

**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**  
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, 2018  
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 \_\_\_\_\_  
Commission file number 001-38067

**VERONA PHARMA PLC**

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

**Not Applicable**

(Translation of Registrant's Name into English)

United Kingdom  
(Jurisdiction of incorporation or organization)

3 More London Riverside  
London SE1 2RE  
United Kingdom  
(Address of principal executive offices)

Jan-Anders Karlsson  
Chief Executive Officer  
Verona Pharma plc  
3 More London Riverside  
London SE1 2RE  
United Kingdom  
Tel: +44 303 283 4200

(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.

Title of each class

Name of each exchange on which registered

American Depositary Shares,  
each representing 8 ordinary shares,  
nominal value £0.05 per share

The Nasdaq Stock Market LLC

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.

Ordinary shares, nominal value £0.05 per share: 105,326,637 as of December 31, 2018

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

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 and posted 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 and post 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. See definition of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange 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.

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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## GENERAL INFORMATION

All references in this Annual Report on Form 20-F, or the Annual Report, to “Verona,” the “company,” the “group”, “we,” “us” and “our” refer to Verona Pharma plc and its consolidated subsidiaries. In this Annual Report, the U.S. Securities and Exchange Commission is referred to as the “SEC”, the Securities Act of 1933, as amended, is referred to as the “Securities Act” and the Securities Exchange Act of 1934, as amended, is referred to as the “Exchange Act.”

## PRESENTATION OF FINANCIAL AND OTHER DATA

We report under International Financial Reporting Standards as issued by the International Accounting Standards Board, or IFRS. None of the financial statements in this Annual Report were prepared in accordance with generally accepted accounting principles in the United States. We present our financial statements in pounds sterling and in accordance with IFRS. We have made rounding adjustments to some of the figures included in this Annual Report. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them. All references in this Annual Report to “\$,” “US\$,” and “U.S. dollars” mean U.S. dollars and all references to “£” and “GBP” mean pounds sterling, unless otherwise noted.

## TRADEMARKS, TRADENAMES AND SERVICE MARKS

This Annual Report may include trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this Annual Report appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains statements that constitute forward-looking statements. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, on-going clinical trials, product candidate development plans, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. These statements involve known and unknown risks, uncertainties and other important factors, including those identified under “Risk Factors” in this Annual Report, that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

Forward-looking statements include, but are not limited to, statements about:

- the development of ensifentrine, including statements regarding the expected initiation, timing, progress and availability of data from our clinical trials and regulatory approval;
- the potential attributes and benefit of ensifentrine and its competitive position;
- our ability to successfully commercialize ensifentrine, if approved;
- our estimates regarding expenses, future revenues, capital requirements and our need for additional financing;
- our ability to acquire or in license new product candidates;
- potential collaborations; and
- the duration of our patent portfolio.

Forward looking statements speak only as of the date they are made, and we do not undertake any obligation to update them in light of new information or future developments or to release publicly any revisions to these statements in order to reflect later events or circumstances or to reflect the occurrence of unanticipated events. You should read this Annual Report and the documents that we reference in this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

This Annual Report contains market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information. While we believe the market position, market opportunity and market size information included in this Annual Report is generally reliable, such information is inherently imprecise.

## PART I

### ITEM 1: IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS

Not applicable.

### ITEM 2: OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

### ITEM 3: KEY INFORMATION

#### A. Selected Financial Data.

The following selected consolidated financial data should be read in conjunction with "Operating and Financial Review and Prospects," our consolidated financial statements and related notes, and other financial information included in this Annual Report. We have derived the consolidated statement of comprehensive income data and the consolidated statement of financial position data as of December 31, 2018, 2017, and 2016 from our audited financial statements included elsewhere in this Annual Report. We have derived the consolidated statement of comprehensive income data and the consolidated statement of financial position data as of December 31, 2015 from our audited financial statements that are not included in this Annual Report. Our historical results are not necessarily indicative of the results that should be expected in the future.

	Year Ended December 31,			
	2018	2017	2016	2015
	(£'000s)			
<b>Consolidated statement of comprehensive income data:</b>				
Research and development costs	(19,294)	(23,717)	(4,522)	(7,270)
General and administrative costs	(6,297)	(6,039)	(2,498)	(1,706)
Operating loss	(25,591)	(29,756)	(7,020)	(8,976)
Finance income	2,783	7,018	1,841	45
Finance expense	(1,325)	(2,465)	(794)	(73)
Loss before taxation	(24,133)	(25,203)	(5,973)	(9,004)
Taxation — credit	4,232	4,706	954	1,509
Loss for the year	(19,901)	(20,497)	(5,019)	(7,495)
Other comprehensive income / (loss):				
Exchange differences on translating foreign operations	38	(29)	43	4
Total comprehensive loss attributable to owners of the company	(19,863)	(20,526)	(4,976)	(7,491)
Loss per ordinary share — basic and diluted (pence)	(18.9)	(23.4)	(15.0)	(37.1)

	Year Ended December 31,			
	2018	2017	2016	2015
	(£'000s)			
<b>Consolidated statement of financial position data:</b>				
Cash and cash equivalents	19,784	31,443	39,785	3,524
Short term investments	44,919	48,819	—	—
Total assets	74,261	89,504	46,143	7,840
Share premium	118,862	118,862	58,526	26,650
Total liabilities	11,327	9,623	11,674	2,407
Accumulated loss	69,117	49,254	28,728	23,752
Total equity	62,934	79,881	34,469	5,434

Our business is primarily conducted in the United Kingdom and we maintain our books and records in pounds sterling.

## **B. Capitalization and Indebtedness.**

Not applicable.

## **C. Reasons for the Offer and Use of Proceeds.**

Not applicable.

## **D. Risk Factors.**

*You should carefully consider the risks and uncertainties described below and the other information in this Annual Report. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occur.*

### **Risks Related to Our Business and Industry**

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

We are a clinical-stage biopharmaceutical company with a limited operating history, and have incurred significant operating losses since our inception. We had net losses of £19.9 million and £20.5 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated loss of £69.1 million. Our losses have resulted principally from expenses incurred in research and development of ensifentrine, our only product candidate, 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, advance our clinical development of ensifentrine, and seek to obtain regulatory approval for and commercialize ensifentrine. We anticipate that our expenses will increase substantially as we:

- conduct our ongoing and planned Phase 2 clinical trials and, subject to regulatory review, initiate and conduct Phase 3 clinical trials and other future clinical trials of ensifentrine for the treatment of COPD;
- conduct any clinical trials of ensifentrine for the treatment of CF, asthma or other indications;
- seek to discover and develop or in-license additional respiratory product candidates;
- conduct pre-clinical studies to support ensifentrine and potentially other future product candidates;
- develop the manufacturing processes and produce clinical and commercial supplies of the ensifentrine active pharmaceutical ingredient and formulated drug products derived from it;
- seek regulatory approvals of ensifentrine;
- potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize ensifentrine, if approved;
- maintain, expand and protect our intellectual property portfolio;
- secure, maintain or obtain freedom to operate for our in-licensed technologies and products;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts; and
- expand our operations in the United States, the United Kingdom and possibly elsewhere.

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 pre-clinical studies or clinical trials, complex results, safety issues or regulatory challenges.

We have devoted substantially all of our financial resources and efforts to the research and development and pre-clinical studies and clinical trials of ensifentrine. We are continuing development of ensifentrine, and we have not completed development of any product candidate or any drugs.

To become and remain profitable, we must succeed in developing, and eventually commercializing, products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials of ensifentrine, discovering and developing additional product candidates, obtaining regulatory approval for ensifentrine and any future product candidates that successfully complete clinical trials, establishing manufacturing and marketing capabilities and ultimately selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most 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 pharmaceutical 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. 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 ensifentrine or any other product candidates, our expenses could increase and revenue could be further delayed.

Even if we do generate product royalties or product sales, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to sustain profitability would depress the market price of our ADSs and ordinary shares and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the market price of our ADSs or ordinary shares also could cause our ADS holders and shareholders to lose all or a part of their investment.

**We will need additional funding to complete development of ensifentrine and any future product candidates, and to commercialize our products, if approved. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.**

We expect our expenses to increase in connection with our ongoing and planned activities, particularly as we conduct our ongoing and planned Phase 2 clinical trials of ensifentrine and, subject to regulatory review, our planned Phase 3 clinical trial, and develop ensifentrine for other indications. In addition, if we obtain regulatory approval for ensifentrine or any other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we expect to incur ongoing costs associated with operating as a public company in the United Kingdom and the United States and maintaining a listing on both AIM, a market of the London Stock Exchange, or AIM, and the Nasdaq Global Market, or 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 estimate that our existing cash resources and short-term investments will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We anticipate these funds will be sufficient to complete each of our ongoing and planned Phase 2 trials of ensifentrine for the treatment of COPD and, subject to favorable results in our Phase 2 trials and regulatory feedback, to commence a Phase 3 program of ensifentrine for the maintenance treatment of COPD. However, we will require additional funds to complete our planned clinical development of ensifentrine. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. In addition, 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. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

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

- the cost, progress and results of our ongoing and planned Phase 2 clinical and any other future clinical trials of ensifentrine for the treatment of COPD;
- the cost, progress and results of our planned Phase 3 clinical trial for the maintenance treatment of COPD, subject to regulatory review;
- the cost, progress and results of any clinical trials for the treatment of CF or other indications;
- the cost of manufacturing clinical and commercial supplies of the ensifentrine active ingredient and derived formulated drug products;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for ensifentrine in other indications and of the development of DPI and pMDI formulations of ensifentrine for the maintenance treatment of COPD and potentially asthma and other respiratory diseases;
- the costs, timing and outcome of regulatory review of ensifentrine, 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 ensifentrine;
- 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 upon their intellectual property rights;
- the timing and amount of revenue, if any, received from commercial sales of ensifentrine;
- the sales price and availability of adequate third-party coverage and reimbursement for ensifentrine;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for ensifentrine, although we currently have no commitments or agreements to complete any such transactions.



Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize ensifentrine. 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 ordinary shares or ADSs.

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 relating to ensifentrine or any commercialization efforts, be unable to expand our operations, or be unable to otherwise capitalize on our business opportunities, as desired, which could harm our business and potentially cause us to discontinue operations.

**We depend heavily on the success of ensifentrine, our only product candidate under development. We cannot give any assurance that ensifentrine will receive regulatory approval for any indication, which is necessary before it can be commercialized. If we, and any collaborators with whom we may enter into agreements for the development and commercialization of ensifentrine, are unable to commercialize ensifentrine, 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 revenues from sales of any products, 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 development of ensifentrine, and we do not have any other product candidate currently under development. 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 ensifentrine, if approved, which may never occur. Ensifentrine will require additional clinical development, management of clinical, pre-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 revenues from product sales. We are not permitted to market or promote ensifentrine or 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 ensifentrine or any future product candidate. We have not submitted a New Drug Application, or NDA, to the FDA, a Marketing Authorization Application, or MAA, 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 ensifentrine will depend on many factors, including the following:

- we may not be able to demonstrate that ensifentrine is safe and effective as a treatment for our targeted indications to the satisfaction of the applicable regulatory authorities;
- the applicable regulatory authorities may require additional pre-clinical or clinical trials, which would increase our costs and prolong our development;
- the results of clinical trials of ensifentrine 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 clinical trials;
- the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the applicable regulatory authorities may not find the data from pre-clinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of ensifentrine outweigh its safety risks or may disagree with our interpretation of data;
- our ability to demonstrate a non-clinical safety profile that is acceptable to the applicable regulatory authorities;
- unexpected operational or clinical issues may prevent completion or interpretation of clinical study results;
- unexpected manufacturing issues, product performance issues or stability issues may delay or otherwise adversely affect the progress of our clinical development program;
- the applicable regulatory authorities may not accept data generated at our clinical trial sites;
- if we submit an 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, or 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;

- if we license ensifentrine to others, the efforts of those parties in completing clinical trials of, receiving regulatory approval for, and commercializing ensifentrine;
- through our clinical trials, we may discover factors that limit the commercial viability of ensifentrine or make the commercialization of ensifentrine unfeasible;
- if we retain rights under a collaboration agreement for ensifentrine, our efforts in completing pre-clinical studies and clinical trials of, receiving marketing approvals for, establishing commercial manufacturing capabilities for, and commercializing ensifentrine; and
- if approved, acceptance of ensifentrine by patients, the medical community and third-party payors, effectively competing with other therapies, a continued acceptable safety profile following approval and qualifying for, maintaining, enforcing and defending our intellectual property rights and claims.

An unfavorable outcome in any of these factors could result in our experiencing significant delays or an inability to successfully commercialize ensifentrine.

We cannot be certain that ensifentrine or any future product candidates will be successful in clinical trials or receive regulatory approval. Further, ensifentrine or any future product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for ensifentrine or any future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to manufacture and market ensifentrine or any future 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 products, if approved.

We plan to seek regulatory approval to commercialize ensifentrine both in the United States and the 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 of ensifentrine, and we cannot predict success in these jurisdictions.

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

Since our inception in 2005, we have devoted substantially all of our resources to developing ensifentrine, building our intellectual property portfolio, developing our supply chain, planning our business, raising capital and providing general and administrative support for these operations. We have completed multiple Phase 1 and 2 clinical trials for ensifentrine, but we have not yet demonstrated our ability to successfully complete any Phase 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we are not profitable and have incurred losses in each year since our inception, and we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Consequently, any predictions investors make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

**Raising additional capital may cause dilution to our 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 expect to finance our cash needs through a combination of securities offerings, debt financings, license and collaboration agreements and research grants. If we raise capital through securities offerings, the ownership interest of our ADS holders and shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect these holders' rights as holders of our ADSs or ordinary shares. 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, or to declare dividends, or other operating restrictions. 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. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our ADS holders and shareholders, and may cause the market price of our ADSs or ordinary shares to decline.

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

As a company based in the United Kingdom, our business is subject to risks associated with conducting business internationally. Almost all of our suppliers and collaborative and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing regulatory requirements for drug approvals in non-U.S. countries;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the euro and currency controls;
- changes in a specific country's or region's political or economic environment, including the implications of the decision of the eligible members of the U.K. electorate for the United Kingdom to withdraw from the EU;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- 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; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

**The United Kingdom's withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our ADSs and ordinary shares.**

Following the vote of a majority of the eligible members of the electorate in the United Kingdom to withdraw from the EU in a national referendum held on June 23, 2016, the U.K. government served notice under Article 50 of the Treaty of the European Union on March 29, 2017 to formally initiate a withdrawal process. The United Kingdom and the EU have had a two-year period under Article 50 to negotiate the terms for withdrawal. The withdrawal agreement and political declaration that were endorsed at a special meeting of the European Council on November 25, 2018 did not receive the approval of the United Kingdom Parliament in January 2019. Further discussions are ongoing, although the European Commission has stated that the EU will not reopen the withdrawal agreement. Any extension of the negotiation period for withdrawal will require the consent of all of the remaining 27 member states.

The referendum and anticipation of withdrawal have created significant uncertainty about the future relationship between the United Kingdom and the EU. Lack of clarity about future U.K. laws and regulations as the United Kingdom determines which EU-derived laws and regulations to replace or replicate as part of a withdrawal, including financial laws and regulations, tax and free trade agreements, intellectual property rights, supply chain logistics, environmental, health and safety laws and regulations, immigration laws and employment laws, could further decrease foreign direct investment in the United Kingdom, increase costs, depress economic activity and restrict our access to capital. If the United Kingdom and the EU are unable to negotiate mutually acceptable withdrawal terms or if other EU member states pursue withdrawal, barrier-free access between the United Kingdom and other EU member states or among the European economic area overall could be diminished or eliminated. These developments, or the perception that any of them could occur, have had and may continue to have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Asset valuations, currency exchange rates and credit ratings may be especially subject to increased market volatility. Any of these factors could have a significant adverse effect on our business, financial condition, results of operations and prospects.

Further, the vote for the United Kingdom's withdrawal from the EU has resulted in a decision to move the EMA from the United Kingdom to the Netherlands, with operations currently scheduled to begin in the Netherlands by

the end of March 2019. This transition has caused, and may continue to cause, disruption in the administrative and medical scientific links between the EMA and the U.K. Medicines and Healthcare products Regulatory Agency, including delays in granting clinical trial authorization or marketing authorization, disruption of importation and export of active substance and other components of new drug formulations, and disruption of the supply chain for clinical trial product and final authorized formulations. The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the EU and/or the United Kingdom.

**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, may adversely affect us. Although we are based in the United Kingdom, we source research and development, manufacturing, consulting and other services from the United States and the EU. Further, potential future revenue may be derived from abroad, particularly from the United States. 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.

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

**Our only product candidate, ensifentrine, is in early-stage clinical development. Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of ensifentrine are prolonged or delayed, or if ensifentrine in later stage clinical trials fails to show the desired safety and efficacy, we or our collaborators may be unable to obtain required regulatory approvals and be unable to commercialize ensifentrine on a timely basis, or at all.**

To obtain the requisite regulatory approvals to market and sell ensifentrine, we or any collaborator for ensifentrine must demonstrate through extensive pre-clinical studies and clinical trials that ensifentrine is 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 ensifentrine 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 approval to commence a trial;
- 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;
- delays in or failure to obtain institutional review board, or IRB, approval 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;
- clinical sites deviating from trial protocol or dropping out of a trial or committing gross misconduct or fraud;
- adding new clinical trial sites;
- inability to achieve or maintain double blinding of ensifentrine;
- unexpected technical issues during manufacture of ensifentrine and the corresponding drug products;
- variability in drug product performance and/or stability;
- inability to manufacture sufficient quantities of ensifentrine for use in clinical trials;
- third-party actions claiming infringement by ensifentrine in clinical trials and obtaining injunctions interfering with our progress;
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, 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 volunteers in clinical trials;

- 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 certain countries in identifying the sub-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;
- the quality or stability of ensifentrine falling below acceptable standards for either safety or efficacy; and
- discoveries that may reduce the commercial viability of ensifentrine.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Review Committee or Data Safety Monitoring Board for such trial or by the FDA 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 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 funding to continue the clinical trial.

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 or other regulatory authority. The FDA or 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 or 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 or other regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of ensifentrine.

If we experience delays in the completion of any clinical trial of ensifentrine or any clinical trial of ensifentrine is terminated, the commercial prospects of ensifentrine may be harmed, and our ability to generate product revenues from ensifentrine, 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 ensifentrine and jeopardize our ability to commence product sales and generate revenue, if any. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize ensifentrine and could impair our ability to commercialize ensifentrine. 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 ensifentrine.

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 at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of ensifentrine produced under current good manufacturing practice, or cGMP, requirements 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 their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice, or 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 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.

**Ensifentrine may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If such side effects are identified during the development of ensifentrine or following approval, if any, we may need to abandon our development of ensifentrine, 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 ensifentrine 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, EMA or other comparable foreign authorities. We have completed 13 Phase 1 and 2 clinical trials of

ensifentrine. In these trials, some patients have experienced mild to moderate adverse reactions, including headache, dizziness, cough, heart palpitation, nausea, dry mouth, throat irritation, paresthesia (tingling) and rash.

To date, ten serious adverse events have been reported (including a suicide), eight of which were assessed as not related to study drug and two of which were assessed by the investigators as possibly related although relevant mitigating factors were subsequently considered.

Results of our future clinical trials 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 ensifentrine for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Additionally, if ensifentrine receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by ensifentrine, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products and require us to take ensifentrine 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 ensifentrine outweigh its risks;
- we may be required to change the way ensifentrine is administered, conduct additional clinical trials or change the labeling of ensifentrine;
- we may be subject to limitations on how we may promote ensifentrine;
- sales of ensifentrine may decrease significantly;
- 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 ensifentrine or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of ensifentrine.

**We depend on enrollment of patients in our clinical trials for ensifentrine. If we are unable to enroll patients in our clinical trials, or enrollment is slower than anticipated, our research and development efforts could be adversely affected.**

Successful and timely completion of clinical trials for ensifentrine will require that we enroll a sufficient number of patient candidates. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. 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 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. Higher than expected numbers of patients could also discontinue participation in the clinical trials. Delays in the completion of any clinical trial of ensifentrine will increase our costs, slow down our development and approval of ensifentrine 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 ensifentrine.

**We may become exposed to costly and damaging liability claims, either when testing ensifentrine 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 research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the current and future use of ensifentrine by us and any collaborators in clinical trials, and the sale of ensifentrine, 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 ensifentrine. Any claims against us, regardless of their merit, could be difficult and costly to defend and could adversely affect the market for ensifentrine or any prospects for commercialization of ensifentrine. In addition, regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for ensifentrine;
- 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;
- regulatory investigation, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize or promote ensifentrine.

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 ensifentrine 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 ensifentrine.

