lung condition, for this reason, our Phase 2 alvelestat trial will be delayed with topline data now expected in 2021. Subject to a partnership, we are also currently planning to initiate a Phase 3 study in children with OI in late 2020, however, the initiation of the study may also be delayed.

In addition, the Directors have considered a downside scenario involving an increase in operating overheads, an increase in the costs of setting up and running the planned Phase 1b study for etiligimab when this study is contracted out to third parties and increased investment in manufacturing development costs for setrusumab. In addition, In this scenario the forecasts also indicate that the group will have sufficient funds to meet its liabilities as they fall due for at least the next 12 months.

In both scenarios the Directors have not taken into account potential income from partnering one or more of its assets which would increase the cash resources available to the Group.

In conclusion, although the Group continues to make losses, the directors believe it is appropriate to prepare the financial information on the going concern basis. This is because the Group's development into new products continues to progress according to plan and the funding secured to date, together with the funds that have come into the Group since the year end (as described more fully in Note 30) will allow it to meet its liabilities as they fall due for at least 12 months from the date of authorization for the issue of these consolidated financial statements.

- Total cash resources are a non-GAAP measure being cash and short-term deposits and short-term investments

2.6 Summary of significant accounting policies

a) Taxes

Tax expense recognized in the statement of comprehensive income comprises the sum of deferred tax and current tax not recognized in other comprehensive income or directly in equity

Current income tax

Current income tax assets and / or liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities that are unpaid at the reporting date. Current tax is payable on taxable profit, which differs from profit or loss in the financial statements. Calculation of current tax is based on tax rates and tax laws that have been enacted or substantively enacted by the end of the reporting period within the jurisdictions that the Group operates in.

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Amounts receivable in respect of research and development tax credits are recognized in the financial statements provided there is sufficient evidence that the amounts are recoverable. These credits are recognized within income tax in the consolidated statement of comprehensive loss.

Deferred tax

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

Deferred income tax assets are recognized for all deductible temporary differences, carry-forward of unused tax credits and unused tax losses, to the extent that it is probable that taxable profit will be available against which the deductible temporary differences and the carry-forward of unused tax credits and unused tax losses can be utilized. The carrying amount of deferred income tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred income tax asset to be utilized. Unrecognized deferred income tax assets are reassessed at the end of each reporting period and are recognized to the extent that it has become probable that future taxable profit will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured on an undiscounted basis at the tax rates that are expected to apply to the year when the asset is realized, based on tax rates (and tax laws) enacted or substantively enacted at the end of the reporting period.

IFRIC 23, Uncertainty over Income Tax Treatments

In June 2017, the IASB issued IFRIC Interpretation 23, Uncertainty over Income Tax Treatments (IFRIC 23), which addresses how uncertain tax positions should be accounted for under IFRS. IFRIC 23 requires that, where acceptance of the tax treatment by the relevant tax authority is considered probable, it should be assumed as an accounting recognition matter that treatment of the item will ultimately be accepted. Therefore, no tax provision would be required in such cases. However, if acceptance of the tax treatment is not considered probable, the entity is required to reflect that uncertainty using an expected value (i.e., a probability-weighted approach) or the single most likely amount. IFRIC 23 is mandatorily effective for accounting periods beginning on or after 1 January 2019 and any resulting change to the tax provisions should be recognized in retained earnings. Mereo has recognized a net tax expense of nil in retained earnings on 1 January 2019 in respect of the adoption of IFRIC 23.

b) Foreign currencies

Items included in the financial statements are measured using the currency of the primary economic environment in which the entity operates (“the functional currency”). The consolidated financial statements are presented in pound sterling (“£”), which is the functional and presentational currency of the Group.

Transactions in foreign currencies are initially recorded by the Group’s entities at the rate ruling on the date the transaction first qualifies for recognition. Differences arising on settlement or translation of monetary items are recognized in the consolidated statement of comprehensive loss, as well as gains or losses on the retranslation of foreign currency balances at the year end.

The results and financial position of Group entities that have a functional currency different from the presentational currency of the Group are translated into the presentational currency (pound sterling). The assets and liabilities of such entities are translated into pound sterling at the rate of exchange ruling at the balance sheet date. Income and expenses are translated at the average rate for the period. Fair value adjustments arising on acquisition of such entities are treated as assets and liabilities of the relevant entity and translated into pound sterling at the closing rate. The exchange differences arising on translation for consolidation are recognized in other comprehensive income.

c) Property, plant and equipment

Property, plant and equipment is stated at cost, net of accumulated depreciation and accumulated impairment losses, if any. Such cost includes the cost of replacing part of the plant and equipment if the recognition criteria are met. All other repair and maintenance costs are recognized in profit or loss as incurred.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, as follows:

- Leasehold improvements ten years
- Office equipment five years
- IT equipment three years

The right-of-use assets are presented within the same line item as that within which the corresponding underlying assets would be presented if they were owned – for the Group this is property, plant and equipment. Right-of-use assets are depreciated over the shorter period of lease term and useful life of the underlying asset.

- Right-of-use asset (building) six to nine years
- Right-of-use asset (equipment) one to two years

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An item of property, plant and equipment and any significant part initially recognized is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the statement of comprehensive loss when the asset is derecognized.

The residual values, useful lives and methods of depreciation of property, plant and equipment are reviewed at each financial year end and adjusted prospectively, if appropriate.

d) Business combinations

Business combinations are accounted for using the acquisition method of accounting. At the date of the acquisition, the Group initially recognizes the fair value of the identifiable assets acquired, the liabilities assumed and any non-controlling interest in the acquired business.

The consideration transferred is measured at fair value at the date acquisition. The excess of the consideration transferred over the fair value of net identifiable assets of the business acquired is recorded as goodwill, unless the amount of consideration transferred is less than the fair value of net identifiable assets of the business acquired in which case the difference is recognized directly in the consolidated statement of comprehensive loss as a bargain purchase. A valuation is performed of assets and liabilities assumed on each acquisition accounted for as a business combination based on our best estimate of fair value.

Where the settlement of any part of cash consideration is deferred, the amounts payable in the future are discounted to their present value. Contingent consideration is classified either as equity or a financial liability and is recognized at fair value on the acquisition date. Amounts classified as a financial liability are subsequently remeasured to fair value in accordance with IFRS 9 (Financial Instruments), with changes in fair value recognized in the consolidated statement of comprehensive loss as an administrative expense.

Directly attributable acquisition-related costs are expensed as incurred within the consolidated statement of comprehensive loss.

d) Leases (IFRS 16)

Effective January 1, 2019, the Group implemented IFRS 16 (Leases). IFRS 16 (Leases) replaces existing guidance, including IAS 17 (Leases), and sets out the principles for recognition and measurement of leases. The new standard results in an increased volume of disclosure information in these consolidated financial statements.

For further information, refer to Note 4.

e) Intangible assets

Intangible assets are initially recorded at cost which has been determined as the fair value of the consideration paid and payable. Assets that have been acquired through a business combination are initially recorded at fair value. The fair value of consideration is regularly reviewed based on the probability of achieving contractual milestones.

Intangible assets are reviewed for impairment at each reporting date by allocating the assets to the cash-generating units to which they relate. The estimated useful life is the lower of the legal duration and economic useful life. The estimated useful lives of intangible assets are regularly reviewed on an at least annual basis.

Where the consideration paid or payable is in shares, the cost is measured in accordance with IFRS 2 (Share Based Payments).

Amortization would commence when product candidates underpinned by the intangible asset become available for commercial use. No amortization has been charged to date, as the product candidates underpinned by the intellectual property rights are not yet available for commercial use.

f) Financial instruments

Financial assets and liabilities are recognized in the consolidated balance sheet only when the Group becomes party to the contractual provisions of the instrument.

Financial assets

On initial recognition, a financial asset is classified into one of three primary measurement categories:

- Amortized cost;
- Fair value through OCI (“FVOCI”); or
- Fair value through profit or loss (“FVTPL”).

The initial classification into a primary measurement category depends on the nature and purpose of the financial asset.

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For each reporting period covered herein, the Group's financial assets were restricted to financial assets held at FVOCI. This relates to short-term investments which are not classified as cash and short-term deposits and are held in a business model whose objective is achieved by both collecting contractual cash flows and selling the short-term investment on maturity.

For short-term investments, interest income and impairment gains or losses are recognized directly in the consolidated statement of comprehensive loss. The difference between cumulative fair value gains or losses and the cumulative amounts recognized in the consolidated statement of comprehensive loss is recognized in other comprehensive income until derecognition, when the amounts in other comprehensive income are reclassified to the consolidated statement of comprehensive loss.

g) Fair value measurement

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either:

- In the principal market for the asset or liability; or
- In the absence of a principal market, in the most advantageous market for the asset or liability.

The principal or the most advantageous market must be accessible by the Group.

The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 — quoted (unadjusted) market prices in active markets for identical assets or liabilities.
- Level 2 — valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable.
- Level 3 — valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

For assets and liabilities that are recognized in the financial statements on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

h) Impairment of non-financial assets

Further disclosures relating to impairment of non-financial assets are also provided in the following notes:

- Disclosures for significant assumptions Note 3
- Property, plant and equipment Note 12
- Intangible assets not yet available for use Notes 13 and 14

The Group assesses, at each reporting date, whether there is an indication that an asset may be impaired. If any indication exists, or when annual impairment testing for an asset is required, the Group estimates the asset's recoverable amount. An asset's recoverable amount is the higher of an asset's or cash-generating unit's fair value less costs of disposal and its value in use. The recoverable amount is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets. When the carrying amount of an asset or cash-generating unit exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount.

In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. In determining fair value less costs of disposal, recent market transactions are taken into account. If no such transactions can be identified, an appropriate valuation model is used. These calculations are corroborated by valuation multiples, quoted share prices for publicly traded companies or other available fair value indicators.

Impairment losses are recognized in the statement of comprehensive loss in expense categories consistent with the function of the impaired asset.

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An assessment is made at each reporting date to determine whether there is an indication that previously recognized impairment losses no longer exist or have decreased. If such indication exists, the Group estimates the asset's or cash-generating unit's recoverable amount. A previously recognized impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's recoverable amount since the last impairment loss was recognized. The reversal is limited so that the carrying amount of the asset does not exceed its recoverable amount, nor exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognized for the asset in prior years. Such reversal is recognized in the statement of comprehensive loss unless the asset is carried at a revalued amount, in which case the reversal is treated as a revaluation increase.

i) Cash and short-term deposits

Cash and short-term deposits in the balance sheet comprise cash at banks and on hand and short-term deposits with a maturity of three months or less, which are subject to an insignificant risk of changes in value.

j) Short-term investments

Cash held on deposit for terms greater than three months are recognized at fair value in the balance sheet with fair value changes recognized in other comprehensive income. Interest revenue, impairment gains and losses, and a portion of foreign exchange gains and losses, are recognized in profit and loss.

When the short-term investment is derecognized or reclassified, changes in fair value previously recognized in other comprehensive income and accumulated in equity are reclassified to profit and loss.

k) Provisions

Provisions are recognized when the Group has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. When the Group expects some or all of a provision to be reimbursed, for example, under an insurance contract, the reimbursement is recognized as a separate asset, but only when the reimbursement is virtually certain. The expense relating to a provision is presented in the statement of comprehensive loss net of any reimbursement.

If the effect of the time value of money is material, provisions are discounted using a current pre-tax rate that reflects, when appropriate, the risks specific to the liability. When discounting is used, the increase in the provision due to the passage of time is recognized as a finance cost.

l) Share-based payments

Employees (including executives) of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments (equity settled transactions).

Incentives in the form of shares are provided to employees under various plans (Note 26). Executive officer have outstanding shares under a deferred bonus share plan ("DBSP Plan") and a long-term incentive plan ("LTIP Plan").

In accordance with IFRS 2 Share-based Payment ("IFRS 2"), charges for these incentives are expensed through the consolidated statement of comprehensive loss on a straight-line basis over their vesting period, based on the Group's estimate of shares that will eventually vest. The total amount to be expensed is determined by reference to the fair value of the options or awards at the date they were granted. For LTIP shares, the fair value on grant date excludes the impact of any non-market vesting conditions – these are instead taken into account by adjusting the number of equity instruments included in the measurement of the share-based payment transaction and are adjusted each period until such time as the equity instruments vest.

Share options awarded to non-employees are accounted for as options awarded to employees as the value of non-employee services could be readily determined.

In accordance with IFRS 2, the cancellation of share options is accounted for as an acceleration of the vesting period and therefore any amount unrecognized that would otherwise have been charged in future accounting periods is recognized immediately. When options are forfeited, the accounting expense for any unvested awards is reversed.

Purchases, where consideration is satisfied by issuing equity shares, is accounted for as equity settled share-based payment transactions in accordance with IFRS 2. Fair value is determined by the share price at the date of purchase.

m) Costs of issuing capital

Incremental costs incurred and directly attributable to the offering of equity securities are deducted from the related proceeds of the offering. The net amount is recorded as share premium in the period when such shares are issued. Where such expenses are incurred prior to the offering they are recorded in prepayments until the offering completes. Other costs incurred in such offerings are expensed as incurred and included in general and administrative expenses.

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n) Convertible loan instrument

Convertible loan notes are regarded as compound instruments consisting of a liability component and an equity component. At the date of issue, the fair value of the liability component is estimated using a discount rate for an equivalent liability without the conversion feature. The difference between the proceeds of issue of the convertible loan note and the fair value assigned to the liability component is included in equity.

o) Employee Benefit Trust

The Group operates an Employee Benefit Trust (“EBT”), the Mereo BioPharma Group plc Employee Benefit Trust.

The EBT has been established to fulfil awards made under the DBSP Plan and the LTIP Plan. The EBT is a Jersey-based trust which is funded by a loan from the Company, which it will utilize to buy shares at nominal value from the Company in sufficient quantity to fulfil the envisaged awards. The EBT will acquire shares in the Company and these will be deducted from the shareholders’ funds on the consolidated balance sheet at the cost of acquisition less proceeds on disposal.

Shares held by the EBT are included in the consolidated balance sheet as a reduction in equity.

The Group treats the EBT as an extension of the Group and the Company as it is ultimately controlled by the Company and therefore consolidated.

p) R&D costs

Expenditure on product development is capitalized as an intangible asset and amortized over the expected useful economic life of the product candidate concerned. Capitalization commences from the point at which technical feasibility and commercial viability of the product candidate can be demonstrated and the Group is satisfied that it is probable that future economic benefits will result from the product candidate once completed. Capitalization ceases when the product candidate receives regulatory approval for launch. No such costs have been capitalized to date.

Expenditure on R&D activities that do not meet the above criteria, including ongoing costs associated with acquired intellectual property rights and intellectual property rights generated internally by the Group, is charged to the statement of comprehensive loss as incurred. Intellectual property and in-process R&D from asset acquisitions are recognized as intangible assets at cost.

q) Provision for deferred cash consideration

Provision for deferred cash consideration consists of future payments which are contractually committed but not yet certain. In respect of products which are not yet approved, such deferred cash consideration excludes potential milestones, royalties or other payments that are deemed to be so uncertain as to be unquantifiable. Deferred cash consideration is recognized as a liability with the amounts calculated as the risk adjusted net present value of anticipated deferred payments.

The provision is reviewed at each balance sheet date and adjusted based on the likelihood of contractual milestones being achieved and therefore the deferred payment being settled. Increases in the provision relating to changes in the probability are recognized as an intangible asset. Increases in the provision relating to the unwinding of the time value of money are recognized as a finance expense.

r) Bank loan

Borrowings (including interest-bearing loans) are initially recognized at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognized in profit or loss over the period of the borrowings using the effective interest method. Under the effective interest method, amortization is included as a finance charge in the consolidated statement of comprehensive loss.

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The Group's policy is to account for non-substantial modifications to financial liabilities measured at amortized cost through a gain or loss which is recorded in the consolidated statement of comprehensive loss. The gain or loss is calculated as the difference between the original contractual cash flows and the modified cash flows, discounted at the original effective interest rate.

For substantial modifications, the Group's policy is to derecognize the existing financial liability and in turn recognize a new financial liability.

Borrowings are removed from the balance sheet when the obligation specified in the contract is discharged, cancelled or expired.

s) Associated warrants

The Group has issued certain warrant instruments to its lenders (Note 19).

As the terms of the warrant instruments allow for a cashless exercise, the Group's policy is to account for the associated warrant instruments at fair value with changes in the fair value recognized in the consolidated statement of comprehensive loss (see Note 21).

t) The Alpha-1 Project (TAP) funding agreement and associated warrants

The agreement is accounted for as a compound instrument which includes both debt and equity components. The liability is measured first at fair value and the residual value allocated to the equity component. The difference between the funding payment amount received and the measurement of the liability will be allocated to the warrants and recognized in equity. The value of warrants in equity will not be subsequently remeasured as the warrants will be settled by providing a fixed number of shares for a fixed amount of cash.

3. Significant judgments, estimates and assumptions

The preparation of these financial statements requires the management of the Group to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. The Group bases its estimates and judgments on historical experience and on various other assumptions that it considers to be reasonable. Actual results may differ from these estimates under different assumptions or conditions.

3.1 Judgments

a) Share-based compensation

Incentives in the form of shares are provided to employees under certain equity award plans (which consist of both share awards and option grants). The fair value of the employee services received in exchange for equity award plans is recognized as an expense. The expense is based upon a number of assumptions disclosed in Note 26. The selection of different assumptions in the measurement of fair value of the equity award plans could affect the results of the Group.

b) Business combination

On April 23, 2019, the Group obtained a 100% controlling interest in OncoMed, a Company based in the U.S. which was previously listed on the Nasdaq Global Market.

Judgement is applied under IFRS 3 (Business Combinations) in determining whether a transaction meets the definition of a business combination, and so accounted for in accordance with its requirements. In applying this judgement, management has considered the underlying economic substance of the transaction in addition to the contractual terms. Our assessment is that OncoMed meets the definition of a 'business' and the transaction has therefore been accounted for as a business combination. Please refer to Note 5 for further details regarding the OncoMed acquisition.

c) Impairment of intangible assets and property, plant and equipment

An assessment was made in respect of indicators of impairment in the carrying value of the Group's intangible assets (see Note 14), right-of-use assets, leasehold improvements, office equipment and IT equipment as at December 31, 2019.

If such an indication exists, the recoverable amount of the asset, being the higher of the asset's fair value less costs to sell and value in use, is compared to the asset's carrying value. Any excess of the asset's carrying value over its recoverable amount is expensed to the income statement. The assessment of intangible assets involves a number of significant judgments regarding the likelihood of successful product approval, the costs of reaching approval, the estimated useful life of intangible assets following commercialization and the subsequent commercial profitability of the product once approved.

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d) IFRS 16 (Leases) discount rate

Following the adoption of IFRS 16 (Leases) on January 1, 2019, the Group is required discount future lease payments using the interest rate implicit in the lease, or, if that rate cannot be readily determined, the incremental borrowing rate. IFRS 16 (Leases) defines the incremental borrowing rate as the rate of interest a lessee would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of similar value to the right-of-use assets in a similar economic environment.

For the year ended December 31, 2019, the determination of an appropriate discount rate has a significant effect on the lease liabilities recognized (see Note 4). For the current lease portfolio, the Group has determined an incremental borrowing rate based on relevant and available information as the interest rate implicit in the lease arrangements cannot be readily determined.

In addition to the determination of an appropriate discount rate, the Group was also required to assess the lease term for qualifying leases. The determination of the lease term is judgmental as for certain qualifying leases held by the Group, the contract includes an extension option beyond the non-cancellable period for which the Group has the right to use the underlying asset. In applying this judgment, the Group considered the period over which it was reasonably certain to make use of the extension option.

3.2 Estimates

a) Fair value of intangible assets acquired in business combination

The Group performed a full valuation of the fair value of assets acquired and liabilities assumed following the acquisition of OncoMed.

Based on the assets acquired and liabilities assumed, specific consideration was applied to the valuation of the intangible asset acquired which required an estimation of the expected useful life and future cash flows of the intangible asset alongside the determination of an appropriate discount rate. The intangible asset acquired was valued using a risk adjusted net present value model.

b) Contingent consideration

The Group makes provision for the estimated fair value of amounts payable to the former shareholders of OncoMed under the Contingent Value Rights Agreement (“CVR”), which is accounted for as a contingent consideration liability.

At December 31, 2019, the Group estimates the fair value of the contingent consideration liability to be £0.4 million (\$0.5 million), which is an increase from £nil on the date of acquisition (see Note 5). The increase in the fair value of the contingent consideration liability reflects the terms subsequently agreed with Oncologie, Inc. (“Oncologie”) with respect to the global licensing agreement of navicixizumab (“Navi”) (see Note 30). Total potential payments under the CVR on a gross, undiscounted basis, are approximately \$80.0 million (see Note 5).

The estimated contingent consideration payable is based on a risk-adjusted, probability-based scenario. Under this approach the likelihood of future payments being made to the former shareholders of OncoMed under the CVR is considered. The estimate could materially change over time in line with the development plan and subsequent commercialization of the Navi product.

c) Deferred license consideration

Deferred consideration in the form of cash is recognized as a provision at each balance sheet date, to the extent its amount is quantifiable at the inception of the arrangement (see Note 20). The amount provided is based on a number of estimates regarding the timing and progress of the related research.

Deferred consideration in the form of shares is recognized as a share-based payment when it is probable that shares will be transferred.

4. Changes in accounting policies

4.1 Changes in accounting policies 2019

Effective January 1, 2019, the Group has adopted IFRS 16 (Leases). IFRS 16 (Leases) replaces existing guidance, including IAS 17 (Leases), and sets out the principles for the recognition and measurement of leases. The new standard has resulted in an increased volume of disclosure information within these consolidated financial statements.

The Group has also implemented other minor amendments to existing standards and interpretations, which have no material impact on the Group’s overall results and financial position.

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a) General impact of application of IFRS 16 (Leases)

The date of initial application of IFRS 16 for the Group is January 1, 2019.

The Group has applied IFRS 16 using the modified retrospective approach, without restatement of the comparative information.

IFRS 16 introduces new or amended requirements with respect to lease accounting. It introduces significant changes to the lessee accounting by removing the distinction between operating and finance lease, requiring the recognition of a right-of-use asset and a lease liability at commencement for all leases, except for short-term leases and leases of low value assets. In contrast to lessee accounting, the requirements for lessor accounting have remained largely unchanged.

b) Definition of a lease

Previously, the Group determined at contract inception whether an arrangement was or contained a lease under IFRIC 4 (Determining Whether an Arrangement contains a Lease). The Group now assesses whether a contract is or contains a lease based on the new definition of a lease under IFRS 16 (Leases). Under IFRS 16 (Leases), a contract is or contains a lease, if the contract conveys a right to control the use of an identified asset in exchange for consideration.

On transition to IFRS 16 (Leases), the Group elected to apply the practical expedient to grandfather the assessment of which transactions are leases. It applied IFRS 16 (Leases) only to contracts that were previously identified as leases. Contracts that were not identified as leases under IAS 17 and IFRIC 4 were not reassessed. In preparation for the first-time application of IFRS 16, the Group has carried out an implementation project.

The new definition in IFRS 16 will not significantly change the scope of contracts that meet the definition of a lease for the Group. At inception or on reassessment of a contract that contains a lease component, the Group allocates the consideration in the contract to each lease and non-lease component based on their relative stand-alone prices.

c) Practical expedients adopted on transition

Certain practical expedients permitted by IFRS 16 are used by the Group, notably:

- 1) To not reassess, upon transition, whether an existing contract contains a lease (grandfather the previous assessment of whether a transaction was a lease under IAS 17 or IFRIC 4). The definition of a lease under IFRS 16 has been applied only to contracts entered into or changed on or after January 1, 2019;
- 2) The recognition exemptions for short-term leases (less than 12 months of lease term) and the leases of low-value assets; and
- 3) Used hindsight when determining the lease term, if the contract contains options to extend or terminate the lease.

d) Financial impact

The application of IFRS 16 to leases previously classified as operating leases under IAS 17 resulted in the recognition of right-of-use assets and lease liabilities.

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The table below sets out the adjustments recognized at the date of initial application of IFRS16, which does not include the leases acquired as part of the OncoMed acquisition.

	As at December 31, 2018	Impact of IFRS 16	Restated as at January 1, 2019
Non-current assets			
Property, plant and equipment	149	2,552	2,701
Prepayments and other	1,067	(50)	1,017
Total impact on assets		2,502	
Current liabilities			
Trade and other payables	4,570	—	4,570
Lease liabilities	—	607	607
Non-current liabilities			
Lease liabilities	—	1,927	1,927
Accruals	4,437	(32)	4,405
Total impact on liabilities		(2,502)	
Total impact on retained earnings		—	

As at January 1, 2019, right-of-use assets related to a leased property (£1.2 million) and a lease of medical equipment used in ongoing clinical trials (£1.3 million).

Following the acquisition of OncoMed on April 23, 2019, the Group acquired an additional right-of-use asset related to a leased property in Redwood City, U.S. (£10.8 million).

The table below presents a reconciliation from operating lease commitments disclosed as at December 31, 2018 to lease liabilities recognized as at January 1, 2019.

Operating lease commitments disclosed under IAS 17 (at December 31, 2018)	536
Effect of discounting	(944)
Reassessment of lease term under IFRS 16	2,942
Lease liabilities recognised under IFRS 16 (at January 1, 2019)	2,534

Certain lease agreements include an option which allows the Group to extend the lease. The Group is reasonably certain that it will invoke the extension option on the lease of medical equipment used in ongoing clinical trials, as the Group expects that the studies will extend beyond the initial lease term. Where the Group is reasonably certain that the lease will be extended, the cash flows are included in the calculation of the lease liability.

The adoption of IFRS 16 (Leases) results in a decrease in other operating expenses in the consolidated statement of comprehensive loss where lease payments were previously recorded. IFRS 16 (Leases) results in an increase in depreciation and interest expense going forwards following the recognition of a right-of-use asset and lease liability.

The weighted average incremental borrowing rate applied to lease liabilities recognized on transition was 15.0%.

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As at December 31, 2019, in relation to leases under IFRS 16 (Leases) the Group has recognized the following amounts in the consolidated statement of comprehensive loss:

Depreciation	1,505
Interest expense	1,314
Foreign exchange gain	29
Income from sub-leasing right-of-use assets	855

For the year ended December 31, 2019, within the consolidated statement of cash flows under IFRS 16 (Leases) the Group has opted to disclose both the cash paid for the interest portion and cash payments for the principal portion of the lease liability as part of financing activities. The adoption of IFRS 16 (Leases) did not have an impact on net cash flows.

The total cash outflow for leases amounted to £2.2 million during the year (2018: £0.3 million).

e) Subsequent updates

As at December 31, 2019, the lease term remaining on the medical equipment has been reassessed in line with the contractual agreement. The reassessment of lease term has been accounted for as a change in accounting estimate and the lease liability has been remeasured accordingly to reflect the change in estimated future lease payments. The carrying amount of the right-of-use asset has been adjusted for the remeasurement of the lease liability, both reduced by £0.3 million respectively.

4.2 Changes in accounting policies 2018

Effective January 1, 2018, the Group has adopted IFRS 9 (Financial Instruments) which introduces new requirements for:

1. The classification and measurement of financial assets and financial liabilities;
2. Impairment for financial assets;
3. General hedge accounting; and
4. New accounting for certain modifications and exchanges of financial liabilities measured at amortized cost.

The only impact on the Group is in relation to the non-substantial modification of the convertible loan notes, as detailed below. The Group has applied IFRS 9 (Financial Instruments) in full without restating comparatives with an initial date of application of January 1, 2018.

In relation to the non-substantial modification of financial liabilities, IFRS 9 (Financial Instruments) requires the recognition of a modification gain or loss for exchanges or modifications of financial liabilities that do not result in the of a financial liability. As a result, under IFRS 9 (Financial Instruments) the carrying value of the convertible loan note as at the date of modification was adjusted to recognize the modification gain in retained earnings as of the date of initial application of January 1, 2018.

At January 1, 2018 (<i>as calculated under IAS 39</i>)	1,977
Amounts restated through retained earnings	(124)
At January 1, 2018 (<i>as calculated under IFRS 9</i>)	<u>1,853</u>

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The Group has considered the adoption of IFRS 9 on receivables and determined the expected credit loss to be immaterial, and therefore no adjustment has been made for this.

5. Acquisition of subsidiary

On April 23, 2019, the Group obtained control of OncoMed, a Company based in the U.S., which was previously listed on the Nasdaq Global Market, by acquiring 100 per cent of its issued share capital. OncoMed is a clinical-stage biopharmaceutical company focused on discovering and developing novel therapeutics that address the fundamental biology driving cancer's growth, resistance, recurrence and metastasis. OncoMed was acquired in order to broaden the Group's asset base, strengthen its cash position and obtain a US listing to diversify international shareholder base of the combined group.

The final acquisition accounting is set out below:

	<u>OncoMed</u>
Cash and short-term deposits	10,074
Short-term investments	29,019
Other receivables	155
Prepayments	1,699
Property, plant and equipment	82
Right-of-use assets	10,755
Identifiable intangible assets	12,693
Other liabilities	(9,215)
Lease liabilities	(10,689)
Net identifiable assets	44,573
Bargain purchase	(3,681)
Total consideration	40,892
Equity instruments (24.8 million ordinary shares)	40,892
Contingent consideration arrangement	—
Total consideration	40,892

The Group acquired net cash of £10.1 million with the acquisition of OncoMed, being the value of the cash and short-term deposits on April 23, 2019.

The fair value of the 24.8 million ordinary shares issued as the consideration paid for OncoMed was measured based on the Group's quoted share price on April 23, 2019.

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As the Group acquired OncoMed for an amount less than the fair market value of the net assets acquired, a gain on bargain purchase of £3.7 million was realized. The was attributable to the following factors:

- Subject to working capital adjustments, the immediately pre-closing proportion of shares in the Company due to be issued to OncoMed's shareholders was agreed in December 2018, based on the Group's 90-day volume-weighted average share price ending on December 4, 2018. Following a movement downward in the Group's quoted share price on the completion date in comparison with the reference share price, this reduced the overall fair value of the consideration paid. The impact in the reduction in the fair value of consideration paid was partly offset by;
- In the period from announcement of the deal and the date of acquisition (April 23, 2019), a period of approximately five months, OncoMed continued to generate losses, reflecting continue research and development activity, together with recurring expenditure on its overheads. This had the effect of reducing net assets acquired on the acquisition date compared with net assets at the time the acquisition was agreed.

Additional cash consideration, accounted for as contingent consideration, becomes payable under a Contingent Value Rights Agreement ("CVR") relating to OncoMed's etigilimab ("TIGIT") and navicixizumab ("Navi") products. The contingent consideration would become payable upon the achievement of certain milestones in the future specific to TIGIT ("the TIGIT milestone") and Navi ("the Navi milestone").

As at the date of acquisition the fair value of the contingent consideration was estimated to be close to £nil. In making that assessment, the following information and factors were considered:

- 1) The uncertain outcomes of current clinical studies;
- 2) The level of uncertainty regarding the availability of future funding partners;
- 3) The level of uncertainty relating to the success of future development of such products; and
- 4) The dependency of the CVR milestones on the occurrence of events that are outside of the control of the Group; and
- 5) The likelihood of Celgene exercising the exclusive option granted by OncoMed to Celgene in relation to OncoMed's TIGIT product, particularly given Bristol-Myers Squibb's proposed acquisition of Celgene.

In June 2019 it was announced that Celgene had decided, in light of strategic product portfolio considerations, not to exercise its option to license TIGIT. Accordingly, the TIGIT milestone can no longer be achieved.

As at December 31, 2019, the Group estimates the fair value of the Navi milestone to be £0.4 million (\$0.5 million) which is accounted for as a contingent consideration liability, (see Note 25 and Note 30). The maximum undiscounted amount of the Navi milestone is subject to an aggregate cap of \$80 million.

The fair value of the financial assets includes receivables from the landlord under OncoMed's office lease arrangement in relation to tenant improvements with a fair value and a gross contractual value of £0.2 million. It is estimated at acquisition date that all contractual cash flows are collectable in full. Short-term investments acquired with OncoMed were treasury bills (recognized at fair value through other comprehensive income), in line with the Group's accounting policy (see Note 25).

Acquisition related costs (presented net against the gain on bargain purchase in the consolidated statement of comprehensive loss) amounted to £2.6 million (rounded). Transaction costs incremental and directly attributable to the issuance of new share capital associated with the acquisition of OncoMed amounted to £0.8 million, which is accounted for within equity. The net gain on bargain purchase in the consolidated statement of comprehensive loss is therefore £1.0 million (rounded).

OncoMed contributed £nil revenue and £5.7 million to the Group's loss for the period between the date of acquisition and the balance sheet date. If the acquisition of OncoMed had been completed on the first day of the financial year, group revenues for the period would have been £3.3 million and the Group's loss would have been £42.9 million. This information is provided for illustrative purposes only and is not necessarily indicative of the results that the Group would have occurred had OncoMed been acquired at the beginning of the year, or indicative of future results of the Group.

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6. Group information

Information about subsidiaries

The consolidated financial statements of the Group include:

<u>Name</u>	<u>Principal activities</u>	<u>Country of incorporation</u>	<u>% equity interest December 31, 2019</u>	<u>% equity interest December 31, 2018</u>
Mereo BioPharma 1 Limited	Pharmaceutical R&D	U.K.	100	100
Mereo BioPharma 2 Limited	Pharmaceutical R&D	U.K.	100	100
Mereo BioPharma 3 Limited	Pharmaceutical R&D	U.K.	100	100
Mereo BioPharma 4 Limited	Pharmaceutical R&D	U.K.	100	100
Mereo BioPharma Ireland Limited	Pharmaceutical R&D	Ireland	100	100
OncoMed Pharmaceuticals, Inc.	Pharmaceutical R&D	U.S.	100	—
Navi Subsidiary, Inc.	Pharmaceutical R&D	U.S.	100	—
Mereo US Holdings Inc.	Holding company	U.S.	100	100
Mereo MergerCo One Inc.	Holding company	U.S.	—	100
Mereo BioPharma Group plc Employee Benefit Trust	Employee share scheme	Jersey	—	—

The registered office of Mereo BioPharma 1 Limited, Mereo BioPharma 2 Limited, Mereo BioPharma 3 Limited and Mereo BioPharma 4 Limited is located at Fourth Floor, 1 Cavendish Place, London W1G 0QF. The registered office of Mereo BioPharma Ireland Limited is 25/28 North Wall Quay, Dublin 1 D01H104, Ireland.

Mereo US Holdings Inc. and Mereo MergerCo One Inc. were incorporated on December 3, 2018 for the sole purpose of effecting the business combination with OncoMed (see Note 5). Following the business combination with OncoMed, Mereo MergerCo One Inc. ceased to exist. The registered office of Mereo US Holdings Inc. is 251 Little Falls Drive, City of Wilmington, County of New Castle, Delaware 19808, U.S. Mereo MergerCo One Inc. was a 100% owned subsidiary of Mereo US Holdings Inc.

OncoMed became a wholly owned subsidiary of Mereo US Holdings Inc. on April 23, 2019 and is therefore an indirect, wholly owned subsidiary of Mereo BioPharma Group plc. The registered office of OncoMed Pharmaceuticals, Inc. is 251 Little Falls Drive, City of Wilmington, Country of New Castle, Delaware 19808, U.S. Navi Subsidiary, Inc, incorporated on April 15, 2019, is a wholly owned subsidiary of OncoMed.

Under IFRS, the Employee Benefit Trust is treated as an extension of the Group and the Company as it is controlled and therefore consolidated.

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7. Loss before taxation

Loss before tax is stated after charging:

	Year ended December 31, 2018	Year ended December 31, 2019
Fees payable to the Company's Auditor for the audit of Group accounts	323	514
Fees payable to the Company's Auditor for other services:		
Audit of subsidiary accounts	30	45
Audit-related assurance services	171	311
Accounting advisory services	10	—
Legal and professional fees including patent costs	936	2,413
Operating lease expense (IAS 17)	293	—
Depreciation of right-of-use assets (IFRS 16)	—	1,505
Depreciation (excluding right-of-use assets)	40	52

Following the adoption of IFRS 16 (Leases) on January 1, 2019, the Group has recognized £1.5 million of expense relating to depreciation of right-of-use assets and £1.3 million of interest expense relating to finance lease liabilities in the consolidated statement of comprehensive loss. No prior year comparative is disclosed, however under IAS 17 (Leases) the Group previously recognized £0.3 million relating to operating lease expense in the consolidated statement of comprehensive loss.

8. Employees

The average monthly number of persons employed by the Group (including Directors) during the year was:

	Year ended December 31, 2018 Number	Year ended December 31, 2019 Number
By activity		
Administrative	24	28
Research and development	12	18
Total	<u>36</u>	<u>46</u>

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Total compensation costs for persons employed by the Group (including Directors) during the year was:

	Year ended December 31, 2018	Year ended December 31, 2019
<i>Included in research and development expenses:</i>		
Salaries	1,792	2,824
Social security costs	(30)	110
Pension contributions	73	62
Share-based payment expense	526	152
<i>Included in administrative expenses:</i>		
Salaries	2,903	3,384
Social security costs	(828)	(124)
Pension contributions	99	114
Share-based payment expense	1,663	1,485
Total employee benefits expense	<u>6,198</u>	<u>8,007</u>

Total compensation costs for Directors during the year was:

	Year ended December 31, 2018	Year ended December 31, 2019
Salaries and fees	1,047	1,106
Benefits in kind	15	17
Pension contributions	11	25
Bonus	512	294
Total	<u>1,585</u>	<u>1,442</u>

During 2019, two Directors were members of a defined contribution pension scheme (period ended December 31, 2018: two).

Further details concerning the remuneration of Key Management Personnel can be found in Note 28.

9. Other income / expenses and adjustments

9.1 Finance income

	Year ended December 31		
	2017	2018	2019
Bank interest earned	827	307	42
Interest earned on short-term investments	—	—	141
Gain on short-term investments	—	—	194
Total finance income	<u>827</u>	<u>307</u>	<u>377</u>

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9.2 Finance charge

	Year ended December 31		
	2017	2018	2019
Interest payable on convertible loan	(103)	(185)	(20)
Interest on TAP funding	—	—	(10)
Interest payable on bank loan	(327)	(1,645)	(1,739)
Interest on lease liabilities	—	—	(1,314)
Accreted interest on bank loan	(67)	(782)	(1,523)
Transaction costs on bank loan	(200)	—	—
Modification (loss)/gain on bank loan	—	(730)*	456
Loss on short-term deposits	(339)	(22)	—
Discounting of provision for deferred cash consideration	—	(443)	(221)
Change in warrant fair value	(54)	716	875
Total finance charge	<u>(1,090)</u>	<u>(3,091)</u>	<u>(3,496)</u>

* We have reclassified the loan modification loss occurring in 2018 resulting in the reduction of administrative expenses by £0.7 million, and the increase in finance charges of an equivalent amount. Please refer to Note 2 for further details.

10. Income tax

	Year ended December 31		
	2017	2018	2019
U.K. corporation tax R&D credit	8,152	5,277	5,149
Other tax income / (expense)	—	—	1,125
Income tax credit	<u>8,152</u>	<u>5,277</u>	<u>6,274</u>

U.K. income tax

The Group is entitled to claim tax credits in the U.K. under the U.K. R&D small or medium-sized enterprise (SME) scheme, which provides additional taxation relief for qualifying expenditure on R&D activities and includes an option to surrender a portion of tax losses arising from qualifying activities in return for a cash payment from HM Revenue & Customs (HMRC). The amount included in the financial statements represents the credit for the year ended December 31, 2018 which was received in early 2020, together with the estimated recoverable credit for the year ended December 31, 2019.

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U.S. income tax

On December 22, 2017, the Tax Cuts and Jobs Act were entered into law. Following the acquisition of OncoMed during the year, the Group has analyzed the effects of the tax reform for the financial year ended December 31, 2019. The new tax law permanently repeals the corporate Alternative Minimum Tax (“AMT”) and provides a transition period where existing AMT credits are refundable. Other tax income of £1.1 million reflects amounts received or receivable by the Group as AMT credits. As at December 31, 2019, £1.0 million is receivable, recognized as other taxes recoverable within the consolidated balance sheet. At December 31, 2019, the Group had an Uncertain Tax Position of £2.5m being held off the Balance Sheet, in respect of the R&D tax credits in the US. The Uncertain Tax Position is calculated based upon historic US R&D claims and equates to around 20% of the outstanding US R&D claims.

Reconciliation of effective tax rate

	Year-ended December 31,		
	2017	2018	2019
Loss on ordinary activities before income tax	(46,951)	(37,306)	(41,118)
Loss on ordinary activities before tax at the U.K.’s statutory income tax rate of 19% (2018: 19%)	9,038	7,088	7,812
Expenses not deductible for income tax purposes (permanent differences)	(13)	(1,070)	(317)
Temporary timing differences	(712)	(277)	(343)
R&D relief uplift	3,447	2,271	2,540
Losses (unrecognized)	(3,785)	(2,804)	(4,380)
Deferred income from MBG loan guarantee costs	177	69	(54)
Differences in overseas tax rates	—	—	340
Gain on bargain purchase	—	—	699
Other	—	—	(23)
Tax credit for the year	<u>8,152</u>	<u>5,277</u>	<u>6,274</u>

Deferred tax

The analysis of unrecognized deferred tax is set out below:

	December 31,		
	2017	2018	2019
Losses	6,121	8,604	19,443
US tax credits	—	—	10,032
Accruals	—	—	947
Fixed assets	—	—	400
Other	—	6	202
Temporary differences trading	2,267	495	4
Net deferred tax asset (unrecognised)	<u>8,388</u>	<u>9,105</u>	<u>31,028</u>

The analysis of recognized deferred tax is set out below:

	At January 1, 2019	Acquisition of subsidiary (Note 5)	Recognized in income	At December 31, 2019
Deferred tax liabilities				
Intangible asset	—	(2,686)	—	(2,686)
Deferred tax asset				
Net operating losses	—	—	2,686	2,686
Net deferred tax asset/(liability)	<u>—</u>	<u>(2,686)</u>	<u>2,686</u>	<u>—</u>

The deferred tax liability has arisen from the recognition of separately identifiable intangible assets on the acquisition of OncoMed (see Note 5). A deferred tax asset on losses has been recognized up to the level of the deferred tax liability, resulting in a net deferred tax liability of £nil.

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The remaining deferred tax assets, as set out in the table above, have not been recognized as there is uncertainty regarding when suitable future profits against which to offset the accumulated tax losses will arise.

U.K. deferred tax

A reduction in the rate of UK corporation tax to 19% from April 1, 2017 and to 17% from April 1, 2020 was substantively enacted at the Balance Sheet date. However subsequently, the UK Government announced that the UK corporation tax rate would remain at 19% and not reduce to 17% on 1 April 2020. This was substantively enacted on 17 March 2020. The standard rate of UK corporation tax applied to reported loss is 19% (2018: 19%). Unrecognized UK deferred tax assets and liabilities are calculated at a rate of 17%, being the rate that was substantively enacted at the Balance Sheet date.

There is no expiration date for accumulated tax losses in the U.K. entities.

At December 31, 2019, the Group had U.K. tax losses to be carried forward of approximately £70.2 million (2018: £50.0 million).

U.S. deferred tax

In the U.S., the Tax Cuts and Jobs Act reduced the corporation tax rate to 21% from January 1, 2018. The effect of the new U.S. corporation tax rate has been considered in these financial statements. U.S. deferred tax assets and liabilities are calculated at a blended rate of approximately 21%.

For OncoMed, with respect to accumulated tax losses carried forward prior to the acquisition of the Company, there is a change of control restriction which will limit the amount available in any one year.

At December 31, 2019, the Group had U.S. federal tax losses to be carried forward of approximately £47.5 million, of which £40.9 million can be carried forward indefinitely and £6.6 million which will begin to expire in 2023. At December 31, 2019, the Group had U.S. state tax losses to be carried forward of approximately £3.2 million which begin to expire in 2028.

11. Loss per share

Basic loss per share is calculated by dividing the loss attributable for the year to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year.

As the net amount attributable for the year to ordinary equity holders of the parent was a loss in the year (2018: loss), the dilutive potential shares are anti-dilutive for the earnings per share calculation.

	December 31,								
	2017			2018			2019		
	Loss £'000	Weighted shares number	Loss per share £	Loss £'000	Weighted shares number	Loss per share £	Loss £'000	Weighted shares number	Loss per share £
Basic and diluted	(38,799)	69,012,348	(0.56)	(32,029)	71,144,786	(0.45)	(34,844)	89,424,476	(0.39)

The Company operates share option schemes (see Note 26) which could potentially dilute basic earnings per share in the future. In addition, there exist within equity nil (2018: 864,988) shares to be issued which also have the potential to dilute basic earnings per share in the future (see Note 18).

As part of a license and option agreement with AstraZeneca (see Note 26) additional future payments of a maximum of 1,349,692 new ordinary shares would be payable on reaching certain clinical milestones.

Warrants totaling 321,444 were issued in 2019 (2018: 41,286) that could potentially dilute basic earnings per share if converted.

The equity-settled transactions were considered to be anti-dilutive as they would have decreased the loss per share and were therefore excluded from the calculation of diluted loss per share.

For transactions involving ordinary shares or potential ordinary shares between the reporting date and the date of authorization of these financial statements, see Note 30.

12. Property, plant and equipment

The Group has decided to present right-of-use assets within property, plant and equipment.

On initial application of IFRS 16 (Leases), the Group recognized a right-of-use asset of £2.6 million. Subsequently, following the acquisition of OncoMed, the Group recognized a right-of-use asset of £10.8 million relating to an acquired property lease.

Further details on the initial application of IFRS 16 (Leases) are presented in Note 4.

	Right-of-use asset (building)	Right-of-use asset (equipment)	Leasehold improvements	Office equipment	IT equipment	Total
Cost or valuation						
At January 1, 2019	—	—	164	31	71	266
Additions	—	—	—	—	21	21
Transition to IFRS 16 (Leases)	1,237	1,314	—	—	—	2,551
Acquisition of subsidiary (Note 5)	10,755	—	—	58	24	10,837
Disposals	—	—	—	(18)	—	(18)
Adjustment to carrying value	—	(290)	—	—	—	(290)
Currency translation effects	(115)	—	—	—	—	(115)
At December 31, 2019	<u>11,877</u>	<u>1,024</u>	<u>164</u>	<u>71</u>	<u>116</u>	<u>13,252</u>
Depreciation and impairment						
At January 1, 2019	—	—	(53)	(16)	(48)	(117)
Disposals	—	—	—	—	—	—
Depreciation for the year	(996)	(509)	(16)	(14)	(42)	(1,577)
At December 31, 2019	<u>(996)</u>	<u>(509)</u>	<u>(69)</u>	<u>(30)</u>	<u>(90)</u>	<u>(1,694)</u>
Net book value						
At January 1, 2019	—	—	111	15	23	149
At December 31, 2019	<u>10,881</u>	<u>515</u>	<u>95</u>	<u>41</u>	<u>26</u>	<u>11,558</u>

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	<u>Leasehold improvements</u>	<u>Office equipment</u>	<u>IT equipment</u>	<u>Total</u>
Cost or valuation				
At January 1, 2018	155	30	48	233
Additions	9	1	25	35
Disposals	—	—	(2)	(2)
At December 31, 2018	<u><u>164</u></u>	<u><u>31</u></u>	<u><u>71</u></u>	<u><u>266</u></u>
Depreciation and impairment				
At January 1, 2018	(37)	(10)	(33)	(80)
Disposals	—	—	2	2
Depreciation for the year	(16)	(6)	(17)	(39)
At December 31, 2018	<u><u>(53)</u></u>	<u><u>(16)</u></u>	<u><u>(48)</u></u>	<u><u>(117)</u></u>
Net book value				
At January 1, 2018	118	20	15	153
At December 31, 2018	<u><u>111</u></u>	<u><u>15</u></u>	<u><u>23</u></u>	<u><u>149</u></u>

	<u>Leasehold improvements</u>	<u>Office equipment</u>	<u>IT equipment</u>	<u>Total</u>
Cost or valuation				
At January 1, 2017	155	20	43	218
Additions	—	10	5	15
Disposals	—	—	—	—
At December 31, 2017	<u><u>155</u></u>	<u><u>30</u></u>	<u><u>48</u></u>	<u><u>233</u></u>
Depreciation and impairment				
At January 1, 2017	<u><u>(21)</u></u>	<u><u>(5)</u></u>	<u><u>(18)</u></u>	<u><u>(44)</u></u>
Disposals	—	—	—	—
Depreciation for the year	(16)	(5)	(15)	(36)
At December 31, 2017	<u><u>(37)</u></u>	<u><u>(10)</u></u>	<u><u>(33)</u></u>	<u><u>(80)</u></u>
Net book value				
At January 1, 2017	134	15	25	174
At December 31, 2017	<u><u>118</u></u>	<u><u>20</u></u>	<u><u>15</u></u>	<u><u>153</u></u>

13. Intangible assets

	Acquired development programs
Cost at January 1, 2018	33,005
Cost at December 31, 2018	33,005
Acquisition of subsidiary (Note 5)	12,693
Currency translation effects	(171)
Cost at December 31, 2019	45,527
Revision to estimated value at January 1, 2018	—
Revisions to estimated value	(373)
Revision to estimated value at December 31, 2018	(373)
Revision to estimated value	(698)
Revision to estimated value at December 31, 2019	(1,071)
Net book value at January 1, 2018	33,005
Net book value at December 31, 2018	32,632
Net book value at December 31, 2019	44,456

The Group's strategy is to acquire and develop clinical-stage development programs for the treatment of non-rare and rare diseases from large pharmaceutical companies.

On April 23, 2019, the Group acquired an intangible asset of £12.7 million following the acquisition of OncoMed (Note 5).

On October 28, 2017, the Group acquired the exclusive license for MPH-966 and included the option to acquire certain assets from AstraZeneca AB ("AstraZeneca"). On that date the fair value of MPH-966 was measured at £7.2 million which consisted of upfront cash and equity payments as well as deferred cash and equity consideration. The provision for deferred cash consideration, in line with the Group's accounting policy, is re-measured to fair value at each balance sheet date and recognized in the intangible asset. During the year, the provision for deferred cash consideration has decreased by £0.7 million (2018: £0.4 million) due to changes in timelines and the probability of contractual milestones being achieved.

	Acquired development programs
Cost at January 1, 2017	25,813
Cost at December 31, 2017	33,005
Cost at December 31, 2018	33,005
Revision to estimate value at January 1, 2017	—
Revisions to estimated value	—
Revision to estimated value at December 31, 2017	—
Revision to estimated value	(373)
Revision to estimate value at December 31, 2018	(373)
Net book value at January 1, 2017	25,813
Net book value at December 31, 2017	33,005
Net book value at December 31, 2018	32,632

14. Impairment testing of acquired development programs not yet available for use

Acquired development programs not yet available for use are assessed annually for impairment.

The carrying amount of acquired development programs is as follows:

	As at December 31, 2019					
	Navicixizumab (navi)	BPS-804 (setrusumab)	MPH-966 (alvelestat)	BGS-649 (leflutrozone)	BCT-197 (acumapimod)	Total
Acquired development programs	<u>12,522</u>	<u>11,616</u>	<u>6,121</u>	<u>9,886</u>	<u>4,311</u>	<u>44,456</u>

	As at December 31, 2018					
	BPS-804 (setrusumab)	MPH-966 (alvelestat)	BGS-649 (leflutrozone)	BCT-197 (acumapimod)	Total	
Acquired development programs	<u>11,616</u>	<u>6,819</u>	<u>9,886</u>	<u>4,311</u>	<u>32,632</u>	

The Group considers the future development costs, the probability of successfully progressing each program to product approval and the likely commercial returns after product approval, among other factors, when reviewing for indicators of impairment. The results of this testing did not indicate any impairment of the acquired products' rights in the year to December 31, 2019. Management believe that the likelihood of a materially different outcome using different assumptions is remote.

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The acquired development programs are assets which are not used in launched products. These assets have not yet begun to be amortized but have been tested for impairment by assessing their value in use. Value in use calculations for each program are utilized to calculate the recoverable amount. The calculations use pre-tax cash flow projections covering the period through product development to commercial sales up to the later of loss of patent protection or market exclusivity, which extend beyond five years from the balance sheet date. Approved products are assumed to be out-licensed such that the Group receives signature fees, milestone receipts and royalties on sales; therefore, the Group does not incur any costs of commercialization after out-licensing.

Key assumptions for the value in use calculations are described as follows:

- Development costs to obtain regulatory approval – costs are estimated net of any contributions expected from collaborative arrangements with future partners. Management have developed cost estimates based on their previous experience and in conjunction with the expertise of their clinical development partners;
- Launch dates of products – these reflect management’s expected date of launch for products based on the timeline of development programs required to obtain regulatory approval. The assumptions are based on management’s and clinical development partners’ prior experience;
- Probability of successful development – management estimates probabilities of success for each phase of development based on industry averages and knowledge of specific programs;
- Out-licensing signature fees, milestones and royalty rates on sales – management estimates these amounts based on prior experience and access to values from similar transactions in the industry, which are collated and accessible from specialist third-party sources;
- Sales projections – these are based on management’s internal projections using external market data and market research commissioned by the Company;
- Profit margins and other operational expenses – these are based on the Company’s internal projections of current product manufacturing costings, with input from manufacturing partners where applicable, and estimates of operating costs based on management’s prior industry experience;
- Cash flow projections – for all assets, cash flows are assessed over an industry-standard asset life of 20 years; and
- Discount rates – the discount rate is estimated on a pre-tax basis reflecting the estimated cost of capital of the Group and is applied consistently across each of the operating segments. The cost of capital was calculated at 15.3% (2018: 15.3%).

Where an out-licensing agreement has been reached with a third party, known and observable inputs replace management assumptions if available.

At this stage of product development, the key sensitivity for all development programs is the probability of successful completion of clinical trials in order to obtain regulatory approval for sale. Therefore, full impairment of a development program is expected should such related trials be unsuccessful.

15. Other receivables

	<u>December 31,</u>	
	<u>2018</u>	<u>2019</u>
Rent deposit	293	293
VAT recoverable	316	269
Other receivables	—	10
	<u>609</u>	<u>572</u>

16. Cash and short-term deposits

	December 31,	
	2018	2019
Cash at banks and on hand	5,344	15,803
Short-term deposits	19,698	544
	<u>25,042</u>	<u>16,347</u>

Cash at banks earns interest at floating rates based on daily bank deposit rates, with maturity of three months or less. Short-term deposits are available immediately and earn fixed interest at the respective short-term deposit rates and are held in a diversified portfolio of counterparties.

17. Short-term investments

	December 31,	
	2018	2019
Short-term investments	<u>2,500</u>	<u>—</u>

Short-term investments consist of cash deposits held with greater than three months term to maturity. None of these investments are held with terms greater than a year.

18. Issued capital and reserves

Ordinary share capital	2017
Balance at beginning of year	193
Issuances in the year	20
Nominal share capital as at December 31	<u>213</u>
Ordinary shares issued and fully paid	
Issued on April 3, 2017 for private placement financing round	5,042,017
Issued on April 26, 2017 for conversion of loan note	1,221,361
Issued on October 28, 2017 for acquisition of license	490,798
At December 31, 2017	<u>71,094,974</u>
Nominal value at December 31, 2017 (£)	0.003
Issued capital at December 31, 2017 (£)	<u><u>213,285</u></u>

Ordinary share capital	2018
Balance at beginning of year	213
Issuances in the year	1
Nominal share capital as at December 31	214
Ordinary shares issued and fully paid	
At January 1, 2018	71,094,974
Issued on June 1, 2018 for public offering	50,076
Issued on August 3, 2018 for exercise of share options	10,000
Issued on October 22, 2018 for exercise of share options	85,222
At December 31, 2018	71,240,272
Nominal value at December 31, 2018 (£)	0.003
Issued capital at December 31, 2018 (£)	213,721
Ordinary share capital	2019
Balance at beginning of year	214
Issuances in the year	80
Nominal share capital as at December 31	294
Ordinary shares issued and fully paid	
At January 1, 2019	71,240,272
Issued on April 23, 2019 for OncoMed acquisition	24,783,320
Issued on June 21, 2019 for conversion of loan note	1,936,030
At December 31, 2019	97,959,622
Nominal value at December 31, 2019 (£)	0.003
Issued capital at December 31, 2019 (£)	293,879

Since January 1, 2017, the following alterations to the Company's share capital have been made:

- Under the private placement dated April 3, 2017, the Company issued and allotted 5,042,017 ordinary shares of £0.003 in nominal value in the capital of the Company on April 3, 2017 at a price of £2.975 per share to institutional investors. Gross cash received was £15,000,000;
- On April 26, 2017 Novartis converted £1,398,552 of loan notes dated June 3, 2016 into 632,829 ordinary shares of £0.003 in nominal value in the capital of the Company at the fixed conversion price of £2.21 per share. Under the terms of the notes, Novartis also received 588,532 bonus shares;

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- On October 31, 2017, Mereo BioPharma Group plc issued 490,798 ordinary shares of £0.003 in nominal value in the capital of the Company to AstraZeneca AB as part payment for the acquisition by Mereo BioPharma 4 Limited of an exclusive license and option to acquire certain assets;
- Under the public offering dated June 1, 2018, the Company issued and allotted 50,076 ordinary shares of £0.003 in nominal value in the capital of the Company on June 1, 2018 at a price of £3.00 per share to investors. Gross cash received was £150,228;
- On August 3, 2018 the Company issued and allotted 10,000 ordinary shares of £0.003 in nominal value in the capital of the Company pursuant to an exercise of employee share options;
- On October 22, 2018 the Company issued and allotted 85,222 ordinary shares of £0.003 in nominal value in the capital of the Company pursuant to an exercise of employee share options;
- On April 23, 2019, the Company issued and allotted 24,783,320 ordinary shares of £0.003 in nominal value in the capital of the Company as consideration for the acquisition of OncoMed. The fair value of the ordinary shares, measured on the date of acquisition, was £1.65; and
- On June 21, 2019, Novartis converted £2.4 million of loan notes dated June 3, 2016 into 1,071,042 ordinary shares of £0.003 in nominal value in the capital of the Company at a fixed conversion price of £2.21 per share. Under the terms of the notes, Novartis also received 864,988 bonus shares.

	<u>December 31,</u> <u>2017</u>
Share premium	
At January 1, 2017	99,975
Issued on April 3, 2017 for private placement financing round	14,985
Issued on April 26, 2017 for conversion of loan note	2,478
Issued on October 28, 2017 for acquisition of license	1,519
Transaction costs for issued share capital	(730)
At December 31, 2017	118,227

	<u>December 31,</u> <u>2018</u>
Share premium	
At January 1, 2018	118,227
Issued on June 1, 2018 for public offering	150
Issued on August 3, 2018 for exercise of share options	13
Issued on October 22, 2018 for exercise of share options	110
Transaction costs for issued share capital	(8)
At December 31, 2018	118,492

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	<u>December 31,</u> <u>2019</u>
<u>Share premium</u>	
At January 1, 2019	118,492
Issued on June 21, 2019 for conversion of loan note	3,953
Transaction costs for issued share capital	(761)
At December 31, 2019	121,684

Other capital reserves

	<u>Shares to be issued</u>	<u>Share-based payments</u>	<u>Equity component of convertible loan</u>	<u>Total</u>
At January 1, 2017	2,673	9,476	517	12,666
Share-based payments expense during the year	—	4,983	—	4,983
Shares issued	(1,083)	—	—	(1,083)
Equity component of convertible loan instrument	—	—	(207)	(207)
At December 31, 2017	<u>1,590</u>	<u>14,459</u>	<u>310</u>	<u>16,359</u>

	<u>Shares to be issued</u>	<u>Share-based payments</u>	<u>Equity component of convertible loan</u>	<u>Warrants issued for TAP funding</u>	<u>Total</u>
At January 1, 2018	1,590	14,459	310	—	16,359
Share-based payments expense during the year	—	2,302	—	—	2,302
Share-based payments release for exercise of options	—	(112)	—	—	(112)
Warrants issued for TAP funding	—	—	—	44	44
At December 31, 2018	<u>1,590</u>	<u>16,649</u>	<u>310</u>	<u>44</u>	<u>18,593</u>

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	Shares to be issued	Share-based payments	Equity component of convertible loan	Warrants issued for TAP funding	Merger reserve	Total
At January 1, 2019	1,590	16,649	310	44	—	18,593
Acquisition of OncoMed (Note 5)	—	—	—	—	40,818	40,818
Shares issued during the year	(1,590)	—	—	—	—	(1,590)
Convertible loan conversion	—	—	(310)	—	—	(310)
Share-based payments expense during the year	—	1,636	—	—	—	1,636
Share-based payments release for exercise of options	—	—	—	—	—	—
At December 31, 2019	—	18,285	—	44	40,818	59,147

Share-based payments

The Group has various share option schemes under which options to subscribe for the Group's shares have been granted to certain executives, NEDs and employees.

The share-based payment reserve is used to recognize a) the value of equity settled share-based payments provided to employees, including key management personnel, as part of their remuneration and b) deferred equity consideration. Refer to Note 26 for further details.

Shares issued or to be issued

At January 1, 2019, a maximum of 864,988 shares were remaining to be issued to Novartis pro rata to their percentage shareholding as and when the Company issued further ordinary shares. The fair value of these shares was £1.84 per share.

On June 21, 2019, the remaining 864,988 shares were issued to Novartis as fully paid up bonus shares for £nil consideration.

Equity component of convertible loan instrument

The convertible loan notes issued to Novartis were a compound instrument consisting of a liability and an equity component.

On June 21, 2019, Novartis exercised the right to convert the instrument therefore the value of the equity component as at December 31, 2019 is £nil.

Merger reserve

The consideration paid to acquire OncoMed was 24,783,320 ordinary shares with an acquisition date fair value of £40.9 million, based on the Group's quoted share price. The nominal value of the issued capital was £0.1 million with the excess, £40.8 million, classified within other capital reserves as a 'Merger reserve'.