Although we maintain product liability insurance for ensifentrine, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for ensifentrine. 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 regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for ensifentrine, our business will be substantially harmed.**

The time required to obtain approval by the FDA, the EMA and comparable foreign regulatory authorities is unpredictable, 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 candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for ensifentrine and it is possible that ensifentrine or any product candidates we may develop in the future will never obtain regulatory approval.

Ensifentrine could fail to receive regulatory approval for many reasons, including the following:

- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable foreign regulatory authorities that ensifentrine is safe and effective, with the required level of statistical significance, for its proposed indication;
- we may be unable to demonstrate that ensifentrine'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 of ensifentrine may, for other reasons, not be sufficient to support the submission of an NDA in the United States, an MMA 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;
- 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; and
- the FDA, the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; and
- the FDA, the EMA or comparable foreign regulatory authorities may disagree with our proposed product specifications and performance characteristics.

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 ensifentrine. 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 ensifentrine. Even if we believe the data collected from clinical trials of ensifentrine are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

In addition, even if we were to obtain approval for any jurisdiction, regulatory authorities may approve ensifentrine for fewer or more limited indications than we request, may not approve the price we intend to charge

for ensifentrine, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve ensifentrine with a label that does not include the labeling claims necessary or desirable for the successful commercialization of ensifentrine. Any of the foregoing scenarios could materially harm the commercial prospects for ensifentrine.

**Even if ensifentrine obtains regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, ensifentrine, 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 ensifentrine.**

If the FDA, the EMA or a comparable foreign regulatory authority approves ensifentrine, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and record keeping for ensifentrine will be subject to extensive and ongoing regulatory requirements. These requirements include payment of annual user fees, submissions of safety and other post-marketing information and reports, facility registration and drug listing, as well as continued compliance with cGMP requirements for the manufacture of ensifentrine 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 ensifentrine. We and our contract manufacturers will also be subject to 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 ensifentrine may also be subject to limitations on the approved indicated uses for which ensifentrine 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 ensifentrine.

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

The policies of the FDA and of 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 or abroad. For example, certain policies of the current presidential administration may impact our business and industry. Namely, the current 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. It is difficult to predict how these orders will be implemented, and the extent to which they will 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.

**We may not be successful in our efforts to develop ensifentrine for multiple indications, including asthma, CF or other respiratory diseases.**

Part of our strategy is to continue to develop ensifentrine in indications other than COPD, such as CF. Although our research and development efforts to date have suggested that ensifentrine has the potential to treat CF, we may not be able to develop ensifentrine in CF or any other disease, or development may not be successful. In addition, the potential use of ensifentrine in other diseases may not be suitable for clinical development, including as a result of difficulties enrolling patients in any clinical studies we plan to initiate or the potential for harmful side effects or other characteristics that might suggest marketing approval and market acceptance are unlikely. If we do not continue to successfully develop and begin to commercialize ensifentrine for multiple indications, we will face difficulty in obtaining product revenues in future periods, which could significantly harm our financial position.

**Even if we obtain marketing approval of ensifentrine for any indication in a major pharmaceutical market such as the United States or EU, we may never obtain approval or commercialize ensifentrine in other major markets, which would limit our ability to realize its full market potential.**



In order to market any products 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 all major markets could result in significant delays, difficulties and costs for us and 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 ensifentrine in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and 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 any jurisdiction, whether in the EU, the United States or any other international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of ensifentrine will be compromised.

**Our employees and independent contractors, including principal investigators, consultants, vendors and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.**

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, vendors and collaboration partners may engage in fraudulent conduct or other illegal activities. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, EMA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad; 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, creating fraudulent data in our 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 and other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

**Interim, "top-line," or 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 studies. 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.

**The ability of the FDA to review and approve new products can be affected by a variety of factors and can lead to delays or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.**

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

#### **Risks Related to Healthcare Laws and Other Legal Compliance Matters**

**Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize ensifentrine and may affect the prices we may set.**

In the United States, the EU and other foreign 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, or collectively the ACA, was enacted, which substantially changes 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, 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 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;
- 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 for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs 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; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, 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. The current presidential administration and Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. Further, on December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the 2017 Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. While the current Presidential Administration and the Centers for Medicare & Medicaid Services have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, will impact the law. At this time, it is uncertain the extent to which any such changes may impact our business or financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 has, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year, which, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional action is taken by Congress. On January 2, 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 laws and any laws enacted in the future may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. 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 products and services, which could result in reduced demand for ensifentrine or additional pricing pressures.

Individual states in the United States have also become increasingly active 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 products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for ensifentrine or put pressure on our product pricing.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize ensifentrine, 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 health care in 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 products 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 products, this could prevent or delay marketing approval of ensifentrine, restrict or regulate post-approval activities and affect our ability to commercialize ensifentrine, if approved. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

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

**Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors 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 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 ensifentrine, 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 false claims and civil monetary penalties laws, including the civil False Claims Act, 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 False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or 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 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, or HITECH, and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding 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 their business associates that perform certain services involving the use or disclosure of individually identifiable health information;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal legislation commonly referred to as 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous 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
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as Regulation 2016/679, known as the General Data Protection Regulation, or GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the EU (including health data).

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations involves 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 significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our 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 in the EU and European Economic Area, or EEA, 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 and eventually in the EEA, including Regulation 2016/679, known as the GDPR. The GDPR applies extraterritorially and implements stringent operational requirements for controllers and processors of personal data. 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.

Complying with these numerous, complex and often changing regulations is expensive and difficult. Failure by us, any partners, our service providers, or our employees or contractors to comply with the GDPR could result in regulatory investigations, enforcement notices and/or fines of up to the higher of €20 million or up to 4% of our total worldwide annual turnover. In addition to the foregoing, a breach of privacy laws or data security laws, particularly those resulting in a significant 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 service providers we engage to process personal data on our behalf, including our CROs. We attempt to mitigate the associated risks by performing security assessments and due diligence of our vendors and requiring all such third-party providers with data access to sign agreements, and 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.

Where we transfer personal data out of the EU and EEA, we do so in compliance with the relevant data export requirements from time to time. There is currently ongoing litigation challenging the commonly used transfer mechanism, the EU Commission approved model clauses. In addition, the U.S. 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 outside the EEA and we are monitoring developments in this area. Further, the withdrawal of the United Kingdom from the EU has created uncertainty with regard to the status of the United Kingdom as an "adequate country" for the purposes of data transfers outside the EEA. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated. These changes may require us to find alternative bases for the compliant transfer of personal data outside the United Kingdom 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.

We are also subject to evolving European privacy laws on cookies, and if we commence any EU marketing campaigns, also on e-marketing. The EU is in the process of replacing the e-Privacy Directive (2002/58/EC) with a new set of rules taking the form of a regulation, which will be directly implemented in the laws of each European member state. The draft 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 greater of €20 million 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.

**We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.**

Our operations, including our research, development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our production and development efforts may be interrupted or delayed.

**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, or Bribery Act, the U.S. Foreign Corrupt Practices Act, or 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 or making other prohibited payments 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 also are 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, or, 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 discovering, developing or commercializing competing products 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 discover, develop and obtain marketing approval for new products on a cost-effective basis and to market them successfully. If ensifentrine is approved for any indication, we will face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in Europe, the United States and other jurisdictions. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing of products that may compete with ensifentrine.

Given the number of products already on the market to treat COPD and CF, we expect to face intense competition if ensifentrine is approved for these indications. Companies including Boehringer Ingelheim, GlaxoSmithKline, AstraZeneca, Mylan, Novartis, Vertex and Sunovion currently have treatments on the market

for COPD, CF and asthma, and we anticipate that new companies will enter these markets in the future. If we successfully develop and commercialize ensifentrine, it will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of, and rapid technological changes in, the biopharmaceutical and pharmaceutical industries could render ensifentrine 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 products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe side effects;
- obtain quicker regulatory approval;
- establish superior proprietary positions covering our products 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 for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, any collaborators we may have may decide to market and sell products that compete with ensifentrine. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than ensifentrine. Our competitors may also obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing or strengthening their market position before we are able to enter the market.

**We may be unable to obtain orphan drug designation from the FDA or EU for ensifentrine for the treatment of CF, and even if we do obtain such designations, we may be unable to obtain or maintain the benefits associated with orphan drug designation, including the potential for orphan drug exclusivity.**

Under 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, or COMP, grants orphan drug designation to promote the development of 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 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, the medicine must be 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 toward clinical trial costs, tax credits for qualified clinical testing and application 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 drug 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 may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

We plan to seek orphan drug designation from the FDA and the EMA for ensifentrine for the treatment of CF. Even if we are able to obtain orphan designation for ensifentrine in the United States and/or the EU, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated

with developing pharmaceutical products, which could prevent us from marketing ensifentrine 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 if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition following approval. Further, even if we obtain orphan drug exclusivity for ensifentrine, that exclusivity may not effectively protect ensifentrine from competition because different drugs with different active moieties can be approved for the same condition. In addition, the FDA or the EMA can subsequently approve products with the same active moiety for the same condition if the FDA or the EMA concludes that the later drug is clinically superior on the basis of greater safety, greater effectiveness, or 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 ensifentrine for the treatment of CF, we may never receive such designation.

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 our products in ways that are difficult to predict. In response to lawsuits against the FDA in 2014 and 2016, Congress included a provision in the Food and Drug Administration Reauthorization Act, or FDARA, enacted in August 2017, that amended the FDCA to require that, as a condition to awarding exclusivity to a designated orphan drug that is the same as a previously approved drug, such drug must demonstrate clinical superiority over the previously approved drug upon approval. In the future, there is the potential for additional legal challenges to the FDA's orphan drug framework, and it is uncertain how new challenges, regulations, or Congressional actions in the orphan drug space might affect our business.

**The successful commercialization of ensifentrine will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies for ensifentrine. Failure to obtain or maintain adequate coverage and reimbursement for ensifentrine, if approved, could limit our ability to market ensifentrine 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 ensifentrine, assuming approval. Our ability to achieve acceptable levels of coverage and reimbursement by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize ensifentrine. Assuming we obtain coverage for ensifentrine by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for ensifentrine 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 products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider ensifentrine 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 ensifentrine, pricing of existing drugs may limit the amount we will be able to charge for ensifentrine. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in ensifentrine. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize ensifentrine, and may not be able to obtain a satisfactory financial return on ensifentrine.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. 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 for how private payors and other governmental payors develop their 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 ensifentrine.

Obtaining and maintaining reimbursement status is time consuming and costly. No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products 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 ensifentrine 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.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of ensifentrine. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for ensifentrine. Accordingly, in markets outside the United States, the reimbursement for ensifentrine 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 products and, as a result, they may not cover or provide adequate payment for ensifentrine. We expect to experience pricing pressures in connection with the sale of ensifentrine due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

**Ensifentrine 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 ensifentrine, whether developed on our own or with a collaborator, physicians, healthcare providers, patients or the medical community may not accept or use ensifentrine. If ensifentrine does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of ensifentrine will depend on a variety of factors, including:

- the timing of market introduction;
- the number and clinical profile of competing products;
- the clinical indications for which ensifentrine is approved;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- relative convenience, frequency, 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 ensifentrine fails to gain market acceptance, this will adversely impact our ability to generate revenues. Even if ensifentrine achieves market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

**We currently have no marketing, sales or distribution infrastructure. If we are unable to develop sales, marketing and distribution capabilities on our own or through collaborations, we may not be successful in commercializing ensifentrine.**

We have no marketing, sales or distribution capabilities and we have no experience with marketing, selling or distributing pharmaceutical products. If ensifentrine is approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize ensifentrine, or to outsource this function to a third party. Either of these options would be expensive and time consuming. Some or all of these costs may be incurred in advance of any approval of ensifentrine. In addition, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of ensifentrine.

To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed or sold ensifentrine, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third-party collaborators, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize ensifentrine. If we are not successful in commercializing ensifentrine, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

#### **Risks Related to Our Dependence on Third Parties**

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

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and CROs, to conduct our pre-clinical studies and clinical trials and to monitor and manage data for our ongoing pre-clinical and clinical programs. We rely on these parties for execution of our pre-clinical studies and clinical trials, and control only certain aspects of their 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 third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we fail to exercise adequate oversight over any of our CROs or if we or any of our CROs fail to comply with applicable GCP 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 provide assurance that upon a regulatory inspection of us or our CROs or other third parties performing services in connection with our clinical trials, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to ensifentrine and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of ensifentrine, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of ensifentrine. 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 will be misappropriated.

Our existing and future CROs have or may have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding CROs involves additional cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays could occur, which could materially impact our ability to meet our desired clinical development timelines. In addition, if our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the 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 commercialize, ensifentrine. As a result, our results of operations and the commercial prospects for ensifentrine would be harmed, our costs could increase and our ability to generate revenues could be delayed.

**If we fail to enter into new strategic relationships for ensifentrine, our business, research and development and commercialization prospects could be adversely affected.**

Our development program for ensifentrine and the potential commercialization of ensifentrine will require substantial additional cash to fund expenses. Therefore, we may decide to enter into collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of

ensifentrine. For example, we may seek a collaborator for development of our DPI or pMDI formulation of ensifentrine for the maintenance treatment of COPD and potentially asthma and other respiratory diseases.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time consuming to negotiate and document. We may also be restricted under existing and future collaboration agreements from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail the development of ensifentrine, reduce or delay its development program, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring ensifentrine to market and generate product revenue. If we do enter into a collaboration agreement, we could be subject to the following risks, among others, any of which could adversely affect our ability to develop and commercialize ensifentrine:

- we may not be able to control the amount and timing of resources that the collaborator devotes to the development of ensifentrine;
- the collaborator may experience financial difficulties;
- we may be required to relinquish important rights such as marketing, distribution and intellectual property rights;
- a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors;
- business combinations or significant changes in a collaborator's business strategy may adversely affect our willingness to complete our obligations under any arrangement; or
- the collaboration may not provide sufficient funds to be profitable for us after we fulfill our payment obligations under our agreement with Ligand Pharmaceuticals, Inc., or Ligand, which acquired Vernalis Development Limited, or Vernalis, in October 2018.

**We currently rely on third-party manufacturers and suppliers for production of the active pharmaceutical ingredient ensifentrine and its derived formulated products. Our dependence on these third parties may impair the advancement of our research and development programs and the development of ensifentrine. Moreover, we intend to rely on third parties to produce commercial supplies of ensifentrine, if approved, and commercialization could be stopped, delayed or made less profitable if those third parties fail to obtain the necessary approvals from the FDA or comparable regulatory authorities, fail to provide us with sufficient quantities of product in a timely manner or fail to do so at acceptable quality levels or prices or fail to otherwise complete their duties in compliance with their obligations to us or other parties.**

We have limited personnel with experience in manufacturing, and we do not own facilities for manufacturing ensifentrine and its derived formulated products. Instead, we rely on and expect to continue to rely on third-party contract manufacturing organizations, or CMOs, for the supply of cGMP-grade clinical trial materials and commercial quantities of ensifentrine and its derived formulated products, if approved. While we may contract with other CMOs in the future, we currently have one CMO for the manufacture of ensifentrine drug substance and one CMO for each formulation of ensifentrine. . The facilities used to manufacture ensifentrine and its derived formulated products must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA to the FDA, and by comparable foreign regulatory authorities for approvals outside the United States. While we provide sponsor oversight of manufacturing activities, we do not and will not directly control the manufacturing process of, and are or will be essentially dependent on, our CMOs for compliance with cGMP requirements for the manufacture of ensifentrine and its derived formulated products. If a CMO cannot successfully manufacture material that conforms to our specifications and the regulatory requirements of the FDA or a comparable foreign regulatory authority, it will not be able to secure or maintain regulatory approval for the manufacture of ensifentrine and its derived formulated products in its manufacturing facilities. In addition, we have very little direct control over the ability of a CMO to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of ensifentrine and its derived formulated products 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 market ensifentrine and its derived formulated products, 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 manufacture of ensifentrine and its derived formulated products or that obtained approvals could be revoked. Furthermore, third-party providers may breach existing agreements they have with us because of factors beyond our control. They

may also terminate or refuse to renew their agreement because of their own financial difficulties or business priorities, at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed. In addition, the fact that we are dependent on our suppliers, CMOs and other third parties for the manufacture, storage and distribution of ensifentrine and its derived formulated products means that we are subject to the risk that ensifentrine and its derived formulated products may have manufacturing defects that we have limited ability to prevent, detect or control.

We rely on and will continue to rely on CMOs to purchase from third-party suppliers the materials necessary to produce ensifentrine and its derived formulated products and the inhalation and nebulization devices to deliver ensifentrine. We do not and will not have any control over the process or timing of the acquisition of these supplies by any CMO or its third-party suppliers, or the quality or quantity of such supplies. Moreover, we currently do not have any agreements for the commercial production of these supplies. These supplies could be interrupted from time to time and, if interrupted, we cannot be certain that alternative supplies could be obtained within a reasonable timeframe, at an acceptable cost or quality, or at all. There are a limited number of suppliers for the raw materials that we may use to manufacture ensifentrine and for the inhalation and nebulization devices we use for delivery of ensifentrine, and we will need to assess alternate suppliers to prevent a possible disruption to our clinical trials, and if approved, ultimately to commercial sales. 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 ensifentrine to complete the clinical trial, any significant delay in the supply of ensifentrine drug products, or the raw material components needed to produce, or devices needed to deliver, ensifentrine, for an ongoing clinical trial due to our CMOs or their third-party suppliers could considerably delay completion of our clinical trials, product testing and potential regulatory approval of ensifentrine. If our CMOs, their third-party supplies, or we are unable to purchase these supplies after regulatory approval has been obtained for ensifentrine, the commercial launch of ensifentrine would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of ensifentrine. In addition, growth in the costs and expenses of these supplies may impair our ability to cost-effectively manufacture ensifentrine.

We rely and will continue to rely on CMOs and third-party suppliers to comply with and respect the proprietary rights of others in conducting their contractual obligations for us. If a CMO or third-party suppliers fails to acquire the proper licenses or otherwise infringes third-party proprietary rights 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 market ensifentrine and any of its derived formulated products, if approved.

#### **Risks Related to Intellectual Property and Information Technology**

**We rely on patents and other intellectual property rights to protect ensifentrine, the 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 rights for ensifentrine, formulations of ensifentrine, polymorphs, salts and analogs of ensifentrine, methods used to manufacture ensifentrine, methods for manufacturing of final drug product for different inhalation devices such as nebulizer, DPI, pMDI, and the methods for treating patients with respiratory diseases using ensifentrine alone or in combination with other available products, or on in-licensing such rights. Our ensifentrine development program relies on the patents and patent applications assigned and know-how licensed from Ligand. The registrations of the assignment of each of these patents and patent applications with the relevant authorities in certain jurisdictions in which the patent and patent applications are registered have been granted, but there is no assurance that any additional registrations will be effected in a timely manner or at all. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could adversely affect our ability to develop and market ensifentrine.

The patent prosecution process is expensive and time-consuming, and we or our licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we or our licensors, licensees or collaborators will 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 on them. Moreover, depending on the terms of any future in-licenses to which we may become a party, in some circumstances 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 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', licensees' or collaborators' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent

others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot provide assurance 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 from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover ensifentrine, third parties may initiate an opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court 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', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such 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 ensifentrine. Furthermore, if third parties have filed such patent applications on or before March 15, 2013, the date on which the U.S. patent filing system changed from a first-to-invent to a first-to-file standard, 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 theirs. 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 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 ensifentrine.**

We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of ensifentrine in any jurisdiction. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States 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 ensifentrine could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover ensifentrine or the use of ensifentrine. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market ensifentrine. We may incorrectly determine that ensifentrine is not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market ensifentrine. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market ensifentrine.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing ensifentrine. We might, if possible, also be forced to redesign ensifentrine so that we no longer infringe the third-party intellectual property rights. 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.

**We may be involved in lawsuits to protect or enforce patents covering ensifentrine, which could be expensive, time consuming and unsuccessful, and issued patents could be found invalid or unenforceable if challenged in court.**

To protect our competitive position, we may from time to time need to resort to litigation in order to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. As enforcement of intellectual property rights is difficult, unpredictable, time consuming and expensive, we may fail in enforcing our rights - in

which case our competitors may be permitted to use our technology without being required to pay us any license fees. In addition, however, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize ensifentrine, and then compete directly with us, without payment to us. If we in-license intellectual property rights, our agreements may give our licensors the first right to control claims of third-party infringement, or to defend validity challenges. Therefore, these patents and patent applications may not be enforced or defended in a manner consistent with the best interests of our business.

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States or 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. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. Patent and Trademark Office, or USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. 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 ensifentrine. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts, industry commentators or investors perceive these results to be negative, it could have an adverse effect on the price of our ADSs and ordinary shares.

**Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.**

Our commercial success depends, in part, upon our ability, and the ability of our future collaborators, 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. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO and corresponding 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 the biopharmaceutical and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing ensifentrine. Some claimants may have substantially greater resources than we do 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 biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that ensifentrine may be subject to claims of infringement of the intellectual property rights of third parties.

We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to ensifentrine and any future product candidates, including interference or derivation proceedings, post grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Similarly, we or our licensors or collaborators may initiate such proceedings or litigation against third parties, for example, to challenge the validity or scope of intellectual property rights controlled by third parties. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. 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 such product candidate 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 candidate unless we obtained a license or until such patent

expires or is finally determined to be invalid or unenforceable. Such licenses may not be available on reasonable terms, or at all, or may be non-exclusive thereby giving our competitors access to the same technologies licensed to us.

If we fail in any such dispute, we may be forced to pay damages, including the possibility of treble damages in a patent case if a court finds us to have willfully infringed certain intellectual property rights. We or our licensees may be temporarily or permanently prohibited from commercializing ensifentrine or from selling, incorporating, manufacturing or using our products in the United States and/or other jurisdictions that use the subject intellectual property. We might, if possible, also be forced to redesign ensifentrine so that we no longer infringe the third-party intellectual property rights, which may result in significant cost or 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.

In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators 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.

**Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.**

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. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, such perceptions could have a substantial adverse effect on the price of our ordinary shares or ADSs. 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.

**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.**

We are party to a license agreement with Ligand, under which we in-license certain intellectual property and were assigned certain patents and patent applications related to our business. We may enter into additional license agreements in the future. We expect that any future license agreements would impose various diligence, milestone payment, royalty, insurance and other obligations on us. Any uncured, material breach under these license agreements could result in our loss of rights to practice the patent rights and other intellectual property licensed to us under these agreements, and could compromise our development and commercialization efforts for ensifentrine or any future product candidates. Under our agreement with Ligand, we may not abandon any of the assigned patents or allow any of the assigned patents to lapse without consent from Ligand, which is not to be unreasonably delayed or withheld. If we do not obtain such consent in a timely manner or at all and such assigned patent rights lapse or are abandoned, our agreement with Ligand may be terminated in its entirety. For example, if we decide for commercial reasons to let an assigned patent lapse in a country of little commercial importance, but Ligand does not provide consent and such patent rights lapse, we may lose all intellectual

property rights covering ensifentrine in multiple markets. Moreover, our future licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

**We may not be successful in maintaining the necessary rights to ensifentrine or obtaining 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 ensifentrine, 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 acquire, in-license, maintain or use these proprietary rights. In addition, ensifentrine may require specific formulations to work effectively and the rights to these 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 ensifentrine. 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 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 ensifentrine or a development program on acceptable terms, we may have to abandon development of ensifentrine or that development program.

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

We do not currently own any registered trademarks. We may not be able to obtain trademark protection in territories that we consider of significant importance to us. If we register trademarks, our trademark applications may be rejected during trademark registration proceedings. Although we will be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. 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. We may not be able to protect our rights to these trademarks and trade names, which we 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, then we may not be able to compete effectively and our business may be adversely affected. If other entities use trademarks similar to ours in different jurisdictions, or have senior rights to ours, it could interfere with our use of our current trademarks throughout the world.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. The issued patents covering the composition of matter for ensifentrine expire in 2020, and our other issued patents will expire in 2031, subject to any patent extensions that may be available for such patents. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2031 to 2036. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering ensifentrine are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Depending upon the timing, duration and conditions of the FDA marketing approval of ensifentrine, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. 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 products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

**We enjoy only limited geographical protection with respect to certain patents and may face difficulties in certain jurisdictions, which may diminish the value of our intellectual property rights in those jurisdictions.**

We generally file our first patent application, or priority filing, at the United Kingdom Intellectual Property Office. International applications under the Patent Cooperation Treaty, or PCT, are usually filed within 12 months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in additional jurisdictions where we believe a product candidate may be marketed or manufactured. We have so far not filed for patent protection for ensifentrine in all national and regional jurisdictions where such protection may be available. Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, we may decide to abandon national and regional patent applications before grant. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

Competitors may use our or our licensors' or collaborators' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we or our licensors or collaborators have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our and our licensors' or collaborators' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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 the EU, 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 products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign 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, 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 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 these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. 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.

**Intellectual property rights do not necessarily address all potential threats to our competitive advantage.**

The degree of future 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.
- 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 patent or pending patent application that we own or have exclusively licensed.
- We or our licensors or any future collaborators might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will 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.
- 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 products for sale in our major commercial markets.
- Third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license.
- We may not develop additional technologies that are patentable.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. In addition, the America Invents Act, or the AIA, which was passed on September 16, 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 had made the invention before it was made by the third party. This requires us to be cognizant of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and 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 procedures 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' or collaboration partners' patent applications and the enforcement or defense of our or our licensors' or collaboration partners' 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 has 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.

**Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and protect other proprietary information.**

We consider proprietary trade secrets and confidential know-how and unpatented know-how to be important to our business. We 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 do not know whether the steps we have taken to protect our proprietary technologies will be effective. We 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. However, 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. Enforcing a claim that a third party obtained illegally and is using trade secrets and/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 obtain or maintain trade secrets and confidential know-how trade protection could adversely affect 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 trade secrets and/or confidential know-how.

**We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.**

Many of our employees, including our senior management, were previously employed at universities or at other biopharmaceutical 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 proprietary information or know-how 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 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 or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

**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 in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse 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 noncompliance can result in abandonment or lapse of the patent or patent application, resulting in 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, non-payment of fees and failure to properly legalize and submit formal documents. If we

or our licensors or collaboration partners fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize any product candidate.

**Our proprietary information, or that of our manufacturers, suppliers and other parties that we use to conduct our pre-clinical and clinical trials and any future collaborators, may be lost or we may suffer security breaches.**

In the ordinary course of our business, we and our manufacturers, suppliers and third parties that we use to conduct our pre-clinical and clinical trials, collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information and personally identifiable information of our clinical trial subjects and employees, in our and third-party data centers and on our and third-party networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. 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 including the GDPR, 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 clinical development of our product candidates.

**Our information technology systems, and that of our manufacturers, suppliers and other third parties that we use to conduct our pre-clinical and clinical trials, could experience serious disruptions that could distract our operations and cause delays in our research and development work.**

Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, and that of our manufacturers, suppliers and other third parties that we use to conduct our pre-clinical and clinical trials, face the risk of systemic failure that could disrupt our operations. A significant disruption in the availability of these information technology and other internal infrastructure systems could cause interruptions in our collaborations and delays in our research and development work.

**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, scientific and technical personnel, many of whom have been instrumental for us and have substantial experience with ensifentrine and related technologies. These key management individuals include our chief executive officer, Jan-Anders Karlsson, our chief financial officer, Piers Morgan, our general counsel, Claire Poll, our chief medical officer, Kathleen Rickard, our senior vice president, chemistry manufacturing and controls, Peter Spargo, our vice president, regulatory affairs, Desiree Luthman, our commercial director, Richard Hennings, and our vice president, R&D operations and global project management, Tara Rheault.

The loss of key managers and senior scientists could delay our research and development activities. In addition, the competition for qualified personnel in the biopharmaceutical and pharmaceutical field 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, universities, public and private research institutions and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to achieve our product candidate development objectives, raise additional capital and implement our business strategy.

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

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to 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 anticipated 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 and Ordinary Shares

### **The price of our ADSs and ordinary shares may be volatile and may fluctuate due to factors beyond our control.**

The trading market for publicly traded emerging biopharmaceutical and drug discovery and development companies has been highly volatile and is likely to remain highly volatile in the future. The market price of our ADSs and ordinary shares may fluctuate significantly due to a variety of factors, including:

- positive or negative results from, or delays in, clinical trials of ensifentrine;
- developments in our competitors' businesses;
- delays in entering into collaborations and strategic relationships with respect to development or commercialization of ensifentrine or entry into collaborations and strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations or commercial product introductions by us or competitors;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of ensifentrine;
- financing or other corporate transactions;
- publication of research reports or comments by securities or industry analysts or commentators;
- general market conditions in the pharmaceutical industry 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 or board members, and significant holders of our ADSs or ordinary shares; 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 and ordinary shares to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ADSs or ordinary shares and may otherwise negatively affect the liquidity of our ADSs and ordinary shares. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of the holders of our 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.

### **We will continue to incur increased costs as a result of operating as a public company in the United States, and our senior management are required to devote substantial time to new compliance initiatives and corporate governance practices.**

As a U.S. public company, and particularly after we no longer qualify as an emerging growth company, or EGC, we will continue to incur significant legal, accounting and other expenses that we did not incur prior to becoming a U.S. public company. 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 have devoted and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

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.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our senior management on our internal control over financial reporting. However, while we remain an EGC, 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 prepare for eventual compliance with Section 404, once we no longer qualify as an EGC, we will be 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 time frame 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 dual listing of our ordinary shares and our ADSs may adversely affect the liquidity and value of our ordinary shares and ADSs.**

Our ADSs are listed on Nasdaq, and our ordinary shares are admitted to trading on AIM. The dual listing of our ADSs and ordinary shares may dilute the liquidity of these securities in one or both markets and may adversely affect the trading market or price for our ADSs or ordinary shares.

**Certain of our shareholders, members of our board of directors, and senior management own a majority of our ordinary shares (including ordinary shares represented by ADSs) and as a result, are able to exercise significant control over us.**

As of December 31, 2018, our senior management, board of directors and greater than 5% shareholders and their respective affiliates, in the aggregate, owned approximately 62% of our ordinary shares (including ordinary shares represented by ADSs) assuming no exercise of outstanding options or warrants, and approximately 67% of our ordinary shares, assuming exercise of all options available for exercise and outstanding warrants. 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 determine 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. 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.

**Future sales, or the possibility of future sales, of a substantial number of our ADSs or ordinary shares could adversely affect the price of our ADSs and ordinary shares.**

Future sales of a substantial number of our ADSs, or the perception that such sales will occur, could cause a decline in the market price of our ADSs and ordinary shares. Sales in the United States of our ADSs and ordinary shares held by our directors, officers and affiliated shareholders are subject to restrictions. If these shareholders sell substantial amounts of ordinary shares or ADSs in the public market, or the market perceives that such sales may occur, the market price of our ADSs or ordinary shares and our ability to raise capital through an issue of equity securities in the future could be adversely affected.

**Because we do not anticipate paying any cash dividends on our ADSs or ordinary shares in the foreseeable future, capital appreciation, if any, will be our ADS holders' and shareholders' sole source of gains and they may never receive a return on their investment.**

Under current 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. We intend to retain earnings, if any, for use in our business and do not anticipate paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, on our ADSs or ordinary shares will be our ADS holders' and shareholders' sole source of gain for the foreseeable future, and they will suffer a loss on their investment if they are unable to sell their ADSs or ordinary shares at or above the price at which they were purchased. Investors seeking cash dividends should not purchase our ADSs or ordinary shares.

**Securities traded on AIM may carry a higher risk than securities traded on other exchanges, which may impact the value of our investors' investments.**

Our ordinary shares are currently traded on AIM. Investment in equities traded on AIM is sometimes perceived to carry a higher risk than an investment in equities quoted on exchanges with more stringent listing requirements, such as the main market of the London Stock Exchange, New York Stock Exchange or Nasdaq. This is because AIM imposes less stringent corporate governance and ongoing reporting requirements than those other exchanges. In addition, AIM requires only half-yearly, rather than quarterly, financial reporting. The value of our ordinary shares may be influenced by many factors, some of which may be specific to us and some of which may affect AIM-quoted companies generally, including the depth and liquidity of the market, our performance, a large or small volume of trading in our ordinary shares, legislative changes and general economic, political or regulatory conditions, and that the prices may be volatile and subject to extensive fluctuations. Therefore, the

market price of our ordinary shares, our ADSs, or of the ordinary shares underlying our ADSs, may not reflect the underlying value of our company.

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

Holders of our ADSs are not be able to exercise voting rights attaching to the ordinary shares evidenced by our ADSs on an individual basis. Holders of our ADSs have appointed a depository as their representative to exercise the voting rights attaching to the ordinary shares represented by their ADSs. Holders of our 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. Furthermore, the depository will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of our ADSs may not be able to exercise voting rights and may lack recourse if their ADSs are not voted as requested. In addition, holders of our ADSs will not be able to call a shareholders' meeting.

**Holders of our ADSs may not receive distributions on our ordinary shares represented by our ADSs or any value for them if it is illegal or impractical to make them available to them.**

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

**Holders of our ADSs may be subject to limitations on transfer of their ADSs.**

ADSs are transferable on the books of the depository. However, the depository may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, 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 deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason in accordance with the terms of the deposit agreement. These limitations on transfer may have a material adverse effect on the value of our ADSs.

**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 Companies Act 2006, and by our Articles of Association. These rights differ in certain material respects from the rights of shareholders in typical U.S. corporations. As a result, investors in our ordinary shares or ADSs may not have the same protections or rights as they would if they had invested in a U.S. corporation. This may make our ADSs less attractive to such investors, which could harm the value of our ADSs.

**Claims of U.S. civil liabilities may not be enforceable against us.**

We are incorporated under English law. Substantially all of our assets are located outside the United States. The majority of our senior management and board of directors reside outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce judgments obtained in U.S. courts against them or us, including judgments predicated upon the civil liability provisions of the U.S. federal securities laws.

The United States and the United Kingdom do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the United Kingdom. In addition, uncertainty exists as to whether U.K. courts would entertain original actions brought in the United Kingdom against us or our directors or senior management predicated upon the securities laws of the United States or any state in the United States. Any final and conclusive monetary judgment for a definite sum obtained against us in U.S. courts would be treated by the courts of the United Kingdom as a cause of action in itself and sued upon as a debt at common law so that no retrial of the issues would be necessary, provided that certain

requirements are met. Whether these requirements are met in respect of a judgment based upon the civil liability provisions of the U.S. securities laws, including whether the award of monetary damages under such laws would constitute a penalty, is an issue for the court making such decision. If an English court gives judgment for the sum payable under a U.S. judgment, the English judgment will be enforceable by methods generally available for this purpose. These methods generally permit the English court discretion to prescribe the manner of enforcement.

As a result, U.S. investors may not be able to enforce against us or our senior management, board of directors or certain experts named herein who are residents of the United Kingdom or countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

**We qualify as a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to reporting obligations under the Exchange Act that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.**

We report under the Exchange Act as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. Although it is not required because we are a foreign private issuer, we furnish quarterly unaudited financial information to the SEC on Form 6-K. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers also are exempt from Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, our investors may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

**As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we rely on certain home country governance practices rather than the corporate governance requirements of Nasdaq.**

As a foreign private issuer, in accordance with the listing requirements of Nasdaq, we follow our home country governance requirements and certain exemptions thereunder rather than the corporate governance requirements of Nasdaq.

For example, we are exempt from Nasdaq regulations that require a listed U.S. company to:

- have a majority of the board of directors consist of independent directors;
- require non-management directors to meet on a regular basis without management present;
- promptly disclose any waivers of its code of conduct for directors or executive officers;
- have an independent nominating committee and compensation committee;
- solicit proxies and provide proxy statements for all shareholder meetings; and
- seek shareholder approval for the implementation of certain equity compensation plans and issuances of ordinary shares.

Our Audit Committee is required to comply with the provisions of Section 301 of the Sarbanes-Oxley Act of 2002 and Rule 10A-3 of the Exchange Act, both of which also are applicable to Nasdaq-listed U.S. companies. Because we are a foreign private issuer, however, our Audit Committee is not subject to additional Nasdaq requirements applicable to listed U.S. companies, including an affirmative determination that all members of the Audit Committee are "independent" using more stringent criteria than those applicable to us as a foreign private issuer.

Because we are exempt from certain Nasdaq governance requirements, our ADS holders may not have the same protections afforded to shareholders of companies that are subject to these Nasdaq requirements.



**We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.**

As a foreign private issuer, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. In order to maintain our current status as a foreign private issuer, either (a) a majority of our ADSs must be either directly or indirectly owned of record by holders who are not U.S. residents or (b)(i) a majority of our executive officers or directors are not U.S. citizens or residents, (ii) more than 50 percent of our assets are located outside the United States and (iii) our business is administered principally outside the United States. If we lose our status as a foreign private issuer, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

**We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to "emerging growth companies" will make our ADSs or ordinary shares less attractive to investors.**

For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404, not being required to present selected financial data for any period prior to the earliest audited period presented in our first registration statement, and exemptions from the requirement of holding a shareholder nonbinding advisory vote on executive compensation and golden parachute payments and from having to disclose the ratio of compensation of our chief executive officer to the median compensation of our employee. We may take advantage of these exemptions until we are no longer an EGC. We could be an EGC for up to five years, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our ADSs and ordinary shares held by non-affiliates exceeds \$700 million as of any June 30 (the end of our second fiscal quarter), in which case we would no longer be an emerging growth company as of the following December 31 (our fiscal year-end). We cannot predict if investors will find our ADSs or ordinary shares less attractive because we may rely on these exemptions. If some investors find our ADSs or ordinary shares less attractive as a result, there may be a less active trading market for our ADSs or ordinary shares and the price of our ADSs or ordinary shares may be more volatile.

**If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ADSs or ordinary shares.**

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ADSs or ordinary shares.

In connection with the preparation for the initial public offering of our ADSs, we reassessed our critical accounting policies to ensure compliance with International Financial Reporting Standards. As part of this reassessment, we identified errors relating to the recognition of assumed liabilities and goodwill in connection with the acquisition of Rhinopharma in September 2006. We concluded that, for the year ended December 31, 2016, a lack of adequate controls surrounding our historical accounting for business combinations constituted a material weakness in our internal control over financial reporting, as defined in the standards established by the U.S. Public Accounting Oversight Board, or PCAOB. The PCAOB defines a material weakness as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable

possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected in a timely basis. We addressed the underlying causes of the material weakness by hiring a new chief financial officer, enhancing our financial reporting team's technical accounting knowledge associated with the accounting rules for business combinations, implementing additional internal controls and engaging expert external consultants for additional technical support. However, we cannot be certain that these efforts will be sufficient to prevent future material weaknesses or significant deficiencies from occurring.

Management will be required to assess the effectiveness of our internal controls annually. However, for as long as we are an EGC, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements requiring us to incur the expense of remediation and could also result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

**We may have inadvertently violated Section 13(k) of the Exchange Act (implementing Section 402 of the Sarbanes-Oxley Act of 2002) and may be subject to sanctions as a result.**

Section 13(k) of the Exchange Act provides that it is unlawful for a company, such as ours, that has a class of securities registered under Section 12 of the Exchange Act to, directly or indirectly, including through any subsidiary, extend or maintain credit in the form of a personal loan to or for any director or executive officer of the company. In August 2018, a receivable arose with respect to taxes due upon the vesting of restricted share units held by one of our directors and two of our executive officers, which may have violated Section 13(k) of the Exchange Act. The receivable was repaid, with interest, in March 2019, as soon as management became aware of the possible violation. Issuers that are found to have violated Section 13(k) of the Exchange Act may be subject to civil sanctions, including injunctive remedies and monetary penalties, as well as criminal sanctions. The imposition of any of such sanctions on us could have a material adverse effect on our business, financial position, results of operations or cash flows.

**If securities or industry analysts or commentators publish inaccurate or unfavorable research, about our business, the price of our ADSs and ordinary shares and our trading volume could decline.**

The trading market for our ADSs and ordinary shares depends in part on the research and reports that securities or industry analysts or commentators publish about us or our business. If one or more of the analysts who cover us downgrade our ADSs or ordinary shares or if they or other industry commentators publish inaccurate or unfavorable research or comments about our business, the price of our ADSs and ordinary shares would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our ADSs or ordinary shares could decrease, which might cause the price of our ADSs and ordinary shares and trading volume to decline.

**We believe we will likely be classified as a passive foreign investment company for U.S. federal income tax purposes for the year ended December 31, 2018, which could result in adverse U.S. federal income tax consequences to U.S. investors in our ordinary shares or ADSs.**

Because we did not earn revenue from our business operations during the year ended December 31, 2018, and because our sole source of income currently is interest on bank accounts held by us, we believe we will likely be classified as a "passive foreign investment company," or PFIC, for the taxable year ended December 31, 2018. A non-U.S. company will be considered a PFIC for any taxable year if (i) at least 75% of its gross income is passive income (including interest income), or (ii) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. If we are classified as a PFIC in any year with respect to which a U.S. Holder (as defined below) owns our ordinary shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns our ordinary shares or ADSs, regardless of whether we continue to meet the PFIC test described above, unless the U.S. Holder makes a specified election once we cease to be a PFIC. If we are classified as a PFIC for any taxable year during which a U.S. Holder holds our ordinary shares or ADSs, certain adverse U.S. federal income tax consequences could apply to such U.S. Holder, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of a deferred interest charge on such gain and the receipt of certain dividends and (iii) the obligation to comply with certain reporting requirements. A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of our ordinary shares or ADSs who is eligible for the benefits of the income tax treaty between the United Kingdom and the United States 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; or an estate or trust the income of which is subject to U.S. federal income taxation regardless of its source. See Item 9.E Taxation.