Warrants issued for TAP funding

The funding arrangements with The Alpha-1 Project are a compound instrument consisting of a liability and an equity component (see Note 21). The value of the equity component (consideration received for the warrants) as at December 31, 2019 is £44,156 (2018: £44,156).

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Accumulated loss

	Year ended December 31		
	2017	2018	2019
Other reserves	7,000	7,000	7,000
Accumulated losses	(79,316)	(111,221)	(146,065)
Accumulated deficit	<u>(72,316)</u>	<u>(104,221)</u>	<u>(139,065)</u>

On March 21, 2016, the Directors of the Company signed a solvency statement with the agreement of all shareholders and undertook a capital reduction, reducing the share premium account by £7.0 million and crediting a new other reserve by the same amount.

19. Interest-bearing loans and borrowings

	Year ended December 31	
	2018	2019
Convertible loan notes (“Novartis Notes”)	2,039	—
Bank loan	19,446	20,512
At December 31	<u>21,485</u>	<u>20,512</u>
Current	6,838	15,139
Non-current	<u>14,647</u>	<u>5,373</u>

19.1 Convertible loan notes (“Novartis Notes”)

On June 21, 2019, Novartis converted the remaining balance of principal and interest of £2.4 million of convertible loan notes into 1,071,042 ordinary shares at a fixed conversion price of £2.21 per share.

This has been recorded as a reduction in interest bearing loans and borrowings of £2.0 million and a reduction in other capital reserves of £0.3 million. Under the terms of the arrangement, Novartis also received 864,988 bonus shares (for full consideration).

There are no convertible loan notes outstanding as at December 31, 2019.

As at December 31, 2018, the carrying value of the convertible loan notes was £2.0 million. The value of the debt component of the convertible loan notes on the date of issuance of the instrument was £2.9 million. Cash flows attached to the convertible loan note up to the date of maturity were calculated and discounted at an appropriate venture debt rate of 10%. The value of the equity component of the instrument as at December 31, 2018 was £0.3 million.

19.2 Bank loan

The bank loan has a principal amount of £20.5 million and will mature on March 1, 2021, unless extended on reaching certain milestones. The terms of the bank loan required interest-only payments up until April 30, 2019, and thereafter payments of interest and principle in 23 equal monthly instalments through maturity. The bank loan bears interest at an annual fixed rate of 8.5% and is secured by substantially all of the Group’s assets, including intellectual property rights owned or controlled by the Group.

On April 23, 2019, the Group agreed an amendment to the terms of its bank loan with its lenders. The new terms extended the interest-only period through to December 31, 2019 followed by a 15-month capital and interest repayment period. The Group has undertaken an assessment believes that the change in terms should not be accounted for as a modification, but instead as a change in expected cash flows. The cash flows under the bank loan were revised from May 1, 2019.

Management estimated the revised carrying value of the loan on May 1, 2019 to be £19.9 million by discounting the revised cash flows at the original discount rate of 18%. The difference between the previous and revised carrying value of the loan on May 1, 2019 was £0.5 million. The gain as a result of the changes in estimated cash flows is recognized as a true-up in total finance cost (i.e. together with interest expense). Following the re-estimation, the financial liability continues to be accounted for at amortized cost using the original effective interest rate.

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On May 3, 2019, under the terms of the loan agreement, the Company issued 321,444 additional warrants (Note 21) to its lenders giving them the right to subscribe for ordinary shares at an exercise price of £2.95. The fair value of the additional warrants on their grant date was £0.1 million.

A total of £1.5 million (2018: £0.8 million) of non-cash interest has been charged to the consolidated statement of comprehensive loss in the year.

The fair value of the bank loan is not materially different from the carrying amount, since the interest payable on the borrowings is reflective of market rates following the most recent amendment to the bank loan on May 1, 2019. In the prior year, the bank loan was modified and a modification loss of £0.7 million was recognized on the consolidated statement of comprehensive loss on the date of modification. This balance has been reclassified from administrative expenses to finance charges within the statement of comprehensive loss.

20. Provisions

	Year ended December 31	
	2018	2019
Social security contributions on share options	842	104
Provision for deferred cash consideration	2,131	1,654
At December 31	<u>2,973</u>	<u>1,758</u>
Current	332	309
Non-current	<u>2,641</u>	<u>1,449</u>

	Year ended December 31		
	2017	2018	2019
<u>Social security contributions on share options</u>			
At beginning of year	1,172	2,288	842
Arising during the year	1,116	—	—
Released	—	(1,446)	(738)
At December 31	<u>2,288</u>	<u>842</u>	<u>104</u>
Current	—	—	—
Non-current	<u>2,288</u>	<u>842</u>	<u>104</u>

The provision for social security contributions on share options is calculated based on the number of options outstanding at the reporting date that are expected to be exercised. The provision is based on the estimated taxable gain arising on exercise of the share options, using the best estimate of the market price at the balance sheet date.

Management assume the options will be held for their full contractual life of ten years (see Note 26) therefore the provision has been classified as non-current. The provision has been discounted.

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The negative charge in 2019 is due to the fall in the Company's share price between December 31, 2018 and December 31, 2019.

Provisions for deferred cash consideration	Year ended December 31		
	2017	2018	2019
At beginning of year	—	2,061	2,131
Arising during the year	2,061	—	—
Increase in provision due to the unwinding of the time value of money	—	443	221
Decrease in provision due to a change in estimates relating to timelines and probabilities of contractual milestones being achieved (see Note 12)	—	(373)	(698)
At December 31	<u>2,061</u>	<u>2,131</u>	<u>1,654</u>
Current	274	332	309
Non-current	<u>1,787</u>	<u>1,799</u>	<u>1,345</u>

The deferred cash consideration is the estimate of the quantifiable but not certain future cash payment obligations due to AstraZeneca for the acquisition of certain assets (see Note 13).

This liability is calculated as the risk-adjusted net present value of future cash payments to be made by the Group. The payments are dependent on reaching certain milestones based on the commencement and outcome of clinical trials.

The likelihood of achieving such milestones is reviewed at the balance sheet date and increased or decreased as appropriate.

21. Warrant liability

	Year ended December 31		
	2017	2018	2019
At beginning of year	—	1,346	1,006
Issued during the year	1,292	376	131
Movement during the year	54	(716)	(1,006)
At December 31	<u>1,346</u>	<u>1,006</u>	<u>131</u>

At December 31, 2018, as part of the bank loan facility, the Company had issued 922,464 warrants (Note 19) to its lenders giving them the right to subscribe for ordinary shares at a range of exercise price between £2.31 and £3.30.

On May 3, 2019, the Company issued a further 321,444 warrants to its lenders giving them the right to subscribe for ordinary shares at an exercise price of £2.95. The fair value of the additional warrants on their grant date was £0.1 million.

At December 31, 2019, a total of 1,243,908 warrants are outstanding which are held by lenders of the bank loan facility. The warrants outstanding are equivalent to 1.27% of the ordinary share capital of the Company. The movement during the year ended December 31, 2019 of £1.0 million was mostly due to the decrease in the market price of ordinary shares (refer to table below).

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The warrant instrument is classified as a financial liability as the terms of the instrument allow for a cashless exercise. At each balance sheet date, the fair value of the warrants will be assessed using the Black Scholes model considering appropriate amendments to inputs in respect of volatility and remaining expected life of the warrants.

The following table lists the weighted average inputs to the models used for the fair value of warrants granted during the year ended December 31:

	Year ended December 31	
	2018	2019
Expected volatility (%)	65	67
Risk-free interest rate (%)	1.56	1.26
Expected life of share options (years)	10	10.0
Market price of ordinary shares (£)	2.31	0.83
Model used	Black Scholes	Black Scholes

Since there is no historical data in relation to the expected life of the warrants, the contractual life of the options was used in calculating the expense for the year.

Volatility was estimated by reference to the share price volatility of a group of comparable companies over a retrospective year equal to the expected life of the warrants.

22. Other liability

	Year ended December 31	
	2018	2019
At beginning of year	—	34
Interest accretion	—	10
Arising during the year	34	—
At December 31	<u>34</u>	<u>44</u>

On October 8, 2018, the Group entered into a funding agreement with The Alpha-1 Project (“TAP”), which provides for total potential payments to Mereo of \$400,000 as contributions towards the development of MPH-966 upon completion of certain milestones by the Group. In exchange, on receipt of such funding, the Group will issue warrants allowing TAP to subscribe for shares in the company (see Note 18). Under the agreement, TAP is potentially entitled to receive a payment equivalent to amounts received by Mereo (up to a maximum of \$400,000) conditional on and within thirty days of the first regulatory approval received by the Group for MPH-966.

The first payment (“Payment 1”) of \$100,000 (£78,445) was made to Mereo on November 16, 2018. The fair value of the liability of Payment 1 on November 16, 2018 was £34,289. Application of the effective interest method is required to accrete the initial liability value up to the face value of the liability over a period of five years, being the estimate of the earliest date that the liability could be repaid and assuming that the agreement is not terminated earlier. This non-cash interest charge will be made in each statutory reporting period. The annual value of this interest charge is 25.8%.

The fair value of warrants issued as part of Payment 1 on November 16, 2018 was £44,156.

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23. Trade and other payables

	Year ended December 31	
	2018	2019
Trade payables	4,393	6,148
Social security and other taxes	161	183
Other payables	16	21
At December 31	<u>4,570</u>	<u>6,352</u>

Terms and conditions of the above financial liabilities:

- Trade payables are non-interest bearing and are normally settled on 30-day terms; and
- Other payables are non-interest bearing and have an average term of one month.

24. Changes in liabilities arising from financing activities

	Contingent consideration	Lease liability	Bank loan	Novartis Notes	Warrant liability	Deferred cash consideration	TAP agreement	Total
Carrying value at January 1, 2018	—	—	18,775	1,977	1,346	2,061	—	24,159
Financing cash flows	—	—	(2,111)	—	—	—	34	(2,077)
Changes in fair values	—	—	(375)	—	(716)	70	—	(1,021)
Interest expense	—	—	2,427	185	—	—	—	2,612
Loss on modification	—	—	730	—	—	—	—	730
Other	—	—	—	(124)	375	—	—	251
Carrying value December 31, 2018	<u>—</u>	<u>—</u>	<u>19,446</u>	<u>2,038</u>	<u>1,005</u>	<u>2,131</u>	<u>34</u>	<u>24,654</u>
Adoption of IFRS 16 (Leases)	—	2,534	—	—	—	—	—	2,534
Financing cash flows	—	(2,212)	(1,739)	—	—	—	—	(3,951)
Changes in foreign exchange	—	(131)	—	—	—	—	—	(131)
Changes in fair values	354	—	—	—	(874)	(477)	10	(987)
Interest expense	—	1,314	3,262	20	—	—	—	4,596
Gain on modification	—	—	(457)	—	—	—	—	(457)
Issuance of equity	—	—	—	(2,058)	—	—	—	(2,058)
Acquisition of subsidiary (Note 5)	—	10,689	—	—	—	—	—	10,689
Lease term reassessment	—	(290)	—	—	—	—	—	(290)
Carrying value at December 31, 2019	<u>354</u>	<u>11,904</u>	<u>20,512</u>	<u>—</u>	<u>131</u>	<u>1,654</u>	<u>44</u>	<u>34,599</u>

25. Financial and capital risk management and fair value measurement

25.1 Capital risk management

For the purpose of the Group's capital management, capital includes issued capital, share premium, the equity component of a convertible loan note and all other equity reserves attributable to the equity holders of the parent.

The Group's objectives when managing capital are to safeguard the ability to continue as a going concern and ensure that sufficient capital is in place to fund the Group's R&D activities. The Group's principal method of adjusting the capital available is through issuing new shares or arranging suitable debt financing, including any related warrants. The Group's share capital and share premium are disclosed in Note 18. The Group's loans are disclosed in Note 19. The Group monitors the availability of capital with regard to its committed and planned forecast future expenditure on an ongoing basis.

The Group has set up an Employee Benefit Trust which makes market purchases of the Company's shares to provide some cover against future exercise of options under the Company's share option schemes (see Note 28).

25.2 Financial risk management objectives and policies

Monitoring of financial risk is part of the Board's ongoing risk management, the effectiveness of which is reviewed annually. Our agreed policies are implemented by the Chief Financial Officer, who submits periodic reports to the Board. The Group seeks to maintain a balance between equity capital and convertible and secured debt to provide sufficient cash resources to execute the business plan. In addition, the Group maintains a balance between cash held on deposit and short-term investments in Sterling and other currencies to reduce its exposure to foreign exchange fluctuations in respect of its planned expenditure.

Except for the bank loan, the Group's principal financial instruments comprise trade payables which arise directly from its operations and are not designed as a means of raising finance for the Group's operations. The Group has various financial assets, such as receivables and cash and short-term deposits. The Group does not consider that its financial instruments gave rise to any material financial risks during the year to December 31, 2019.

Interest rate risk

The Group's policy in relation to interest rate risk is to monitor short and medium-term interest rates and to place cash on deposit for periods that optimize the amount of interest earned while maintaining access to sufficient funds to meet day-to-day cash requirements.

The interest payable on the bank loan is fixed. Consequently, there is no material exposure to interest rate risk in respect of interest payable.

Foreign currency risk

The Group currently has no revenue. The majority of operating costs are denominated in pound sterling, Euros and U.S. Dollars. Funding to date has been secured in a mixture of pound sterling and U.S. Dollars and therefore a level of natural hedging exists in respect of operating costs. Foreign exchange risk arises from commercial transactions and recognized assets and liabilities in foreign currencies.

Credit risks

The Group's policy is to place funds with financial institutions which have a minimum long-term credit rating with Standard & Poor's of A. The Group also allocates a quota to individual institutions in respect of cash deposits and also seeks to diversify its investments where this is consistent with achieving competitive rates of return. It is the Group's policy to place not more than £10 million with any one investment counterparty and no more than £5 million with any one cash deposit counterparty.

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Cash flow and liquidity risk

Credit risk from balances with banks and financial institutions is managed by the Group's finance department in accordance with the Group's policy. Investments of surplus funds are made only with approved counterparties and within credit limits assigned to each counterparty. Counterparty credit limits are reviewed by the Group's Board of Directors on an annual basis and may be updated throughout the year subject to approval of the Group's Audit and Risk Committee. The limits are set to minimize the concentration of risks and therefore mitigate financial loss through a counterparty's potential failure to make payments.

The Group's maximum exposure to credit risk for the components of the balance sheet at December 31, 2019 is the carrying amounts. The Group does not face a significant liquidity risk with regards to its lease liabilities.

The Group monitors its funding requirements through preparation of short-term, mid-term and long-term forecasts. All short-term deposits are immediately convertible to liquid funds without penalty and are recorded in the balance sheet at their open market value. Please refer to Note 2 "Going concern" regarding the Directors' assessment of liquidity for further information.

25.3 Fair value hierarchy

	Date of valuation	Fair value measurement using			
		Total	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Liabilities measured at fair value					
Provision for deferred cash consideration (Note 20)	December 31, 2019	1,654	—	—	1,654
Provision for contingent consideration (Note 5)	December 31, 2019	354	—	—	354
Warrant liability (Note 21)	December 31, 2019	131	—	131	—
Liabilities for which fair values are disclosed					
Bank loan (Note 19)	December 31, 2019	20,512	—	20,512	—

There were no transfers between Level 1 and Level 2 during 2019.

Fair value measurement hierarchy for liabilities as at December 31, 2018:

	Date of valuation	Fair value measurement using			
		Total	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Liabilities measured at fair value					
Provision for deferred cash consideration (Note 20)	December 31, 2018	2,061	—	—	2,061
Warrant liability (Note 21)	December 31, 2018	1,346	—	1,346	—
Liabilities for which fair values are disclosed					
Convertible loan (Note 19)	December 31, 2018	1,977	—	1,977	—
Bank loan (Note 19)	December 31, 2018	18,775	—	18,775	—

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There were no transfers between Level 1 and Level 2 during 2018.

The management of the Group assessed that the fair values of cash and short-term deposits, other receivables, trade payables, and other current liabilities approximate their carrying amounts largely due to the short-term maturities of these instruments.

The following table presents the changes in level 3 items for the periods ended December 31, 2019 and December 31, 2018:

	Provision for deferred cash consideration	Provision for contingent consideration
January 1, 2018	2,061	—
Unwinding of the time value of money recognised as a finance charge	443	—
Change in estimate relating to probabilities (revision to intangible asset, see Note 13)	(373)	—
December 31, 2018	2,131	—
January 1, 2019	2,131	—
Unwinding of the time value of money (recognized as a finance charge)	221	—
Change in estimate relating to probabilities (revision to intangible asset, see Note 13)	(698)	—
Change in estimate relating to probabilities (recognized as an administrative expense)	—	354
December 31, 2019	1,654	354

The following methods and assumptions were used to estimate the fair values:

- The warrant liability is estimated using a Black Scholes model, taking into account appropriate amendments to inputs in respect of volatility, remaining expected life of the warrants, cost of capital, probability of success and rates of interest at each reporting date.
- The fair value of the provision for deferred cash consideration is estimated by discounting future cash flows using rates currently available for debt on similar terms and credit risk. In addition to being sensitive to a reasonably possible change in the forecast cash flows or the discount rate, the fair value of the deferred cash consideration is also sensitive to a reasonably possible change in the probability of reaching certain milestones. The valuation requires management to use unobservable inputs in the model, of which the significant unobservable inputs are disclosed in the tables below. Management regularly assesses a range of reasonably possible alternatives for those significant unobservable inputs and determines their impact on the total fair value.

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- At December 31, 2019, the Group estimates the fair value of the contingent consideration liability to be £0.4 million, which is an increase from £nil on the date of acquisition. Total potential payments under the CVR arrangement on a gross, undiscounted basis are approximately \$80.0 million (see Note 13). The increase in the fair value of the contingent consideration liability reflects the terms subsequently agreed with Oncologie, Inc. (“Oncologie”) with respect to the global licensing agreement of navicixizumab (“Navi”) (see Note 30). The estimated contingent consideration payable is based on a risk-adjusted, probability-based scenario. Under this approach the likelihood of future payments being made to the former shareholder of OncoMed under the CVR arrangement is considered. The estimate could materially change over time as the development plan and subsequent commercialization of the Navi product progresses.

The significant unobservable inputs used in the fair value measurements categorized within Level 3 of the fair value hierarchy, together with a quantitative sensitivity analysis as at December 31, 2019 and 2018 are as shown below:

	Valuation technique	Significant unobservable inputs	Input range (weighted average)	Sensitivity of the input to fair value
Provision for deferred cash consideration	DCF	WACC	2019: 15.3%	1% increase would result in a decrease in fair value by £38,000.
		WACC	2018: 15.3%	1% decrease would result in an increase in fair value by £18,000
		Probability of success	2019: 15.8–95%	10% increase would result in an increase in fair value by £0.4 million
		Probability of success	2018: 28%–95%	10% decrease would result in a decrease in fair value by £0.9 million
Contingent consideration liability	DCF	Ongoing uncertainty in the clinical development of the Navi product. Regulatory approval and commercialisation risks.	Not applicable	Total potential payments future payments relating to the contingent consideration liability on a gross, undiscounted basis are approximately \$80.0 million (see Note 30). Sensitivity of the input to fair value is primarily driven by uncertainty in the clinical development of the Navi product. As at December 31, 2019, we are completing a Phase 1b clinical trial. Future potential payments under the CVR arrangement are contingent on i) future development milestones and ii) future sales of the Navi product, following regulatory approval and commercialisation.

25.4 Financial assets at fair value through other comprehensive income

During the year, the Group acquired £29.0 million of short-term debt investments following the acquisition of OncoMed (Note 5). The short-term debt investments acquired were in U.S. Treasury Bills (“T-Bill”) securities.

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All the short-term debt investments have reached maturity and been sold during the year, therefore the carrying value as at December 31, 2019 is £nil. On maturity, the related balance held within other comprehensive income has been reclassified to finance income within the consolidated statement of comprehensive loss.

25.5 Liquidity risk

The table below summarizes the maturity profile of the Group's financial liabilities based on contractual undiscounted payments at December 31, 2019:

	Payments due by period				Total
	Up to 1 year	1-3 years	3-5 years	Over 5 years	
Bank loan (Note 19)	17,185	5,484	—	—	22,669
Leases (Note 4)	2,634	4,643	4,913	8,105	20,295
Trade and other payables (Note 23)	6,352	—	—	—	6,352
Contingent consideration liability (Note 5)	354	—	—	—	354
	<u>26,525</u>	<u>10,127</u>	<u>4,913</u>	<u>8,105</u>	<u>49,670</u>

Further details regarding the contingent consideration liability following the acquisition of OncoMed are provided in Note 5.

The table below summarizes the maturity profile of the Group's financial liabilities based on contractual undiscounted payments at December 31, 2018:

	Payments due by period				Total
	Up to 1 year	1-3 years	3-5 years	Over 5 years	
Convertible loan (Note 19)	83	2,162	—	—	2,245
Bank loan (Note 19)	8,260	15,589	—	—	23,849
Leases (Note 27)	332	204	—	—	536
Trade and other payables (Note 23)	4,570	—	—	—	4,570
	<u>13,245</u>	<u>17,955</u>	<u>—</u>	<u>—</u>	<u>31,200</u>

The Group may incur potential payments upon achievement of clinical, regulatory and commercial milestones, as applicable, or royalty payments that may be required to be made under license agreements the Group entered into with various entities pursuant to which the Group has in-licensed certain intellectual property, including license agreements with Novartis and AstraZeneca. Due to the uncertainty of the achievement and timing of the events requiring payment under these agreements, the amounts to be paid are not fixed or determinable at this time.

25.6 Market risk

The functional currency of the Company and all subsidiaries is pound sterling except for OncoMed whose functional currency is US dollars. The Group incurs expenditures in foreign currencies and is exposed to the risks of foreign exchange rate movements, with the impact recognized in the consolidated statement of comprehensive loss. The Group seeks to minimize this exposure by passively maintain foreign currency cash balances at levels appropriate to meet foreseeable foreign currency expenditures.

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The table below shows analysis of the pound sterling equivalent of period-end cash and cash equivalent balances by currency:

	Year ended December 31, 2019	Year ended December 31, 2018
Cash at bank and in hand:		
Pound sterling	2,525	23,189
US dollars	13,807	1,809
Swiss francs	11	—
Euro	4	44
	<u>16,347</u>	<u>25,042</u>

The table below shows those transactional exposures that give rise to net currency gains and losses recognized in the consolidated income statement. Such exposures comprise the net monetary assets and monetary liabilities of the Group that are not denominated in the functional currency of the relevant Group entity. As at year end, these exposures were as follows:

	Year ended December 31, 2019	Year ended December 31, 2018
Net foreign currency assets / (liabilities):		
US dollars	(219)	(542)
Swiss francs	(6)	—
Euro	(812)	(1,430)
	<u>(1,037)</u>	<u>(1,972)</u>

The most significant currencies in which the Group transacts, other than pound sterling, are the US dollar and the Euro. The Group also trades in other currencies in small amounts as necessary.

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The following table details the Group's sensitivity to a 10% change in the period-end rate, which the Group feels is the maximum likely change in rate based upon recent currency movements, in the US dollar and the Euro against pound sterling:

<u>Year ended December 31, 2019</u>	<u>US dollar</u>	<u>Euro</u>
Net foreign currency assets / (liabilities):		
Loss before tax	20	74
Equity	20	74

<u>Year ended December 31, 2018</u>	<u>US dollar</u>	<u>Euro</u>
Net foreign currency assets / (liabilities):		
Loss before tax	49	130
Equity	49	130

In management's opinion, the sensitivity analysis is unrepresentative of the inherent foreign exchange risk as the period end exposure does not reflect the exposure during the period.

26. Share-based payments

The charge for share-based payments under IFRS 2 arises across the following schemes:

	<u>Year ended December 31,</u>		
	<u>2017</u>	<u>2018</u>	<u>2019</u>
2019 Equity Incentive Plan	—	—	635
2019 NED Equity Incentive Plan	—	—	160
2015 Plan	2,442	806	63
Mereo BioPharma Group plc Share Option Plan	586	1,064	685
Long Term Incentive Plan	299	320	93
Deferred Bonus Share Plan	325	—	—
	<u>3,652</u>	<u>2,190</u>	<u>1,636</u>

26.1 2019 Equity Incentive Plan ("EIP")

Our Board adopted the 2019 EIP on April 4, 2019. The 2019 EIP provides for the grant of market value options over ADR's (each ADR represented by 5 ordinary shares) to executive directors and employees.

During the year, market value options were granted to executive directors and employees. Subject to the executive director or employees continued employment, one fourth of each such market value option grant shall vest on the first anniversary of the grant date and the remainder shall vest in equal monthly instalments over the three-year period following the first anniversary. No performance conditions apply to such market value options.

The fair value of share options granted was estimated at the date of grant using a Black Scholes pricing model, taking into account the terms and conditions upon which the share options were granted. The fair value calculation does not include any allowance for dividends as the Company has no available profits for distribution.

The exercise price of the share options will be equal to the market price of the underlying shares on the date of grant. The contractual term of the share options is 10 years.

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Movements during the year

The following table illustrates the number and weighted average exercise prices (WAEP) of, and movements in, options for the 2019 EIP during the year:

	2019	
	Options over ADR's Number	WAEP \$
Outstanding at beginning of the year	—	—
Granted during the year	801,200	4.29
Cancelled during the year	3,150	5.40
Forfeited during the year	—	—
Exercised during the year	—	—
Outstanding at December 31	<u>798,050</u>	<u>4.29</u>
Exercisable at December 31	<u>—</u>	<u>—</u>

The weighted average remaining contractual life for the share options outstanding as at December 31, 2019 was 9.5 years.

The weighted average fair value of options granted during the year was £0.49 (2018: £nil).

Options outstanding at the end of the year had an exercise price of between \$2.60 and \$5.40.

26.2 2019 Non-Executive Director Equity Incentive Plan (“NED EIP”)

Our Board adopted the 2019 NED EIP on April 4, 2019. The 2019 NED EIP provides for the grant of market value options over ADR's to non-executive directors.

Subject to the participant holding the participant's current office (or being otherwise employed) through each applicable vesting date, such awards shall vest in equal monthly instalments over a one-year period following the grant date. No performance conditions apply to such market value options.

The fair value of share options granted was estimated at the date of grant using a Black Scholes pricing model, taking into account the terms and conditions upon which the share options were granted. The fair value calculation does not include any allowance for dividends as the Company has no available profits for distribution.

The exercise price of the share options will be equal to the market price of the underlying shares on the date of grant. The contractual term of the share options is 10 years.

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Movements during the year

The following table illustrates the number and weighted average exercise prices (WAEP) of, and movements in, options for the 2019 NED EIP during the year:

	2019	
	Options over ADR's Number	WAEP \$
Outstanding at beginning of the year	—	—
Granted during the year	77,000	4.20
Cancelled during the year	—	—
Forfeited during the year	—	—
Exercised during the year	—	—
Outstanding at December 31	<u>77,000</u>	<u>4.20</u>
Exercisable at December 31	<u>38,472</u>	<u>4.40</u>

The weighted average remaining contractual life for the share options outstanding as at December 31, 2019 was 9.5 years.

The weighted average fair value of options granted during the year was £0.49 (2018: £nil).

Options outstanding at the end of the year had an exercise price of between \$3.00 and \$5.40.

26.3 The 2015 Plan

Under the Mereo BioPharma Group Limited Share Option Plan (the “2015 Plan”), the Group, at its discretion, granted share options to employees, including executive management and NEDs. Share options vest over four years for executive management and employees and over three years for NEDs. No further share option grants are envisaged under the 2015 Plan.

Movements during the year

The following table illustrates the number and weighted average exercise prices (WAEP) of, and movements in, options for the 2015 Plan during the year:

	2017		2018		2019	
	Number	WAEP £	Number	WAEP £	Number	WAEP £
Outstanding at beginning of the year	9,198,655	1.32	9,124,610	1.32	8,983,133	1.32
Granted during the year	—	—	—	—	—	—
Cancelled during the year	—	—	—	—	—	—
Forfeited during the year	(74,045)	1.29	(46,255)	1.29	(59,533)	1.29
Exercised during the year	—	—	(95,222)	1.29	—	—
Outstanding at December 31	<u>9,124,610</u>	<u>1.32</u>	<u>8,983,133</u>	<u>1.32</u>	<u>8,923,600</u>	<u>1.32</u>
Exercisable at December 31	<u>5,655,676</u>	<u>1.31</u>	<u>8,007,029</u>	<u>1.31</u>	<u>8,901,478</u>	<u>1.32</u>

The weighted average remaining contractual life for the share options outstanding as at December 31, 2019 was 5.6 years (2018: 6.6 years).

Options outstanding at the end of the year had an exercise price of between £1.29 and £2.21.

26.4 The Mereo BioPharma Group plc Share Option Plan

The Mereo BioPharma Group plc Share Option Plan (“Share Option Plan”) provides for the grant of options to acquire our ordinary shares to employees, executive directors and executive officers. Options may be granted to all eligible employees on commencement of employment and may be granted on a periodic basis after that. Under the Share Option Plan, our Board of Directors may determine if the vesting of an option will be subject to the satisfaction of a performance condition. Following the introduction of the EIP and NED EIP, no further share option grants under the Share Option Plan are envisaged.

Movements during the year

The following table illustrates the number and weighted average exercise prices (WAEP) of, and movements in, options for the Option Plan during the year:

	2017		2018		2019	
	Number	WAEP £	Number	WAEP £	Number	WAEP £
Outstanding at beginning of the year	—	—	1,578,188	3.05	1,881,555	3.10
Granted during the year	1,593,188	3.05	388,000	3.14	—	—
Cancelled during the year	—	—	—	—	—	—
Forfeited during the year	(15,000)	3.03	(84,633)	3.03	(357,490)	3.21
Outstanding at December 31	<u>1,578,188</u>	<u>3.05</u>	<u>1,881,555</u>	<u>3.10</u>	<u>1,524,065</u>	<u>3.07</u>
Exercisable at December 31	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>40,141</u>	<u>3.03</u>

The weighted average remaining contractual life for the share options outstanding as at December 31, 2019 was 7.6 years (2018: 8.6 years).

The weighted average fair value of options granted during the year was £nil (2018: £2.29).

Options outstanding at the end of the year had an exercise price of between £2.76 and £3.25.

26.5 Long Term Incentive Plan

Under the Company’s Long Term Incentive Plan (LTIP), initiated in 2016, the Group, at its discretion, may grant nil-cost options to acquire shares to employees. Under the LTIP rules, vesting of 75% of the options issued to employees is subject to a share price performance condition (the “Share Price Element”) and vesting of 25% of the options is subject to achievement of strategic operational targets (the “Strategic Element”). Share options vest over a maximum of five years, dependent upon achievement of these targets.

The fair value of the LTIP Share Price Element is estimated at the date of grant using a Monte Carlo pricing model, taking into account the terms and conditions upon which the share options were granted. The fair value of the LTIP Strategic Element is estimated at the date of grant using a Black Scholes pricing model, taking into account the terms and conditions upon which the share options were granted, and the expense recorded is based upon the expected level of achievement of non-marked based performance measures (strategic targets).