**If a United States person is treated as owning at least 10% of our ordinary shares or ADSs, such holder may be subject to adverse U.S. federal income tax consequences.**

If a U.S. Holder is treated as owning, directly, indirectly or constructively, at least 10% of the value or voting power of our ordinary shares or ADSs, such U.S. Holder may be treated as a “United States shareholder” with respect to each “controlled foreign corporation” in our group, if any. If our group includes one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries could be treated as controlled foreign corporations, regardless of whether we are treated as a controlled foreign corporation. A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of “Subpart F income,” “global intangible low-taxed income” and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with these reporting obligations may subject a United States shareholder to significant monetary penalties and may prevent the statute of limitations with respect to such shareholder’s U.S. federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist our investors in determining whether any of our non-U.S. subsidiaries are treated as a controlled foreign corporation or whether such investor is treated as a United States shareholder with respect to any of such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any United States shareholder information that may be necessary to comply with the reporting and tax paying obligations described in this risk factor. United States shareholders should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares or ADSs.

#### **ITEM 4 INFORMATION ON THE COMPANY**

##### **A. History and Development of the Company.**

We were incorporated in February 2005 under the laws of England and Wales with the Registrar of Companies of England and Wales under the name Isis Resources plc. In September 2006, we acquired Rhinopharma Limited, a private company incorporated in Canada, and changed our name to Verona Pharma plc. Our principal office is located at 3 More London Riverside, London SE1 2RE, United Kingdom, and our telephone number is +(44) 203 283 4200. The principal legislation under which we operate is the Companies Act 2006.

Our agent for service of process in the United States is Cogency Global Inc., whose address is 10 E. 40<sup>th</sup> Street, 10<sup>th</sup> floor, New York, New York 10016.

Our principal capital expenditures for the year ended December 31, 2018 were £0.3 million. These capital expenditures primarily consisted of patent costs. We expect our expenditure on patent costs to increase in the near term as we continue to advance our research and development programs for ensifentrine and grow our operations. We anticipate our capital expenditure in 2019 to be financed from our current cash and short term investments resources. For more information on our capital expenditures, see Item 5.B. Liquidity and Capital Resources —Capital Expenditures.

The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers, such as we, that file electronically, with the SEC at [www.sec.gov](http://www.sec.gov). Our website address is [www.veronapharma.com](http://www.veronapharma.com). Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

##### **B. BUSINESS OVERVIEW**

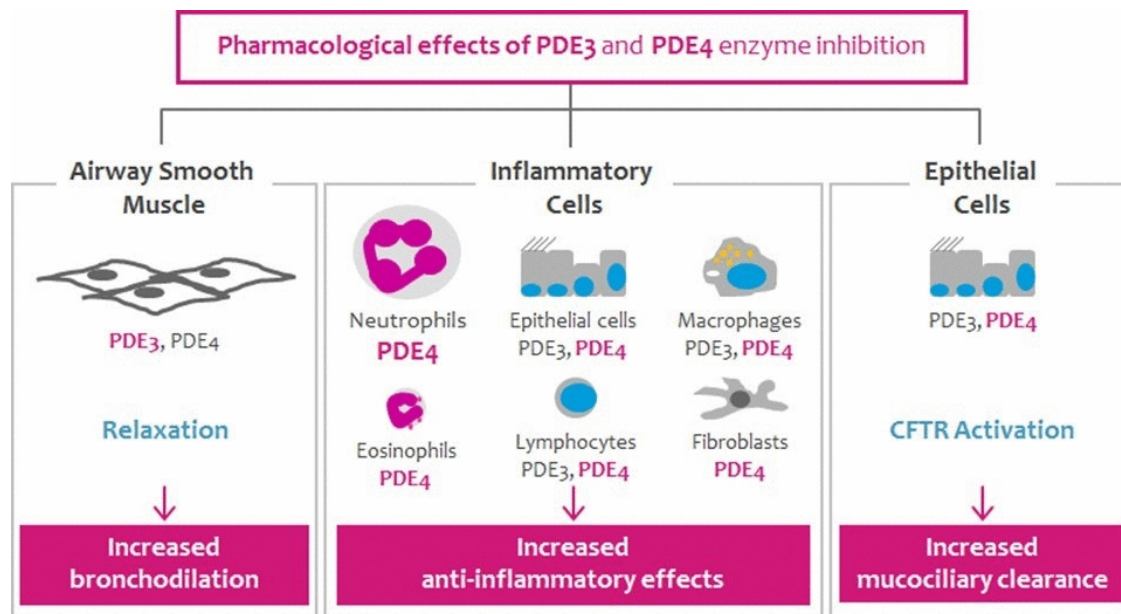
We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapeutics for the treatment of respiratory diseases with significant unmet medical need. Our product candidate, ensifentrine (RPL554) is an investigational, potential first-in-class, inhaled, dual inhibitor of the enzymes phosphodiesterase 3 and 4, or PDE3 and PDE4, that is designed to act as both a bronchodilator and an anti-inflammatory agent. We are not aware of any other product formulated in a single compound in clinical development or approved by the U.S. Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA, for the treatment of respiratory diseases as both a bronchodilator and anti-inflammatory agent. We believe ensifentrine has the potential to be the first novel class of bronchodilator in over 40 years. A nebulized formulation of ensifentrine is currently in Phase 2 clinical development for the treatment of COPD. Successful Phase 1 and 2 studies have been completed with nebulized ensifentrine in healthy volunteers and in patients with cystic fibrosis, or CF, chronic asthma and allergic rhinitis, in addition to COPD. A Phase 2 study in

COPD with ensifentrine formulated in a dry powder inhaler is ongoing, and a Phase 2 study in COPD with ensifentrine formulated in a pressurized metered dose inhaler is planned to commence in 2019. We intend to first develop ensifentrine as a nebulized therapy for the treatment of COPD.

For the past 40 years, the treatment of COPD has been dominated by three classes of inhaled therapies approved for use by the FDA or EMA: antimuscarinic agents and beta2-agonists, both available as either short-acting or long-acting bronchodilators, and inhaled corticosteroids, or ICS, known for their anti-inflammatory effects. However, despite existing treatment with one or multiple combinations of these therapies, and owing to the progressive and incurable nature of COPD, many COPD patients on maximum inhaled therapy still experience significant lung function impairment and symptoms for which limited further approved treatment options are available. One such treatment is an oral formulation of a PDE4 inhibitor with anti-inflammatory properties, although frequency of adverse events has limited its use in COPD patients.

Despite treatment with currently approved therapies, many patients with COPD experience daily symptoms impairing their quality of life. Airway obstruction and air trapping due to narrow air passages are major causes of debilitating breathlessness (dyspnea) reducing the patient's physical ability and causing anxiety and depression. Of the patients treated with dual bronchodilator (long-acting antimuscarinic agents, or LAMA/long-acting beta2 agonists, or LABA) and triple therapy (LAMA/LABA/ICS), research suggests that up to 40% (approximately 800,000 patients in the United States alone) are uncontrolled, remaining symptomatic and at an increased risk of exacerbations. Existing anti-inflammatory therapies used in COPD, ICS and the oral PDE4 inhibitor, roflumilast, have been shown to be effective in only subsets of COPD patients. Furthermore, significant side effects and adverse events such as pneumonia are associated with inhaled or systemic corticosteroid use, and significant gastrointestinal side effects are associated with roflumilast, which can limit compliance. Thus we believe there is a need for alternative anti-inflammatory therapies.

Ensifentrine is an investigational, potential first-in-class, inhaled, dual inhibitor of phosphodiesterase, or PDE, enzymes PDE3 and PDE4. PDEs are well known and validated therapeutic targets, and many PDE inhibitors, with different specificities, are currently available in the market for a range of indications. PDE3 is present in airways and the lung, and inhibition of this enzyme is primarily responsible for the bronchodilatory action of ensifentrine. PDE4 is predominantly found in inflammatory and epithelial cells, and inhibition of this enzyme contributes to ensifentrine's anti-inflammatory design. PDEs metabolize the critical signaling molecules, cyclic adenosine monophosphate, or cAMP, and cyclic guanosine monophosphate, or cGMP. By inhibiting PDE3 and PDE4, ensifentrine is designed to increase the levels of cAMP and cGMP, resulting in bronchodilator and anti-inflammatory effects. Ensifentrine is also designed to stimulate the cystic fibrosis transmembrane conductance regulator, or CFTR, which is an ion channel in the epithelial cells lining the airways. Mutations in the CFTR protein result in poorly or non-functioning ion channels, which cause CF and are potentially important in COPD. CFTR stimulation leads to improved electrolyte balance in the lung and thinning of the mucus, which facilitates mucociliary clearance and leads to improved lung function and potentially a reduction in lung infections. Dual inhibition of PDE3 and PDE4 has been observed to be more effective than inhibition of either PDE alone at relaxing airway smooth muscle cells and suppressing the activation and functions of pro-inflammatory cells residing in the lung, both of which are commonly understood to play a significant role in COPD and CF. Ensifentrine is designed to target multiple aspects of respiratory diseases such as COPD and CF through its combined bronchodilatory, anti-inflammatory and mucociliary clearance mechanisms.



COPD patients are commonly treated with bronchodilators, which seek to relieve airway constriction and make it easier to breathe, and ICS, which seek to reduce lung inflammation. For patients with more severe disease who experience recurrent exacerbations, and for whom ICS are not effective, an oral formulation of a PDE4 inhibitor, which is an anti-inflammatory agent, may also be used. Despite these therapies, many COPD patients continue to suffer exacerbations and respiratory symptoms, which limit their daily activities. Furthermore, current therapies have not demonstrated an ability to change the progressive decline in lung function or reduce the mortality associated with COPD. We believe there is an urgent and unmet medical need for new and more effective treatments for COPD to reduce the number and burden of symptoms, reduce exacerbations and establish a consistent and durable treatment response.

Based on our pre-clinical studies, we believe that ensifentrine also has the potential to reduce the deleterious inflammation in CF patients, which seems to be largely driven by neutrophils, to reduce airway obstruction through bronchodilation and to enhance mucociliary clearance through stimulation of the CFTR on airway epithelial cells. We believe the bronchodilator and anti-inflammatory properties of ensifentrine, combined with its ability to decrease mucus viscosity thereby improving mucociliary clearance, suggest that inhibition of PDE3 and PDE4 is an attractive therapeutic strategy to treat CF.

Furthermore, ensifentrine may be a suitable treatment for patients with asthma. Asthma is also an inflammatory disease of the airways and causes symptoms such as shortness of breath and cough that vary over time in their frequency and intensity. These symptoms are associated with patients having difficulty breathing due to reversible airway obstruction, airway wall thickening, and mucus production. Asthma attacks can be triggered by allergens, infections, stress etc and by certain drugs. Such exacerbations may occur even if patients are taking their medications, especially in those that are more severe. We believe ensifentrine's bronchodilator and anti-inflammatory properties may be useful also in patients with asthma.

We have completed 13 Phase 1 and Phase 2 clinical trials with ensifentrine which have enrolled over 800 subjects with COPD, asthma, cystic fibrosis, or allergic rhinitis or healthy volunteers. In our clinical trials, treatment with ensifentrine has been repeatedly observed to result in statistically significant improvements in lung function as compared to placebo, whether dosed alone or in combination with commonly used short- and long-acting classes of bronchodilators, with or without ICS. Statistically significant means that there is a low statistical probability, typically less than 5%, that the observed results occurred by chance alone. In our Phase 2b clinical trial of nebulized ensifentrine as a maintenance treatment for COPD, patients with moderate-to-severe COPD treated with ensifentrine showed clinically meaningful and statistically significant improvements in daily reported COPD symptom scores. In addition, our clinical trials have also shown clinically meaningful and statistically significant additional improvements in certain measures of lung function following combined treatment with ensifentrine as add-on to other approved bronchodilators; COPD patients experienced a marked reduction in residual lung volume, which is believed to be related to one of the most debilitating symptoms, breathlessness. The rapid onset of action observed when adding ensifentrine on top of tiotropium, a commonly used LAMA, was also notable, and may be particularly helpful to those patients suffering from morning

breathlessness. We believe that the clinical effects observed with ensifentrine are driven by its bronchodilator, anti-inflammatory and mucociliary clearance mechanisms.

Ensifentrine has been observed to be well tolerated in our clinical trials to date and has not been observed to result in the gastrointestinal or other side effects commonly associated with roflumilast (Daxas/Daliresp), the only PDE4 inhibitor currently on the market for the treatment of COPD.

We believe ensifentrine, having shown improvement in forced expiratory volume in one second, or FEV<sub>1</sub>, a measure of lung function, and symptoms (which commonly are a precursor to exacerbations) in clinical trials, may be an attractive additional treatment for COPD patients. In the United States, approximately three million COPD patients are treated with single bronchodilator (either a LAMA or LABA) therapy. In our clinical trials, ensifentrine has been observed to improve lung function, measured by FEV<sub>1</sub>, and residual volume, when used in addition to existing approved bronchodilators, and we believe it is well placed to potentially meet the need for a safe and effective dual bronchodilator/anti-inflammatory treatment regimen as an add-on to, for example, a LAMA. Furthermore, in the United States, approximately another two million COPD patients are treated with dual bronchodilator therapy (LAMA/LABA) with or without ICS. In January 2019, we announced results from our Phase 2 clinical trial evaluating nebulized ensifentrine administered twice daily on top of treatment with tiotropium and olodaterol. Treatment with ensifentrine showed improvement in FEV<sub>1</sub>, particularly after the second dose in the evening, which we believe suggests that ensifentrine could be an effective addition to dual bronchodilator therapy, in particular during the second half of the day following treatment, when patients may derive less benefit from their LAMA/LABA dual bronchodilator therapy.

We are also developing nebulized ensifentrine for the treatment of patients with CF. We believe ensifentrine, if approved, has the potential to become a novel treatment option for these patients. We may also explore, alone or with a collaborator, the development of ensifentrine to treat asthma and other respiratory diseases.

We believe there is a need for nebulized therapies for COPD, as well as more convenient handheld inhalers such as a dry powder inhaler, or DPI, or pressurized metered-dose inhaler, or pMDI. Initially, we are developing ensifentrine in a nebulized formulation for the maintenance treatment of COPD patients. Patients with moderate to severe COPD, who tend to suffer more frequent symptoms and exacerbations, generally prefer treatment with a nebulizer as they view its perceived benefits, including greater confidence in effective drug administration and a reduced need to visit health care providers, as outweighing its perceived disadvantages, which include length of treatment administration and required cleaning.

We also are developing ensifentrine in both DPI, and pMDI, formulations for the maintenance treatment of COPD. Handheld DPI and pMDI devices are the most common forms of drug delivery in non-hospitalized patients with COPD and are well suited for maintenance therapy. About 5.5 million COPD patients in the United States are believed to use such devices. We believe the development of DPI and pMDI formulations has the potential to substantially increase the market opportunity for ensifentrine, if approved, for the maintenance treatment of COPD.

In addition, we may explore the development of ensifentrine in DPI and pMDI formulations for the treatment of asthma and other respiratory diseases.

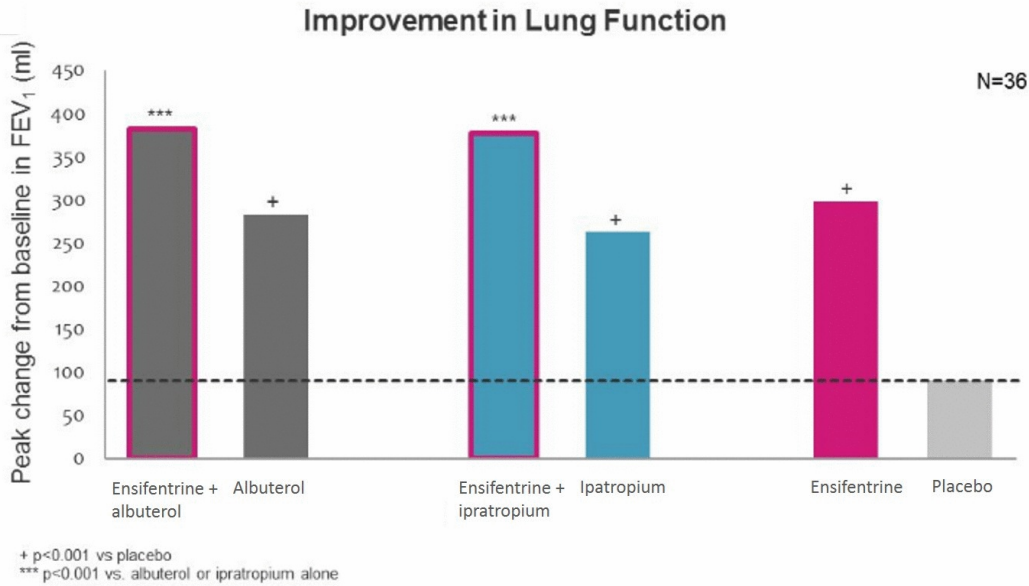
## **DEVELOPMENT OF NEBULIZED ENSIFENTRINE**

### *Clinical development of ensifentrine in COPD*

We have completed five studies with a nebulized suspension formulation of ensifentrine in patients with moderate-to-severe COPD.

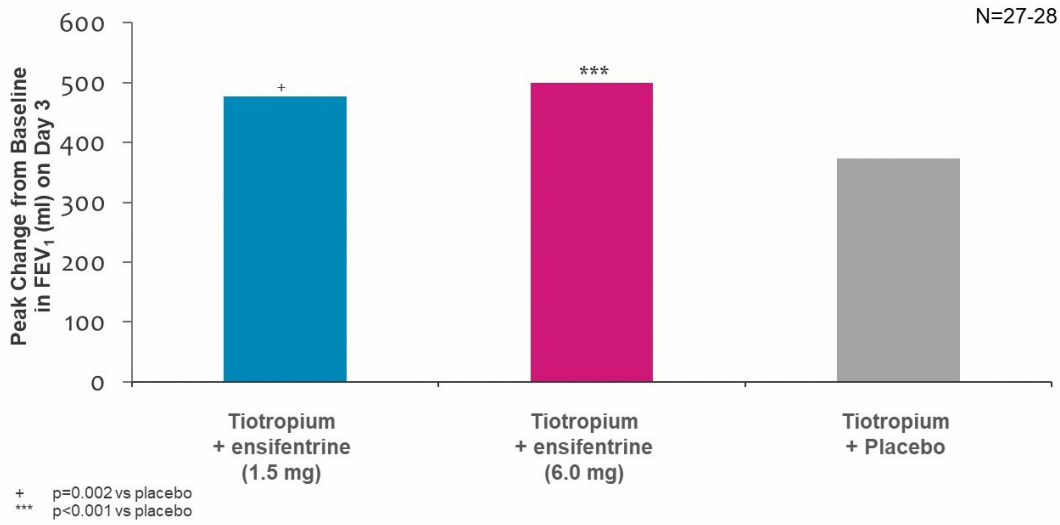
We conducted a Phase 1 randomized, double-blind, placebo controlled study in which single ascending doses of ensifentrine in the range 1.5 mg to 24 mg were administered to 35 healthy subjects, multiple ascending doses in the range 6 mg to 24 mg twice daily for up to 5.5 days were administered to 21 healthy subjects and multiple ascending doses in the range 1.5 mg to 12 mg twice daily for 5.5 days were administered to 23 COPD patients. In this study, ensifentrine was observed to be well tolerated and showed an increase in FEV<sub>1</sub> up to 25% in COPD patients.

We conducted a Phase 2, randomized, double-blind, double-dummy, placebo controlled, six-way complete block crossover study in 36 patients with moderate-to-severe COPD. Patients received albuterol (200 mg), ipratropium (40 mg) or placebo pMDI followed immediately by nebulized ensifentrine (6 mg) or placebo. As shown in the graph below, ensifentrine alone was as effective as albuterol or ipratropium as a bronchodilator, and treatment with ensifentrine showed a significant additive bronchodilation (peak and average FEV<sub>1</sub> over 8 hours) when dosed with either albuterol or ipratropium (p<0.001 compared to albuterol or ipratropium alone). Ensifentrine also resulted in an additive and significant reduction in lung volume and airway resistance.

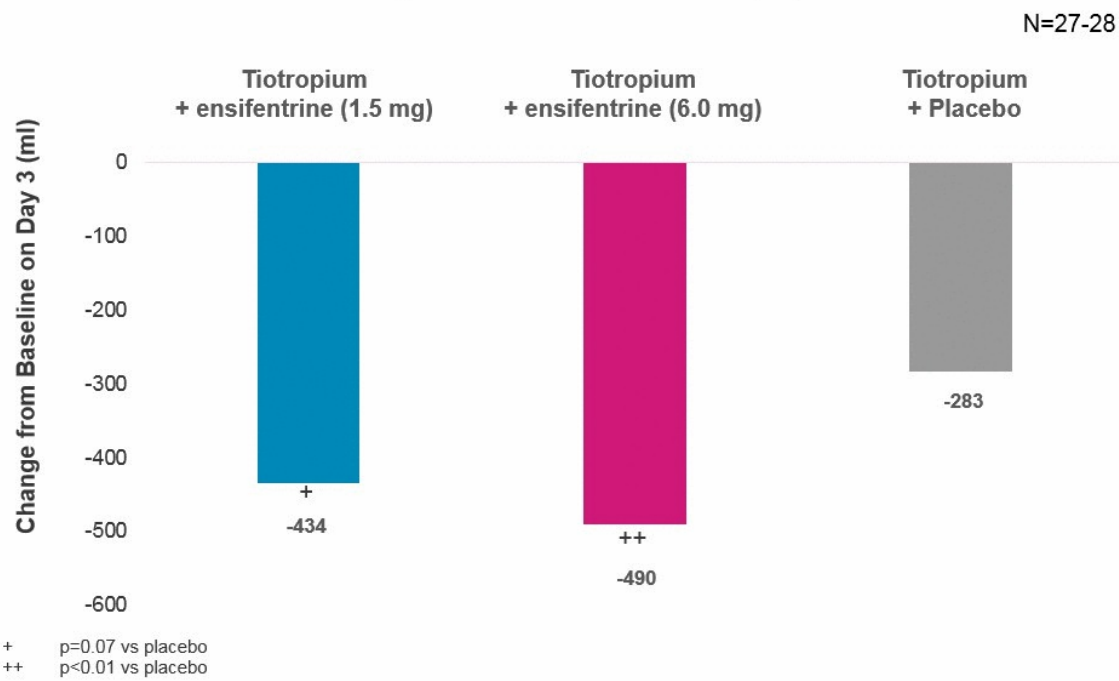


We conducted a Phase 2a crossover study in 30 patients with moderate-to-severe COPD to examine the effect of ensifentrine when added to a standard dose of a single bronchodilator (LAMA, tiotropium or Spiriva®) in the United Kingdom. Patients received tiotropium 18 µg once daily, plus ensifentrine 1.5 mg, ensifentrine 6 mg or placebo twice daily for 3 days. In this study, we observed a significant increase in peak FEV<sub>1</sub> when administering ensifentrine on top of tiotropium (103 mL and 127 mL for ensifentrine 1.5 mg and 6 mg, respectively) as compared to tiotropium and placebo. Average FEV<sub>1</sub> on the third day of dosing (0 - 12 hours) of ensifentrine when added on top of tiotropium was larger than that of tiotropium alone (1.5mg, p=0.099; 6 mg, p<0.001), thus the co-primary endpoints of peak FEV<sub>1</sub> and FEV<sub>1</sub> average AUC 0-12h were met. (AUC, or area under the curve, is a measure of effectiveness over a period of time.) As shown in the graph below, there was also significant improvement in both trough FEV<sub>1</sub> and lung volume, including residual volume and functional residual capacity. The time to onset of ensifentrine and tiotropium was faster than with tiotropium alone (less than 5 minutes versus 37 minutes as shown in the graph below).

### Improvement in Lung Function



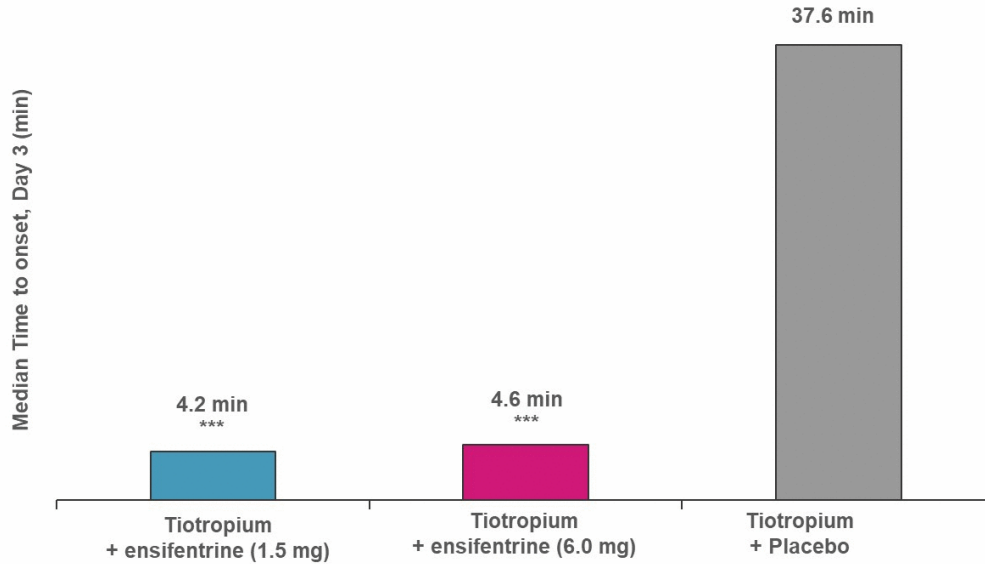
### Change in Residual Volume (ml)





### Median Time to Onset ( $\geq 10\%$ improvement in FEV<sub>1</sub>; mins) on Day 3

N=27-28

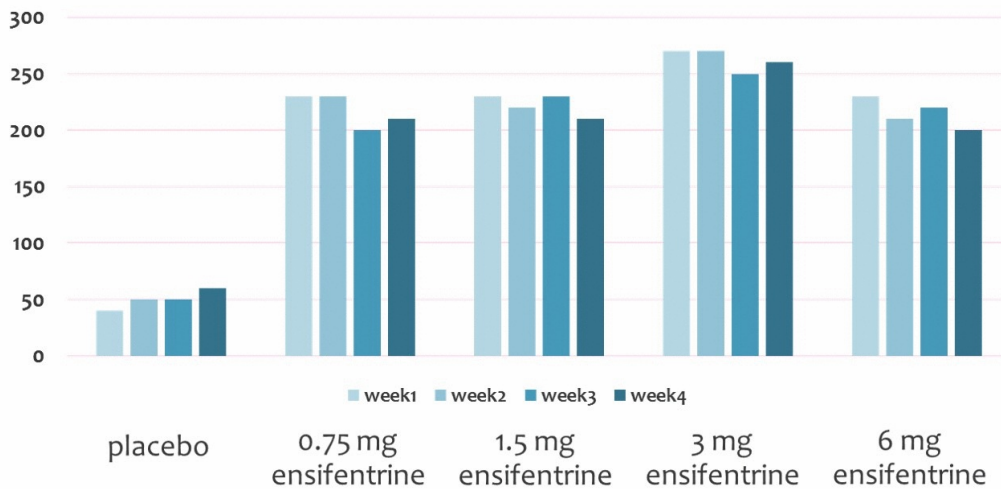


\*\*\* p<0.001 vs placebo

We conducted a Phase 2b parallel group study in 403 patients with COPD in Europe to examine the effect in patients without concomitant bronchodilator therapy. Patients received either placebo or ensifentrine at doses ranging from 0.75 mg to 6 mg twice daily over 4 weeks. Treatment with ensifentrine met the primary endpoint for all doses, showing a statistically significant increase in peak forced expiratory volume in 1 second (FEV<sub>1</sub>) compared to placebo (p<0.001) with absolute changes from baseline >200 mL in peak FEV<sub>1</sub> after 4 weeks of dosing. In addition, statistically significant improvements in average FEV<sub>1</sub> over 12 hours were observed at all doses after the first administration, and this effect was sustained over 4 weeks. Notably, statistically significant and clinically meaningful improvements in total COPD symptoms (p<0.002) and dyspnea (p<0.02) were shown using the E-RS (EXACT-PRO) - a recognized patient-reported outcome measure for use in clinical studies of COPD, and the Transition Dyspnea Index. We believe that the progressive improvement in COPD symptoms over the 4 week treatment period, which was different from the immediate onset of the bronchodilator response, suggest the involvement of an anti-inflammatory effect.

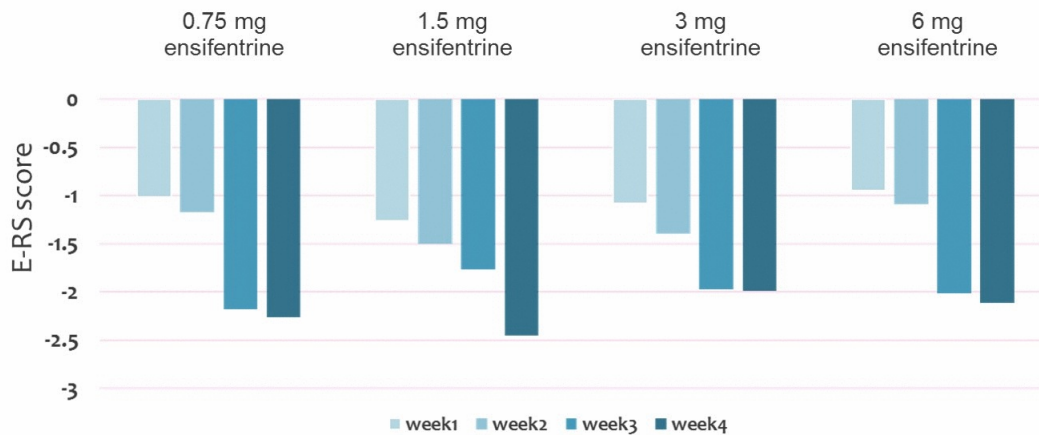
## Peak Change from Day 1 in Baseline in FEV<sub>1</sub>(mL) on week 4 (p<0.001)

N=403



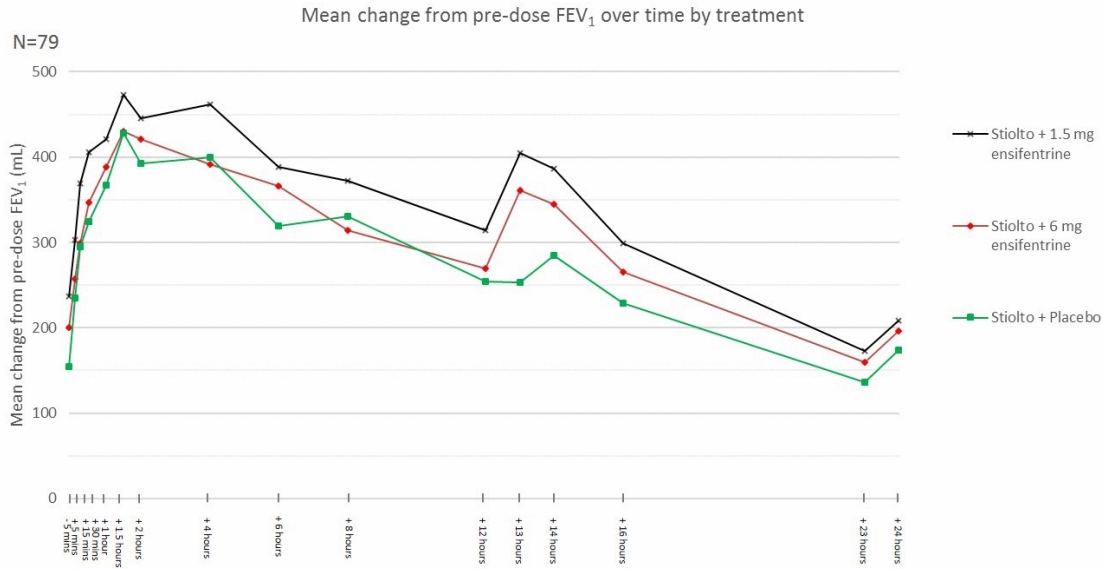
## Total score (0-40) E-RS: COPD by week (placebo corrected, p<0.02)

N=403



In January 2019, we announced top-line data from a Phase 2 three-way crossover study in 79 moderate-to-severe COPD patients to study the effect of ensifentrine when added to dual bronchodilators (LAMA/LABA). The study was conducted in the United States and the United Kingdom. Patients were administered ensifentrine 1.5 mg or 6 mg or placebo twice daily for 3 days in addition to a tiotropium/olodaterol fixed dose combination (Stiolto® Respimat®). Patients were allowed to remain on a stable dose of ICS. The study was completed in January 2019, and the final full data set is not yet available. Top line data showed a tolerability and safety profile generally in line with previous studies. This study was conducted in the challenging setting of COPD patients treated with what is thought to be "maximal inhaled therapy". Although the primary endpoint of improvement in morning peak FEV<sub>1</sub> on the third day of dosing was not statistically significant and was not met, improvement in average FEV<sub>1</sub> (additional bronchodilation) following the morning dose on the third day (0 - 4 hours) with 1.5 mg of ensifentrine was statistically significant when added on top of Stiolto® Respimat® compared to placebo (1.5 mg, p=0.039). Statistically significant improvements in evening peak FEV<sub>1</sub> (additional bronchodilation) on the third day of dosing, and significant reductions in lung volume after the evening dose of ensifentrine were observed with both the 1.5 mg and 6 mg dose groups, compared to placebo, when administered on top of Stiolto

RespiMat (evening peak FEV<sub>1</sub>: 1.5 mg, p<0.001; 6 mg p=0.002 (as shown in the graph below); post-evening dose residual volume: 1.5 mg, p=0.002; 6 mg, p=0.036).



Enfentrine has been observed to be well tolerated in our clinical studies performed to date when administered alone and as an add-on therapy to commonly used bronchodilators at dose levels ranging from 0.4 mg to 24 mg. Dose-limiting toxicities have not been observed. To date across all studies and populations, 10 subjects with serious adverse events, or SAEs, have been reported. Of these events, eight were assessed as not related to enfentrine and two were assessed as possibly related, although relevant mitigating factors were subsequently considered. In our completed clinical trials, we did not observe any gastrointestinal adverse events or cardiovascular effects, other than a small increase in heart rate at the highest doses tested. Enfentrine had no observed effect on cardiac function as measured by electrocardiograms, including QT intervals, a measure of time between certain waves in the heart's electrical cycle and measure of a potential cardiovascular adverse event. In addition, we did not observe an increase in incidence of any adverse event compared to commonly used bronchodilators when enfentrine was used alone. In our studies, the most common adverse events have been mild to moderate, and included headache, dizziness, cough, heart palpitation, nausea, dry mouth, parenthesis (tingling), nasopharyngitis (throat irritation) and rash, which occurred with comparable frequency to placebo.

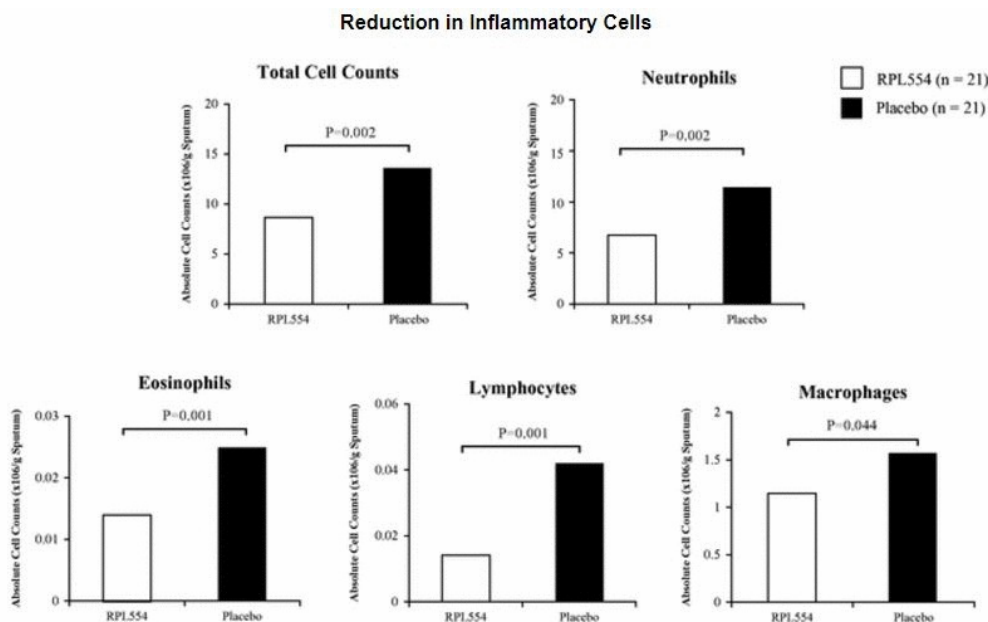
In the second quarter of 2019 we plan to initiate a dose ranging Phase 2b study with enfentrine in COPD patients to further support dose selection for our planned Phase 3 clinical trial. This study will evaluate multiple doses of enfentrine added on to tiotropium. We expect to report data from this study at the end of 2019. We intend to use the data from all our completed studies, including the data from this additional Phase 2b study to be conducted in 2019, to inform our future studies, including the design of our planned Phase 3 program for the maintenance treatment of COPD.

Additional studies have been completed in healthy volunteers, and in patients with asthma and with cystic fibrosis.

We conducted a single-dose pharmacokinetic, or PK, trial in 12 healthy volunteers in the United States. A PK trial involves the study of the process of bodily absorption, distribution, metabolism and excretion of a drug. With any inhaled or nebulized medication, a portion of the substance is deposited in the mouth and then swallowed by the patient. The results showed that in the study subjects only 10.4 percent of the inhaled dose of enfentrine entered the bloodstream via the gastrointestinal tract. The low oral bioavailability of nebulized enfentrine, as shown in this study, is consistent with optimal inhaled delivery of medications for the treatment of COPD and asthma. Therefore the results from this study support our approach of developing inhalation formulations for the administration of enfentrine.

Enfentrine also has shown anti-inflammatory effects in sputum samples from a model of COPD-like lung inflammation in human subjects. In a Phase 1 clinical trial, 21 healthy evaluable subjects were treated with

either ensifentrine or placebo once daily for six days before airway challenge with aerosolized lipopolysaccharide, or LPS. LPS challenge induces an inflammatory response in the lung with a large proportion of neutrophils, which is a common type of white blood cell widely recognized as the most important inflammatory cell in COPD. LPS challenge is a well-validated and commonly used measure to assess the anti-inflammatory effects of novel compounds and is of particular relevance to drugs used in the treatment of COPD. Subjects treated with ensifentrine were observed to have significantly lower absolute numbers of neutrophils in sputum collected six hours after LPS challenge, and a significant reduction in the absolute numbers of other inflammatory cells, including lymphocytes, macrophages and eosinophils, at the same time point (as shown in the graph below). Eosinophils are prevalent in the lungs of some patients with COPD and in the vast majority of patients with asthma. These observations suggest that ensifentrine has the potential to target the chronic inflammatory processes in COPD, CF and other respiratory diseases, including asthma.



#### Clinical Development of Ensifentrine in Cystic Fibrosis and Asthma

We conducted a Phase 2, double-blind, placebo-controlled, seven-way complete block crossover study in 29 patients with mild-to-moderate chronic asthma. Patients received four single doses of ensifentrine (0.4 mg, 1.5 mg, 6 mg and 24 mg), two doses of nebulized albuterol (2.5 mg and 7.5 mg) and placebo in a randomized sequence. ensifentrine produced a dose dependent bronchodilation with a magnitude that was comparable to a maximal dose of albuterol.

In March 2018, we reported top-line data from a Phase 2a single-dose PK and pharmacodynamics, or PD, trial in the United Kingdom evaluating ensifentrine in ten CF patients. A PD trial involves the study of the biochemical and physiological effects of a drug and its mechanism of action. The PK profile was consistent with that observed in patients with COPD, although with lower peak serum levels of ensifentrine in CF patients. The serum half-life was dose dependent: 7.5 to 10.1 hours for 1.5 mg and 6 mg, respectively. Ensifentrine elicited a statistically significant increase in average FEV<sub>1</sub> in treated patients for 1.5 mg (all time points, p<0.01) and 6 mg (all time points p<0.05) at 4, 6 and 8 hour time points. Ensifentrine was observed to be well-tolerated in this patient group with an adverse event profile consistent with other studies with ensifentrine.