With respect to the LTIP Strategic Element, during the year the non-market based performance measures were reassessed. Based on that reassessment, an adjustment with respect to the cumulative compensation expense recognized in equity has been recorded which resulted in a credit of £0.1 million recorded in the consolidated statement of comprehensive loss.

The fair value calculations do not include any allowance for dividends as the Company has no available profits for distribution.

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The contractual term of the LTIP options is five years.

The expense recognized for employee services received during the year to December 31, 2019 was £0.1 million (2018: £0.3 million).

	2017 Number	2018 Number	2019 Number
Granted during the year	185,950	—	—
Cancelled during the year	—	—	—
Lapsed during the year	—	—	(241,374)
Outstanding at December 31	<u>1,151,446</u>	<u>1,151,446</u>	<u>910,072</u>
Exercisable at December 31	<u>—</u>	<u>—</u>	<u>—</u>

During the year 241,373 options under the LTIP Share Price Element lapsed as the performance conditions for a tranche were not met.

The weighted average remaining contractual life for the LTIP options outstanding as at December 31, 2019 was 0.9 years (2018: 1.8 years).

The weighted average fair value of LTIP options granted during the year to December 31, 2019 was £nil (2018: £nil).

The following tables list the weighted average inputs to the models used for the fair value of LTIP options granted during the years ended December 31, 2017, 2018 and 2019.

LTIP Share Price Element

	Year ended December 31		
	2017	2018	2019
Expected volatility (%)	51.7	—	—
Risk-free interest rate (%)	0.17-0.39	—	—
Expected life of share options (years)	3-5	—	—
Market price of ordinary shares (£)	3.03	—	—
Model used	Monte Carlo	—	—

LTIP Strategic Element

	Year ended December 31		
	2017	2018	2019
Expected volatility (%)	51.7	—	—
Risk-free interest rate (%)	0.39	—	—
Expected life of share options (years)	5	—	—
Market price of ordinary shares (£)	3.03	—	—
Model used	Black Scholes	—	—

Since there is no historical data in relation to the expected life of the LTIP options, the contractual life of the options has been used in calculating the expense for the year.

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Volatility is estimated by reference to the share price volatility of a group of comparable companies over a retrospective period equal to the expected life of the LTIP options.

26.6 Deferred Bonus Share Plan

Under the previous terms of the Company's Deferred Bonus Share Plan (DBSP), 30% of the annual bonus for 2017 for the senior management team was payable in deferred shares, which are governed by the DBSP plan rules. At the date of grant of the awards, the monetary bonus amount will be divided by the closing share price to give the number of shares issued to the employee under the DBSP. The number of shares is fixed and not subject to adjustment between the issue date and vesting date. Under the DBSP, awards vest after three years from the date of the award.

There are no further performance conditions attached to the award, nor any service conditions (including no requirement for continued employment once the awards have been made).

Since the awards are issued at nil cost, they will be satisfied by the issue of shares from the Employee Benefit Trust.

The following table illustrates the number of, and movements in, DBSP options during the year:

	<u>2017</u> <u>Number</u>	<u>2018</u> <u>Number</u>	<u>2019</u> <u>Number</u>
Outstanding at January 1	62,180	163,000	163,000
Awarded during the year	100,820	—	—
Granted during the year	—	—	—
Outstanding at December 31	<u>163,000</u>	<u>163,000</u>	<u>163,000</u>
Exercisable at December 31	<u>—</u>	<u>—</u>	<u>—</u>

The weighted average remaining contractual life for the DBSP options outstanding as at December 31, 2019 was 1.6 years (2018: 2.6 years).

The weighted average fair value of DBSP options granted during the year was £nil (2018: £nil).

From January 1, 2018, under the new Deferred Bonus Plan ("2019 DBP"), 100% of the annual bonus is paid in cash, of which 30% of amounts granted to Executive Directors (after deduction of income tax and the relevant employee's national insurance contributions) is required to be utilized to acquire shares in the Company in the open market within 12 months of the grant of the award. No further grants under the DBSP are envisaged.

26.7 Deferred equity consideration

In October 2017, our wholly owned subsidiary Mereo BioPharma 4 Limited entered into an exclusive license and option agreement (the "License Agreement"), to obtain from AstraZeneca an exclusive worldwide, sub-licensable license under AstraZeneca's intellectual property rights relating to MPH-966, with an option to acquire such intellectual property rights following commencement of a pivotal trial and payment of related milestone payments (the "Option"), together with the acquisition of certain related assets.

Under the agreement with AstraZeneca, the Company may issue up to 1,349,693 ordinary shares which are dependent on achieving certain milestones.

In respect of milestones that are probable, the Group has accounted for, but not yet issued, 429,448 ordinary shares which have been measured at fair value on grant date, being £3.10, giving a total of £1.3 million.

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26.8 Weighted average inputs

The following tables list the weighted average inputs to the models used for the fair value of share options granted during the year ended December 31, 2019:

	<u>EIP 2019 grants</u>	<u>NED EIP 2019 grants</u>
Expected volatility (%)	66	66
Risk-free interest rate (%)	0.95	0.97
Expected life of share options (years)	10	10
Market price of ordinary shares (£)	0.66	0.63
Model used	Black Scholes	Black Scholes

During the year ended December 31, 2019, grants were issued under the EIP 2019 and NED EIP 2019 plans.

The following tables list the weighted average inputs to the models used for the fair value of share options granted during the year ended December 31, 2018:

	<u>Share option plan grants</u>
Expected volatility (%)	65 – 67
Risk-free interest rate (%)	1.39 – 1.53
Expected life of share options (years)	10
Market price of ordinary shares (£)	2.76 – 3.25
Model used	Black Scholes

During the year ended December 31, 2018, grants were issued under the share option plan. Grants issued in previous years under the LTIP Strategic element are subject to fair value movements at each reporting date.

27. Commitments and contingencies

27.1 Group as a lessee

Following the adoption of IFRS 16 (Leases), information relating to the Group as a lessee can be found in Note 4 (Changes in accounting policies), Note 12 (Property, Plant and Equipment) and Note 25 (Financial and capital risk management).

27.2 Operating lease arrangements

Operating leases, in which the Group is the sublessor, relate to a portion of an office leased by the Group, with lease terms of between one to two years. One of the subleases has an automatic extension on a month-to-month basis following the initial lease term, with rental increasing at a set percentage on each annual anniversary of the agreement. The lessee does not have an option to purchase the property at the expiry of the lease period.

The unguaranteed residual values do not represent a significant risk for the Group, as the lease terms are for a remaining period of 12 months or less, and the Group expects to be able to enter into new leases at market value at the end of the sublease term.

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The maturity analysis of payments receivable by the Group in its capacity as sublessor is disclosed below:

	December 31, 2019	December 31, 2018
Within one year	552	—
After one year but not more than five years	—	—
More than five years	—	—
	<u>552</u>	<u>—</u>

The Group does not have any leasing arrangements classified as finance leases at December 31, 2019 (2018: £nil).

27.3 Financial commitments

Each of Mereo BioPharma 1 Limited, Mereo BioPharma 2 Limited and Mereo BioPharma 3 Limited issued to Novartis loan notes (the “Novartis Notes”) (which were assigned by Novartis to the Company in exchange for ordinary shares pursuant to the Subscription Agreement) and each of Mereo BioPharma 1 Limited, Mereo BioPharma 2 Limited and Mereo BioPharma 3 Limited agreed to make future payments to Novartis comprising amounts equal to ascending specified percentages of tiered annual worldwide net sales (beginning at high single digits and reaching into double digits at higher sales) by such subsidiary of products that include the assets acquired. The levels of ascending percentages of tiered annual worldwide net sales are the same for each of Mereo BioPharma 1 Limited, Mereo BioPharma 2 Limited and Mereo BioPharma 3 Limited under the respective Purchase Agreements.

Each of Mereo BioPharma 1 Limited, Mereo BioPharma 2 Limited and Mereo BioPharma 3 Limited further agreed that in the event it transfers, licenses, assigns or leases all or substantially all of its assets, it will pay Novartis a percentage of the proceeds of such transaction. The Company will retain the majority of the proceeds from such a transaction. Such percentage is the same for each of Mereo BioPharma 1 Limited, Mereo BioPharma 2 Limited and Mereo BioPharma 3 Limited under the respective Purchase Agreements. The payment of a percentage of proceeds is not payable with respect to any transaction involving equity interests of Mereo BioPharma Group plc, a merger or consolidation of Mereo BioPharma Group plc, or a sale of any assets of Mereo BioPharma Group plc.

In October 2017, the Group’s wholly owned subsidiary Mereo BioPharma 4 Limited entered into an exclusive license and option agreement (“the License Agreement”), to obtain from AstraZeneca an exclusive worldwide, sub-licensable license under AstraZeneca’s intellectual property rights relating to MPH-966, with an option to acquire such intellectual property rights following commencement of a pivotal trial and payment of related milestone payments (“the Option”), together with the acquisition of certain related assets. Upon entering into the License Agreement, the Group made a payment of \$3.0 million and issued 490,798 ordinary shares to AstraZeneca, for an aggregate upfront payment equal to \$5.0 million. In connection with certain development and regulatory milestones, the Group has agreed to make payments of up to \$115.5 million in the aggregate and issue additional ordinary shares to AstraZeneca for licensed products containing MPH-966. In addition, the Group has agreed to make payments to AstraZeneca based on specified commercial milestones of the product. The Group has also agreed to pay a specified percentage of sub-licensing revenue to AstraZeneca and to make royalty payments to AstraZeneca equal to ascending specified percentages of tiered annual worldwide net sales by the Group of licensed products (subject to certain reductions), ranging from the high single digits to low double digits. Royalties will be payable on a licensed-product-by-licensed-product and country-by-country basis until the later of ten years after the first commercial sale of such licensed product in such country and expiration of the last patent covering such licensed product in such country that would be sufficient to prevent generic entry. Under the License Agreement, the Group may freely grant sub-licenses to affiliates upon notice to AstraZeneca and must obtain AstraZeneca’s consent, which is not be unreasonably withheld, to grant sub-licenses to a third party. The Group has agreed to use commercially reasonable efforts to develop and commercialize at least one licensed product.

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The License Agreement will expire on the expiry of the last-to-expire royalty term with respect to all licensed products. Upon the expiration of the royalty term for a licensed product in a particular country, the licenses to the Group for such product in such country will become fully paid and irrevocable. Prior to exercise of the Option, if at all, the Group may terminate the License Agreement upon prior written notice. Either party may terminate the agreement upon prior written notice for the other party's material breach that remains uncured for a specified period of time or insolvency. AstraZeneca has agreed to a three-year non-competition restriction in relation to the direct or indirect commercialization or development of NE inhibitors for the treatment of AATD. In addition, AstraZeneca agreed not to assert any AstraZeneca intellectual property rights that were included in the scope of the License Agreement against the Group.

28. Related party disclosures

28.1 Compensation of key management personnel of the Group

The remuneration of key management personnel of the Group is set out below in aggregate:

	<u>Year ended December 31,</u>		
	<u>2017</u>	<u>2018</u>	<u>2019</u>
Short-term benefits	2,757	3,176	3,488
Post-employment benefits	87	60	64
IFRS 2 share-based payment charge	2,726	1,470	1,152
Total compensation paid to key management personnel	<u>5,570</u>	<u>4,706</u>	<u>4,704</u>

The amounts disclosed in the table above are the amounts recognized as an expense during the reporting period related to key management personnel. Key management personnel of the Group consist of executive directors (the Chief Executive Officer and Chief Financial Officer), non-executive directors and other members of management (the General Counsel, the Chief Medical Officer, the Head of Corporate Development, the Head of Patient Access and Commercial Planning and the US Site Head (SVP Regulatory Affairs)).

28.2 Employee Benefit Trust

In 2016 the Company set up an Employee Benefit Trust ("EBT") for the purposes of buying and selling shares on the employees' behalf.

A total of £1.0 million of funding was paid into the EBT by the Company during the year ended December 31, 2019 (2018: £0.3 million). A total of 1,074,274 shares were purchased by the EBT during the year ended December 31, 2019 (2018: 163,000).

As at December 31, 2019 a cash balance of £21,762 (2018: £21,762) was held by the EBT.

28.3 Novartis Notes

On June 6, 2019, Novartis delivered to the Company a notice of conversion with respect to the aggregate principal amount and interest of the Novartis Notes. Pursuant to such notice, on June 21, 2019, £2.4 million aggregate principal amount of Novartis Notes was converted into 1,071,042 fully paid ordinary shares at a fixed conversion price of £2.21 per ordinary share (see Note 18). Additionally, in connection with such conversion, the Company issued 864,966 bonus shares to Novartis.

On February 10, 2020, the Company entered into a £3.8 million convertible equity financing with Novartis Pharma (AG) ("Novartis"). Under the terms of the convertible equity financing, Novartis will purchase \$5 million in a convertible loan note (see Note 30).

29. Standards issued but not yet effective

Certain new accounting standards and interpretations have been published that are not mandatory for December 31, 2019 reporting periods and have not been early adopted by the Group. These standards are not expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

30. Events after the reporting period

30.1 Global licensing agreement

On January 13, 2020, the Company and Oncologie, Inc. (“Oncologie”) announced a global licensing agreement for the development and commercialization of navicixizumab (“Navi”).

Under the terms of the global licensing agreement, Oncologie will receive an exclusive worldwide license to develop and commercialize Navi. The Company received an upfront payment of \$4 million on January 17, 2020. The Company is also eligible for an additional payment of \$2 million conditional on a Chemistry, Manufacturing and Controls (“CMC”) milestone. Oncologie will be responsible for all future research, development and commercialization of Navi. Additionally, the Company will be eligible to receive up to \$300 million in future clinical, regulatory and commercial milestones, tiered royalties ranging from the mid-single digit to sub-teen percentages on global annual net sales of Navi, as well as a negotiated percentage of sublicensing revenues from certain sublicenses.

As a consequence of the global licensing agreement with Oncologie, and in accordance with the terms and conditions of the Contingent Value Rights Agreement for former stockholders of OncoMed, dated April 23, 2019, by and among the Company and Computershare Inc., as rights agent, (the “Mereo CVR Agreement”), holders of contingent value rights (“CVRs”) pursuant to the Mereo CVR Agreement will be entitled to receive certain eligible cash milestone payments made to the Company under the global licensing agreement relating to Navi.

Those eligible cash milestone payments are equal to 70% of the aggregate principal amount received by the Company after deduction of costs, charged and expenditures within a period of five years following completion of the OncoMed acquisition on April 23, 2019. Such eligible milestone payments are subject to a cash consideration cap of approximately \$79.7 million.

As at December 31, 2019, the Company was reasonably certain payment of approximately \$0.5 million (£0.4 million) would be made under the Mereo CVR Agreement. The full amount is recorded as a contingent consideration payable on the consolidated balance sheet as at December 31, 2019 and was subsequently paid out in the Q1 2020.

30.2 Novartis convertible equity financing

On February 10, 2020, the Company entered into a £3.8 million convertible equity financing with Novartis Pharma (AG) (“Novartis”). Under the terms of the convertible equity financing, Novartis will purchase £3.8 million in a convertible loan note (“Loan Note”).

The Loan Note is convertible at any time at the option of the holder, at a fixed price of £0.265 per ordinary share. The maturity of the Loan Note is three years from issuance, and it bears an interest rate of 6% per annum.

In connection with the Loan Note issuance, the Company also issued a warrant instrument to Novartis to purchase up to 1,449,614 of the Company’s ordinary shares, which are exercisable at an exercise price of £0.265 per ordinary share at any time before the close of business on February 10, 2025.

30.3 Aspire Capital Securities Purchase Agreement

On February 10, 2020, the Company entered into a Securities Purchase Agreement (the “Agreement”) to issue up to \$28 million of the Company’s ordinary shares exchangeable for American Depositary Shares (“ADSs”), including a \$3 million initial purchase, with Aspire Capital Fund, LLC (“Aspire Capital”), a Chicago-based institutional investor.

Under the terms of the Agreement, Aspire Capital has made an initial investment of \$3 million to purchase 11,423,925 of the Company’s ordinary shares (equivalent to 2,286,585 ADSs) at a price equivalent to \$1.31 per ADS, which represents a 16% discount over Mereo’s ADS closing stock price of \$1.56 on February 8, 2020.

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Under the terms of the Agreement, Aspire Capital has also committed to subscribe at Mereo's request from time to time during a 30-month period for up to an additional \$25 million of Mereo's ordinary shares exchangeable for ADSs at prices based on the ADS market price at the time of each sale.

In consideration for Aspire Capital's initial investment and its commitment to purchase up to an additional \$25 million ADSs, Mereo has agreed to pay Aspire Capital a commission to be satisfied wholly by the issue to Aspire Capital of a further 2,862,595 of the Company's ordinary shares (equivalent to 572,519 ADSs).

30.4 Equity investment from Boxer Capital, LLC

On February 19, 2020, the Company entered into a Securities Purchase Agreement with Boxer Capital, LLC to make an investment of \$3 million to purchase 12,252,715 of the Company's ordinary shares (equivalent to 2,450,543 ADSs) at a price equivalent to 18.8 pence per share, which represents a 20% discount over the Company's closing share price of 23.5 pence on AIM on February 18, 2020.

30.5 Share-based payments

On February 20, 2020, the Company granted 962,836 market value options over ADSs under the Mereo 2019 EIP (Note 26.1) to certain Executive Directors and other employees at an exercise price of \$1.84 per ADS.

On the same date, the Company granted 77,000 market value options over ADSs under the Mereo 2019 NED EIP (Note 26.2) to certain Non-Executive Directors at an exercise price of \$1.84 per ADS.

30.6 Issuance of additional warrants to lenders

Following the transactions noted above, it is anticipated that a further 362,534 additional warrants will be issued to the lenders of the bank loan facility giving them the right to subscribe for ordinary shares at an exercise price of £2.95 (see Note 21).

30.7 Resignation of Chief Financial Officer ("CFO")

On March 27, 2020, we announced the resignation of Richard Jones. Michael Wyzga, a Non-Executive Director, will assume the role of Interim Chief Financial Officer following the departure of Richard Jones. Richard Jones will remain in his position as CFO for a transitional period of up to five months.

For further details, refer to Executive Officer Remuneration within the annual report on Form 20-F.

30.8 Coronavirus ("COVID-19")

Public health epidemics or outbreaks could adversely impact our business. In late 2019, a novel strain of COVID-19, also known as coronavirus, was reported in Wuhan, China. Since, COVID-19 has now spread to several other countries, including the U.K. and U.S., and infections have been reported globally. The extent to which COVID-19 impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak.

At the date of this report, the Company continues to monitor the outbreak and impact of COVID-19 and is actively implementing specific precautionary measures to mitigate potential disruptions accordingly.

30.9 Equity Fund Raise

On June 3, 2020, Mereo BioPharma Group plc completed a private placement (the "Fundraising") of \$70 million (£56 million) before commission and expenses with a number of new and existing principally U.S based institutional and accredited investors (the "Purchasers"). The net proceeds from the Fundraising will be used primarily to fund clinical development activities of the Company's lead product candidates and for general corporate purposes. The Company will utilise \$13 million (£10.4 million) to reduce current indebtedness (including interest) of \$17.6 million (£14.1 million). In the absence of the receipt of any other income, the Board expects that the resulting net proceeds of the Fundraising will fund the Company into early 2022.

The Fundraising comprised proceeds of a total of \$19.4 million (£15.5 million) through the issue of 89.1 million new Ordinary Shares of £0.003 each in the Company at a price of 17.4 pence per share and proceeds of a total of \$50.6 million (£40.5 million) through the issue by the Company of convertible notes (the "Tranche 1 Notes"). The Purchasers also received conditional warrants to subscribe for further Ordinary Shares (the "Warrants").

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The ability for the Tranche 1 Notes to be converted into Ordinary Shares and for the Warrants to be exercised is conditional on the passing of certain resolutions (the “Resolutions”) at a general meeting of shareholders scheduled for June 30, 2020 (the “General Meeting”).

If the Resolutions are passed, the Tranche 1 Notes will automatically convert into Ordinary Shares at 17.4p, subject to limitations that apply to the percentage of voting shares that may be held by Purchasers. Any Tranche 1 Notes not so converted will remain outstanding. The Tranche 1 Notes will not be separately admitted to trading on AIM, but the Ordinary Shares which will arise following any valid conversion of the Tranche 1 Notes will be admitted to trading as part of the Company’s single class of shares admitted to trading on AIM or the relevant exchange on which the Company’s shares are traded at the time the Tranche 1 Notes are converted. The Board estimates that 21,674,143 Tranche 1 Notes will convert automatically if the Resolutions are passed on June 30, 2020, resulting in 124,564,033 Ordinary Shares (excluding Ordinary Shares resulting in respect of interest on the converted Tranche 1 Notes) being issued, leaving 18,859,528 Tranche 1 Notes in issue.

If the Resolutions are not passed on or before 7 August 2020 the convertible notes will not convert into ordinary shares, the warrants will not become capable of exercise and the holders of the convertible notes and warrants will become entitled to certain amounts up to £137.1 million that will represent material liabilities for the Company. The Purchasers, representing in aggregate approximately 40 per cent. of the Company’s total number of shares and votes have undertaken to vote in favour of the Resolutions relating to the warrants and the convertible notes.

The Tranche 1 Notes are constituted by the Note Instrument, details of which are set out below. The Warrants are constituted by the Warrant Instrument, details of which are also set out below.

Note Instrument

The Note Instrument constitutes three potential tranches of Loan Note:

- an initial tranche of 40,533,671 Tranche 1 Notes representing \$50.6 million (£40.5 million) issued to all

Purchasers;

- a second tranche of up to £40.0 million Tranche 2 Notes representing approximately 115,034,554 ordinary shares which may be issued following the third anniversary of the date on which the Resolutions are passed to certain holders of Tranche 1 Notes in lieu of the holder exercising its subscription rights under the Warrants and in return for payment by that holder of the aggregate exercise price of the relevant Warrants; and
- a third tranche of up to £56.0 million Tranche 3 Notes, which may be issued, if the Resolutions are not passed at the General Meeting (or at any subsequent general meeting) held on or before August 7, 2020.

The Tranche 1 Notes have a maturity date of June 2023 unless otherwise extended, converted or accelerated. The Tranche 2 Notes have a maturity date of three years from their date of issue (i.e. such that they would be anticipated as becoming due in 2026) unless otherwise extended, converted or accelerated. The Tranche 3 Notes have a maturity date of August 2025 unless otherwise extended, converted or accelerated. The Tranche 1 Notes and Tranche 2 Notes may be extended by certain holders beyond the initial maturity date to have a longstop maturity date of 10 years from the date of the Note Instrument. Tranche 3 Notes may also be extended by certain holders beyond the initial maturity date up to the same longstop maturity date of 10 years from the date of the Loan Note Instrument, however, such extension is subject to the consent of the Company.

Tranche 1 Notes will initially bear interest at a fixed rate of 10 per cent. per annum, which will be retroactively reduced to a rate of 6 per cent. per annum to the date of issue if the Resolutions are passed on or before August 7, 2020. If the Tranche 1 Notes are extended, they cease to bear interest from that extension. Tranche 2 Notes and Tranche 3 Notes do not accrue interest (unless default interest applies). Following an event of default by the Company, default interest will accrue on all Loan Notes at 2 per cent. above the applicable interest rate in force at that time for the relevant Loan Notes.

All the Loan Notes are unsecured and have been contractually subordinated to the Company’s existing senior debt facility with Silicon Valley Bank and Kreos Capital pursuant to the terms of a Subordination Agreement to which all Purchasers have acceded as part of the Fundraising.

If the Resolutions are not passed on or before August 7, 2020, the holders of Tranche 1 Notes are entitled to an additional fee (the “Uplift Payment”). The Uplift Payment is designed to compensate the Tranche 1 Noteholders for being unable to participate in the equity of the Company through the conversion of the Tranche 1 Notes and the exercise of Warrants. The value of the Uplift Payment for each Purchaser shall be equal to the aggregate principal amount of the Loan Notes held by such Purchaser on August 7, 2020. Any Purchaser who fails to attend the General Meeting (in person or by proxy) and vote in favour of the Resolutions relating to the Warrants and the Tranche 1 Notes shall not be entitled to the Uplift Payment. Any Uplift Payment if due, is payable on the redemption date of the relevant Loan Notes.

If the Resolutions are not passed on or before August 7, 2020, an original holder of the Warrants may elect without payment to convert its Warrants into fully paid Tranche 3 Notes with a principal amount equal to the aggregate exercise price (being 34.8 pence per Warrant Share) of those Warrants, in compensation for the right to exercise those Warrants not having arisen.

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If the Resolutions have not been passed at a time when the Company undergoes a change of control, each Noteholder on the date of such change of control, shall (to the exclusion of the Uplift Payment) be entitled to a payment equal to the amount of consideration they would have received on such change of control had the Resolutions been passed and they had received their full entitlement of Ordinary Shares and all Warrants they held had become exercisable, less the aggregate principal and interest outstanding on the Tranche 1 Notes and certain residual interests in the Warrants (if any) they held on the date of the change of control (the “Change of Control Payment”).

Until the Resolutions have been passed, no Tranche 1 Notes are capable of conversion. If the Resolutions are passed on or before August 7, 2020, the Tranche 1 Notes will automatically convert into Ordinary Shares, except that no new Ordinary Shares will be issued which would result in any person holding in excess of 9.99 per cent. of the aggregate voting rights in the Company as a result of the relevant conversion. Any Tranche 1 Notes not converted will remain outstanding.

After the Resolutions have been passed, those Tranche 1 Notes not automatically converted and any Tranche 2 Notes that may be issued, will be convertible into Ordinary Shares at the election of the Noteholders at any time prior to their maturity date, and subject to the 9.99 per cent. beneficial ownership limit. The Tranche 3 Notes are not capable of conversion.

The Loan Notes are required to be repaid on the earlier of (i) the applicable maturity date; and (ii) a change of control taking place in respect of the Company, and are otherwise not able to be prepaid other than with the consent of a noteholder majority, or if accelerated following an event of default.

The Loan Notes are subject to customary events of default (for example, insolvency events in respect of the Company and default under the Company’s material contracts, amongst others) and any principal amount and interest outstanding is capable of being accelerated following the occurrence of such an event of default and the expiry of any cure periods applicable thereto.

Warrants

All the participants in the Fundraising have received conditional warrants to subscribe for further Ordinary Shares in an aggregate number equal to 50 per cent. of both the Ordinary Shares purchased in the Fundraising and the Ordinary Shares initially issuable upon conversion of the Tranche 1 Notes. A total of 161,048,366 Warrants have been issued.

The Warrants have an exercise price of 34.8 pence per Ordinary Share, which is equal to 200 per cent. of the Fundraising issue price, and will be capable of being exercised at any time from and after the date the Resolutions are passed at the General Meeting (or at any subsequent general meeting) until the third anniversary of the date the Resolutions are passed. The Warrants can be exercised for cash or on a cashless basis.

If the Resolutions are not passed at the General Meeting (or at any subsequent general meeting), the Warrants remain non-exercisable but will, until August 8, 2025, continue to benefit from rights to participate in certain transactions. These include if the Company is acquired, following which the Company is required to use its best efforts to ensure that Warrant holders receive alternate warrants in the acquirer. In certain circumstances, Warrant holders may require the Company (or the acquirer) pay them (to the extent lawful) the value of the Warrants, determined in accordance with a Black-Scholes valuation provision.

The Warrant exercise price and the number of shares issuable upon exercise of the Warrants will be adjusted in certain circumstances, including if the Company effects a subdivision or consolidation of its Ordinary Shares, declares a dividend or distribution, or there is a reorganisation of its Ordinary Shares.

Arrangements with OrbiMed

In recognition of OrbiMed’s participation in, and assistance with, the Fundraising, the Company has agreed to grant OrbiMed certain rights. OrbiMed will have the right to nominate two persons to be appointed to the Board of Directors (out of a maximum number of 9 directors), within a period of 180 days of the fundraising subject to the appropriateness of the nominees. OrbiMed has also been granted the right to participate in future financings of the Company, subject, amongst other things, to the existing pre-emption rights of the Shareholders under the Companies Act 2006 and certain existing agreements to which the Company is a party. OrbiMed has been paid a subscription fee of \$325,000 by the Company by way of a commission in consideration of its participation in the Fundraising.

Item 19. Exhibits**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
1.1*	Articles of Association of Mereo BioPharma Group plc (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 24, 2019 (File No. 333-229351)).
2.1*	Form of American Depositary Receipt of Mereo BioPharma Group plc (incorporated into this Form 20-F by reference to Mereo's Form F-4/A filed March 15, 2019 (File No. 333-229351)).
2.2**	Description of Securities Registered under Section 12 of the Exchange Act.
4.1*	Agreement and Plan of Merger and Reorganization, dated December 5, 2018, by and among Mereo BioPharma Group plc, Mereo US Holdings Inc., Mereo MergerCo One Inc. and OncoMed Pharmaceuticals, Inc. (incorporated into this Form 20-F by reference to Mereo's Form F-4/A filed March 15, 2019 (File No. 333-229351)).
4.1*	Rules of the Mereo BioPharma Group plc Share Option Scheme, as adopted June 9, 2016 and amended April 4, 2017 and March 20, 2018 and form of option documentation (incorporated into this Form 20-F by reference to Mereo's Form F-1 filed March 23, 2018 (File No. 333-223883)).
4.2*	Rules of Mereo BioPharma Group Limited Share Option Scheme, as adopted July 8, 2015 (incorporated into this Form 20-F by reference to Mereo's Form F-1 filed December 1, 2018 (File No. 333-223883)).
4.3*	Rules of the Mereo BioPharma Group plc Long Term Incentive Plan, as adopted June 9, 2016 and amended March 20, 2018 (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).
4.4*	Rules of the Mereo BioPharma Group plc Deferred Bonus Share Plan, as adopted June 9, 2016 and amended March 20, 2018 (incorporated into this Form 20-F by reference to Mereo's Form F-1 filed March 23, 2018 (File No. 333-223883)).
4.5*	Rules of the Mereo BioPharma Group plc New Deferred Bonus Plan, as adopted January 15, 2019 (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).
4.6*	Rules of the Mereo BioPharma Group plc Share Option Scheme for Non-Executive Directors, as adopted March 20, 2018 and form of option documentation (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).
4.7*	Rules of the Mereo 2019 Equity Incentive Plan and 2019 NED Equity Incentive Plan for Non-Executive Directors, as adopted April 4, 2019 (incorporated by reference to Exhibit 4.7 to the registrant's Annual Report on Form 20-F for the year ended December 31, 2018, filed with the SEC on April 29, 2019 (File No. 001-38452)).
4.8*†	BCT197 Asset Purchase Agreement, dated July 28, 2015, by and between Mereo BioPharma 1 Limited and Novartis Pharma AG (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).
4.8.1*	Amendment Agreement for BCT197, dated October 19, 2018, by and between Mereo BioPharma 1 Limited and Novartis Pharma AG (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).
4.8.2*	Addendum to the Asset Purchase Agreement, dated October 4, 2017, by and between Mereo BioPharma 1 Limited and Novartis Pharma AG (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).
4.8.3*	Addendum to the Asset Purchase Agreement, dated April 12, 2016, by and between Mereo BioPharma 1 Limited and Novartis Pharma AG (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).
4.9*†	BGS649 Asset Purchase Agreement, dated July 28, 2015, by and between Mereo BioPharma 2 Limited and Novartis Pharma AG (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).
4.9.1*	Amendment Agreement for BGS649, dated October 19, 2018, by and between Mereo BioPharma 2 Limited and Novartis Pharma AG (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).
4.9.2*	Addendum to the Asset Purchase Agreement, dated August 17, 2017, by and between Mereo BioPharma 2 Limited and Novartis Pharma AG (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).