## FURTHER INFORMATION

According to the World Health Organization, over one billion people suffer from chronic respiratory diseases. Among the most common of these afflictions is COPD, which is a progressive respiratory disease for which there is no cure. COPD damages the airways and the lungs and leads to shortness of breath, impacting a person's ability to perform daily activities. Chronic inflammation plays a central role in the pathology of the disease, and is particularly prominent in the airways of COPD patients. COPD includes chronic bronchitis, which refers to the inflammation of the lung and airways that results in coughing and sputum production, and emphysema, which refers to a destruction of distal lung tissue, or air sacs. In some cases, patients with COPD experience exacerbations, which are estimated to cause approximately 1.5 million emergency department visits, 687,000 hospitalizations and 129,000 deaths per year in the United States alone. According to the World Health Organization, COPD is expected to become the third leading cause of death globally by 2030, with 210 million people worldwide suffering from the disease. It is estimated that there are 24 million people with COPD in the United States, only about half of whom have been diagnosed. Of those diagnosed with COPD in the United States, more than 2 million suffer from severe or very severe forms of the disease. Total annual medical costs relating to COPD in the United States were estimated to be \$32 billion in 2010 and are projected to rise to \$49 billion in 2020. While the number of patients diagnosed with COPD in the United States continues to increase annually, the growth in numbers in countries like China is significantly higher. The prevalence of COPD in China is estimated to be about 8% of the population aged over 40, and this percentage is expected to increase in coming years. Global sales of drugs currently indicated for COPD in major markets were approximately \$15 billion in 2015 and are expected to grow to \$20 billion by 2025.

CF is the most common fatal inherited disease in the United States and Europe. CF causes impaired lung function and is commonly associated with repeat and persistent lung infections due to the inability to clear thickened phlegm, or mucus, from the lung. This condition often results in frequent exacerbations and hospitalizations. There is no cure for CF and although current therapies are leading to longer lifespans the median age of death for CF patients is still only around 40 years. CF is considered a rare, or orphan, disease by both the FDA and the EMA. According to the Cystic Fibrosis Foundation, more than 30,000 people in the United States and more than 70,000 people worldwide are living with CF and approximately 1,000 new cases of CF are diagnosed each year. The FDA and the EMA provide incentives for sponsors to develop products for orphan diseases, and we plan to seek orphan drug designation for ensifentrine in treating CF. CF patients require lifelong treatment with multiple daily medications, frequent hospitalizations and, ultimately, lung transplants in some end-stage patients. The quality of life for CF patients is compromised as a result of spending significant time on self-care every day and frequent outpatient doctor visits and hospitalizations. CF patients take an average of seven medications daily. In the 12-month period ended June 30, 2016, global sales of drugs currently indicated for CF totaled \$4.1 billion. The global market for CF drugs is expected to increase to \$7.0 billion in 2020.

Asthma is widely seen as a result of chronic inflammation in the lungs. In the United States 18 million people are diagnosed with asthma and the 2015 prescription medicine market sales totaled \$13 billion. Established treatments include those adopted from the treatment of COPD (for example, bronchodilators and ICS), anti-IgE agents and leukotriene inhibitors. Approximately 1 million patients in the United States are refractory asthmatic patients who remain uncontrolled on established therapies. These patients are the target for injectable biologic anti-IL-5 agents. Sales of biologics in the United States for the treatment of asthma are forecast to exceed \$1.0 billion by 2025.

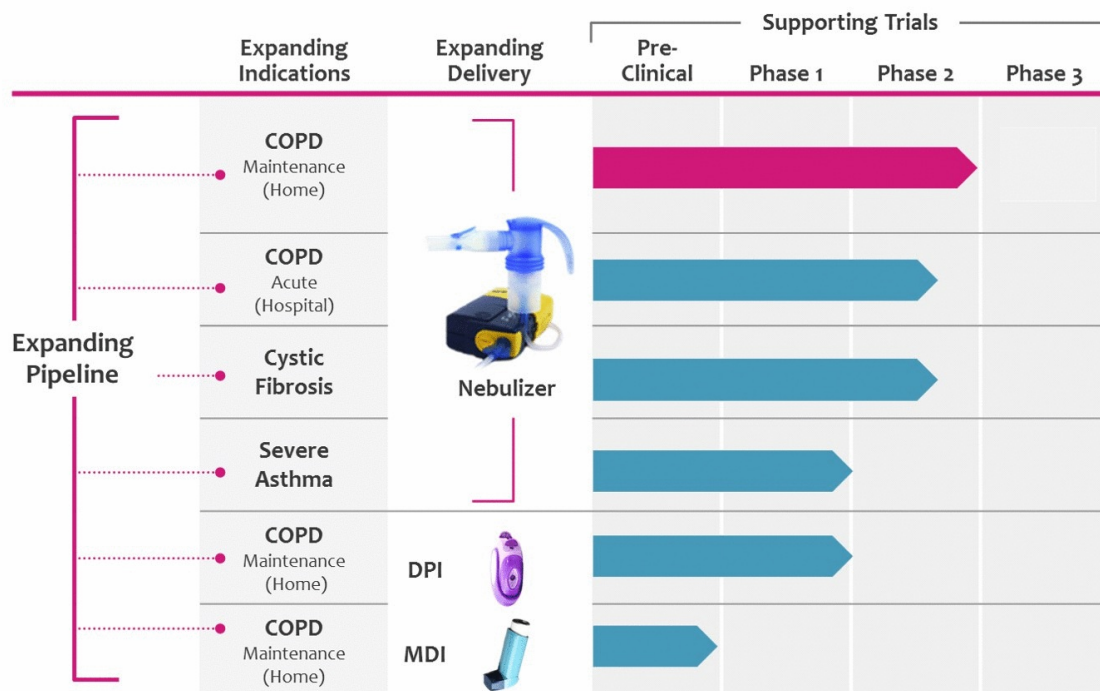
We have worldwide commercialization rights for ensifentrine. Our intellectual property portfolio includes granted and issued patents as well as pending patent applications. These patents and patent applications include claims directed to ensifentrine composition of matter, new dosage formulations and a crystalline polymorph, as well as methods of making and using ensifentrine in the treatment of respiratory diseases, with expected expiry dates between 2020 and 2037, as described further below.

We were incorporated in February 2005 and are headquartered in the United Kingdom. Since September 2006, our ordinary shares have traded on AIM, a market of the London Stock Exchange, under the symbol "VRP". We have raised approximately £145 million in gross proceeds from investors since such listing, of which approximately £70.3 million was raised in our initial public offering of our American Depositary Shares, or ADSs, in April and May 2017, which are listed on The Nasdaq Global Market, or Nasdaq, under the symbol "VRNA," and the accompanying private offering in Europe of our ordinary shares, or the global offering, and a concurrent private placement to certain shareholders of our ordinary shares, or the shareholder private placement, and £45 million was raised in our July 2016 private placement of equity securities with a number of European and U.S.-based healthcare specialist investment firms, or the July 2016 Placement Members of our management team and board of directors have extensive experience in large pharmaceutical and biotechnology companies in respiratory product development from drug discovery through commercialization and have played important roles

in the development and commercialization of several approved respiratory treatments, including Symbicort, Daliresp/Daxas, Flutiform, Advair, Incruse Ellipta and Anoro Ellipta.

## Our Product Candidate Pipeline

The following table depicts the potential indications for ensifentrine and their current development status:



## Our Strengths

We believe that our company has the following key distinguishing characteristics:

- Potential for multiple targeted indications, formulations and add-on therapies.** We are initially developing ensifentrine in a nebulized formulation for the maintenance treatment of COPD patients. While ensifentrine can be used as a standalone treatment in these patients, we are focusing on COPD patients who are symptomatic despite using currently available standard-of-care COPD treatments, because ensifentrine has shown improvements in lung function when administered as an add-on therapy to single and dual bronchodilators. We also are developing ensifentrine in both DPI and pMDI formulations for the maintenance treatment of COPD. In addition, we may explore the development of ensifentrine in inhaled formulations for the treatment of CF, asthma and other respiratory diseases. Based on the favorable properties of ensifentrine that we have observed in our clinical trials, we believe ensifentrine has broad potential applicability in the treatment of other respiratory diseases, either as a single agent or as an add-on therapy.
- Observed benefit and favorable tolerability as a single agent and as an add-on therapy in clinical trials.** We have reported data from thirteen Phase 1 and 2 clinical trials for ensifentrine with over 800 subjects enrolled. We have observed statistically significant improvements in lung function as compared to placebo, as well as clinically meaningful and statistically significant improvements in lung function when ensifentrine is added to several commonly used bronchodilators as compared to such bronchodilators administered as a single agent or in combination. In addition, we observed a more rapid time of onset of bronchodilation when ensifentrine was administered as an add-on therapy to these bronchodilators. We have also observed in a four-week study in COPD patients statistically significant improvements in COPD patient symptom scores. Notably, statistically significant and clinically meaningful improvements in total COPD symptoms ( $p < 0.002$ ) and dyspnea ( $p < 0.02$ ) were shown using the E-RS (EXACT-PRO) - a recognized patient-reported outcome measure for use in clinical studies of COPD, and the Transition Dyspnea Index. We believe that the progressive improvement in COPD symptoms over the 4 week treatment period, which was different from the immediate onset of the

bronchodilator response, suggest the involvement of an anti-inflammatory effect. Ensifentrine has been observed to be well tolerated in our clinical trials, and has not been observed to result in the gastrointestinal or other side effects commonly associated with roflumilast, the only PDE4 inhibitor currently on the market approved for treatment of COPD. In addition, ensifentrine has not been observed to result in any cardiovascular effects, other than a small increase in heart rate at the highest doses tested.

- **Differentiated mechanism of action in a single compound.** Ensifentrine is an investigational potential first-in-class, inhaled, dual inhibitor of PDE3 and PDE4 that is designed to act as both a bronchodilator and an anti-inflammatory agent in a single compound and stimulate the CFTR. Dual inhibition of PDE3 and PDE4 has been shown to be more effective than inhibition of either PDE alone at relaxing airway smooth muscle cells and suppressing the activation and functions of pro-inflammatory cells residing in the lung, both of which are commonly understood to play a significant role in COPD, CF and asthma. In addition, through this dual mechanism, ensifentrine is also designed to stimulate the CFTR, which we believe is important in the treatment of CF and potentially COPD. We believe that ensifentrine, if successfully developed and approved, has the potential to be a more effective and better tolerated treatment of COPD than existing treatments, including roflumilast, the only currently approved PDE4 inhibitor. This dual mechanism of action also suggests that ensifentrine could be a useful treatment for patients with moderate to severe asthma and symptomatic despite being treated with standard-of-care.
- **Established regulatory pathway and well-defined clinical endpoints.** Our planned clinical trials for ensifentrine for the maintenance treatment of COPD will be designed to evaluate the effect on FEV<sub>1</sub>, COPD symptoms, exacerbations and duration of action of ensifentrine. We will also monitor COPD-like symptoms as an improvement would be considered very important to these patients. These clinical endpoints are commonly used in clinical trials for respiratory diseases and have been used by other companies in obtaining FDA approval of drugs addressing respiratory diseases.
- **Addressing significant market opportunities.** Despite the availability of bronchodilators and anti-inflammatory corticosteroid or PDE4 inhibitor treatments for COPD, many patients continue to suffer from significant symptoms and may experience acute exacerbations leading to hospitalization. Furthermore, current therapies have not demonstrated an ability to change the progressive decline in lung function or reduce the mortality associated with COPD. We believe a large market opportunity with significant unmet medical need exists in COPD and especially in moderate to severe patients with limited further treatment alternatives. We believe the properties of ensifentrine, bronchodilation, and reduction of COPD-like symptoms, make it attractive as an important and novel potential treatment of patients with COPD, as well as for patients with CF and asthma. We plan to seek orphan drug designation of ensifentrine for the treatment of CF.
- **Experienced management team.** Members of our management team and board of directors have extensive experience in large pharmaceutical and biotechnology companies in respiratory product development from drug discovery through commercialization and have played important roles in the development and commercialization of several approved respiratory treatments. We believe that the experience of our management team and our network of relationships within the industry and medical community provides us with insight into product development and identification of other opportunities in the respiratory field.

## Our Strategy

We intend to become a leading biopharmaceutical company focused on the treatment of respiratory diseases with significant unmet medical needs. The key elements of our strategy to achieve this goal include:

- **Advance the development of nebulized ensifentrine for the maintenance treatment of COPD.** We intend to initially develop nebulized ensifentrine for the maintenance treatment of COPD. We believe there is a large market opportunity for ensifentrine as a maintenance treatment as many of the moderate-to-severe COPD patients continue to be uncontrolled and symptomatic despite treatment with currently available medications. In order to further validate dose and commercial positioning, we will conduct a four-week Phase 2b dose ranging clinical trial in COPD patients who are symptomatic despite treatment with tiotropium. In this trial, we will compare the use of ensifentrine in a nebulized formulation to placebo, when added to tiotropium, in approximately 400 patients. We expect to commence this study in the second quarter of 2019.

- We have shown that ensifentrine can provide additional bronchodilation as add-on to patients treated with maximum approved bronchodilator therapy (LAMA/LABA), as measured by FEV<sub>1</sub> and residual volume, both in the morning and, in particular, following the evening dose. This data is very encouraging in a large but hard-to-treat population who have very limited alternative treatment options.
- Taking into account the data from all clinical trials conducted with ensifentrine to date, interactions with regulatory authorities and our commercial assessment of different development options for nebulized ensifentrine, we are focusing our development plans on proceeding rapidly towards Phase 3 clinical trials with nebulized ensifentrine for the maintenance treatment of COPD. Therefore our focus is currently on the COPD maintenance market as a priority in the short term over progressing our planned trials to evaluate nebulized ensifentrine as a treatment for acute exacerbations of COPD hospitalized patients and as a treatment for CF and asthma patients.
- **Adapt the current nebulized formulation and presentation of ensifentrine.** Ensifentrine for nebulized administration is currently presented in a glass vial with a flip, tear-up cap. This format is adequate for clinical trials but patient acceptance in a commercial setting is expected to be improved by a switch to presenting the suspension formulation of ensifentrine in plastic ampules, which is also more cost effective for manufacturing in larger volumes. This development work is ongoing.
- **Develop ensifentrine for the treatment of CF.** We have completed a Phase 2a single-dose trial in the United Kingdom of ensifentrine in ten CF patients to evaluate the PK and PD profile and tolerability of ensifentrine, as well as examine the effect on lung function. Ensifentrine demonstrated a statistically significant bronchodilator effect, a PK profile that is consistent with that observed in patients with COPD while being well tolerated.
- **Develop DPI and pMDI formulations of ensifentrine.** In addition to our nebulized formulation of ensifentrine, we are developing ensifentrine in both DPI and pMDI formulations for the maintenance treatment of COPD. We believe the development of DPI and pMDI formulations has the potential to substantially increase the market opportunity for ensifentrine, if approved, for the maintenance treatment of COPD. We have now developed DPI and MDI formulations of ensifentrine, and initiated the first DPI clinical trial in COPD patients in December 2018. We plan to start clinical trials with the pMDI formulation in the first half of 2019. In addition, we may explore the development of ensifentrine in these formulations for the treatment of asthma and other respiratory diseases.
- **Pursue development of ensifentrine in other forms of respiratory disease.** We believe that ensifentrine's properties as an inhaled, dual inhibitor of PDE3 and PDE4 give it broad potential applicability in the treatment of other respiratory diseases. We may explore development of ensifentrine to treat other forms of respiratory disease following development of ensifentrine for the treatment of COPD, CF and asthma.
- **Seek strategic collaborative relationships.** We may seek strategic collaborations with market-leading biopharmaceutical companies to develop and commercialize ensifentrine. We believe these collaborations could provide significant funding to advance the development of ensifentrine while allowing us to benefit from the development or commercialization expertise of our collaborators.
- **Acquire or in-license product candidates for the treatment of respiratory diseases.** We plan to leverage our respiratory disease expertise to identify and in-license or acquire additional clinical-stage product candidates that we believe have the potential to become novel treatments for respiratory diseases with significant unmet medical needs.

#### Ligand (formerly Vernalis) Agreement

In February 2005, Rhinopharma Limited, or Rhinopharma, entered into an assignment and license agreement with Vernalis Development Limited, or Vernalis (in October 2018, Vernalis was acquired by, and became a wholly owned subsidiary of, Ligand Pharmaceuticals, Inc., or Ligand). We refer to the assignment and license agreement as the Ligand Agreement. In 2006, we acquired Rhinopharma and all of its rights and obligations under the Ligand Agreement. Pursuant to the Ligand Agreement, Ligand has assigned to us all of its rights to certain patents and patent applications relating to ensifentrine and related compounds, or the Ligand Patents. We cannot further assign the Ligand Patents to a third party without Ligand's prior consent. Ligand also granted to us an exclusive, worldwide, royalty-bearing license under certain Ligand know-how to develop, manufacture and commercialize products, or the Licensed Products, based on PDE inhibitors developed using Ligand Patents, Ligand know-how and the physical stock of certain compounds, including ensifentrine, which we refer to as the Program IP, in the treatment of human or animal allergic or inflammatory disorders. Pursuant to the Ligand Agreement, we must maintain the Ligand Patents and use commercially reasonable and diligent efforts to develop and commercialize the Licensed Products.



Under the Ligand Agreement, we are obligated to pay Ligand a milestone payment of £5.0 million upon the first approval of any regulatory authority for the commercialization of any Licensed Product, and a portion equal to a percentage in the mid-twenties of any consideration received from any of our sublicensees for Ligand Patents or Ligand know-how, excluding royalties. We must also pay Ligand, on a Licensed Product-by-Licensed Product and country-by-country basis, a low to mid-single digit percentage royalty based on net sales of each Licensed Product for a period beginning with the first commercial sale of such Licensed Product in a country and ending on the later of the expiration of a certain number of years after such first commercial sale and if applicable the expiration of the last to expire valid claim in the Ligand Patents covering the development, manufacture or commercialization of such Licensed Product in such country. Prior to the first commercial sale of each Licensed Product, such royalties also are due in the same percentages for any named patient sales.

The Ligand Agreement continues until terminated by either party in accordance with its terms. Either party may terminate the Ligand Agreement for an uncured material breach, bankruptcy or insolvency of the other party. We may terminate the Ligand Agreement upon 90 days' prior written notice. Ligand may terminate the Ligand Agreement if we notify Ligand of our intention to abandon any Ligand Patents or allow any Ligand Patents to lapse. Upon termination of the Ligand Agreement, we must cease use of any Program IP and assign the Ligand Patents and any improvements thereto back to Ligand.

### **Manufacturing**

We have little experience in product candidate formulation or manufacturing, and no in-house manufacturing capability. We rely on, and expect to continue to rely, on third-party contract manufacturing organizations, or CMOs, for the supply of current good manufacturing practices, or cGMP, compliant clinical trial materials of ensifentrine and any future product candidates, as well as for commercial quantities of ensifentrine and any future product candidates, if approved. We currently do not have any agreements for the commercial production of ensifentrine. While we may contract with other CMOs in the future, we currently contract with only one pharmaceuticals CMO for the manufacture of ensifentrine drug substance. For ensifentrine drug product in our nebulized formulation, we currently have one CMO for the manufacture in glass vials and one CMO with which we are developing a presentation of the same nebulized formulation in plastic ampules. Similarly, we currently have one CMO for our DPI development and manufacturing program and one CMO for our pMDI development and manufacturing program. We believe that the ensifentrine manufacturing processes can be transferred to other CMOs for the production of clinical and commercial supplies of ensifentrine in the ordinary course of business.

Manufacturing of any product candidate is subject to extensive regulations that impose various procedural and documentation requirements governing record-keeping, manufacturing processes and controls, personnel, quality control, quality assurance, and quality by design among others. We require that all of our CMOs will manufacture ensifentrine in accordance with cGMP guidelines.

### **Commercialization, Sales and Marketing**

We believe ensifentrine, if successfully developed and approved, has the potential to address the unmet clinical need in a number of commercially attractive respiratory conditions and markets including the treatment of COPD in the maintenance and acute settings, asthma and CF. Based on market research, we believe that the key markets for ensifentrine, if approved, are the United States, European Union and China. Our commercial priority is to develop and launch ensifentrine for the U.S. COPD maintenance setting, initially delivered via a standard jet nebulizer.

Ensifentrine's clinical profile offers the potential to further reduce COPD symptoms and exacerbations when added on top of current therapies. US physicians, responding to Verona Pharma market research, reported a willingness to prescribe ensifentrine on top of current therapies including patients currently receiving maximum available dual bronchodilatory therapy (LAMA plus LABA, with or without ICS). We believe 2 million US COPD patients are currently treated with dual bronchodilatory therapy, and of these approximately 800,000 have uncontrolled disease and continue to experience debilitating symptoms of breathlessness and flare ups of disease called 'exacerbations', requiring hospitalization.