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<u>Exhibit No.</u>	<u>Description</u>
4.10*†	<u>BPS804 Asset Purchase Agreement, dated July 28, 2015, by and between Mereo BioPharma 3 Limited and Novartis Pharma AG (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).</u>
4.10.1*†	<u>Amendment Agreement, dated August 10, 2018, by and between Mereo BioPharma 3 Limited and Novartis Pharma AG (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).</u>
4.10.2*	<u>Addendum to the Asset Purchase Agreement, dated December 21, 2016, by and between Mereo BioPharma 3 Limited and Novartis Pharma AG (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).</u>
4.11*†	<u>Sublicense Agreement, dated July 29, 2015, by and between Mereo BioPharma 3 Limited and Novartis Pharma AG (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).</u>
4.12*†	<u>Exclusive License and Option Agreement, dated October 28, 2017, by and between Mereo BioPharma 4 Limited and AstraZeneca AB (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).</u>
4.13*	<u>Loan Agreement, dated September 28, 2018, by and among Mereo BioPharma Group plc, as borrower, the guarantors party thereto, Silicon Valley Bank, as a lender, and Kreos Capital V (UK) Limited, as a lender, agent and security agent (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).</u>
4.13.1*	<u>Deed of Consent and Amendment, dated April 17, 2019, by and among Mereo BioPharma Group plc, as borrower, the guarantors party thereto, Silicon Valley Bank, as a lender, and Kreos Capital V (UK) Limited, as a lender, agent and security agent (incorporated by reference to Exhibit 4.13.1 to the registrant's Annual Report on Form 20-F for the year ended December 31, 2018, filed with the SEC on April 29, 2019 (File No. 001-38452)).</u>
4.14*	<u>Form of Deed of Indemnity for members of the board of directors of Mereo BioPharma Group plc (incorporated into this Form 20-F by reference to Mereo's Form F-4 filed January 25, 2019 (File No. 333-229351)).</u>
4.15*	<u>Form of Contingent Value Rights Agreement by and between Computershare, Inc., as rights agent, and Mereo BioPharma Group plc (incorporated into this Form 20-F by reference to Mereo's Form F-4/A filed March 15, 2019 (File No. 333-229351)).</u>
4.16*	<u>Contingent Value Rights Agreement, dated March 14, 2019, by and between Computershare, Inc., as rights agent, and OncoMed Pharmaceuticals, Inc. (incorporated into this Form 20-F by reference to OncoMed's Form 8-K filed March 15, 2019 (File No. 001-35993)).</u>
4.16.1*	<u>Amendment Number One to the Contingent Value Rights Agreement, dated April 15, 2019, by and between Computershare, Inc., as rights agent, and OncoMed Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.17.1 to the registrant's Annual Report on Form 20-F for the year ended December 31, 2018, filed with the SEC on April 29, 2019 (File No. 001-38452)).</u>
4.17*†	<u>Master Research and Collaboration Agreement, dated December 2, 2013, by and between OncoMed Pharmaceuticals, Inc., Celgene Corporation and Celgene Alpine Investment Company II, LLC (incorporated into this Form 20-F by reference to OncoMed's 10-K filed March 18, 2014 (File No. 001-35993)).</u>
4.18*	<u>Form of Letter of Appointment for members of the board of directors of Mereo BioPharma Group plc (incorporated by reference to Exhibit 4.19 to the registrant's Annual Report on Form 20-F for the year ended December 31, 2018, filed with the SEC on April 29, 2019 (File No. 001-38452)).</u>
4.19*	<u>Amended and Restated Employment Agreement, dated September 1, 2019, by and between Mereo BioPharma Group PLC and John Richard (incorporated by reference to Exhibit 10.1 to the registrant's report on Form 6-K filed with the SEC on September 3, 2019 (File No. 001-38452)).</u>
4.20**	<u>Settlement Agreement, dated March 27, 2020, by and between Mereo BioPharma Group plc and Richard Jones.</u>
4.21**	<u>Consulting and Interim Chief Financial Officer Agreement, dated May 14, 2020, by and among Mereo BioPharma Group plc, MSW Consulting Inc. and Michael Wyzga.</u>
4.22*	<u>Form of Convertible Loan Note Instrument, dated June 3, 2020, relating to Mereo BioPharma Group PLC (incorporated by reference to Exhibit 10.3 to the registrant's report on Form 6-K filed with the SEC on June 5, 2020 (File No. 001-38452)).</u>

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<u>Exhibit No.</u>	<u>Description</u>
4.23*	Form of Warrant Instrument, dated June 3, 2020, relating to Mereo BioPharma Group PLC (incorporated by reference to Exhibit 10.4 to the registrant's report on Form 6-K filed with the SEC on June 5, 2020 (File No. 001-38452)) .
4.24*	Mereo BioPharma Group plc 2019 Equity Incentive Plan, as amended on February 13, 2020 (incorporated by reference to Exhibit 99.1 to Mereo' Form S-8 filed February 18, 2020 (File No. 333-236498)) .
4.25*	Mereo BioPharma Group plc 2019 Non-Employee Equity Incentive Plan, as amended on February 13, 2020 (incorporated by reference to Exhibit 99.2 to Mereo' Form S-8 filed February 18, 2020 (File No. 333-236498)) .
4.26**	Letter of Appointment, dated May 14, 2020, by and between Mereo BioPharma Group plc and Michael Wyzga .
8.1**	List of Subsidiaries of Mereo BioPharma Group plc
10.1*	Securities Purchase Agreement, dated February 10, 2020, by and between Mereo BioPharma Group PLC and Aspire Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to the registrant's report on Form 6-K filed with the SEC on February 10, 2020 (File No. 001-38452)) .
10.2*	Registration Rights Agreement, dated February 10, 2020, by and between Mereo BioPharma Group PLC and Aspire Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to the registrant's report on Form 6-K filed with the SEC on February 10, 2020 (File No. 001-38452)) .
10.3*	Securities Purchase Agreement, dated February 19, 2020, by and between Mereo BioPharma Group PLC and Boxer Capital, LLC (incorporated by reference to Exhibit 10.1 to the registrant's report on Form 6-K filed with the SEC on February 19, 2020 (File No. 001-38452)) .
10.4*	Registration Rights Agreement, dated February 19, 2020, by and between Mereo BioPharma Group PLC and Boxer Capital, LLC (incorporated by reference to Exhibit 10.2 to the registrant's report on Form 6-K filed with the SEC on February 19, 2020 (File No. 001-38452)) .
10.5*	Form of Securities Purchase Agreement, dated June 3, 2020, by and among Mereo BioPharma Group PLC and the several purchasers named therein (incorporated by reference to Exhibit 10.1 to the registrant's report on Form 6-K filed with the SEC on June 5, 2020 (File No. 001-38452)) .
10.6*	Form of Registration Rights Agreement, dated June 3, 2020, by and between Mereo BioPharma Group PLC and the several purchasers named therein (incorporated by reference to Exhibit 10.2 to the registrant's report on Form 6-K filed with the SEC on June 5, 2020 (File No. 001-38452)) .
12.1**	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2**	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1***	Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2***	Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1**	Consent of Independent Registered Public Accounting Firm
101	The following materials from this annual report on Form 20-F formatted in XBRL (Extensible Business Reporting Language) are furnished herewith: (i) the Report of Independent Registered Public Accounting Firm, (ii) the consolidated statements of financial position data, (iii) the consolidated statements of comprehensive loss data, (iv) the consolidated statements of changes in shareholders' equity (capital deficiency), (v) the consolidated statements of cash flows, and (vi) the notes to consolidated financial statements, in each case tagged as blocks of text and in detail.
*	Previously filed
**	Filed herewith
***	Furnished herewith
†	Portions of this exhibit are subject to a previously filed confidential treatment order pursuant to Rule 406 under the Securities Act

SIGNATURES

Mereo BioPharma Group plc hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

MEREO BIOPHARMA GROUP PLC

By: /s/ Denise Scots-Knight

Name: Denise Scots-Knight

Title: Chief Executive Officer

Date: June 15, 2020

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following is a description of the ordinary shares, par value £0.003 per share, of Mereo BioPharma Group plc (the "Company," "we" or "us") which are represented by American Depositary Shares ("ADSs") with each ADS representing five of our ordinary shares registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). This description also summarizes relevant provisions of English law. The following summary does not purport to be complete and is subject to, and is qualified in its entirety by reference to, the applicable provisions of English law and the Company's articles of association, a copy of which is filed as Exhibit 1.1 to the Annual Report on Form 20-F of the Company for the fiscal year ended December 31, 2019. We encourage you to read the articles and the applicable provisions of English law for additional information.

General

We were incorporated as a private limited company with the legal name Mereo BioPharma Group Limited under the laws of England and Wales on March 10, 2015 with the company number 09481161. On June 3, 2016, we re-registered as a public limited company with the legal name Mereo BioPharma Group plc. Our principal executive offices are located at 4th Floor, One Cavendish Place, London, W1G 0QF, United Kingdom. The principal legislation under which we operate and our ordinary shares are issued is the U.K. Companies Act 2006.

Share Capital

As of June 8, 2020, our issued share capital was £640,957.46 equivalent to 213,652,487 ordinary shares. The nominal value of our ordinary shares, including ordinary shares in the form of ADSs, is £0.003 per ordinary share. Each issued ordinary share is fully paid. As of June 8, 2020, 11.5% of our ordinary shares are represented by 4,915,739 ADSs.

According to the resolutions passed in our annual general meeting held on June 19, 2019, our Board was authorized to (i) allot new shares or grant rights to subscribe for, or convert other securities into, shares up to an amount equal to 100% of our total issued ordinary share capital as at May 17, 2019, comprising ordinary shares with an aggregate nominal value of £288,070.78; and (ii) allot equity securities for cash without first being required to offer them to existing ordinary shareholders up to the same aggregate maximum nominal amount of £288,070.78 (including, for this purpose, the sale on a non-pre-emptive basis of any shares held in treasury). In each case, the authorization will last until the next annual general meeting or, if earlier, 15 months from the date of the passing of these resolutions. In addition, according to written resolutions of our shareholders passed on June 2, 2016, our Board was authorized (i) to allot new ordinary shares up to a maximum nominal value of £350,000.00 of our ordinary shares of £0.003 each; and (ii) allot equity securities for cash without first being required to offer them to existing ordinary shareholders up to the same aggregate maximum nominal amount of £350,000.00. In each case, the authorization will last until the fifth anniversary of the passing of these written resolutions.

Options

As of December 31, 2019, there were options to purchase 12,430,806 ordinary shares outstanding under our equity incentive plans with a weighted average exercise price of £1.45 per ordinary share. The options generally lapse after 10 years from the date of the grant.

As of December 31, 2019, there were options to purchase 782,400 ADSs outstanding under our equity incentive plans with a weighted average exercise price of \$3.51 per ADS. The options generally lapse after 4 years from the date of grant.

As of December 31, 2019, there were nil-cost options to purchase 162,997 ordinary shares outstanding under our DSP, which generally lapse one year after vesting.

On February 20, 2020, we issued options to purchase 565,000 ADSs with an exercise price of \$1.84 per ADS to employees pursuant to the 2019 EIP. One quarter of the options become exercisable on the first anniversary of their grant date and, thereafter, vest in equal monthly installments over three years.

On February 20, 2020, we also issued options to purchase 77,000 ADSs with an exercise price of \$1.84 per ADS to non-employees pursuant to the 2019 NED EIP. These options vest in equal monthly installments over the year following their grant date.

Each of our equity incentive plans includes provisions for potential adjustment of outstanding equity awards in connection with certain corporate transactions, in order to prevent dilution or enlargement of the intended benefits under such plans.

Novartis Notes

On June 3, 2016, we issued 3,463,563 notes to Novartis (the “Novartis Notes”). The Novartis Notes included an adjustment provision to prevent the dilution of the ordinary shares issuable to Novartis under certain circumstances.

On April 6, 2017, Novartis delivered to us a notice of conversion with respect to £1,398,552 aggregate principal amount of Novartis Notes. Pursuant to such notice, on April 26, 2017, £1,398,552 aggregate principal amount of Novartis Notes was converted into 632,829 fully paid ordinary shares. Additionally, in connection with such conversion, we issued 588,532 ordinary shares to Novartis.

On June 6, 2019 Novartis delivered to us a notice of conversion with respect to the aggregate principal amount and interest of the Novartis Notes. Pursuant to such notice, on June 21, 2019 the aggregate principal amount and interest of £2,367,004 due under the Novartis Notes was converted into 1,071,042 fully paid ordinary shares at the fixed conversion price of £2.21 per share. Additionally, in connection with such conversion, we issued 864,988 ordinary shares to Novartis. At June 30, 2019, there was no further liability under the Novartis Notes which were converted in full as at that date.

On February 10, 2020, we entered into a £3,841,479 convertible loan note instrument relating to the issue of 3,841,479 New Novartis Notes. The New Novartis Notes are convertible at any time at a fixed price of £0.265 per ordinary share. The New Novartis Notes included an adjustment provision to prevent the dilution of the ordinary shares issuable to Novartis under certain circumstances.

Warrants

As of December 31, 2019, there were warrants to purchase 1,243,908 ordinary shares at a weighted average exercise price of £2.95 per ordinary share, including 621,954 warrants exercisable by Silicon Valley Bank and 621,954 warrants exercisable by Kreos Capital V (UK) Limited. These warrants will be capable of exercise until October 1, 2028. The warrants include an adjustment provision to prevent the dilution of the ordinary shares issuable to Silicon Valley Bank and Kreos Capital V (UK) Limited under certain circumstances. Following the issuance of the New Novartis Notes and the Initial Shares under the Aspire Purchase Agreement, we expect to issue an additional 362,534 warrants at an average exercise price of £2.95 per ordinary share, including 101,939 warrants exercisable by Silicon Valley Bank and 101,939 warrants exercisable by Kreos Capital V (UK) Limited.

As of December 31, 2019, there were warrants to purchase 41,286 ordinary shares at an exercise price of £0.003 per ordinary share exercisable by The Alpha-1 Project, Inc.

On February 10, 2020, in connection with the New Novartis Notes, we entered into a warrant instrument with Novartis to issue 1,449,614 ordinary shares at a weighted average exercise price of £0.265 per ordinary share. These warrants will be capable of exercise until February 10, 2025. The warrants include an adjustment provision to prevent the dilution of the ordinary shares issuable to Novartis under certain circumstances.

Ordinary Shares

The following summarizes the rights of holders of our ordinary shares:

- each holder of our ordinary shares is entitled to one vote per ordinary share at a meeting of shareholders (provided that certain shareholders each have their votes limited to 19.5% of the total voting share capital and any votes which would have otherwise been exercisable by them shall be deemed to be held and exercisable by the other shareholders, other than those and certain other shareholders, on a pro rata basis);

- the holders of the ordinary shares shall be entitled to receive notice of, attend, speak, and vote at our general meetings; and
- holders of our ordinary shares are entitled to receive such dividends as are recommended by our directors and declared by our shareholders.

Registered Shares

We are required by the U.K. Companies Act 2006 to keep a register of our shareholders. Under English law, the ordinary shares are issued when the name of the shareholder is entered in our share register. The share register therefore is prima facie evidence of the identity of our shareholders, and the shares that they hold. The share register generally provides limited, or no, information regarding the ultimate beneficial owners of our ordinary shares. Our share register is maintained by our registrar, Link Asset Services.

Holders of our ADSs will not be treated as shareholders and their names will therefore not be entered in our share register. The depositary, the custodian or their nominees will be the holder of the ordinary shares underlying our ADSs. For discussion on our ADSs and ADS holder rights see “Description of American Depository Shares” in this prospectus. Holders of our ADSs have a right to receive the ordinary shares underlying their ADSs as discussed in “Description of American Depository Shares” in this prospectus.

Under the U.K. Companies Act 2006, we must enter an allotment of ordinary shares in our share register as soon as practicable and in any event within two months of the allotment. We will perform all procedures necessary to update the share register with the number of ordinary shares to be issued to the depositary upon the closing of the offering. We also are required by the U.K. Companies Act 2006 to register a transfer of ordinary shares (or give the transferee notice of and reasons for refusal as the transferee may reasonably request) as soon as practicable and in any event within two months of receiving notice of the transfer.

We, any of our shareholders or any other affected person may apply to the court for rectification of the share register if:

- the name of any person, without sufficient cause, is entered in or omitted from our register of members; or
- a default is made or unnecessary delay takes place in entering on the register the fact of any person having ceased to be a member or on which we have a lien, provided that such refusal does not prevent dealings in the shares taking place on an open and proper basis.

Pre-emptive Rights

English law generally provides shareholders with pre-emptive rights when new shares are issued for cash; however, it is possible for the articles of association, or shareholders by special resolution, to exclude pre-emptive rights. Such an exclusion of pre-emptive rights may be for a maximum period of up to five years from the date of adoption of the articles of association, if the exclusion is contained in the articles of association, or from the date of the shareholder resolution, if the exclusion is by shareholder resolution. In either case, this exclusion would need to be renewed by our shareholders upon its expiration (i.e., at least every five years).

On June 19, 2019, our shareholders, in addition to the authorization noted above, authorized our Board to exclude pre-emptive rights for a period until the end of our next annual general meeting or, if earlier, 15 months from June 19, 2019 in respect of the allotment of ordinary shares or the grant of rights to subscribe for or convert securities into ordinary shares up to a maximum aggregate nominal amount of £288,070.78. The nominal value of our ordinary shares is £0.003 per ordinary share. For further information relating to the Company’s existing authority to issue additional ordinary shares, see “—Share Capital.” On June 2, 2016, our shareholders authorized our Board to exclude pre-emptive rights in respect of the allotment of ordinary shares of £0.003 each in the capital of the Company up to a maximum aggregate nominal amount of £350,000, which authority expires on June 2, 2021.

As at March 1, 2020, non pre-emptive authorization up to a maximum aggregate nominal amount of £323,768 remained available to the Company.

Articles of Association

The following is a description of our Articles as at the date hereof.

Shares and Rights Attaching to Them

Objects

The objects of our company are unrestricted.

Share Rights

Subject to any special rights attaching to shares already in issue, our shares may be issued with or have attached to them any rights or restrictions as we may resolve by ordinary resolution of the shareholders or, failing such determination, as the board may determine.

Voting Rights

Without prejudice to any special rights, privileges or restrictions as to voting rights attached to any shares forming part of our share capital from time to time, the voting rights attaching to shares are as follows:

- on a show of hands, every shareholder who (being an individual) is present in person and (being a corporation) is present by a duly authorized representative shall have one vote;
- on a show of hands, each proxy present in person has one vote for and one vote against a resolution if the proxy has been duly appointed by more than one shareholder and the proxy has been instructed by one or more of those shareholders to vote for the resolution and by one or more other of those shareholders to vote against it;
- on a show of hands, each proxy present in person has one vote for and one vote against a resolution if the proxy has been duly appointed by more than one shareholder entitled to vote on the resolution and either: (1) the proxy has been instructed by one or more of those shareholders to vote for the resolution and has been given any discretion by one or more other of those shareholders to vote and the proxy exercises that discretion to vote against it; or (2) the proxy has been instructed by one or more of those shareholders to vote against the resolution and has been given any discretion by one or more other of those shareholders to vote and the proxy exercises that discretion to vote for it; or
- on a poll every shareholder who is present in person or by proxy shall have one vote for each share of which he or she is the holder, provided that certain shareholders each have their votes limited to 19.5% of the total voting share capital and any votes which would have otherwise been exercisable by them shall be deemed to be held and exercisable by the other shareholders, other than those and certain other shareholders, on a pro rata basis.

At any general meeting a resolution put to the vote of the meeting shall be decided on a show of hands unless a poll is demanded. Subject to the provisions of the U.K. Companies Act 2006, as described in “Differences in Corporate Law—Voting Rights” in this prospectus, a poll may be demanded by:

- the chairman of the meeting;
- the directors;
- two or more persons having the right to vote on the resolution; or
- a person or persons representing not less than 10% of the total voting rights of all shareholders having the right to vote on the resolution.

Restrictions on Voting

No shareholder shall (unless the Directors otherwise determine) be entitled to vote at any general meeting in respect of any share held by him or her unless all sums payable by him or her in respect of that share have been paid.

The board may from time to time make calls upon the shareholders in respect of any money unpaid on their shares and each shareholder shall (subject to at least 14 days' notice specifying when and how the payment is to be made) pay at the time or times so specified the amount called on his or her shares.

Dividends

We may, subject to the provisions of the U.K. Companies Act 2006 and our Articles, by ordinary resolution of shareholders declare dividends out of profits available for distribution in accordance with the respective rights of shareholders but no such dividend shall exceed the amount recommended by the directors. The board may from time to time pay shareholders such interim dividends as appear to the board to be justified by our financial position but, if at any time, our share capital is divided into different classes the board may not pay such interim dividends in respect of those shares which confer on the holders thereof deferred or non-preferential rights with regard to dividends if, at the time of payment, any preferential dividend is in arrears.

Subject to any special rights attaching to or the terms of issue of any share, all dividends shall be declared and paid according to the amounts paid up on the shares and shall be apportioned and paid pro rata according to the amounts paid up on the shares during any part or parts of the period in respect of which the dividend is paid.

No dividend or other moneys payable by us on or in respect of any share shall bear interest against us unless otherwise provided by the rights attached to the share or the provisions of another agreement between the shareholder and us. Any dividend unclaimed after a period of 12 years from the date such dividend became due for payment shall be forfeited and cease to remain owing.

Dividends may be declared or paid in any currency and the board may decide the rate of exchange for any currency conversions that may be required, and how any costs involved are to be met, in relation to the currency of any dividend.

Any general meeting declaring a dividend may by ordinary resolution of shareholders, upon the recommendation of the board, direct payment or satisfaction of such dividend wholly or in part by the distribution of non-cash assets of equivalent value, including shares or other securities in any company.

The directors may, if authorized by an ordinary resolution of shareholders, offer any holders of ordinary shares the right to elect to receive in lieu of a dividend, or part of a dividend, an allotment of ordinary shares credited as fully paid up.

Change of Control

There is no specific provision in our Articles that would have the effect of delaying, deferring, or preventing a change of control.

Distributions on Winding Up

If we are in liquidation, the liquidator may, if authorized by a special resolution of shareholders and any other authority required at law, divide among shareholders (excluding us to the extent we are a shareholder by virtue only of holding treasury shares) in specie or in kind the whole or any part of our assets (whether or not the assets consist of property of one kind or consist of properties of different kinds and the liquidator may for such purpose set such value as the liquidator deems fair upon any one or more class or classes of property and may determine how such division shall be carried out as between the shareholders or different classes of shareholders), or vest the whole or any part of such assets in trustees upon such trusts for the benefit of the shareholders as the liquidator determines (and our liquidation may be closed and we may be dissolved), but no shareholder shall be compelled to accept any shares or other assets upon which there is any liability.

Variation of Rights

All or any of the rights and privileges attached to any class of shares issued may be varied or abrogated only with the consent in writing of the holders of not less than three-fourths in nominal value of the issued shares of that class (excluding any shares held as treasury shares) or by special resolution passed at a separate general meeting of the holders of such shares, subject to the other provisions of the U.K. Companies Act 2006 and the terms of their issue. The U.K. Companies Act 2006 also provides a right to object to the variation of the share capital by the shareholders who did not vote in favor of the variation. Should 15% or more of the shareholders of the issued shares in question apply to the court to have the variation cancelled, the variation shall have no effect unless and until it is confirmed by the court.

Alteration to Share Capital

We may, by ordinary resolution of shareholders, consolidate all or any of our share capital into shares of larger amount than our existing shares, or sub-divide our shares or any of them into shares of a smaller amount. We may, by special resolution of shareholders, confirmed by the court, reduce our share capital or any capital redemption reserve or any share premium account in any manner authorized by the U.K. Companies Act 2006. We may redeem or purchase all or any of our shares as described in “—Other U.K. Law Considerations—Purchase of Own Shares.”

Preemption Rights

In certain circumstances, our shareholders may have statutory preemption rights under the U.K. Companies Act 2006 in respect of the allotment of new shares as described in “—Pre-emptive Rights” and “—Differences in Corporate Law—Pre-emptive Rights” in this prospectus.

Transfer of Shares

Any shareholder holding shares in certificated form may transfer all or any of his or her shares by an instrument of transfer in any usual form or any other form approved by the board. Any written instrument of transfer shall be signed by or on behalf of the transferor and (in the case of a partly paid share) the transferee.

In the case of uncertificated shares, the directors may take such action as they consider appropriate to achieve a transfer. The Uncertificated Securities Regulations 2001 permit shares to be issued and held in uncertificated form and transferred by means of a computer based system.

The board may decline to register any transfer of any share:

- which is not a fully paid share;
- where the transfer is not lodged at our registered office or such other place as the directors have appointed;
- where the transfer is not accompanied by the share certificate to which it relates, or such other evidence as the board may reasonably require to show the transferor’s right to make the transfer, or evidence of the right of someone other than the transferor to make the transfer on the transferor’s behalf;
- where the transfer is in respect of more than one class of share; and
- where the number of joint holders to whom the share is to be transferred exceeds four.

If the board declines to register a transfer, it must return to the transferee the instrument of transfer together with notice of the refusal, unless the board suspects that the proposed transfer may be fraudulent.

Shareholder Meetings

Annual General Meetings

In accordance with the U.K. Companies Act 2006, we are required in each year to hold an annual general meeting in addition to any other general meetings in that year and to specify the meeting as such in the notice convening it. The annual general meeting shall be convened whenever and wherever the board sees fit, subject to the requirements of the U.K. Companies Act 2006, as described in “—Differences in Corporate Law—Annual General Meeting” and “—Differences in Corporate Law—Notice of General Meetings” in this prospectus.

Notice of General Meetings

The arrangements for the calling of general meetings are described in “—Differences in Corporate Law—Notice of General Meetings” in this prospectus.

Quorum of General Meetings

No business, other than the appointment of the chair of the meeting, shall be transacted at any general meeting unless a quorum is present. At least two shareholders present in person or by proxy and entitled to vote shall be a quorum for all purposes.

Class Meetings

The provisions in the Articles relating to general meetings apply to every separate general meeting of the holders of a class of shares.

Directors

Number of Directors

We may not have less than two directors on the Board and not more than nine. We may, by ordinary resolution of the shareholders, vary the minimum and maximum number of directors from time to time.

Appointment of Directors

Subject to the provisions of the Articles, we may, by ordinary resolution of the shareholders or a decision of the directors, elect any person to be a director, either to fill a casual vacancy or as an addition to the existing board, provided the total number of directors does not exceed the maximum number fixed by or in accordance with the Articles. However, any person that is not a director retiring from the existing board must be recommended by the board or the person must have confirmed in writing to us their willingness to be elected as a director not later than seven days before the general meeting at which the relevant resolution is proposed.

Any director appointed by the board will hold office only until the next following annual general meeting at which they must retire. In addition, all directors must retire at the third annual general meeting following the annual general meeting at which such director was elected or last re-elected. Such directors are eligible for re-election at the annual general meeting at which they retire.

The shareholders may, at the meeting at which a director retires, fill the vacated office by electing a person and in default the retiring director shall, if willing to continue to act, be deemed to have been re-elected, unless at such meeting it is expressly resolved not to fill such vacated office or unless a resolution for the re-election of such director shall have been put to the meeting and lost.

Other U.K. Law Considerations

Notification of Voting Rights

A shareholder in a public company incorporated in the United Kingdom whose shares are admitted to trading on AIM is required pursuant to Chapter 5 of the Disclosure Guidance and Transparency Rules of the U.K. Financial Conduct Authority to notify us of the percentage of his or her voting rights if the percentage of voting rights which he or she holds as a shareholder or through his or her direct or indirect holding of financial instruments (or a combination of such holdings) reaches, exceeds, or falls below 3%, 4%, 5%, and each 1% threshold thereafter up to 100% as a result of an acquisition or disposal of shares or financial instruments.

Mandatory Purchases and Acquisitions

Pursuant to Sections 979 to 991 of the U.K. Companies Act 2006, where a takeover offer has been made for us and the offeror has acquired or unconditionally contracted to acquire not less than 90% in value of the shares to which the offer relates and not less than 90% of the voting rights carried by those shares, the offeror may give notice to the holder of any shares to which the offer relates which the offeror has not acquired or unconditionally contracted to acquire that he or she wishes to acquire, and is entitled to so acquire, those shares on the same terms as the general offer. The offeror would do so by sending a notice to the outstanding minority shareholders telling them that it will compulsorily acquire their shares. Such notice must be sent within three months of the last day on which the offer can be accepted in the prescribed manner. The compulsory acquisition of the minority shareholders' shares can be completed at the end of six weeks from the date the notice has been given, subject to the minority shareholders failing to successfully lodge an application to the court to prevent such compulsory acquisition any time prior to the end of those six weeks following which the offeror can execute a transfer of the outstanding shares in its favor and pay the consideration to us, which would hold the consideration on trust for the outstanding minority shareholders. The consideration offered to the outstanding minority shareholders whose shares are compulsorily acquired under the U.K. Companies Act 2006 must, in general, be the same as the consideration that was available under the takeover offer.

Sell Out

The U.K. Companies Act 2006 also gives our minority shareholders a right to be bought out in certain circumstances by an offeror who has made a takeover offer for all of our shares. The holder of shares to which the offer relates, and who has not otherwise accepted the offer, may require the offeror to acquire his or her shares if, prior to the expiry of the acceptance period for such offer, (i) the offeror has acquired or unconditionally agreed to acquire not less than 90% in value of the voting shares, and (ii) not less than 90% of the voting rights carried by those shares. The offeror may impose a time limit on the rights of minority shareholders to be bought out that is not less than three months after the end of the acceptance period. If a shareholder exercises his or her rights to be bought out, the offeror is required to acquire those shares on the terms of this offer or on such other terms as may be agreed.

Disclosure of Interest in Shares

Pursuant to Part 22 of the U.K. Companies Act 2006, we are empowered to give notice in writing to any person whom we know or have reasonable cause to believe to be interested in our shares, or to have been so interested at any time during the three years immediately preceding the date on which the notice is issued requiring such persons, within a reasonable time to disclose to us particulars of that person's interest and (so far as is within his or her knowledge) particulars of any other interest that subsists or subsisted in those shares.

Under our Articles, if a person defaults in supplying us with the required particulars in relation to the shares in question ("default shares"), within the prescribed period, the directors may by notice direct that:

- in respect of the default shares, the relevant shareholder shall not be entitled to vote (either in person or by proxy) at any general meeting or to exercise any other right conferred by a shareholding in relation to general meetings;
- where the default shares represent at least 0.25% of their class, (a) any dividend or other money payable in respect of the default shares shall be retained by us without liability to pay interest and/or (b) no transfers by the relevant shareholder of any default shares may be registered (unless the shareholder himself is not in default and the shareholder provides a certificate, in a form satisfactory to the directors, to the effect that after due and careful enquiry the shareholder is satisfied that none of the shares to be transferred are default shares); and
- any shares held by the relevant shareholder in uncertificated form shall be converted into certificated form and that shareholder shall not after that be entitled to convert all or any shares held by him or her into uncertificated form (except with the authority of the directors) unless the shareholder himself is not in default and the shares which the shareholder wishes to convert are part only of the shareholder's holding and the shareholder provides a certificate, in a form satisfactory to the directors, to the effect that after due and careful enquiry the shareholder is satisfied that none of the shares to be converted into uncertificated form are default shares.

Purchase of Own Shares

Under English law, a limited company may only purchase its own shares out of the distributable profits of the company or the proceeds of a fresh issue of shares made for the purpose of financing the purchase, provided that they are not restricted from doing so by their articles. A limited company may not purchase its own shares if, as a result of the purchase, there would no longer be any issued shares of the company other than redeemable shares or shares held as treasury shares. Shares must be fully paid in order to be repurchased.

Subject to the above, we may purchase our own shares in the manner prescribed below. We may make a market purchase of our own fully paid shares pursuant to an ordinary resolution of shareholders. The resolution authorizing the purchase must:

- specify the maximum number of shares authorized to be acquired;
- determine the maximum and minimum prices that may be paid for the shares; and
- specify a date, not being later than five years after the passing of the resolution, on which the authority to purchase is to expire.

We may purchase our own fully paid shares otherwise than on a recognized investment exchange pursuant to a purchase contract authorized by resolution of shareholders before the purchase takes place. Any authority will not be

effective if any shareholder from whom we propose to purchase shares votes on the resolution and the resolution would not have been passed if he or she had not done so. The resolution authorizing the purchase must specify a date, not being later than five years after the passing of the resolution, on which the authority to purchase is to expire.

Distributions and Dividends

Under the U.K. Companies Act 2006, before a company can lawfully make a distribution or dividend, it must ensure that it has sufficient distributable reserves (on a non-consolidated basis). The basic rule is that a company's profits available for the purpose of making a distribution are its accumulated, realized profits, so far as not previously utilized by distribution or capitalization, less its accumulated, realized losses, so far as not previously written off in a reduction or reorganization of capital duly made. The requirement to have sufficient distributable reserves before a distribution or dividend can be paid applies to us and to each of our subsidiaries that has been incorporated under English law.

It is not sufficient that we, as a public company, have made a distributable profit for the purpose of making a distribution. An additional capital maintenance requirement is imposed on us to ensure that the net worth of the company is at least equal to the amount of its capital. A public company can only make a distribution:

- if, at the time that the distribution is made, the amount of its net assets (that is, the total excess of assets over liabilities) is not less than the total of its called up share capital and undistributable reserves; and
- if, and to the extent that, the distribution itself, at the time that it is made, does not reduce the amount of the net assets to less than that total.

City Code on Takeovers and Mergers

As a public company incorporated in England and Wales with our registered office in England and Wales which has shares admitted to AIM, we are subject to the U.K. City Code on Takeovers and Mergers (the "City Code"), which is issued and administered by the U.K. Panel on Takeovers and Mergers (the "Panel"). The City Code provides a framework within which takeovers of companies subject to it are conducted. In particular, the City Code contains certain rules in respect of mandatory offers. Under Rule 9 of the City Code, if a person:

- acquires an interest in our shares which, when taken together with shares in which he or she or persons acting in concert with him or her are interested, carries 30% or more of the voting rights of our shares; or
- who, together with persons acting in concert with him, is interested in shares that in the aggregate carry not less than 30% and not more than 50% of the voting rights of our shares, and such persons, or any person acting in concert with him, acquires additional interests in shares that increase the percentage of shares carrying voting rights in which that person is interested,

the acquirer and depending on the circumstances, its concert parties, would be required (except with the consent of the Panel) to make a cash offer for our outstanding shares at a price not less than the highest price paid for any interests in the shares by the acquirer or its concert parties during the previous 12 months.

Exchange Controls

There are no governmental laws, decrees, regulations or other legislation in the United Kingdom that may affect the import or export of capital, including the availability of cash and cash equivalents for use by us, or that may affect the remittance of dividends, interest, or other payments by us to non-resident holders of our ordinary shares or ADSs, other than withholding tax requirements. There is no limitation imposed by English law or in the Articles on the right of non-residents to hold or vote shares.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

American Depositary Shares

Citibank, N.A. (“Citibank”) has agreed to act as the depository for the ADSs. Citibank’s depository offices are located at 388 Greenwich Street, New York, New York 10013. ADSs represent ownership interests in securities that are on deposit with the depository. ADSs may be represented by certificates that are commonly known as American Depositary Receipts (“ADRs”). The depository typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Citibank, N.A., London Branch, located at 25 Canada Square, Canary Wharf, London, E14 5LB, United Kingdom.

We have appointed Citibank as depository pursuant to a deposit agreement. A copy of the form of the deposit agreement is on file with the SEC under cover of a registration statement on Form F-6. A copy of the deposit agreement is available from the SEC’s website (www.sec.gov). Please refer to registration number 333-223890 when retrieving such copy.

“Holder” means the person or persons in whose name an ADS is registered on the register maintained by the depository for such purpose.

Each ADS represents the right to receive, and to exercise the beneficial ownership interests in, five ordinary shares that are on deposit with the depository and/or custodian. An ADS also represents the right to receive, and to exercise the beneficial interests in, any other property received by the depository or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. We and the depository may agree to change the ADS-to-Share ratio by amending the deposit agreement. This amendment may give rise to, or change, the depository fees payable by ADS owners. The custodian, the depository and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depository, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADSs. The depository, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of the ADSs, the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the depository, and the depository (on behalf of the owners of the corresponding ADSs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

If you become an owner of ADSs, you will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents your ADSs. The deposit agreement and the ADR specify our rights and obligations as well as your rights and obligations as owner of ADSs and those of the depository. As an ADS holder you appoint the depository to act on your behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of ordinary shares will continue to be governed by the laws of England and Wales, which may be different from the laws in the United States.

In addition, applicable laws and regulations may require you to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. You are solely responsible for complying with such reporting requirements and obtaining such approvals. Neither the depository, the custodian, us or any of their or our respective agents or affiliates shall be required to take any actions whatsoever on your behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

The manner in which you own the ADSs (e.g., in a brokerage account vs. as registered holder, or as holder of certificated vs. uncertificated ADSs) may affect your rights and obligations, and the manner in which, and extent to which, the depository’s services are made available to you. As an owner of ADSs, we will not treat you as one of our shareholders and you will not have direct shareholder rights. The depository will hold on your behalf the shareholder rights attached to the ordinary shares underlying your ADSs. As an owner of ADSs you will be able to exercise the

shareholders rights for the ordinary shares represented by your ADSs through the depositary only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement you will, as an ADS owner, need to arrange for the cancellation of your ADSs and become a direct shareholder.

As an owner of ADSs, you may hold your ADSs either by means of an ADR registered in your name, through a brokerage or safekeeping account, or through an account established by the depositary in your name reflecting the registration of uncertificated ADSs directly on the books of the depositary (commonly referred to as the direct registration system or DRS). The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the depositary. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the depositary to the holders of the ADSs. The direct registration system includes automated transfers between the depositary and DTC, the central book-entry clearing and settlement system for equity securities in the United States. If you decide to hold your ADSs through your brokerage or safekeeping account, you must rely on the procedures of your broker or bank to assert your rights as ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit your ability to exercise your rights as an owner of ADSs. Please consult with your broker or bank if you have any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC.

The registration of the ordinary shares in the name of the depositary or the custodian shall, to the maximum extent permitted by applicable law, vest in the depositary or the custodian the record ownership in the applicable ordinary shares with the beneficial ownership rights and interests in such ordinary shares being at all times vested with the beneficial owners of the ADSs representing the ordinary shares. The depositary or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of the ADSs representing the deposited property.

Dividends and Other Distributions

Holders generally have the right to receive the distributions we make on the securities deposited with the custodian. A Holder's receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deduction the applicable fees, taxes, and expenses.

Distributions of Cash

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary will arrange for the funds received in a currency other than U.S. dollars to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to the laws and regulations of England and Wales.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depositary will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes, and governmental charges payable by holders under the terms of the deposit agreement. The depositary will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

Distributions of Shares

Whenever we make a free distribution of ordinary shares for the securities on deposit with the custodian, we will deposit the applicable number of ordinary shares with the custodian. Upon receipt of confirmation of such deposit, the depositary will either distribute to holders new ADSs representing the ordinary shares deposited or modify the ADS-to-ordinary shares ratio, in which case each ADS a Holder holds will represent rights and interests in the additional ordinary shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADSs or the modification of the ADS-to-ordinary shares ratio upon a distribution of ordinary shares will be made net of the fees, expenses, taxes, and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depositary may sell all or a portion of the new ordinary shares so distributed.

No such distribution of new ADSs will be made if it would violate a law (*e.g.*, the U.S. securities laws) or if it is not operationally practicable. If the depositary does not distribute new ADSs as described above, it may sell the ordinary shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

Distributions of Rights

Whenever we intend to distribute rights to subscribe for additional ordinary shares, we will give prior notice to the depositary and we will assist the depositary in determining whether it is lawful and reasonably practicable to distribute rights to purchase additional ADSs to holders.

The depositary will establish procedures to distribute rights to purchase additional ADSs to holders and to enable such holders to exercise such rights if it is lawful and reasonably practicable to make the rights available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). Holders may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of a Holder's rights. The depositary is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to subscribe for new ordinary shares other than in the form of ADSs.

The depositary will *not* distribute the rights to a Holder if:

- we do not timely request that the rights be distributed to such Holder or we request that the rights not be distributed to such Holder; or
- we fail to deliver satisfactory documents to the depositary; or
- it is not reasonably practicable to distribute the rights.

The depositary will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary is unable to sell the rights, it will allow the rights to lapse.

Elective Distributions

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to a Holder. In such case, we will assist the depositary in determining whether such distribution is lawful and reasonably practicable.

The depositary will make the election available to a Holder only if it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary will establish procedures to enable such Holder to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement.

If the election is not made available to a Holder, such Holder will receive either cash or additional ADSs, depending on what a shareholder in England and Wales would receive upon failing to make an election, as more fully described in the deposit agreement.

Other Distributions

Whenever we intend to distribute property other than cash, ordinary shares, or rights to purchase additional ordinary shares, we will notify the depositary in advance and will indicate whether we wish such distribution to be made to a Holder. If so, we will assist the depositary in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to a Holder and if we provide to the depositary all of the documentation contemplated in the deposit agreement, the depositary will distribute the property to the holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes, and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depositary may sell all or a portion of the property received.

The depositary will *not* distribute the property to a Holder and will sell the property if:

- we do not request that the property be distributed to such Holder or if we request that the property not be distributed to such Holder; or
- we do not deliver satisfactory documents to the depositary; or
- the depositary determines that all or a portion of the distribution to such Holder is not reasonably practicable.
- The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

Redemption

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the depositary in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depositary will provide notice of the redemption to the holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depositary will convert into U.S. dollars upon the terms of the deposit agreement the redemption funds received in a currency other than U.S. dollars and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the depositary. A Holder may have to pay fees, expenses, taxes, and other governmental charges upon the redemption of such Holder's ADSs. If less than all ADSs are being redeemed, the ADSs to be retired will be selected by lot or on a *pro rata* basis, as the depositary may determine.

Changes Affecting Ordinary Shares

The ordinary shares held on deposit for a Holder's ADSs may change from time to time. For example, there may be a change in nominal (or par) value, split-up, cancellation, consolidation, or any other reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation, or sale of assets of ours.

If any such change were to occur, such Holder's ADSs would, to the extent permitted by law and the deposit agreement, represent the right to receive the property received or exchanged in respect of the ordinary shares held on deposit. The depositary may in such circumstances deliver new ADSs to a Holder, amend the deposit agreement, the ADRs and the applicable registration statement(s) on Form F-6, call for the exchange of such Holder's existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to the ADSs the change affecting the Shares. If the depositary may not lawfully distribute such property to a Holder, the depositary may sell such property and distribute the net proceeds to such Holder as in the case of a cash distribution.

Issuance of ADSs upon Deposit of Ordinary Shares

The depositary may create ADSs on a Holder's behalf if such Holder or such Holder's broker deposit ordinary shares with the custodian. The depositary will deliver these ADSs to the person a Holder indicates only after such Holder pays any applicable issuance fees and any charges and taxes payable for the transfer of the ordinary shares to the custodian. A Holder's ability to deposit ordinary shares and receive ADSs may be limited by the legal considerations in the United States and England and Wales applicable at the time of deposit.

The issuance of ADSs may be delayed until the depository or the custodian receives confirmation that all required approvals have been given and that the ordinary shares have been duly transferred to the custodian. The depository will only issue ADSs in whole numbers.

When a Holder makes a deposit of ordinary shares, such Holder will be responsible for transferring good and valid title to the depository. As such, a Holder will be deemed to represent and warrant that:

- the ordinary shares are duly authorized, validly allotted and issued, fully paid, not subject to any call for the payment of further capital, and legally obtained;
- all pre-emptive (and similar) rights, if any, with respect to such ordinary shares have been validly waived, disappplied or exercised;
- such Holder is duly authorized to deposit the ordinary shares;
- the ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage, or adverse claim, and are not, and the ADSs issuable upon such deposit will not be, “Restricted Securities” (as defined in the deposit agreement); and
- the ordinary shares presented for deposit have not been stripped of any rights or entitlements.

If any of the representations or warranties is incorrect in any way, we and the depository may, at such Holder’s cost and expense, take any and all actions necessary to correct the consequences of the misrepresentation.

Transfer, Combination and Split Up of ADRs

ADR holders will be entitled to transfer, combine, or split up such Holder’s ADRs and the ADSs evidenced thereby. For transfers of ADRs, a Holder will have to surrender the ADRs to be transferred to the depository and also must:

- ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;
- provide such proof of identity and genuineness of signatures as the depository deems appropriate;
- provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes, and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have a Holder’s ADRs either combined or split up, such Holder must surrender the ADRs in question to the depository with such Holder’s request to have them combined or split up, and such Holder must pay all applicable fees, charges, and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

Withdrawal of Ordinary Shares Upon Cancellation of ADSs

A Holder will be entitled to present such Holder’s ADSs to the depository for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian’s offices. A Holder’s ability to withdraw the ordinary shares held in respect of the ADSs may be limited by the legal considerations in the United States and England and Wales applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by a Holder’s ADSs, such Holder will be required to pay to the depository the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the ordinary shares.

A Holder assumes the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADSs will not have any rights under the deposit agreement.

If a Holder holds ADSs registered in such Holder’s name, the depository may ask such Holder to provide proof of identity and genuineness of any signature and such other documents as the depository may deem appropriate before it will cancel such Holder’s ADSs. The withdrawal of the ordinary shares represented by such Holder’s ADSs may be delayed until the depository receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depository will only accept ADSs for cancellation that represent a whole number of securities on deposit.

A Holder will have the right to withdraw the securities represented by such Holder's ADSs at any time except for:

- temporary delays that may arise because (i) the transfer books for the ordinary shares or ADSs are closed, or (ii) ordinary shares are immobilized on account of a shareholders' meeting or a payment of dividends;
- obligations to pay fees, taxes, and similar charges; and/or
- restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit.

The deposit agreement may not be modified to impair a Holder right to withdraw the securities represented by such Holder's ADSs except to comply with mandatory provisions of law.

Voting Rights

A Holder generally has the right under the deposit agreement to instruct the depository to exercise the voting rights for the ordinary shares represented by such Holder's ADSs. The voting rights of holders of ordinary shares are described in "Description of Share Capital and Articles of Association—Articles of Association" in this prospectus.

At our request, the depository will distribute to a Holder any notice of shareholders' meeting received from us together with information explaining how to instruct the depository to exercise the voting rights of the securities represented by ADSs.

If the depository timely receives voting instructions from a holder of ADSs, it will endeavor to vote the securities (in person or by proxy) represented by the holder's ADSs as follows:

- *In the event of voting by show of hands*, the depository will vote (or cause the custodian to vote) all ordinary held on deposit at that time in accordance with the voting instructions received from a majority of holders of ADSs who provide timely voting instructions.
- *In the event of voting by poll*, the depository will vote (or cause the custodian to vote) the ordinary shares held on deposit in accordance with the voting instructions received from the holders of ADSs. The depository will give a discretionary proxy to a person designated by us to vote any ordinary shares held on deposit for which voting instructions were not received from the holders of ADSs, unless we inform the depository that (a) we do not wish such proxy to be given, (b) substantial opposition exists, or (c) the rights of holders of ADSs may be adversely affected.

Securities for which no voting instructions have been received will not be voted (except as otherwise contemplated in the Deposit Agreement). Please note that the ability of the depository to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure a Holder that such Holder will receive voting materials in time to enable such Holder to return voting instructions to the depository in a timely manner.

Fees and Charges

ADS holders will be required to pay the following fees under the terms of the deposit agreement:

<u>Service</u>	<u>Fee</u>
Issuance of ADSs (e.g., an issuance of ADS upon a deposit of ordinary shares or upon a change in the ADS(s)-to-ordinary shares ratio), excluding ADS issuances as a result of distributions of ordinary Shares	Up to \$5.00 per 100 ADSs (or fraction thereof) issued
Cancellation of ADSs (e.g., a cancellation of ADSs for delivery of deposited property or upon a change in the ADS(s)-to-ordinary shares ratio)	Up to \$5.00 per 100 ADSs (or fraction thereof) cancelled
Distribution of cash dividends or other cash distributions (e.g., upon a sale of rights and other entitlements)	Up to \$5.00 per 100 ADSs (or fraction thereof) held

<u>Service</u>	<u>Fee</u>
Distribution of ADSs pursuant to (i) stock dividends or other free stock distributions, or (ii) exercise of rights to purchase additional ADSs	Up to \$5.00 per 100 ADSs (or fraction thereof) held
Distribution of securities other than ADSs or rights to purchase additional ADSs (e.g., upon a spin-off)	Up to \$5.00 per 100 ADSs (or fraction thereof) held
ADS Services	Up to \$5.00 per 100 ADSs (or fraction thereof) held on the applicable record date(s) established by the depositary
Registration of ADS Transfers (e.g., upon a registration of the transfer of registered ownership of ADSs, upon a transfer of ADSs into DTC and vice versa, or for any other reason)	Up to \$5.00 per 100 ADSs (or fraction thereof) transferred
Conversion of ADSs of one series for ADSs of another series (e.g., upon conversion of Partial Entitlement ADSs for Full Entitlement ADSs, or upon conversion of Restricted ADSs (each as defined in the Deposit Agreement) into freely transferable ADSs, and vice versa)	Up to \$5.00 per 100 ADSs (or fraction thereof) converted

ADS holders will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary, or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex, and facsimile transmission and delivery expenses;
- the expenses and charges incurred by the depositary in the conversion of foreign currency;
- the fees and expenses incurred by the depositary in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs, and ADRs; and
- the fees, charges, costs and expenses incurred by the depositary, the custodian, or any nominee in connection with the ADR program.

ADS fees and charges payable upon (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person to whom the ADSs are issued (in the case of ADS issuances) and to the person whose ADSs are cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs. In the case of (i) registration of ADS transfers, the ADS transfer fee will be payable by the holders of ADSs whose ADSs are being transferred or by the person to whom the ADSs are transferred, and (ii) conversion of ADSs of one series for ADSs of another series, the ADS conversion fee will be payable by the holder whose ADSs are converted or by the person to whom the converted ADSs are delivered.

In the event of refusal to pay the depositary fees, the depositary may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees

from any distribution to be made to the ADS holder. Certain of the depositary fees and charges (such as the ADS services fee) may become payable shortly after the closing of the ADS offering. Note that the fees and charges Holders may be required to pay may vary over time and may be changed by us and by the depositary. Holders will receive prior notice of such changes. The depositary may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary agree from time to time.

Amendments and Termination

We may agree with the depositary to modify the deposit agreement at any time without a Holder's consent. We undertake to give holders 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to a Holder's substantial rights any modifications or supplements that are reasonably necessary for the ADSs to be registered under the Securities Act or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges a Holder is required to pay. In addition, we may not be able to provide a Holder with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

A Holder will be bound by the modifications to the deposit agreement if a Holder continues to hold such Holder's ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent a Holder from withdrawing the ordinary shares represented by such Holder's ADSs (except as permitted by law).

We have the right to direct the depositary to terminate the deposit agreement. Similarly, the depositary may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depositary must give notice to the holders at least 30 days before termination. Until termination, a Holder's rights under the deposit agreement will be unaffected.

Termination

After termination, the depositary will continue to collect distributions received (but will not distribute any such property until a Holder requests the cancellation of such Holder's ADSs) and may sell the securities held on deposit. After the sale, the depositary will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the depositary will have no further obligations to holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses).

In connection with the termination of the deposit agreement, the depositary may, independently and without the need for any action by us, make available to holders of ADSs a means to withdraw the ordinary shares and other deposited securities represented by their ADSs and to direct the deposit of such ordinary shares and other deposited securities into an unsponsored American depositary shares program established by the depositary, upon such terms and conditions as the depositary may deem reasonably appropriate, subject however, in each case, to satisfaction of the applicable registration requirements by the unsponsored American depositary shares program under the Securities Act, and to receipt by the depositary of payment of the applicable fees and charges of, and reimbursement of the applicable expenses incurred by, the depositary.

Books of Depositary

The depositary will maintain ADS holder records at its depositary office. Holders may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADSs and the deposit agreement.

The depositary will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up, and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

Transmission of Notices, Reports and Proxy Soliciting Material

The depositary will make available for a Holder's inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. Subject to the terms of the deposit agreement, the depositary will send a Holder copies of those communications or otherwise make those communications available to such Holder if we ask it to.

Limitations on Obligations and Liabilities

The deposit agreement limits our obligations and the depositary's obligations to Holders. Please note the following:

- We and the depositary are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- The depositary disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and in accordance with the terms of the deposit agreement.
- The depositary disclaims any liability for any failure to determine the lawfulness or practicality of any action, for the content of any document forwarded to Holders on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADSs, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices, or for our failure to give notice.
- We and the depositary will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.
- We and the depositary disclaim any liability if we or the depositary are prevented or forbidden from or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, or by reason of present or future provision of any provision of our Articles, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.
- We and the depositary disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our Articles or in any provisions of or governing the securities on deposit.
- We and the depositary further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting Shares for deposit, any holder of ADSs or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.
- We and the depositary also disclaim liability for the inability by a holder to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to Holders.
- We and the depositary may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.
- We and the depositary also disclaim liability for any consequential or punitive damages for any breach of the terms of the deposit agreement.
- No disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.
- Nothing in the deposit agreement gives rise to a partnership or joint venture, or establishes a fiduciary relationship, among Mereo, the depositary and Holders.
- Nothing in the deposit agreement precludes Citibank (or its affiliates) from engaging in transactions in which parties adverse to Mereo or the ADS owners have interests, and nothing in the deposit agreement obligates Citibank to disclose those transactions, or any information obtained in the course of those transactions, to Mereo or to the ADS owners, or to account for any payment received as part of those transactions.

Taxes

Holders will be responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs. We, the depositary and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. Holders will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary may refuse to issue ADSs; to deliver, transfer, split, and combine ADRs; or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depositary and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on a Holder's behalf. However, a Holder may be required to provide to the depositary and to the custodian proof of taxpayer status and residence and such other information as the depositary and the custodian may require to fulfill legal obligations. A Holder is required to indemnify us, the depositary and the custodian for any claims with respect to taxes based on any tax benefit obtained for such Holder.

Foreign Currency Conversion

The depositary will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. Holders may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practical or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the depositary may take the following actions in its discretion:

- Convert the foreign currency to the extent practical and lawful and distribute the U.S. dollars to the holders for whom the conversion and distribution is lawful and practical.
- Distribute the foreign currency to holders for whom the distribution is lawful and practical.
- Hold the foreign currency (without liability for interest) for the applicable holders.

Governing Law/Waiver of Jury Trial

The deposit agreement and the ADRs will be interpreted in accordance with the laws of the State of New York. The rights of holders of ordinary shares (including ordinary shares represented by ADSs) is governed by the laws of England and Wales.

AS A PARTY TO THE DEPOSIT AGREEMENT, HOLDERS IRREVOCABLY WAIVE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING AGAINST US AND/OR THE DEPOSITARY ARISING OUT OF, OR RELATING TO, THE DEPOSIT AGREEMENT, ANY ADR AND ANY TRANSACTIONS CONTEMPLATED IN THE DEPOSIT AGREEMENT (WHETHER BASED ON CONTRACT, TORT, COMMON LAW OR OTHERWISE).

**WITHOUT PREJUDICE &
SUBJECT TO CONTRACT**

DATED

27 March 2020

SETTLEMENT AGREEMENT

between

MERO BIOPHARMA GROUP PLC

and

RICHARD JONES

PARTIES

- (1) **Mereo BioPharma Group plc** (a company incorporated and registered in England and Wales with company number 9841161 whose registered office is at 4th Floor, One Cavendish Place, London, W1G 0QF (the “**Company**”); and
- (2) Richard Jones of [] (the “**Employee**”).

BACKGROUND

- (A) The Company and the Employee are parties to an employment agreement dated 7 November 2016 (the “**Employment Agreement**”)
- (B) The parties have entered into this agreement to record and implement the terms on which they have agreed to settle any claims that the Employee has or may have in connection with his employment or its termination or otherwise against the Company or any Group Company (as defined below) or their Affiliates (as defined below) following the voluntary resignation of the Employee, whether or not those claims are, or could be, in the contemplation of the parties at the time of signing this agreement, and including, in particular, the statutory complaints that the Employee raises in this agreement.
- (C) The parties intend this agreement to be an effective waiver of any such claims and to satisfy the conditions relating to settlement agreements in the relevant legislation.

AGREED TERMS

1. ARRANGEMENTS ON TERMINATION

- 1.1 The Employee’s employment with the Company and any Group Company shall terminate on 4 September 2020 or such earlier date as the Company may determine in its absolute discretion on or after 15 May 2020 (subject to clause 1.2 below) by notifying the Employee in writing no less than four weeks in advance of such date (the “**Termination Date**”).
- 1.2 Notwithstanding clause 1.1 above, the Company may terminate the Employee’s employment with the Company and any Group Company prior to 15 May 2020 or at any other time prior to the Termination Date, in circumstances where the Company or any Group Company is entitled to summarily terminate the Employee’s employment pursuant to clause 19 of the Employment Agreement.
- 1.3 The Employee will receive his P45 (made up to the Termination Date) as soon as reasonably practicable after the Termination Date.

- 1.4 Save as set out in this agreement, the Employee's entitlement to salary and all other benefits associated with his employment by the Company and any Group Company shall continue until the Termination Date when they shall cease.
- 1.5 The Company shall pay the Employee his salary up to the Termination Date in the usual way. The Company shall deduct from the final salary payment any outstanding sums due from the Employee to the Company.
- 1.6 The Company shall continue to provide benefits to the Employee in the usual way up to the Termination Date.
- 1.7 The Company shall within 7 days of the Termination Date make a payment to the employee for any annual leave accrued to his credit as at the Termination Date.
- 1.8 The payments and benefits in this clause 1 shall be subject to the income tax and National Insurance contributions that the Company is obliged by law to pay or deduct.
- 1.9 The Company shall reimburse the Employee for all expenses properly incurred by him in the performance of his duties in accordance with the Company's expenses policy.

2. HANDOVER

- 2.1 It is agreed that between now and the Termination Date the Employee will use his reasonable efforts to ensure a smooth transition of his duties, which will include but not be limited to the following:
 - (a) using his reasonable endeavours to deliver each of: (i) the Group's preliminary financial results for the year ended 31 December 2019, (ii) the Group's annual report and accounts for the year ended 31 December 2019 and (iii) the Company's Form 20-F and any related opinions, documents and statements as soon as is reasonably practicable prior to the statutory and regulatory deadlines for such financial results or filings; and
 - (b) using his reasonable endeavours to assist the Company (i) with the recovery of any R&D tax credits from HMRC, (ii) with any financing or (iii) by providing financial input to any business development activity, between the date of this agreement and the Termination Date.

3. PERFORMANCE-RELATED BONUS AND SHARE OPTIONS

- 3.1 In consideration for the Employee entering into this agreement, the Company shall pay the Employee a bonus of £[], less such deductions for income tax and

Employee's National Insurance Contributions as are legally required (the "**Performance Related Bonus**") and shall be payable in three instalments £[], £[] and £[] (the "**First Instalment**", the "**Second Instalment**" and the "**Third Instalment**" respectively), in accordance with clause 3.2 below subject to and conditional upon:

- (a) the receipt by the Company of a copy of this agreement signed by the Employee and a letter from the Adviser in the form as set out in Schedule 3;
- (b) the Employee having complied with clause 10 of this agreement;
- (c) the Employee having provided evidence that is satisfactory to the Company that the nature of the business carried out by the Employee's new employer means that he will not be engaged in any Restricted Business in the Restricted Area (where the terms Restricted Business and Restricted Area shall have the same meanings as in the Employment Agreement); and
- (d) the Company (or any Group Company) not being entitled to summarily terminate the Employee's employment pursuant to clause 19 of the Employment Agreement,

and the Employee shall not be entitled to any Performance Related Bonus unless each of the conditions out in this clause 3.1 are satisfied.

3.2 Subject to and conditional upon the Employee's compliance with all the terms of clause 3.1 above:

- (a) the Company shall pay the First Instalment to the Employee, which shall be treated as salary, by the earlier of 15 May 2020 and the filing of the Company' Form 20-F and any related opinions, documents and statements;
- (b) the Company shall pay the net amount of Second Instalment (with all legally required deductions for tax and national insurance having already been made) to a bank account in the name of [] (the "**Advisor's Client Account**") by the earlier of the Termination Date and 15 June 2020 and, subject to clause 3.2(c) below, and having received payment from the Company, the Adviser will procure that the Employee is paid the Second Instalment from the Advisor's Client Account on the 14th day after the Termination Date (and shall not be entitled to procure that such payment is made to the Employee prior to that date);
- (c) notwithstanding clause 3.2(b) above, if on or prior to the 7th day after the Termination Date: (i) the Employee has not complied with all of terms of each of clause 2, clause 3.1 and clause 7 of this agreement, and (ii) the Company has by that date notified the Adviser in writing of such non-compliance, then the Adviser will procure that no amounts in respect of the Second Instalment are paid to the Employee from the Advisor's Client Account (or otherwise), and will procure that such amounts are returned to

the same bank account in the name of the Company which transferred such amount to the Advisor's Client Account, within three days of the Advisor receiving such notification from the Company;

- (d) subject to and conditional upon the further condition that other executives of the Company have been paid a bonus in respect of the financial year ending 31 December 2019, and the Employee's compliance with each of clause 2 and clause 7 of this agreement, then the Company shall pay the Employee the Third Instalment within 7 days of other executives receiving such a bonus payment.