### **Competition**

Ensifentrine is a unique, first-in-class drug candidate with both bronchodilator and anti-inflammatory properties. No other dual PDE3 and PDE4 inhibitor is on the market nor in clinical development, as far as we can ascertain. Generically, we consider ensifentrine's current closest potential competitors in the nebulized maintenance treatment of COPD in the U.S. market to be long-acting beta2-agonist bronchodilators and long-acting anti-muscarinic bronchodilators. However, neither class of drug provides an anti-inflammatory effect. We consider ensifentrine's current closest potential competitors in the DPI/pMDI maintenance treatment of COPD to be Symbicort, a combination of a long-acting beta2-agonist bronchodilator and ICS marketed by AstraZeneca plc, Spiriva, a long-acting anti-muscarinic bronchodilator marketed by Boehringer Ingelheim GmbH, Advair, a combination of a long-acting beta2-agonist bronchodilator and ICS marketed by GlaxoSmithKline plc, or

GlaxoSmithKline, Utibron Neohaler, a combination of a long-acting beta2-agonist and long-acting anti-muscarinic bronchodilator marketed by Novartis International AG, Breo, a combination of a long-acting beta2-agonist bronchodilator and ICS marketed by GlaxoSmithKline, and Anoro, a combination of a long-acting beta2-agonist bronchodilator and long-acting anti-muscarinic bronchodilator marketed by GlaxoSmithKline. A triple-combination therapy of a LAMA, a LABA and ICS, developed by GlaxoSmithKline and Chiesi Farmaceutici S.p.A. has been approved in the United States and the European Union and AstraZeneca also has a triple-therapy combination product in development.

We compete directly with biotechnology and pharmaceutical companies that focus on the treatment of respiratory diseases. We 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 ensifentrine, that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Mergers and acquisitions in the pharmaceutical and biotechnology 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 and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The key competitive factors affecting the success of ensifentrine, if approved, are likely to be its 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.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe side effects than any products that we may develop. Our competitors may also obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if ensifentrine achieves marketing approval, it may be priced at a significant premium over competitive products or be priced at a level that makes it difficult for us to supply ensifentrine in a cost-efficient and profitable way.

### **Intellectual Property**

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 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.

As of February 11, 2019 our patent portfolio consisted of eight issued U.S. patents, five pending U.S. patent applications, twenty-nine issued foreign patents and fifty-four pending foreign applications including one patent application made under the Patent Cooperation Treaty. These patents and patent applications include claims directed to ensifentrine (RPL554) composition of matter, new dosage formulations and a crystalline polymorph, as well as methods of making and using ensifentrine in the treatment of respiratory diseases, with expected expiry dates between 2020 and 2039.

The patent portfolio relating to ensifentrine includes nine patent families:

- The first of these patent families relates to ensifentrine *per se*. As of February 11, 2019, this patent family includes granted patents in Australia, Brazil, Canada, China, Europe, Japan, Mexico as well as four granted patents in the United States. We expect patents in this family to expire in March 2020.
- The second of these patent families relates to a crystalline polymorph of ensifentrine. As of February 11, 2019, this patent family included granted patents in Australia, Canada, China, Europe, Indonesia, Israel, Japan, South Korea, Malaysia, Mexico, the Philippines, Russia, the United States and Taiwan and patent applications in Thailand and the Gulf Cooperation Council. We expect patents in this family to expire in August 2031.
- The third of these patent families relates to the combination of ensifentrine with a beta-adrenergic receptor agonist. As of February 11, 2019, this patent family included granted patents in Europe and

the United States and a patent application in Canada. We expect patents in this family to expire in March 2034.

- The fourth of these patent families relates to the combination of ensifentrine with a muscarinic receptor antagonist. As of February 11, 2019, this patent family included granted patents in Australia, Europe, Russia and the United States and patent applications in Canada, China, India, Japan, South Korea, Mexico, Thailand and the United States (continuation application). We expect patents in this family to expire in March 2034.
- The fifth of these patent families relates to certain specific salts of ensifentrine. As of February 11, 2019, this patent family included patent applications in Australia, Canada, China, Europe, Israel, Japan, Mexico, New Zealand, the United States and South Africa. We expect patents in this family to expire in February 2036.
- The sixth of these patent families relates to use of ensifentrine to treat certain diseases associated with the function of CFTR (including CF). As of February 11, 2019, this patent family included a granted patent in Europe and patent applications in Australia, Canada, Europe (divisional application), Israel, Mexico, Russia, the United States and South Africa. We expect patents in this family to expire in May 2035.
- The seventh of these patent families relates to an inhalable formulation of ensifentrine. As of February 11, 2019, this patent family included granted patents in Europe, Hong Kong, the United States, Singapore and South Africa and patent applications in Australia (parent and divisional applications), Brazil, Canada, China (parent and divisional applications), Europe (two divisional applications), Hong Kong (divisional application), Indonesia, Israel, India, Japan (parent and divisional applications), South Korea, Mexico, Malaysia, New Zealand, the Philippines, Russia, Thailand and the United States (continuation application). A notice of allowance has been received on the European divisional application. We expect patents in this family to expire in September 2035.
- The eighth of these patent families relates to a new intermediate for the manufacture of ensifentrine and to processes useful for the production of ensifentrine and related compounds. As of February 11, 2019, this patent family included a PCT application and patent applications in China, Europe, India, Japan, United States and Taiwan. We expect patents in this family to expire in July 2037.
- The ninth of these patent families relates to a formulation comprising ensifentrine for a pMDI. As of February 11, 2019, this patent family included a pending, unpublished patent application in the United Kingdom. We expect patents in this family to expire in October 2039.

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 U.S. Patent and Trademark Office, or 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 is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product by product basis, from country to country and depends upon 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.

Furthermore, we rely upon 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 drugs 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 future drugs 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 "Item 3.D. Risk Factors - Risks Related to Intellectual Property and Information Technology."

### **Government Regulation**

The FDA 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 drug 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 Federal Food, Drug, and Cosmetic Act, or FDCA, 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 NDAs, 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 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 good laboratory practice, or GLP, regulations;
- Submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- Approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug product for each indication;
- Submission to the FDA of an NDA;
- 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 current good manufacturing practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

#### ***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. 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 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 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, or NIH, for public dissemination on their [www.clinicaltrials.gov](http://www.clinicaltrials.gov) website.

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

- Phase 1: The drug 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 drug 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 drug 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 drug has been associated with unexpected serious harm to patients.

### **Special Protocol Assessment**

The special protocol assessment, or SPA, process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate issues related to the adequacy of certain clinical trials, including Phase 3 clinical trials that are intended to form the primary basis for a drug product's efficacy claim in an NDA. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis, within 45 days of receipt of the request.

The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the product candidate with respect to effectiveness of the indication studied. All agreements and disagreements between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA.

Even if the FDA agrees to the design, execution and analyses proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement under the following circumstances:

- Public health concerns emerge that were unrecognized at the time of the protocol assessment:
- The director of the review division determines that a substantial scientific issue essential to determining safety or efficacy has been identified after testing has begun;
- A sponsor fails to follow a protocol that was agreed upon with the FDA; or
- The relevant data, assumptions, or information provided by the sponsor in a request for SPA change, are found to be false statements or misstatements, or are found to omit relevant facts.

A documented SPA may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study.

## **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 requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug 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 risk evaluation and mitigation strategy, or REMS, plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, 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 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 NDA 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 NDA to determine, among other things, whether the drug is safe and effective 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 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 NDA, 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 NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA 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 drug 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 that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug'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 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 products under which NDA applicants must pay a substantial "program fee" for each prescription drug product approved in an NDA.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. 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, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs 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 NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- Product seizure or detention, or refusal to permit the import or export of products; or
- Injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs 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**

To the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, privacy 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 products in the EEA (which is comprised of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein) and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or 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 Products for Human Use of the European Medicines Agency, or EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of human medicinal products, such as medicines derived from biotechnology processes, advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products), orphan designated medicinal products, products that contain a new active substance indicated for the treatment of certain diseases such as HIV/AIDS, cancer,

neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. Under the centralized procedure the maximum timeframe for the evaluation of a Marketing Authorization Application, or MAA, by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use, or CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding clock stops; 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 products 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.

In the EEA, new products authorized for marketing, or reference products, 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.

In the EEA, marketing authorization applications for new medicinal products not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or 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 is 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 six months' supplementary protection certificate extension. For orphan-designated medicinal products, the 10-year period of market exclusivity is extended to 12 years.

We are also subject to privacy laws in the jurisdictions in which we are established or in which we sell or market our products or run clinical trials. For example, in Europe, we are subject to Regulation (EU) 2016/679 (General Data Protection Regulation, or GDPR) in relation to our collection, control, processing and other use of personal data (i.e. data relating to an identifiable living individual). We process personal data in relation to participants in our clinical trials in the EEA., including the health and medical information of these participants. The GDPR is directly applicable in each EU Member State, however, it provides that EU Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of personal data; defines for the first time pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. We are also subject to EU rules with



respect to cross-border transfers of personal data out of the EU and EEA. We are subject to the supervision of local data protection authorities in those EU jurisdictions where we are established or otherwise subject to the GDPR. Fines for certain breaches of the GDPR are significant: up to the greater of €20 million or 4% of total global annual turnover. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease/change our use of data, enforcement notices, as well potential civil claims including class action type litigation where individuals suffer harm.

#### **Other U.S. Healthcare Laws**

In addition to FDA restrictions on marketing of pharmaceutical and biological products, other U.S. federal and state healthcare regulatory laws restrict business practices in the pharmaceutical industry, which include, but are not limited to, state and federal anti-kickback, false claims, data privacy and security and physician payment and drug 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 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 its 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, 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 False Claims Act. 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.

The federal false claims and civil monetary penalties laws, including the civil False Claims Act, 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 claim includes "any request or demand" for money or property presented to the U.S. government. Actions under the civil False Claims Act 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 False Claims Act 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 products 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.

Violations of fraud and abuse laws, including federal and state anti-kickback and false claims 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 fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or 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 recent 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 covered 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 of up to an aggregate of \$165,786 per year and up to an aggregate of \$1.105 million per year for "knowing failures." Covered 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 the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations 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.

#### **Coverage and Reimbursement**

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological products 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 products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of any products 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 biological 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 products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products 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 biological 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 products 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 products to each payor separately and will be a time-consuming process.

In the EEA, governments influence the price of products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products 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 may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription products, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low-priced markets 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 products have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products 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 products. For example, in March 2010, the ACA was enacted, which, 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 drugs 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 drug 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; creation of the Independent Payment Advisory Board, once empaneled, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs; and establishment of a Center for Medicare Innovation at the 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. In addition, Congress could consider subsequent legislation to replace those elements of the ACA if so repealed. Further, on December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the entire ACA is invalid based primarily on the fact that the Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the ACA, on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate". While the Texas District Court Judge, as well as the current presidential administration and Centers for Medicare & Medicaid Services, have stated that this ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the law. The ultimate content, timing or effect of any healthcare reform legislation on the U.S. healthcare industry is unclear.

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 products. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Additionally, on August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions was enacted, which, among other things, included aggregate reductions of Medicare payments to providers of 2%

per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2027 unless additional action is taken by Congress. On January 2, 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. More recently, there has been heightened governmental scrutiny recently over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted legislation 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 products.

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 products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

#### **Employees**

As of December 31, 2018, we had 15 employees. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union.

#### **Facilities**

Our principal office is located at 3 More London Riverside, London, SE1 2RE, United Kingdom, where we lease office space under leases that terminate in early 2020. We also lease office space at 434 West 33rd Street, New York City, New York, under leases that terminate in 2019. We intend to add new facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

#### **Legal Proceedings**

We are not subject to any material legal proceedings.

#### **C. Organizational Structure.**

We have two wholly-owned subsidiaries, Verona Pharma Inc., which is incorporated in the United States in the State of Delaware, and Rhinopharma Ltd., which is incorporated in Canada.

#### **D. Property, Plants and Equipment.**

Our principal office is located at 3 More London Riverside, London SE1 2RE, United Kingdom, where we lease office space. We also lease office space in Manhattan, New York. The office space in these two locations is held under six leases that terminate between October 2019 and January 2020. We intend to add new facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

#### **Environmental Issues**

For information on environmental issues that may affect our utilization of our facilities, see Item 3.D. Risk Factors — Risks Related to Healthcare Laws and Other Legal Compliance Matters — *We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.*

#### **ITEM 4A: UNRESOLVED STAFF COMMENTS**

None.

## ITEM 5: OPERATING AND FINANCIAL REVIEW AND PROSPECTS

### A. OPERATING RESULTS

#### Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapeutics for the treatment of respiratory diseases with significant unmet medical need. Our product candidate, ensifentrine (RPL554) is an investigational, potential first-in-class, inhaled, dual inhibitor of the enzymes phosphodiesterase 3 and 4, or PDE3 and PDE4, that is designed to act as both a bronchodilator and an anti-inflammatory agent. We are not aware of any other product formulated in a single compound in clinical development or approved by the U.S. Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA, for the treatment of respiratory diseases as both a bronchodilator and anti-inflammatory agent. We believe ensifentrine has the potential to be the first novel class of bronchodilator in over 40 years. A nebulized formulation of ensifentrine is currently in Phase 2 clinical development for the treatment of COPD. Successful Phase 1 and 2 studies have been completed with nebulized ensifentrine in healthy volunteers and in patients with cystic fibrosis, or CF, chronic asthma and allergic rhinitis, in addition to COPD. A Phase 2 study in COPD with ensifentrine formulated in a dry powder inhaler is ongoing, and a Phase 2 study in COPD with ensifentrine formulated in a pressurized metered dose inhaler is planned to commence in 2019. We intend to first develop ensifentrine as a nebulized therapy for the treatment of COPD.

For the past 40 years, the treatment of COPD has been dominated by three classes of inhaled therapies approved for use by the FDA or EMA: antimuscarinic agents and beta2-agonists, both available as either short-acting or long-acting bronchodilators, and inhaled corticosteroids, or ICS, known for their anti-inflammatory effects. However, despite existing treatment with one or multiple combinations of these therapies, and owing to the progressive and incurable nature of COPD, many COPD patients on maximum inhaled therapy still experience significant lung function impairment and symptoms for which limited further approved treatment options are available. One such treatment is an oral formulation of a PDE4 inhibitor with anti-inflammatory properties, although frequency of adverse events has limited its use in COPD patients.

We have completed 13 Phase 1 and Phase 2 clinical trials with ensifentrine which have enrolled over 800 subjects with COPD, asthma, cystic fibrosis, or allergic rhinitis or healthy volunteers. In our clinical trials, treatment with ensifentrine has been repeatedly observed to result in statistically significant improvements in lung function as compared to placebo, whether dosed alone or in combination with commonly used short- and long-acting classes of bronchodilators, with or without ICS. Statistically significant means that there is a low statistical probability, typically less than 5%, that the observed results occurred by chance alone. In our Phase 2b clinical trial of nebulized ensifentrine as a maintenance treatment for COPD, patients with moderate-to-severe COPD treated with ensifentrine showed clinically meaningful and statistically significant improvements in daily reported COPD symptom scores. In addition, our clinical trials have also shown clinically meaningful and statistically significant additional improvements in certain measures of lung function following combined treatment with ensifentrine as add-on to other approved bronchodilators; COPD patients experienced a marked reduction in residual lung volume, which is believed to be related to one of the most debilitating symptoms, breathlessness. The rapid onset of action observed when adding ensifentrine on top of tiotropium, a commonly used LAMA, was also notable, and may be particularly helpful to those patients suffering from morning breathlessness. We believe that the clinical effects observed with ensifentrine are driven by its bronchodilator, anti-inflammatory and mucociliary clearance mechanisms.

Ensifentrine has been observed to be well tolerated in our clinical trials to date and has not been observed to result in the gastrointestinal or other side effects commonly associated with roflumilast (Daxas/Daliresp), the only PDE4 inhibitor currently on the market for the treatment of COPD.

We believe ensifentrine, having shown improvement in forced expiratory volume in one second, or FEV<sub>1</sub>, a measure of lung function, and symptoms (which commonly are a precursor to exacerbations) in clinical trials, may be an attractive additional treatment for COPD patients. In the United States, approximately three million COPD patients are treated with single bronchodilator (either a LAMA or LABA) therapy. In our clinical trials, ensifentrine has been observed to improve lung function, measured by FEV<sub>1</sub>, and residual volume, when used in addition to existing approved bronchodilators, and we believe it is well placed to potentially meet the need for a safe and effective dual bronchodilator/anti-inflammatory treatment regimen as an add-on to, for example, a LAMA. We are also developing nebulized ensifentrine for the treatment of patients with CF. We believe ensifentrine, if approved, has the potential to become a novel treatment option for these patients. We may also explore, alone or with a collaborator, the development of ensifentrine to treat asthma and other respiratory diseases.

In March 2018, earlier than expected, we reported data from our Phase 2b parallel group study in 403 patients with COPD in Europe to examine the effect in patients without concomitant bronchodilator therapy. The patients received either placebo or ensifentrine at doses ranging from 0.75 mg to 6 mg twice daily over 4 weeks .

Treatment with ensifentrine met the primary endpoint for all doses, showing a statistically significant increase in peak FEV<sub>1</sub> compared to placebo (p<0.001) with absolute changes from baseline >200 mL in peak FEV<sub>1</sub> after 4 weeks of dosing. In addition, statistically significant improvements in average FEV<sub>1</sub> over 12 hours were observed at all doses after the first administration, and this effect was sustained over 4 weeks. Notably, statistically significant and clinically meaningful improvements in total COPD symptoms (p<0.002) and dyspnea (p<0.02) were shown using the E-RS (EXACT-PRO) - a recognized patient-reported outcome measure for use in clinical studies of COPD, and the Transition Dyspnea Index. We believe that the progressive improvement in COPD symptoms over the 4 week treatment period, which was different from the immediate onset of the bronchodilator response, suggest the involvement of an anti-inflammatory effect.

In March 2018, we reported top-line data from a Phase 2a single-dose PK and pharmacodynamics, or PD, trial in the United Kingdom evaluating ensifentrine in ten CF patients. A PD trial involves the study of the biochemical and physiological effects of a drug and its mechanism of action. The PK profile was consistent with that observed in patients with COPD, although with lower peak serum levels of ensifentrine in CF patients. The serum half-life was dose dependent: 7.5 to 10.1 hours for 1.5 mg and 6 mg, respectively. Ensisentrine elicited a statistically significant increase in average FEV<sub>1</sub> in treated patients for 1.5 mg (all time points, p<0.01) and 6 mg (all time points p<0.05) at 4, 6 and 8 hour time points. Ensisentrine was observed to be well-tolerated in this patient group with an adverse event profile consistent with other studies with ensifentrine.

We do not have any approved products and, as a result, have not generated any revenue from product sales or otherwise. Ensisentrine is our only current product candidate and our ability to generate revenue sufficient to achieve profitability will depend on our successful development and eventual commercialization of ensifentrine, if approved, for one or more of its targeted indications. Since our inception, we have incurred significant operating losses. For the years ended December 31, 2017 and 2018 we incurred net losses of £20.5 million and £19.9 million, respectively. As of December 31, 2018, we had an accumulated loss of £69.1 million.

We expect to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of ensifentrine, and seek regulatory approval and pursue commercialization of ensifentrine, if approved. In addition, if we obtain regulatory approval for ensifentrine, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In addition, we may incur expenses in connection with the in-license or acquisition of additional product candidates and the potential clinical development of any such product candidates.

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, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. 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. We will need to generate significant revenue to achieve profitability, and we may never do so.

We were incorporated in February 2005 and are headquartered in the United Kingdom. Since September 2006, our ordinary shares have traded on AIM, a market of the London Stock Exchange, under the symbol "VRP". We have raised approximately £145 million in gross proceeds from investors since such listing, of which approximately £70.3 million was raised in our initial public offering of our American Depositary Shares, or ADSs, in April and May 2017, which are listed on The Nasdaq Global Market, or Nasdaq, under the symbol "VRNA," and the accompanying private offering in Europe of our ordinary shares, or the global offering, and a concurrent private placement to certain shareholders of our ordinary shares, or the shareholder private placement, and £45 million was raised in our July 2016 private placement of equity securities with a number of European and U.S.-based healthcare specialist investment firms, or the July 2016 Placement.

#### **License Agreement with Ligand (formerly Vernalis)**

In February 2005, Rhinopharma Limited, or Rhinopharma, entered into an assignment and license agreement with Vernalis Development Limited, or Vernalis (in October 2018, Vernalis was acquired by, and became a wholly owned subsidiary of, Ligand Pharmaceuticals, Inc., or Ligand). We refer to the assignment and license agreement as the Ligand Agreement. In 2006, we acquired Rhinopharma and all of its rights and obligations under the Ligand Agreement. Pursuant to the Ligand Agreement, Ligand has assigned to us all of its rights to certain patents and patent applications relating to ensifentrine and related compounds, or the Ligand Patents. We cannot further assign the Ligand Patents to a third party without Ligand's prior consent. Ligand also granted to us an exclusive, worldwide, royalty-bearing license under certain Ligand know-how to develop, manufacture and commercialize products, or the Licensed Products, based on PDE inhibitors developed using Ligand Patents, Ligand know-how and the physical stock of certain compounds, including ensifentrine, which we refer to as the Program IP, in the treatment of human or animal allergic or inflammatory disorders. Pursuant to the Ligand Agreement, we must maintain the Ligand Patents and use commercially reasonable and diligent efforts to develop and commercialize the Licensed Products.