- 3.3 Pursuant to option agreements between the Employee and the Company, on 4 April 2017, the Employee was awarded [] options (the "**Options**") in respect of the Mereo BioPharma Group plc Share Option Plan (the "**Option Plan**") which, subject to and in accordance with the rules of the Option Plan (the "**Option Plan Rules**"), will all vest on 4 April 2020. It is further agreed that in consideration for the Employee entering into this agreement, notwithstanding that the Option Plan Rules require all the Options to be exercised within six months of the Termination Date, subject to and conditional upon the Employee complying with clauses 2.1 and clause 10 of this agreement and the Company not being entitled to summarily terminate the Employee's employment pursuant to clause 19 of the Employment Agreement, the Company will permit any of the Options that have vested, to be exercised (whether partially or otherwise) at any time prior to the second anniversary of the Termination Date following the Termination Date after which date they will lapse.
- 3.4 Any payment, grant or other benefit made or conferred to the Employee in respect of the performance-Related Payment or the Options, will be paid, granted or conferred to the Employee less such deductions for income tax and Employee's National Insurance Contributions as are legally required (whether in respect of this payment or the provision of any other payment or benefit to the Employee).

4. PENSION

The Employee's active membership of any pension arrangement in which he participates in connection with his employment with the Company or any Group Company shall continue in its current form either by way of contributions to the Company's pension scheme or via salary contributions and shall cease with effect from the Termination Date.

5. LEGAL FEES

The Company agrees to pay the Employee's reasonable legal fees in connection with taking advice leading to the completion of this agreement up to a maximum of £[] plus VAT to be paid within 14 days of receipt from the Employee's lawyer of a properly drawn invoice for costs addressed to the Employee as client and marked payable by the Company.

6. FULL AND FINAL SETTLEMENT

- 6.1 The Employee represents to the Company, any Group Company and their Affiliates that he agrees and he does hereby accept that the terms of this agreement are offered by the Company without any admission of liability on the part of the Company and are, apart from the Excluded Claims, in full and final settlement of all and any claims or rights of action that the Employee has or may have against the Company or any of its Affiliates in respect of breach of contract or unfair dismissal or any claim in respect of his bonus in respect of the financial year ending 31 December 2019 as notified him in a letter from Denise Scots-Knight dated 21 January 2020, being claims previously made or intimated by or on behalf of the Employee.
- 6.2 Without prejudice to clause 6.1 the Employee further represents to the Company (for itself and on behalf of all its Affiliates) that he accepts and he does hereby accept the terms of this agreement in full and final settlement of any Claims, including but not limited to any claims relating to his employment, his resignation from his employment or any other matter including (without limitation) any action that might be commenced before an Employment Tribunal or Court of law in respect of the Claims in schedule 2 of this agreement, save in respect of any Excluded Claims.
- 6.3 For the purposes of clause 6.2, "Claims" shall mean claims that have arisen at the date of this agreement or which subsequently arise in respect of acts or omissions occurring prior to the date of this agreement and shall include all and any claims or rights of action of which at the time of entering into this agreement:
- (a) neither the Employee nor the Company (nor any Affiliate) is aware, or
 - (b) the Employee but not the Company (nor any Affiliate) is aware, or
 - (c) one or more of the Company and the Affiliates is aware but the Employee is not aware,

including any claim or right of action arising from a subsequent retrospective change or clarification of the law. The Employee acknowledges that he agrees to the terms of clause 6.2 notwithstanding that he acknowledges that he may be mistaken as to the facts and/or the law concerning any potential claim or right of action.

- 6.4 The Employee acknowledges that the compromise and settlement of each of the claims set out in clauses 6.1 and 6.2 (including schedule 2) is and shall be construed as separate and severable (including in relation to each of the types of claim covered by the definition of Claims in clause 6.3) and in the event of the compromise and settlement of any such claim being determined as being void for any reason, such invalidity shall not affect or impair the validity of the compromise and settlement of the other claims.
- 6.5 It is a condition of this agreement, and the Employee warrants that:
- (a) before entering into this agreement he received independent advice from the Adviser as to the terms and effect of this agreement and, in particular, on its effect on his ability to pursue any complaint before an Employment Tribunal or other court;
 - (b) the Adviser has confirmed to the Employee that they are a solicitor holding a current practising certificate and that there is in force a policy of insurance covering the risk of a claim by the Employee in respect of any loss arising in consequence of their advice;
 - (c) the Adviser shall sign and deliver to the Company forthwith upon the execution by the Employee of this agreement a letter duly signed in the form attached as Schedule 3 to this agreement in which, amongst other things, the Adviser provides a formal undertaking to comply with the Adviser's obligations set out in clause 3.2 above;
 - (d) before receiving the advice the Employee disclosed to the Adviser all facts and circumstances that may give rise to a claim by the Employee against the Company, any Group Company or their Affiliates;
 - (e) the only claims that the Employee has or may have against the Company, any Group Company or their Affiliates (whether at the time of entering into this agreement or in the future) relating to his employment with the Company or its termination are specified in clauses 6.1 and 6.2 (including schedule 2); and
 - (f) the Employee is not aware of any facts or circumstances that may give rise to any claim against the Company, any Group Company or their Affiliates other than those claims specified in clauses 6.1 and 6.2 (including schedule 2).
- 6.6 The Employee acknowledges that the conditions relating to settlement agreements under section 147(3) of the Equality Act 2010, section 288(2B) of the Trade Union and Labour Relations (Consolidation) Act 1992, section 203(3) of the Employment Rights Act 1996, regulation 35(3) of the Working Time Regulations 1998, section 49(4) of the National Minimum Wage Act 1998, regulation 41(4) of the Transnational Information and Consultation etc. Regulations 1999, regulation 9 of the Part-Time Workers (Prevention of Less Favourable Treatment) Regulations 2000, regulation 10 of the Fixed-Term Employees (Prevention of Less Favourable Treatment) Regulations 2002, regulation 40(4) of the Information and Consultation of Employees

Regulations 2004, paragraph 13 of the Schedule to the Occupational and Personal Pension Schemes (Consultation by Employers and Miscellaneous Amendment) Regulations 2006, regulation 62 of the Companies (Cross Border Mergers) Regulations 2007 and section 58 of the Pensions Act 2008 have been satisfied.

7. COMPANY PROPERTY

7.1 The Employee shall on or before the Termination Date, return to the Company's premises:

- (a) all Confidential Information and Copies;
- (b) all property belonging to the Company in satisfactory condition including (but not limited to) any, company credit card, keys, security passes, identity badge, mobile telephone, tablet, pager, lap-top computer, computer drives, disks, other computer equipment (including leads and cables), tapes and/or other tangible items; and
- (c) all documents and copies (whether written, printed, electronic, recorded or otherwise and wherever located) made, compiled or acquired by him during his employment with the Company or relating to the business or affairs of the Company or any Group Company or its or their business contacts,

in the Employee's possession or under his control.

7.2 The Employee shall, immediately on request, provide to the Company full details of all then current passwords used by the Employee in respect of computer equipment belonging to the Company or any Group Company and, having forwarded a copy to the Company, irretrievably delete from any computer drives, tablets, mobile telephones, disks, tapes or other re-usable material and/or email account in the Employee's possession or under his control (but which do not belong to the Company or any Group Company), and/or communications systems and devices owned or used by him outside the premises of the Company, including such systems and data storage services provided by third parties (to the extent technically practicable) any information belonging or relating to the business or affairs of the Company or any Group Company, their customers, clients and suppliers.

7.3 The Employee shall, if requested to do so by the Company or Board, provide a signed statement that he has complied fully with his obligations under clause 7.1 and clause 7.2 and shall provide it with such reasonable evidence of compliance as may be requested.

8. EMPLOYEE WARRANTIES AND ACKNOWLEDGEMENTS

8.1 As at the date of this agreement, the Employee warrants and represents to the Company that:

- (a) there are no circumstances of which the Employee is aware or of which the Employee ought reasonably to be aware that would amount to a repudiatory breach by the Employee of any express or implied term of the Employment Agreement that would entitle (or would have entitled) the Company to terminate the Employee's employment without notice or payment in lieu of notice and any payment to the Employee pursuant to clause 2 is conditional on this being so; and
- (b) he has not contacted ACAS pursuant to section 18A of the Employment Rights Act 1996 or presented or issued a claim to the Employment Tribunals, a County Court or a High Court in respect of any matter connected with the Employee's employment or its termination and that neither the Employee nor anyone acting on the Employee's behalf will contact ACAS pursuant to section 18A of the Employment Rights Act 1996 or present or issue such a claim.
- (c) The Employee acknowledges and warrants that, except for the payments and benefits provided for in this agreement, and subject to the waiver in clause 6.1 and 6.2, he shall not be eligible for any further payment and/or compensation from the Company or any Group Company relating to his employment or its termination and without limitation to the generality of the foregoing, he expressly waives any right or claim that he has or may have to: any accrued or future bonus, including but not limited to any bonus in respect of the financial year ending 31 December 2019 as notified to him in a letter from Denise Scots-Knight dated 21 January 2020, commission, profit-sharing or other incentive payment shares pursuant to the holding or loss of any right under or in connection with any share scheme or equity participation arrangement and/or any future allocation of shares, equities or securities, in each case against the Company or any Group Company or any person connected to any such company.

8.2 The Employee agrees to make himself available to, and to cooperate with, the Company and any Group Company or its advisers to provide assistance in any litigation or potential litigation (whether criminal or civil and whether before a court or tribunal) or any arbitration or mediation or any inquiry or investigation by a statutory or regulatory tribunal, authority or other body with which the Company, or any Group Company may be involved, including but not limited to any ongoing litigation in which the employee may be a witness and/or any potential litigation that has been intimated to the Company or any Group Company. The Employee agrees to provide such reasonable assistance (at such time and place as may be mutually convenient for the parties) as the Company or any Group Company may reasonably

require, including but not limited to assisting in preparing witness statements and attending at court or tribunal or other body to give evidence and, save where such litigation or potential litigation is or is connected with criminal proceedings being taken or proposed against the Company the Company or any Group Company shall meet such costs and expenses incurred by the Employee in providing such assistance as the Company or any Group Company considers as reasonable, including fees at a pro-rata daily rate based on his annual salary at termination divided by 220, and only to the extent permitted and provided for by any applicable rules, including any rules of Court or Practice Direction, from time to time.

- 8.3 The Employee agrees not to hold himself out as remaining employed by or otherwise continuing to work for the Company or any Group Company after the Termination Date, and on the Termination Date to update his LinkedIn profile and any other online presence accordingly.
- 8.4 The Employee agrees to resign in writing from all directorships and other offices which the Employee holds with the Company or any Group Company with effect from the Termination Date or such other date as the Company or any Group Company may in their absolute discretion determine, and authorises the Company and any Group Company to do any acts necessary in his name and on his behalf to give effect to those resignations
- 8.5 The Employee undertakes that he will not make a statutory grievance in relation to claims accepted as settled pursuant to clauses 6.1 or 6.2 (including Schedule 2).
- 8.6 The Employee acknowledges that the Company has agreed these terms in reliance on the warranties, representations and undertakings set out in clauses 6.1, 6.2 (including Schedule 2), 6.5 (a-f), 7.1, 7.2, 8.1 (a-b), 8.2, 8.3, 8.4, 8.5 and 8.6.

9. REFERENCE AND ANNOUNCEMENT

- 9.1 On receipt of a written request from a potential employer, the Company shall provide a reference in the form set out in Schedule 1 to this agreement. If the Company obtains information after the date of this agreement which would have affected its decision to provide a reference in the form in Schedule 1, it shall inform the Employee and may decline to give a reference.
- 9.2 Upon signature of this agreement an announcement will be made without delay on the RNS service of the London Stock Exchange broadly based on the form set out in Schedule 4 with the Company entitled to make any changes provided that they do not have any adverse impact on the Employee.

10. COVENANTS

The Employee acknowledges and agrees that without prejudice to his ongoing common law obligations his contractual obligations with respect to confidentiality, intellectual property, restrictions after employment and all other post termination obligations as stated in the Employment Agreement, including but not limited to those set out in paragraphs 16, 17 and 21 thereof, shall continue to apply after the Termination Date.

11. CONFIDENTIALITY

11.1 Subject to clause 11.4, the Employee undertakes as a condition of this agreement to the Company for itself and on behalf of all its Group Companies as follows:

- (i) the Employee will treat the contents of this agreement as confidential and will not disclose or cause to be disclosed the negotiations surrounding this agreement, the existence of this agreement and any of its terms to any person, firm or company save to the Employee's spouse or registered civil partner or for the purpose of receiving professional advice;
- (ii) save with the prior written consent of the Company, the Employee will not make or issue or cause to be made or issued any derogatory or critical comments or statements (internally or externally whether orally or in writing and including, for the avoidance of doubt, electronically or online) relating to his employment with the Company or any Group Company, his departure from the Company and any of its Group Companies or the reasons for his departure other than in connection, and consistent, with the terms of the reference and the announcement to be provided to him pursuant to this agreement; and
- (iii) the Employee will not make, publish or cause to be made or published any statement or remark which may harm the business or reputation of the Company or any of its Group Companies or any current or former officer, Employee, agent, customer, supplier or shareholder of any such company.

11.2 The Company will treat the contents of this agreement as confidential and will not disclose or cause to be disclosed the negotiations surrounding this agreement, the existence of this agreement and any of its terms to any person, firm or company save to appropriate employees or officers of the Company or any Group Company, for business needs or for the purpose of receiving professional advice

11.3 The Employee warrants that he has not engaged in any conduct prior to or on the date of this agreement which would amount to a breach of sub-clauses 11.1 if carried out after the date of this agreement.

- 11.4 Nothing in this agreement shall preclude the Employee or the Company or any Group Company from:
- (a) complying with any order of a court of competent jurisdiction, any law, any regulations of any statutory or regulatory authority, or any request of any government body (including, for the avoidance of doubt, HM Revenue & Customs, the SEC or any listing rules);
 - (b) making a protected disclosure under section 43A of the Employment Rights Act 1996 and nothing in this clause 11 shall prevent the Company from making such disclosure as it is required by law to make; or
 - (c) without prejudice to the foregoing, disclosing any information to and/or cooperate with the U.S. Securities Exchange Commission (“SEC”), the Financial Conduct Authority and/or any other governmental or regulatory agency or to receive a monetary award from the SEC as an SEC Whistleblower, pursuant to the bounty provision under Section 922(a)-(g) of the Dodd Frank Act, 7 U.S.C. Sec. 26(a)-(g), or directly from any other governmental, federal or state agency pursuant to a similar program.
- 11.5 The Employee acknowledges that any breach of his confidentiality obligations may cause irreparable harm to the Company which the Employee agrees may be entitled to injunctive relief in addition to all other remedies available to the Company or any Group Company at law or in equity. Furthermore, any breach of confidentiality may be a fundamental breach of this agreement and may entitle the Company to withhold making the Termination Payment or, in the event the Termination Payment has been made to the Employee, the Company shall be entitled to recover the Termination Payment (less any payment to which the Employee may be legally entitled) from the Employee as a debt.

12. ENTIRE AGREEMENT

- 12.1 Each party on behalf of itself and, in the case of the Company, as agent for any Group Companies acknowledges and agrees with the other party (the Company acting on behalf of itself and as agent for each Group Company) that:
- (a) this agreement and any agreements referred to herein, constitute the entire agreement between the parties and any Group Company and supersedes and extinguishes all agreements, promises, assurances, warranties, representations and understandings between them whether written or oral, relating to its subject matter;
 - (b) in entering into this agreement it does not rely on, and shall have no remedies in respect of, any statement, representation, assurance or warranty (whether made innocently or negligently) that is not set out in this agreement; and

- (c) it shall have no claim for innocent or negligent misrepresentation or negligent misstatement based on any statement in this agreement.

12.2 Nothing in this agreement shall, however, operate to limit or exclude any liability for fraud.

13. VARIATION

The parties to this agreement may agree to rescind or vary any term of this agreement without the consent of any Group Companies or Affiliates. No variation of this agreement shall be binding on either party unless and to the extent that the same is recorded in a written document executed by both parties.

14. THIRD PARTY RIGHTS

14.1 The Company is entering into this agreement for itself and as agent for and trustee of all its Group Companies and their Affiliates. The parties intend that each Group Company and Affiliates should be able to enforce in its own right the terms of this agreement which expressly or impliedly confer a benefit on that company subject to and in accordance with the provisions of the Contracts (Rights of Third Parties) Act 1999.

14.2 The rights of the Group Companies or Affiliates to enforce the terms of this agreement are subject to the term that the Company has the right (which it may waive in whole or in part and without the consent of or consultation with the Group Company) to have the sole conduct of any proceedings in relation to the enforcement of such rights (including any decision as to commencement or compromise or settlement of such proceedings) but will not owe any duty or have any liability to any of the Group Companies in relation to such conduct.

15. GOVERNING LAW

This agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.

16. JURISDICTION

Each party irrevocably agrees that the courts and tribunals of England and Wales shall have exclusive jurisdiction to settle any dispute, claim arising out of or in connection with this agreement or its subject matter or formation (including non-contractual disputes or claims).

17. MISCELLANEOUS

- 17.1 The Employee hereby agrees irrevocably that the Company may forthwith on written notice to the Employee assign its rights and transfer (whether by novation or otherwise) or delegate its obligations under this agreement to any Group Company from time to time or to any third party acquiring the business of the Company and that the Employee shall execute all documents and do all things necessary to effect such assignment or transfer, and any reference to the Company in this agreement shall thereafter be a reference to any such company. The Employee shall not assign or otherwise seek to transfer or delegate his rights and/or obligations under this agreement to any other person.
- 17.2 Each of the provisions in this agreement are separate and severable and, in the event of any such provision (including the defined expressions in clause 19.1) being determined as being unenforceable in whole or in part for any reason, such unenforceability shall not affect the enforceability of the remaining provisions or, in the case of part of a provision being unenforceable, the remainder of that provision.

18. SUBJECT TO CONTRACT AND WITHOUT PREJUDICE

This agreement is without prejudice and subject to contract until it is dated and signed by all of the parties, at which point it shall be treated as an open document evidencing an agreement binding on the parties (notwithstanding that it may still be labelled “Draft”, “Without Prejudice” or “Subject to Contract”). This agreement may be executed in any number of counterparts each in the like form, all of which taken together shall constitute one and the same document and any party may execute this agreement by signing and dating any one or more of such counterparts.

19. INTERPRETATION

The following definitions and rules of interpretation apply in this agreement.

19.1 Definitions:

“**Adviser**”: [];

“**Affiliates**”: any Group Company and the former and current and future officers, shareholders, managers, employees and agents of the Company and any Group Company;

“**Associate**”: means a body corporate:

- (a) which for the time being is a holding company of the Company or a subsidiary (other than the Company or a subsidiary of the Company) of such a holding company; or

- (b) in whose equity share capital for the time being an interest of 20 per cent or more is held directly or indirectly (through another body corporate or other bodies corporate or otherwise) by a holding company of the Company or by a subsidiary (including the Company) of such a holding company or by a combination of two or more such holding companies or subsidiaries;

“Board”: the board of directors of the Company from time to time and includes any person or committee duly authorised by the boards of directors to act on its behalf for the purposes of this agreement;

“Confidential Information”: any information, whether or not recorded, of the Company or of any Group Company which the Employee (or, where the context so requires, another person) has obtained by virtue of his employment or engagement and which the Company or any Group Company regards as confidential or in respect of which the Company or any Group Company is bound by an obligation of confidence to a third party, including:

- (a) all and any information relating to business methods, corporate plans, future business strategy, management systems, finances, and maturing new business opportunities;
- (b) all and any information relating to research and/or development projects;
- (c) all and any information concerning the curriculum vitae, remuneration details, work-related experience, attributes and other personal information concerning those employed or engaged by the Company or any Group Company;
- (d) all and any information relating to marketing or sales of any past present or future product or service of the Company or any Group Company including sales targets and statistics, market share and pricing statistics, marketing surveys and strategies, marketing research reports, sales techniques, price lists, mark-ups, discounts, rebates, tenders, advertising and promotional material, credit and payment policies and procedures, and lists and details of customers, prospective customers, suppliers and prospective suppliers including their identities, business requirements and contractual negotiations and arrangements with the Company or any Group Company; and
- (e) all and any trade secrets, secret formulae, processes, inventions, design, know-how, technical specification and other technical information in relation to the creation, production or supply of any past, present or future product or service of the Company or any Group Company, including all and any information relating to the working of any product, process, invention, improvement or development carried on or used by the Company or any Group Company and information concerning the intellectual property portfolio and strategy of the Company or of any Group Company; and
- (f) any inside information (as defined in section 118C of the Financial Services and Markets Act 2000),

but excluding any information which:

- (i) is part of the Employee's own stock in trade;
- (ii) is readily ascertainable to persons not connected with the Company or any Group Company without significant expenditure of labour, skill or money; or
- (iii) which becomes available to the public generally other than by reason of a breach by the Employee of his obligations under this Agreement;

"Copies": copies or records of any Confidential Information in whatever form (including, without limitation, in written, oral, visual or electronic form or on any magnetic or optical disk or memory and wherever located) including, without limitation, extracts, analysis, studies, plans, compilations or any other way of representing or recording and recalling information which contains, reflects or is derived or generated from Confidential Information;

"Employment Agreement": shall have the meaning set out in Recital (A);

"Excluded Claims": any claims: (a) to enforce the terms of this agreement; and/or (b) for personal injury (save for any claims for compensation, or damages, for personal injury which may be brought pursuant to discrimination legislation and/or pursuant to part V of the Employment Rights Act 1996) of which the Employee is not aware and could not reasonably be expected to be aware as at the Termination Date (and by entering into this agreement the Employee warrants that he is not nor could reasonably be aware of any such claims); and/or (c) in respect of the payment of accrued entitlements under any Relevant Pension Scheme that he has or may have against the Company or any of its Affiliates relating to his employment, the termination of his employment;

"Group Company": means a subsidiary of the Company or an Associate as defined in this clause 19.1;

"subsidiary", "holding company" and "equity share capital" shall have the respective meanings attributed to them by sections 1159 and 548 of the Companies Act 2006 provided that the term "subsidiary" shall also include a subsidiary undertaking (as defined in section 1162(2) of the Companies Act;

- 19.2 the headings and bold type face inserted in this agreement are inserted for convenience only and shall not affect the interpretation of this agreement;
- 19.3 references to clauses, sub-clauses and schedules are to clauses, sub-clauses and schedules of this agreement;
- 19.4 words in the singular include the plural and vice versa, and a reference to any gender includes a reference to all genders or, where appropriate, is to be read as a reference to the opposite gender;

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- 19.5 a reference to a person includes a reference to a firm, a body corporate, an unincorporated association or a partnership;
- 19.6 a reference to a statute or statutory provision shall include a reference to any subordinate legislation made under the relevant statute or statutory provision and is a reference to that statute, provision or subordinate legislation as from time to time amended, consolidated, modified, re-enacted or replaced.

This agreement has been entered into on the date stated at the beginning of it.

Signed by DENISE SCOTS-KNIGHT for
and on behalf of Mereo BioPharma Group plc

.....
/s/ Denise Scots-Knight

Director

Signed by Richard Jones

.....
/s/ Richard Jones

**CONSULTING
AND
INTERIM CHIEF FINANCIAL OFFICER AGREEMENT**

This Consulting and Interim Chief Financial Officer Agreement (“**Agreement**”) is effective as of the 14th day of May, 2020 by and among Mereo BioPharma Group plc, a company incorporated in England and Wales with a registered office at 1 Cavendish Place, London W1G 0QF (the “**Company**”), MSW Consulting Inc., a corporation with headquarters located at 49 Beacon Street, Unit 3 Boston, MA 02108 (“**Consultant**”), and Michael Wyzga (“**Wyzga**” or “**Executive**”).

WHEREAS, the Company desires to retain Consultant as an independent contractor to perform consulting services for the Company for a period of time, and Consultant is willing to perform such services, on terms set forth more fully below.

WHEREAS, upon the departure of the Company’s current chief financial officer, the Company wishes to appoint Executive as its interim chief financial officer (“**Interim CFO**”), on terms also set forth more fully below, for an expected period of less than one year; and

WHEREAS, Executive desires to accept his appointment as Interim CFO;

NOW THEREFORE, in consideration of the mutual promises contained herein, the parties agree as follows:

Part I. Consulting Services

1. **Consulting Period.** The engagement of Consultant pursuant to this Agreement will commence on the date first written above, and unless terminated earlier pursuant to Part I, Section 3 (Termination of Consulting Period) of this Agreement, will terminate upon Wyzga’s assuming the position of Interim CFO. The period during which Consultant is providing the Services (as defined below) pursuant to this Agreement shall constitute the “**Consulting Period**.”
2. **Services and Compensation.** During the Consulting Period, Consultant agrees to perform for the Company the services requested by the Company, including the duties and tasks described in Exhibit A (collectively, “**Services**”). Consultant agrees to devote such time to these Services as is reasonably necessary to perform them, which shall be at least as much time as is set forth on Exhibit A.

Except as expressly stated herein, only Michael Wyzga, the authorized service provider (“**Authorized Service Provider**”), will provide the Services on behalf of Consultant. Consultant acknowledges and agrees that the Company entered into this Agreement for the Consulting Period to retain the Consultant to perform the Services. Services are unique to the Company and the Company has determined that Michael Wyzga is exceptionally qualified to perform them by virtue of his education, training and experience, and the Services are not to be performed by other individuals.

During the Consulting Period, with effect from the date notified in writing by the Consultant to the Company, the Company agrees to pay Consultant the compensation set forth in Exhibit A as sole compensation for the performance of the Services. It is understood and agreed that Consultant will be an independent contractor. Consultant will perform the Services under the Company's general direction as to the result of activity but Consultant shall determine, in Consultant's discretion, the time, manner and means by which the Services are accomplished, subject to the express conditions that Consultant will at all times comply with applicable law. Wyzga need not perform the Services on the Company's premises. It is also expressly understood that during the Consulting Period, neither Consultant nor the Authorized Service Provider shall be considered an agent or employee of the Company, and shall have no authority whatsoever to bind the Company by contract or otherwise. Consultant, on behalf of itself and the Authorized Service Provider, expressly waives any right to participate in any of the Company's employee benefit plans or perquisites. Consultant, on behalf of itself and the Authorized Service Provider, further disclaims any intention or right to participate in any of the Company's employee benefit plans or perquisites even if Consultant's or the Authorized Service Provider's status with the Company is determined by a third party tribunal to be that of an employee.

Consultant agrees that during the Consulting Period, Consultant will from time to time keep the Company advised as to Consultant's progress in performing the Services hereunder and that Consultant will, as requested by the Company, prepare written reports with respect thereto. It is understood that the time required in the preparation of such written reports shall be considered time devoted to the performance of Consultant's Services.

Consultant, on behalf of itself and the Authorized Service Provider, acknowledges that Company may publicize Consultant's and the Authorized Service Provider's role with Company by including Consultant's and the Authorized Service Provider's name and publicly available information regarding Consultant and/or the Authorized Service Provider in Company's published materials (including but not limited to its website, presentations, and business plan materials). Consultant and the Authorized Service Provider understand that this Agreement may be part of one or more federal securities filings.

3. Termination of Consulting Period. Either Consultant or the Company may terminate the Consulting Period upon giving thirty (30) days prior written notice thereof to the other party. The Consulting Period and this Agreement shall terminate immediately upon the Authorized Service Provider's death. The Company may, in addition to any other rights it may have at law or in equity, also terminate this Agreement immediately and without prior notice if Consultant or the Authorized Service Provider refuses to or is unable to perform the Services, or is in breach of any material provision of this Agreement. Upon such termination all rights and duties of the parties with respect to the Consultant's provision of Services and the Company's compensation of the Consultant and the Authorized Service Provider for such Services shall cease except that the Company shall be obligated to pay, within thirty (30) days of the effective date of termination, all amounts owing to Consultant pursuant to Exhibit A for Services actually performed and reimbursable expenses actually incurred prior to termination, if any, in accordance with the provisions of Exhibit A.

4. Independent Contractor; Taxes; Indemnification. Nothing in this Agreement shall in any way be construed to render Consultant or the Authorized Service Provider to be an agent, employee or representative of the Company. Consultant shall (and shall cause the Authorized Service Provider to) perform the Services hereunder as an independent contractor. Consultant acknowledges and agrees that Consultant is obligated to report as income all compensation received by Consultant pursuant to this Agreement, and Consultant agrees to and acknowledges the obligation to pay all taxes, including without limitation all federal and state income tax, social security taxes and unemployment, disability insurance and workers' compensation applicable to Consultant and any person who performs Services in connection with this Agreement, and that Consultant will not be eligible for any employee benefits (nor does Consultant desire any of them) and expressly waives any entitlement to such benefits. Consultant further agrees to indemnify the Company and hold it harmless to the extent of any obligation imposed on the Company (i) to pay withholding taxes or similar items or (ii) resulting from Consultant's being determined not to be an independent contractor.

Except insofar as it would preclude the Consultant from providing the Services under this Agreement or violate Part III, Section 7 (Avoidance of Conflict of Interest) hereof, Consultant is free to perform services for any other person. Consultant, on behalf of itself and the Authorized Service Provider, further acknowledges and agrees to the following:

(a) While providing the Services pursuant to Part I of this Agreement, Consultant and the Authorized Service Provider is, and shall at all times be and remain, an independent contractor;

(b) Consultant is customarily engaged in an independently established trade, occupation, profession or business of the same nature as that involved in providing Services;

(c) Nothing in this Agreement or otherwise shall be construed as identifying Consultant as an employee, agent or legal representative of the Company or any of the Company's related or affiliated entities during the Consulting Period for any purpose whatsoever;

(d) Consultant and the Authorized Service Provider are not authorized to transact business, incur obligations, sell goods, receive payments, solicit orders or assign or create any obligation of any kind, express or implied, on behalf of the Company or any of the Company's related or affiliated entities, or to bind in any way whatsoever, or to make any promise, warranty or representation on behalf of the Company or any of the Company's related or affiliated entities with respect to any matter, except as expressly authorized in writing by the Company;

(e) While Consultant will receive instruction on the objects and goals for which he or she is responsible, during the Consulting Period, the Company has no right to control the manner in which Consultant performs Services under this Agreement and Consultant is free to perform Services in the manner Consultant deems fit and in accordance with recognized standards for such services;

(f) Consultant shall not (and shall not permit the Authorized Service Provider to) use the Company's trade names, trademarks, service names or service marks without the prior written approval of the Company; and

(g) If, at any time, Consultant's or the Authorized Service Provider's status with the Company as an independent contractor changes or Consultant or the Authorized Service Provider is ever deemed, with respect to the Services performed during the Consulting Period, to be an employee of the Company, each of the covenants set forth above and this Agreement remains in full force and effect in its entirety until and unless it is replaced with a subsequent and superseding agreement.

5. **Limited Warranty.** Consultant, on behalf of itself and the Authorized Service Provider, represents and warrants that all services rendered hereunder during the Consulting Period will be performed in compliance with all applicable laws and regulations and in a professional manner in accordance with the highest industry standards and practices. Consultant, on behalf of itself and the Authorized Service Provider, represents and warrants that Consultant and the Authorized Services Provider will perform Consultant's and the Authorized Services Provider's responsibilities under this Agreement in a manner that does not infringe, or constitute an infringement or misappropriation of any patent, copyright or other proprietary right of any third party. Except as expressly stated in this Agreement, Consultant, on behalf of itself and the Authorized Services Provider, disclaims all other express or implied warranties with respect to his or her performance of the Services.

II. Employment as Interim Chief Financial Officer of the Company

1. **Employment Period.** The employment of Wyzga as Interim CFO pursuant to this Agreement will commence on the date on which his appointment as Interim CFO becomes effective and, unless terminated earlier pursuant to Part II, Section 8 hereof (Termination of Employment), will terminate on the date on which the employment of his successor as the chief financial officer of the Company commences. The period during which Wyzga is employed by the Company as Interim CFO pursuant to this Agreement shall constitute the "**Employment Period.**"

2. **Position, and Duties.** During the Employment Period, Wyzga shall serve as chief financial officer of the Company and shall have the normal duties and responsibilities which are consistent with Wyzga's position as chief financial officer and as the board of directors of the Company ("**Board**") may direct from time to time direct.. Wyzga shall report to the chief executive officer of the Company.

3. **Best Efforts.** During Wyzga's employment, Wyzga shall: (i) devote Wyzga's full professional time and attention to the performance of Wyzga's duties for the Company and its subsidiaries and related divisions and business lines; (ii) use Wyzga's best efforts to dutifully, faithfully and efficiently perform his duties hereunder, and obey all reasonable and lawful directions given by or under the authority of the Board; and (iii) refrain from engaging in any other business, profession or occupation for compensation or otherwise which would conflict, directly or indirectly, with the rendition of services to the Company. Wyzga may engage in charitable, civic and community activities and manage Wyzga's personal investments provided that such activities do not materially interfere with the performance of his duties hereunder or conflict with the conditions of his employment, all in a manner consistent with his duties and responsibilities.

4. Adherence to Company Policies and Applicable Rules. During the Employment Period, Wyzga shall: (i) comply with the Company's articles of association, rules, and regulations; (ii) comply with the rules of any securities or investment exchange or regulatory or governmental body to which the Company is subject from time to time (including the US Securities and Exchange Commission and Nasdaq); (iii) comply with, and procure compliance with, so far as he is able, that his spouse or civil partner and dependent children (if any) or any trust in which he, his spouse, or civil partner or dependent children may be concerned or interested in as trustee or beneficiary, any code of conduct relating to securities transactions by directors and specified employees applicable in the Company and its subsidiaries; (iv) exercise his duties in compliance with the requirements of the United Kingdom's Bribery Act 2010; and (v) comply with such office policies, procedures, and practices as may be established from time to time through office manuals, policy statements, memoranda, or other communications to the Company's officers, directors, and employees. Wyzga understands that these policies, procedures, and practices are subject to change, do not constitute contractual rights or obligations, and that no employee has any right to the continuance of any given policy or practice unless specifically set forth herein.

5. During the Employment Period, Executive's primary work location shall be in Boston, Massachusetts; provided, however, that (i) Wyzga may elect to perform his duties from other locations from time to time; and (ii) Wyzga shall travel to other locations and countries as and when required by the Board including, but not limited to, travel to the Company's offices in the United Kingdom.

6. Compensation. During the Employment Period, the Company agrees to pay Wyzga the compensation set forth in Exhibit B as sole compensation for the performance of his duties as Interim CFO. In addition, during the Employment Period, Wyzga shall be eligible to be granted Company stock options on the same basis as other senior executives of the Company.

7. Business Expenses. During the Employment Period, the Company shall reimburse Wyzga for all reasonable expenses incurred by Wyzga in the course of performing Wyzga's duties under this Agreement that are consistent with the Company's policies in effect from time to time with respect to travel, entertainment and other business expenses, subject to the Company's requirements applicable generally with respect to reporting and documentation of such expenses.

8. Termination of Employment. Wyzga's employment with the Company is at-will and not for any specified period. Either the Company or Wyzga may terminate the Employment Period and this Agreement upon giving thirty (30) days prior written notice thereof to the other party. The Employment Period and this Agreement shall terminate immediately upon Wyzga's death. The Company may, in addition to any other rights it may have at law or in equity, also terminate this Agreement immediately and without prior notice if Wyzga refuses to or is unable to perform his duties as Interim CFO, has committed an act of material misconduct or gross negligence, or is in breach of any material provision of this Agreement. Upon such termination, the Company's compensation obligations to Wyzga shall cease except that the Company shall be obligated to pay, within thirty (30) days of the effective date of termination (or such earlier time as may be required by law), (i) the compensation earned and owing to Wyzga pursuant to Exhibit B for the period through and including the date on which his employment terminates, and (ii) reimbursable expenses actually incurred by Wyzga prior to termination. If, on the date of termination, Wyzga

holds any other office or position with the Company or its subsidiaries (other than that of being a member of the Board, which unless he has resigned or has been removed, Wyzga shall continue to hold following the end of the Employment Period) (“**Other Offices and Positions**”), Wyzga shall be deemed to have resigned from all Other Offices and Positions as of his employment termination date. Wyzga hereby covenants that upon and following the date of termination, he will take such actions and execute such instruments as the Company determines to be necessary or advisable in order to effect such resignations.

9. **Executive’s Cooperation.** During the Employment Period and thereafter, Wyzga shall reasonably cooperate with the Company and its affiliates or subsidiaries in any internal investigation or administrative, regulatory or judicial proceeding as reasonably requested by the Company (including, without limitation, Wyzga’s being reasonably available to the Company upon reasonable notice for interviews and factual investigations, appearing at the Company’s reasonable request to give testimony without requiring service of a subpoena or other legal process, volunteering to the Company all pertinent information and turning over to the Company all relevant documents which are or may come into Wyzga’s possession, all at times and on schedules that are reasonably consistent with Wyzga’s other permitted activities and commitments) at reasonable times. In the event the Company requires Wyzga’s cooperation in accordance with this section, the Company shall reimburse Wyzga solely for reasonable travel expenses (including lodging and meals, upon submission of receipts). Nothing about the foregoing shall preclude Wyzga from testifying truthfully in any forum or from providing truthful information to any government agency or commission.

Part III

In this Part III, “Wyzga” shall refer to Consultant, Michael Wyzga in his capacity as authorized service provider, and Michael Wyzga in his capacity as Interim CFO, and the promises, duties, and obligations imposed on “Wyzga” under this Part III (i) are each made by Consultant and by Michael Wyzga in his capacity as Interim CFO, and (ii) Consultant will cause Michael Wyzga, in his capacity as authorized service provider, to perform or refrain from, as applicable, each of the promises, duties and obligations imposed on Consultant by this Part III.

1. **Confidentiality.** “**Confidential Information**” means all trade secrets and confidential or proprietary information, whether or not in writing, concerning the Company’s business, technology, business relationships or financial affairs which the Company has not released to the general public. By way of illustration, Confidential Information may include, but is not limited to, information or material which has not been made generally available to the public, such as: (a) *corporate information*, including plans, strategies, methods, policies, resolutions, negotiations or litigation; (b) *marketing information*, including strategies, methods, customer identities or other information about customers, prospect identities or other information about prospects, or market analyses or projections; (c) *financial information*, including cost and performance data, debt arrangements, equity structure, investors and holdings; and (d) *operational and technological information*, all proprietary data, plans, specifications, manuals, forms, templates, software, designs, methods, procedures, formulas, discoveries, inventions, improvements, concepts and ideas; and (e) *personnel information*, including personnel lists, reporting or organizational structure, resumes, personnel data, compensation structure, performance evaluations and termination arrangements or documents. Confidential Information also includes information received in confidence by the Company from its customers or suppliers or other third parties.

2. **Recognition of Company Rights.** Wyzga will not, at any time, without the Company's prior written permission, either during or after the term of this Agreement, disclose any Confidential Information to anyone outside of the Company, or use or permit to be used any Confidential Information for any purpose other than (i) the performance of the Services during the Consulting Period, and (ii) Wyzga's performance of his duties and responsibilities as Interim CFO during the Employment Period, for or on behalf of the Company. Wyzga will cooperate with the Company and use best efforts to prevent the unauthorized disclosure or use of any and all Confidential Information. Wyzga will deliver to the Company all copies of Confidential Information in Wyzga's possession or control upon the earlier of a request by the Company or termination of this Agreement for any reason.

3. **Rights of Others.** Wyzga understands that the Company is now and may hereafter be subject to non-disclosure or confidentiality agreements with third persons which require the Company to protect or refrain from use of Confidential Information. Wyzga, agrees to be bound by the terms of such agreements in the event Wyzga has access to such Confidential Information.

4. **Prior Agreements.** Wyzga agrees that Wyzga will not, during the term of this Agreement, improperly use or disclose any proprietary information or trade secrets of any former or current employer or other person or entity with which Wyzga has an agreement or duty to keep in confidence information acquired by Wyzga, if any, and that Wyzga will not bring onto the premises of the Company any unpublished document or proprietary information belonging to such employer, person or entity unless consented to in writing by such employer, person or entity.

5. **Ownership.** Wyzga will make full and prompt disclosure to the Company of all inventions, discoveries, designs, developments, methods, modifications, improvements, ideas, products, processes, databases, computer programs, formulae, techniques, know-how, trade secrets, graphics or images, and audio or visual works and other works of authorship (collectively "**Developments**"), whether or not patentable or copyrightable, that are created, made, conceived or reduced to practice by Wyzga (alone or jointly with others) or under Wyzga's direction during the term of this Agreement. Wyzga acknowledges that all work performed by Wyzga is on a "work for hire" basis, and Wyzga hereby assigns and transfers and, to the extent any such assignment cannot be made at present, will assign and transfer, to the Company and its successors and assigns all Wyzga's right, title and interest in all Developments that (i) relate to the business of the Company or any customer of the Company or any of the products or services being researched, developed, manufactured, performed or sold by the Company or which may be used with such products or services; or (ii) result from tasks assigned to Wyzga by the Company and/or the Services and/or Wyzga's employment; or (iii) result from the use of premises or personal property (whether tangible or intangible) owned, leased or contracted for by the Company ("**Company-Related Developments**"), and all related patents, patent applications, trademarks and trademark applications, service marks and service mark applications, copyrights and copyright applications, and other intellectual property rights in all countries and territories worldwide and under any international conventions ("**Intellectual Property Rights**"). Wyzga shall, at the request of Company execute all documents as are

required to vest ownership of any Company-Related Developments and Intellectual Property Rights in Company and will assist Company in obtaining and enforcing patent, copyright and other forms of legal protection for the Company-Related Developments in any country. Wyzga irrevocably appoints Company as Wyzga's attorney-in-fact to execute all such documents as may be required by Company to so vest such ownership of such Inventions in Company. Wyzga shall treat all Inventions as Confidential and Proprietary Information of Company.

This Agreement does not obligate Wyzga or require Wyzga to assign to the Company any Development which, in the sole judgment of the Company, reasonably exercised, is developed entirely on Wyzga's own time and does not relate to the business efforts or research and development efforts in which, during the term of this Agreement, the Company actually is engaged or reasonably would be engaged, and does not result from the use of premises or equipment owned or leased by the Company. However, Wyzga will also promptly disclose to the Company any such Developments for the purpose of determining whether they qualify for such exclusion. Wyzga, understands that to the extent this Agreement is required to be construed in accordance with the laws of any state which precludes a requirement in an agreement to assign certain classes of inventions made by a Wyzga, this Part III, Section 5 (Ownership) will be interpreted not to apply to any invention which a court rules and/or the Company agrees falls within such classes. Wyzga also hereby waives all claims to any moral rights or other special rights which Wyzga may have or accrue in any Company-Related Developments.

6. Records; Reports. Wyzga will keep and maintain adequate and current records of all Confidential Information and Company-Related Developments developed by Wyzga during the term of this Agreement, which records will be available to and remain the sole property of the Company at all times. All Developments, files, letters, notes, memoranda, reports, records, data, sketches, drawings, notebooks, layouts, charts, quotations and proposals or other written, photographic or other tangible material containing Confidential Information, whether created by Wyzga or others, which come into Wyzga's custody or possession, are the exclusive property of the Company to be used by Wyzga only in the performance of the Services and Wyzga's employment duties. Any property situated on the Company's premises and owned by the Company, including without limitation computers, disks and other storage media, filing cabinets or other work areas, is subject to inspection by the Company at any time with or without notice. In the event of the termination of this Agreement for any reason, Wyzga will promptly deliver to the Company all files, letters, notes, memoranda, reports, records, data, sketches, drawings, notebooks, layouts, charts, quotations and proposals, specification sheets, or other written, photographic or other tangible material containing Confidential Information, and other materials of any nature pertaining to the Confidential Information of the Company and to the Services and Wyzga's employment by the Company, and will not take or keep in Wyzga's possession any of the foregoing or any copies.

7. Avoidance of Conflicts of Interest. Wyzga represents and warrants that Wyzga has no outstanding agreement or obligation that is in conflict with any of the provisions of this Agreement, or that would preclude Wyzga from fully complying with the provisions hereof, and further certifies that Wyzga will not enter into such conflicting agreement during the term of this Agreement. Wyzga will advise the Company at such time as any activity of either the Company or another business presents Wyzga with a conflict of interest or the appearance of a conflict of interest. Wyzga will take whatever action is requested by the Company to resolve any conflict or

appearance of conflict which it finds to exist. Wyzga further represents and warrants that Wyzga has full power and authority to enter into this Agreement and perform his or her obligations hereunder.

8. Indemnification. Wyzga shall indemnify and hold the Company, its affiliates and their respective directors, officers, agents and employees harmless from and against all claims, demands, losses, damages and judgments, including court costs and attorneys' fees, arising out of or based upon (i) any claim that the Services provided hereunder or, any related Intellectual Property Rights or the exercise of any rights in or to any Company-Related Development or related Intellectual Property Rights infringe on, constitute a misappropriation of the subject matter of, or otherwise violate any patent, copyright, trade secret, trademark or other proprietary right of any person or breaches any person's contractual rights; and (ii) any breach or alleged breach by Wyzga or the Authorized Services Provider of any representation, warranty, certification, covenant, obligation or other agreement set forth in this Agreement.

9. Limitation of Liability. Except for liability arising from Wyzga's or the Authorized Service Provider's breach of Sections 2 (Recognition of Company Rights), 3 (Rights of Others), 5 (Ownership) of this Part III, or Wyzga's indemnification obligations hereunder, Wyzga shall not be liable to the Company for special, indirect, reliance, incidental, or consequential damages. Wyzga's liability arising out of or in connection with this Agreement during the Consulting Period shall not exceed the fees paid to Wyzga under this Agreement. The Company's liability arising out of or in connection with this Agreement during the Consulting Period shall not exceed the fees paid to Wyzga under this Agreement. The Company shall not be liable to the Wyzga for special, indirect, reliance, incidental, or consequential damages.

10. Term. The term of this Agreement will commence on the date first written above, and will continue until the earlier of (i) the termination of the Consulting Period unless the Employment Period commences immediately following the end of the Consulting Period, or (ii) the termination of the Employment Period (the "**Term**"). The termination of the Term shall not affect the continuation of obligations that do not expressly cease pursuant to this Agreement.

11. Assignment. Neither this Agreement nor any right hereunder or interest herein may be assigned or transferred by Wyzga without the express written consent of the Company. The Company may assign any or all of its rights and obligations under this Agreement without Wyzga's written consent to any affiliate or to another third party affiliate by way of merger, acquisition, consolidation, or sale or transfer of all or substantially all of the Company's assets or capital stock. Wyzga expressly consents to be bound to the provisions of this Agreement for the benefit of the Company or any parent, subsidiary or affiliate without the necessity that this Agreement be re-executed. Any attempted assignment, delegation or transfer by a third party hereto in violation hereof shall be null and void. Subject to the foregoing, this Agreement shall be binding on the parties and their successors and assigns.

12. Equitable Relief. Wyzga and the Company agree that it would be impossible or inadequate to measure and calculate the Company's damages from any breach by Wyzga of any part(s) of Sections 2 (Recognition of Company Rights), 5 (Ownership), 6 (Records; Reports), or 7 (Avoidance of Conflicts of Interest) of this Part III (the "**Specified Sections**"). Accordingly, Wyzga and the Company agree that if Wyzga breaches this Agreement, the Company will have

available, in addition to any other right or remedy available, the right to obtain from any court of competent jurisdiction an injunction restraining such breach or threatened breach and specific performance of the Specified Sections. Wyzga and the Company further agree that no bond or other security shall be required in obtaining such equitable relief and Wyzga and the Company, hereby consent to the issuances of such injunction and to the ordering of such specific performance.

13. Notices. Notices. Any notice provided for in this Agreement shall be in writing and shall be either personally delivered, sent by reputable overnight courier service or mailed by first class mail, return receipt requested, to the recipient at the address below indicated:

Notice to Consultant and Michael Wyzga:

To Michael Wyzga at such address as most currently appears in the records of the Company

Email: []

Notices to the Company:

Mereo BioPharma Group plc
One Cavendish Place
London W1G 0QF
United Kingdom
Attention: The General Counsel
Email: []

With a copy to:

Charles Sermon
General Counsel
Mereo Biopharma Group plc
1 Cavendish Place
London W1G 0QF
United Kingdom
Email: []

or such other address or to the attention of such other person as the recipient party shall have specified by prior written notice to the sending party. Notice shall be sufficient in all respects if given and delivered in person, by electronic mail, by facsimile, by overnight courier, or by mail, postage prepaid, to the receiving party at such party's address. Such notice shall be deemed to have been given as of one (1) day following the date deposited with a recognized overnight courier service, three (3) days following the date deposited in the mail to an address in the same country, seven (7) days following the date deposited in the mail to an address in another country, and immediately following the notice being sent if sent by electronic mail or by facsimile.

14. Severability. If any provision in this Agreement shall be found or be held to be invalid or unenforceable in any jurisdiction in which this Agreement is being performed, then the meaning of said provision shall be construed, to the extent feasible, so as to render the provision

enforceable, and if no feasible interpretation would save such provision, it shall be severed from the remainder of this Agreement which shall remain in full force and effect. In such event, the parties shall negotiate, in good faith, a substitute, valid and enforceable provision which most nearly effects the parties' intent in entering into this Agreement.

15. Amendment. This Agreement (including Exhibits A and B) may not be amended in any respect except by a writing signed by the parties.
16. Effect on Directors Appointment Letter. This Agreement shall have no effect on Wyzga's status as a member of the Board, except that during the Employment Period,
 - (a) Wyzga shall be an executive member of the Board;
 - (b) Wyzga shall receive compensation from the Company solely in his capacity as Interim CFO pursuant to Exhibit B, serving as a member of the Board for no additional consideration; and
 - (c) Wyzga's letter of appointment to the Board (the "**Appointment Letter**") shall be amended in accordance with the terms set out in Exhibit C.

In addition, in order to comply with current Nasdaq rules, while serving as Interim CFO and for a period of three years thereafter, Wyzga shall not serve as a member of the Board's Audit and Risk Committee. To the extent necessary to effect the forgoing provisions of this Part III, Section 16, this Part III, Section 16 shall be constitute an amendment to the Appointment Letter and to the relevant Company option grant agreements.

17. Entire Agreement. The terms and conditions herein contained constitute the entire agreement between the parties and supersede all previous agreements and understandings, whether oral or written, between the parties hereto with respect to the subject matter hereof, and no agreement or understanding varying or extending the same shall be binding upon either party hereto unless in a written document which expressly refers to this Agreement and which is signed by the party to be bound thereby. For the avoidance of doubt, Wyzga's Appointment Letter, as modified by Part III, Section 16 (Effect on Directors Appointment Letter) remains in effect.
18. Governing Law and Personal Jurisdiction. This Agreement and any action related thereto will be governed, controlled, interpreted, and defined by and under the laws of the State of New York, without giving effect to any conflicts of laws principles that require the application of the law of a different state. Any disputes under this Agreement may be brought in the state courts and the Federal courts located in the Borough of Manhattan of the City of New York in the State of New York, and each of the parties and the Authorized Service Provider hereby consent to the personal jurisdiction and exclusive venue of these courts.
19. Costs. Each party hereby agrees that if it is held by any court of competent jurisdiction to be in violation, breach, or nonperformance of any of the terms of this Agreement, then the prevailing party will pay all reasonable costs of such action or suit, including reasonable attorney's fees.

20. No Waiver. No waiver of any term or condition of this Agreement shall be valid or binding on either party unless the same shall be been mutually assented to in writing by the parties to the waiver. The failure of a party to enforce at any time any of the provisions of this Agreement, or the failure to require at any time performance by the another party of any of the provisions of this Agreement, shall in no way be construed to be a present or future waiver of such provisions, nor in any way affect the right of any party to enforce each and every such provision thereafter. The express waiver by a party of any provision, condition or requirement of this Agreement shall not constitute a waiver of any future obligation to comply with such provision, condition or requirement.
21. Defend Trade Secrets Act of 2016. Wyzga acknowledges receipt of the following notice under 18 U.S.C § 1833(b)(1): “An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.”
22. Counterparts. This Agreement may be signed in one or more counterparts.
23. Taxes. The Company may withhold, or cause to be withheld, from any amounts payable under this Agreement all federal, state, city or other taxes as the Company or any of its Affiliates, is required to withhold pursuant to any applicable law, regulation or ruling. Notwithstanding any other provision of this Agreement, the Company shall not be obligated to guarantee any particular tax result to any party with respect to any amount paid by the Company to such other party as fees or compensation. Each of the Consultant, the Authorized Service Provider, and Wyzga shall be responsible for any taxes imposed on any amount received by them from the Company as a payment of fees or compensation.
24. Personal Information. Wyzga acknowledges and agrees that the Company is permitted to hold personal information about him as part of its personnel and other business records and, in accordance with applicable law, may use such information in the course of the Company’s business.
25. Advice of Counsel. Each party represents and warrants that it has had a full opportunity to seek advice and representation by independent counsel of its own choosing in connection with this Agreement and it has either received such advice or, in its business judgment, decided not to seek such advice.
26. Section Headings; Interpretation. The section headings in this Agreement are for convenience of reference only, and they form no part of this Agreement and shall not affect its interpretation. It is the parties’ intention that this Agreement not be construed more strictly with regard to Wyzga or the Company.
27. 409A Compliance. The intent of the parties is that payments and benefits under this Agreement comply with Section 409A and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith. In no event shall the Company or its subsidiaries or affiliates be liable for any additional tax, interest or penalty that may be imposed on a party under Section 409A or damages for failing to comply with Section 409A.

(a) Notwithstanding anything herein to the contrary, to the extent required by Section 409A, upon a termination of Executive's employment (other than as a result of death), if Executive is at the time a "specified employee" (within the meaning of Section 409A), distributions under this Agreement determined, in whole or in part, to constitute "nonqualified deferred compensation" within the meaning of Section 409A and payable to Executive on account of Executive's termination of employment or other "separation from service" (within the meaning of Section 409A(a)(2)(A)(i) of the Code and the Treasury regulations issued thereunder) will be delayed until six months after such termination of employment, and such distributions will be made at the beginning of the seventh month following the date of such termination of employment or other separation from service. A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or following a termination of employment unless such termination is also a "separation from service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment" or like terms shall mean "separation from service."

(b) To the extent that reimbursements or other in-kind benefits under this Agreement or any amounts otherwise due to a party from the Company constitute "nonqualified deferred compensation" for purposes of Section 409A: (i) all such expenses or other reimbursements hereunder shall be made on or prior to the last day of the taxable year following the taxable year in which such expenses were incurred by the party; (ii) any such right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit; and (iii) no such reimbursement, expenses eligible for reimbursement, or in-kind benefits provided in any taxable year shall in any way affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year.

(c) For purposes of Section 409A, a right to receive any installment payments pursuant to this Agreement shall be treated as a right to receive a series of separate and distinct payments.

(d) Notwithstanding any other provision of this Agreement to the contrary, in no event shall any payment under this Agreement that constitutes "nonqualified deferred compensation" for purposes of Section 409A be subject to offset by any other amount unless otherwise permitted by Section 409A.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have caused to be executed or executed this Consulting Agreement as of the day and year first above written.

MEREO BIOPHARMA GROUP PLC

By: /s/ Denise Scots-Knight

Name: Denise Scots-Knight

Title: Chief Executive Officer

MSW CONSULTING INC.

By: /s/ Michael S Wyzga

Name: Michael S Wyzga

Title: President, MSW Consulting Inc.

MICHAEL WYZGA (In his individual capacity as and as
Authorized Service Provider)

EXHIBIT A

CONSULTING SERVICES AND COMPENSATION

EXHIBIT B

INTERIM CFO COMPENSATION

EXHIBIT C

DIRECTOR'S APPOINTMENT LETTER

Michael S Wyzga

[—]
[—]
[—]
[—]

14 May 2020

Dear Mike

Letter of appointment between (1) Mereo BioPharma Group plc (the “Company”) and (2) Mike Wyzga (“you”) dated 23 April 2019 (the “Appointment Letter”)

We refer to the Appointment Letter and to the consulting and interim chief financial officer agreement between (1) the Company, (2) MSW Consulting Inc. (the “Consultant”) and (3) you to be entered into on or about the date of this letter (the “Consulting/Interim CFO Agreement”).

Pursuant to the Consulting/Interim CFO Agreement, the Company will retain the Consultant as an independent contractor to perform consulting services during the Consulting Period (as defined in the Consulting/Interim CFO Agreement). As the Authorized Service Provider (as defined in the Consulting/Interim CFO Agreement) under the Consulting/Interim CFO Agreement, you will provide those consulting services on behalf of the Consultant. Upon your appointment as the Company’s interim chief financial officer on the terms of the Consulting/Interim CFO Agreement for the Employment Period (as defined in the Consulting/Interim CFO Agreement), the Consulting Period will end.

In consideration for each of us entering into the Consulting/Interim CFO Agreement, it is agreed that the Appointment Letter shall be amended as follows:

1. During the Consulting Period and the Employment Period, you shall continue as a director of the Company and the Appointment Letter shall continue in full force and effect except to the extent provided otherwise in this letter. Your responsibilities under the Consulting/Interim CFO Agreement are incremental, and without prejudice, to your responsibilities under the Appointment Letter (as amended by this letter).
2. Immediately following the Consulting Period (unless the Employment Period commences immediately following the end of the Consulting Period) or the Employment Period, and unless the Appointment Letter is terminated pursuant to paragraph 9 below, the Appointment Letter shall be reinstated on the terms applicable immediately prior to this letter and the Consulting/Interim CFO Agreement.
3. During the Employment Period, the annual fees payable to you pursuant to paragraph 1.1 of the Appointment Letter shall not accrue or be payable.
4. Notwithstanding the references to “non-executive director” in any of paragraphs 2.1 to 2.11 of the Appointment Letter, all of those paragraphs will continue to apply to you as a director during the Consulting Period and the Employment Period except to the extent provided otherwise in this letter.
5. Without prejudice to paragraph 4 of this letter, during the Employment Period, paragraphs 2.6(a) and (b) of the Appointment Letter shall be varied so as to continue to apply to you to the extent that executive directors are also charged with the responsibilities contemplated by those paragraphs in relation to management (but not in relation to your own role as a member of management and you shall recuse yourself from any evaluation by the directors of your performance).
6. Without prejudice to paragraph 4 of this letter, during the Employment Period, paragraph 2.6(c) of the Appointment Letter shall be varied so as to continue to apply to you but it is acknowledged that as Interim CFO, your duties will include ensuring the integrity of the Company’s financial controls and ensuring that the Company’s systems of risk management are robust and defensible;
7. Without prejudice to paragraph 4 of this letter, during the Employment Period, paragraph 2.6(d) of the Appointment Letter shall not form part of your responsibilities but shall continue to fall within the terms of reference of the remuneration committee.

8. During the Employment Period, paragraph 2.11 of the Appointment Letter shall not apply.
9. If the Consulting/Interim CFO Agreement is terminated:
 - (a) pursuant to the second or third sentence of Part I, Section 3 of the Consulting/Interim CFO Agreement; or
 - (b) pursuant to the third or fourth sentence of Part II, Section 8 of the Consulting/Interim CFO Agreement; or
 - (c) otherwise by reason of any material or repeated breach of any obligations applying to you and whether under the Appointment Letter (as amended by this letter) or the Consulting/Interim CFO Agreement, the Appointment Letter shall automatically terminate simultaneously without any requirement to provide separate notice.
10. During the Employment Period, any duty or responsibility of a director described in the Appointment Letter that must only be performed by a non-executive director shall not apply to you but, save where there is a legal or regulatory or governance reason precluding such a duty or responsibility by an executive director, then any duty or responsibility of a director described in the Appointment Letter will continue to apply unless expressly stated otherwise above.

This letter is governed by, and shall be construed in accordance with, English law. Please countersign and return to us the attached copy of this letter to signify your acceptance of its terms.

Yours sincerely

MEREO BIOPHARMA GROUP PLC

By: /s/ Denise Scots-Knight

Agreed and accepted:

MEREO BIOPHARMA GROUP PLC

By: /s/ Michael S Wyzga

Date: _____

Subsidiaries of Mereo BioPharma Group plc

Legal Name of Subsidiary

Mereo BioPharma 1 Limited
Mereo BioPharma 2 Limited
Mereo BioPharma 3 Limited
Mereo BioPharma 4 Limited
Mereo BioPharma Ireland Limited
Mereo US Holdings Inc.
OncoMed Pharmaceuticals, Inc.
NAVI Subsidiary, Inc.

Jurisdiction of
Organization

United Kingdom
United Kingdom
United Kingdom
United Kingdom
Ireland
Delaware
Delaware
Delaware

**Certification by the Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Denise Scots-Knight, certify that:

1. I have reviewed this annual report on Form 20-F of Mereo BioPharma Group plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: June 15, 2020

/s/ Denise Scots-Knight, Ph.D

Name: Denise Scots-Knight, Ph.D.

Title: Chief Executive Officer

**Certification by the Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Richard Jones, certify that:

1. I have reviewed this annual report on Form 20-F of Mereo BioPharma Group plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: June 15, 2020

/s/ Richard Jones

Name: Richard Jones

Title: Chief Financial Officer

**Certification by the Chief Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the annual report of Mereo BioPharma Group plc (the "Company") on Form 20-F for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Denise Scots-Knight, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: June 15, 2020

By: /s/ Denise Scots-Knight, Ph.D
Name: Denise Scots-Knight, Ph.D.
Title: Chief Executive Officer

**Certification by the Chief Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the annual report of Mereo BioPharma Group plc (the "Company") on Form 20-F for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Richard Jones, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: June 15, 2020

By: /s/ Richard Jones
Name: Richard Jones
Title: Chief Financial Officer

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8) pertaining to the Mereo Biopharma Group plc 2019 Equity Incentive Plan and the Mereo Biopharma Group plc 2019 Non-Employee Equity Incentive Plan of Mereo Biopharma Group plc of our report dated June 15, 2020, with respect to the consolidated financial statements of Mereo Biopharma Group included in this Annual Report (Form 20-F) for the year ended December 31, 2019.

/s/ Ernst & Young LLP

London, United Kingdom

June 15, 2020