Under the Ligand Agreement, we are obligated to pay Ligand a milestone payment of £5.0 million upon the first approval of any regulatory authority for the commercialization of any Licensed Product, and a portion equal to a percentage in the mid-twenties of any consideration received from any of our sublicensees for Ligand Patents or Ligand know-how, excluding royalties. We must also pay Ligand, on a Licensed Product-by-Licensed Product and country-by-country basis, a low to mid-single digit percentage royalty based on net sales of each Licensed Product for a period beginning with the first commercial sale of such Licensed Product in a country and ending on the later of the expiration of a certain number of years after such first commercial sale and if applicable the expiration of the last to expire valid claim in the Ligand Patents covering the development, manufacture or commercialization of such Licensed Product in such country. Prior to the first commercial sale of each Licensed Product, such royalties also are due in the same percentages for any named patient sales. See "Business — Vernalis Agreement" for further information regarding this agreement.

We have recorded a liability in our statement of financial position reflecting the contingent obligation we assumed from Rhinopharma to make payments to Ligand under the Ligand Agreement. Cost relating to the unwinding of the discount rate of the carrying value of this assumed contingent obligation in any reporting period is recorded as finance expense or finance income in our statement of comprehensive income. See "— Financial Operations Overview — Finance Income and Expense" and Note 2.12 of our Annual Consolidated Financial Statements.

## **Financial Operations Overview**

### **Revenue**

We do not have any approved products. Accordingly, we have not generated any revenue, and we do not expect to generate any revenue from the sale of any products unless or until we obtain regulatory approvals of and commercialize ensifentrine or any other product candidate we may develop in the future, which may never occur.

### **Research and Development Costs**

Research and development costs include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel expense, for our research and development personnel;
- costs for production of drug substance by contract manufacturing organizations;
- fees and other costs paid to contract research organizations and consultants to conduct our clinical trials and pre-clinical and non-clinical studies;
- costs of related facilities, materials and equipment;
- costs associated with obtaining and maintaining patents and other intellectual property; and
- amortization and depreciation of intangible and tangible fixed assets used to develop ensifentrine.

Research and development activities will continue to be central to our business model. Product candidates in later stages of clinical development, such as ensifentrine for the maintenance treatment of COPD, 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. We expect our research and development costs to be significant over the next several years as we hire additional research and development personnel and increase compensation costs, advance the clinical development of ensifentrine, develop new formulations of ensifentrine for the treatment of COPD, continue the clinical development of ensifentrine for the treatment of CF and asthma and potentially pursue the development of ensifentrine for other forms of respiratory disease.

The successful development and commercialization of ensifentrine 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, ensifentrine or any future product candidates. This is due to numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our research and development activities;
- the progress and results of clinical trials and pre-clinical and non-clinical studies;
- the terms and timing of regulatory approvals;
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- the ability to market, commercialize and achieve market acceptance for ensifentrine or any other future product candidate, if approved.

Any of these variables with respect to the development of ensifentrine or any other future product candidate that we may develop could result in a significant change in the costs and timing associated with the development of ensifentrine or such future product candidate. For example, if the FDA, the EMA or other regulatory authority were to require us to conduct pre-clinical studies and clinical trials beyond those 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.

#### **General and Administrative Costs**

Our general and administrative costs 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 requirements of being a listed public company on AIM and Nasdaq. 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 expected 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. Additionally, we anticipate continued 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 ensifentrine obtains regulatory approval for marketing, we expect that we will incur expenses associated with building a sales and marketing team. In addition, we expect to continue to grant share-based compensation awards to key management personnel and other employees.

#### **Finance Income and Expense**

Finance income consists of interest earned on our cash and cash equivalents and any decrease in the fair value of the derivative financial liability related to the 31,115,926 units issued by us to new and existing institutional and other investors in the July 2016 Placement.

Finance expense consists of any increase in the carrying value resulting from the unwinding of the discount factor related to the assumed contingent arrangement under the Ligand Agreement and any increase in the fair value of the derivative financial liability related to the July 2016 Placement.

#### **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 inception. As a company that carries out extensive research and development activities, we benefit from the U.K. research and development 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 research and development expenditure. Qualifying expenditures largely comprise employment costs for research staff, consumables and certain internal overhead costs incurred as part of research projects. In the event we generate revenues in the future, we may benefit from the "patent box" initiative that allows profits attributable to revenues from patents or patented products to be taxed at a lower rate than other revenue of 10%.

#### **Critical Accounting Judgments and Estimates**

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with IFRS as issued by the IASB. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in the notes to our financial statements appearing elsewhere in this Annual Report. We believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

#### **Assumed Contingent Obligation**

A significant management estimate relates to the probability, amount and timing of any payment relating to the assumed contingent obligation under the Ligand Agreement, a provision for which is recorded in our statement of financial position. See "- License Agreement with Ligand," "Item 4.B. Business Overview - Ligand Agreement" and Note 18 to our Annual Consolidated Financial Statements included elsewhere in this Annual Report. A change in the probability and timing of any payment relating to the assumed contingent obligation could result in a significant fluctuation in our financial results in future periods.



### **Valuation of Derivative Financial Liability**

In connection with the July 2016 Placement, we issued 31,115,926 warrants to new and existing institutional and other investors. Each warrant is entitled to purchase 0.4 of an ordinary share at a price of £1.7238. Each warrant became exercisable upon the closing of the global offering and will expire on the fifth anniversary of the closing of the global offering.

We classify these warrants as a derivative financial liability to be presented on our consolidated statement of financial position. The fair value of these warrants is determined by applying the Black-Scholes model. Assumptions are made on inputs such as time to maturity, the share price, volatility and risk free rate, in order to determine the fair value per warrant. For valuation purposes at recognition of the liability, we used the closing share price of our ordinary shares as reported on AIM on July 29, 2016, the date of issuance of the warrants.

At the date of issuance of the warrants we calculated a fair value and recorded a derivative financial liability, which on initial recognition was offset against the share premium in relation to the funds received in connection with the July 2016 Placement. Subsequent updates to the fair value of the derivative financial liability will not result in changes to share premium, but will result in an adjusting entry in the consolidated derivative financial liability statement of comprehensive income. We will continue to adjust the derivative financial liability until the earlier of the exercise of the warrants or expiration of the warrants occurs.

### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

### **Recent Accounting Pronouncements**

We refer to Note 2.18 to our Annual Consolidated Financial Statements for the year ended December 31, 2018 included elsewhere in this Annual Report for a discussion of new standards and interpretations not yet adopted by us.

### **JOBS Act**

Section 107(b) of the Jumpstart Our Business Startups Act of 2012 provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can 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 extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

### **Internal Control Over Financial Reporting**

In connection with the preparation for our listing on Nasdaq, we reassessed our critical accounting policies to ensure compliance with IFRS. As part of this reassessment, we identified errors relating to the recognition of assumed liabilities and goodwill in connection with the acquisition of Rhinopharma in September 2006.

We concluded that a lack of adequate controls surrounding our historical accounting for business combinations constituted a material weakness in our internal control over financial reporting, as defined in the standards established by the U.S. Public Accounting Oversight Board, or the PCAOB. The PCAOB defines a material weakness as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected in a timely basis. We remediated this material weakness by the hiring of our chief financial officer in September 2016 and enhancing our financial reporting team. We also instituted a program of controls over financial reporting that will ensure we manage our financial reporting in accordance with good business practice and Sarbanes-Oxley legislation. However, we cannot be certain that these efforts will prevent future material weaknesses or significant deficiencies from occurring.

## Results of Operations

### Comparison of Operations for the Years ended December 31, 2018 and 2017

The following table sets forth our results of operations for the periods indicated. For the convenience of the reader, we have translated pound sterling amounts as of December 31, 2018 at the noon buying rate of the Federal Reserve Bank of New York on December 31, 2018, which was £1.00 to \$1.2763. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars at that or any other exchange rate as of that or any other date.

	Year Ended December 31,		
	2017	2018	
	£000's	£000's	\$000's
Research and development costs	£ (23,717)	£ (19,294)	\$ (24,625)
General and administrative costs	(6,039)	(6,297)	(8,037)
Operating loss	(29,756)	(25,591)	(32,662)
Finance income	7,018	2,783	3,552
Finance expense	(2,465)	(1,325)	(1,691)
Loss before taxation	(25,203)	(24,133)	(30,801)
Taxation — credit	4,706	4,232	5,401
Loss for the year	(20,497)	(19,901)	(25,400)
Other comprehensive (loss) / income			
Exchange differences on translating foreign operations	(29)	38	48
Total comprehensive loss attributable to owners of the company	£ (20,526)	£ (19,863)	\$ (25,352)

### **Comparison of Operations for the Years ended December 31, 2018 and 2017**

The operating loss for the year ended December 31, 2018 was £25.6 million (2017: £29.8 million) and the loss after tax for the year ended December 31, 2018 was £19.9 million (2017: £20.5 million).

#### *Research and Development Costs*

Research and development costs were £19.3 million for the year ended December 31, 2018 as compared to £23.7 million for the year ended December 31, 2017, a decrease of £4.4 million. The cost of clinical trials reduced by £5.9 million as there were four active trials in the year ended December 31, 2017, including a four week Phase 2b trial for COPD maintenance treatment, compared to two clinical trials in the year ended December 31, 2018. Pre-clinical costs also reduced by £0.4 million. These reductions were offset by a £2.0 million increase in contract manufacturing and formulation development costs. Personnel related costs increased by £0.1 million in the year ended December 31, 2018, compared to the prior year.

#### *General and Administrative Costs*

General and administrative costs were £6.3 million for the year ended December 31, 2018 as compared to £6.0 million for the year ended December 31, 2017, an increase of £0.3 million. The increase was primarily attributable to a £0.3 million increase in the non-cash share-based payment charge, a £0.2 million increase in personnel related costs and a £0.4 million increase in other overhead costs. This was offset by a £0.6 million decrease in commercial research costs and a decrease in professional fees related to the global offering and shareholder private placement, which occurred in 2017.

#### *Finance Income and Expense*

Finance income was £2.8 million for the year ended December 31, 2018 and £7.0 million for the year ended December 31, 2017. The decrease was primarily due to an increase in the fair value of the warrant liability in the year ended December 31, 2018 (which is a non-cash item, recorded as a finance expense) compared to a decrease in the liability in the year ended December 31, 2017, which resulted in a non-cash gain (recorded as finance income) of £6.7 million in 2017. There was a foreign exchange gain on cash and short term investments of £1.9 million in the year ended December 31, 2018, and a loss in the prior year (recorded in finance expense). Furthermore, £0.9 million of interest was received in the year ended December 31, 2018 (2017: £0.3 million).

Finance expense was £1.3 million for the year ended December 31, 2018 as compared to £2.5 million for the year ended December 31, 2017. The movement was due to an increase in the fair value of the warrant liability of £1.2 million, recorded in finance expense, compared to a reduction in the value of the liability in 2017 (recorded in finance income), both non-cash items. In addition, there was a foreign exchange loss on cash and short-term investments in 2017 of £2.4 million. In the year ended December 31, 2018, there was a foreign exchange gain (recorded in finance income).

As at December 31, 2018, there was approximately £19.8 million in cash and cash equivalents (2017: £31.4 million) and £44.9 million in short-term investments (2017: £48.8 million).

#### *Taxation*

Taxation for the year ended December 31, 2018 amounted to a credit of £4.2 million as compared to a credit of £4.7 million for the year ended December 31, 2017, a decrease in the credit amount of £0.5 million. The credits are obtained at a rate of 14.5% of 230% of our qualifying research and development expenditure, and the decrease in the credit amount was primarily attributable to our reduced expenditure on research and development.

### Comparison of Operations for the Years ended December 31, 2017 and 2016

The following table sets forth our results of operations for the periods indicated.

	Year Ended December 31,	
	2017	2016
	£000's	£000's
Research and development costs	(23,717)	(4,522)
General and administrative costs	(6,039)	(2,498)
Operating loss	(29,756)	(7,020)
Finance income	7,018	1,841
Finance expense	(2,465)	(794)
Loss before taxation	(25,203)	(5,973)
Taxation — credit	4,706	954
Loss for the year	(20,497)	(5,019)
Other comprehensive (loss) / income:		
Exchange differences on translating foreign operations	(29)	43
Total comprehensive loss attributable to owners of the company	(20,526)	(4,976)

### Comparison of Operations for the Years ended December 31, 2017 and 2016

The operating loss for the year ended December 31, 2017 was £29.8 million (2016: £7.0 million) and the loss after tax for the year ended December 31, 2017 was £20.5 million (2016: £5.0 million).

#### Research and Development Costs

Research and development costs were £23.7 million for the year ended December 31, 2017 as compared to £4.5 million for the year ended December 31, 2016, an increase of £19.2 million. The increase was attributable to a £12.3 million increase in clinical trial expenses related to the initiation of four, and completion of two, Phase 2 clinical trials of ensifentrine. In addition, spending on contract manufacturing and other formulation work increased by £2.7 million and toxicology and other pre-clinical development by £1.2 million. Salary costs increased by £0.3 million and share-based payment charge by £1.2 million as we expanded our team and initiated a new long term incentive plan to drive development of ensifentrine. Furthermore, expenses for third-party consultants increased by £0.8 million and patent and other costs by £0.3 million.

#### General and Administrative Costs

General and administrative costs were £6.0 million for the year ended December 31, 2017 as compared to £2.5 million for the year ended December 31, 2016, an increase of £3.5 million. The increase was attributable to £0.8 million increase in our salary costs and a £1.1 million increase in share-based payment charge as we built the team to support our activities. There was an increase of £1.3 million of costs in preparation for and relating to the global offering, as well as ongoing compliance and other costs due to listing our ADSs on Nasdaq. We also incurred costs of £0.4 million developing our commercial strategy for ensifentrine.

#### Finance Income and Expense

Finance income was £7.0 million for the year ended December 31, 2017 and £1.8 million for the year ended December 31, 2016. The increase in finance income was primarily due to a decrease in the fair value of the warrant liability of £6.6 million caused by changes in the underlying assumptions for measuring the liability of the warrants issued in the July 2016 Placement, including the price and volatility of our ordinary shares and the unwinding of the expected life of the warrants.

Finance expense was £2.5 million for the year ended December 31, 2017 as compared to £0.8 million for the year ended December 31, 2016. The increase was primarily due to the foreign exchange loss on translation of foreign currency denominated cash and cash equivalents and short-term investments.

As of December 31, 2017, there was approximately £31.4 million in cash and cash equivalents (2016: £39.8 million) and £48.8 million in short-term investments (2016: £nil).

#### Taxation

Taxation for the year ended December 31, 2017 amounted to a credit of £4.7 million as compared to a credit of £1.0 million for the year ended December 31, 2016, an increase in the credit amount of £3.7 million. The credits are obtained at a rate of 14.5% of 230% of our qualifying research and development expenditure, and the

increase in the credit amount was primarily attributable to our increased expenditure on research and development.

## B. Liquidity and Capital Resources

### Overview

Since our inception, we have incurred significant operating losses. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative costs will increase in connection with conducting clinical trials for ensifentrine and seeking marketing approval for ensifentrine in the United States and Europe as well as other jurisdictions. As a result, we will need additional capital to fund our operations, which we may obtain from additional financings, research funding, collaborations, contract and grant revenue or other sources.

We do not currently have any approved products and have never generated any revenue from product sales or otherwise. To date, we have financed our operations primarily through the issuances of our equity securities, including warrants. Since our inception, we raised gross proceeds of approximately £145 million from sales of equity securities, of which approximately £70.3 million was raised in April and May 2017 in the global offering and shareholder private placement and £45 million was raised in the July 2016 Placement. As of December 31, 2018, we had cash and cash equivalents of £19.8 million and short-term investments (representing bank deposits with maturities of greater than three months at inception) of £44.9 million.

We have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than leases.

### Cash Flows

The table below summarizes our cash flows for each of the periods presented. For the convenience of the reader, we have translated pound sterling amounts as of December 31, 2018 at the noon buying rate of the Federal Reserve Bank of New York on December 31, 2018, which was £1.00 to \$1.2763. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars at that or any other exchange rate as of that or any other date.

	Year Ended December 31,					
	2017		2018			
		£000's		£000's		\$000's
Net cash used in operating activities	£	(20,696)	£	(18,111)	\$	(23,115)
Net cash (used in) / generated from investing activities		(49,469)		5,281		6,740
Net cash from financing activities		63,246		—		—
Net decrease in cash and cash equivalents	£	(6,919)	£	(12,830)	\$	(16,375)

The decrease in net cash used in operating activities to £18.1 million for the year ended December 31, 2018 from £20.7 million for the year ended December 31, 2017 was due to a decrease in operating activities of £4.2 million and an increase in net tax inflow of £3.8 million relating principally to cash received from UK research and development tax credits. Offsetting this was a £5.4 million movement in timing of supplier payments.

Net cash (used in) / generated from investing activities predominantly reflects the net movement of cash being placed on deposit for more than three months and such deposits maturing, because deposits of more than three months are disclosed as short-term investments, separately from cash. Net cash generated from investing activities was £5.3 million for the year ended December 31, 2018, compared to net cash used in investing activities of £49.5 million for the year ended December 31, 2017. This reflects the placement of a significant proportion of the proceeds from the global offering on deposit as short-term investments in 2017. In 2018, there was a net decrease in short-term deposits of three months or more reflecting a higher value of short-term deposits maturing, and being transferred to cash, than being placed. We balance the objective of obtaining higher interest income from longer-term deposits with short-term liquidity requirements.

There was no net cash received from financing activities for the year ended December 31, 2018. The £63.2 million received for the year ended December 31, 2017 was the cash raised from the global offering and shareholder private placement.

## **Operating and Capital Expenditure Requirements**

As of December 31, 2018, we had an accumulated loss of £69.1 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of ensifentrine and any future product candidate we develop.

We anticipate that our expenses will increase substantially if and as we:

- initiate and conduct any clinical trials for ensifentrine for the maintenance treatment of COPD and as a treatment for acute COPD;
- continue the clinical development of our DPI and pMDI formulations of ensifentrine and research and develop other formulations of ensifentrine;
- initiate and conduct clinical trials for ensifentrine for the treatment of CF or any other indication;
- initiate and progress pre-clinical studies relating to other potential indications of ensifentrine;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our continuing operations as a UK and U.S. public company; and
- 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, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements through the end of our Phase 2 development of nebulized ensifentrine for the maintenance treatment of COPD, as well as preparatory activities to enable us to undertake Phase 3 development in this indication, pending regulatory review. We have based this estimate 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 ensifentrine and any future product candidates and because the extent to which we may enter into collaborations with third parties for development of ensifentrine is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of ensifentrine. Our future capital requirements for ensifentrine or any future product candidates will depend on many factors, including:

- the progress, timing and completion of pre-clinical testing and clinical trials for ensifentrine or any future product candidates and the potential that we may be required to conduct additional clinical trials for ensifentrine;
- the number of potential new product candidates we decide to in-license and develop;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of ensifentrine or any future product candidates;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties;
- the time and costs involved in obtaining regulatory approvals for ensifentrine or any future product candidate we develop and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to ensifentrine or any future product candidates;
- any licensing or milestone fees we might have to pay during future development of ensifentrine or any future product candidates;
- selling and marketing activities undertaken in connection with the anticipated commercialization of ensifentrine or any future product candidates, if approved, and costs involved in the creation of an effective sales and marketing organization; and

- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of ensifentrine or any future product candidates, if approved.

Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, 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, the ownership interest of our shareholders and ADS holders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect such holders' rights as a shareholder or ADS holder. 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 our securityholders' 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.

### C. Research and Development, Patent and Licenses, etc.

For a discussion of our research and development activities, including amounts spent on company-sponsored research and development activities for the last three financial years, see Item 4.B. Business Overview and Item 5.A. Operating Results.

### D. Trend Information

Other than as disclosed elsewhere in this Annual Report, we are not aware of any trends, uncertainties, demands, commitments or events that are reasonably likely to have a material adverse effect on our net revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause the disclosed financial information to be not necessarily indicative of future operating results or financial conditions. For more information, see Item 4.B. Business Overview, Item 5.A. Operating Results, and Item 5.B. Liquidity and Capital Resources.

### E. Off-Balance Sheet Arrangements

During the periods presented, we did not, and we do not currently, have any off-balance sheet arrangements.

### F. Contractual Obligations and Commitments

The table below summarizes our contractual obligations at December 31, 2018.

	Payments Due by Period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
	(€000's)				
Operating lease obligations	600	572	28	—	—
Total	600	572	28	—	—

The table above does not include assumed contingent obligation payments we may be required to make under the Ligand Agreement because the amount, timing and likelihood of payment are not known. Such additional payment obligations may be material. See sections titled "— License Agreement with Ligand" and "Business — Ligand Agreement."

In addition, we enter into contracts in the ordinary course of business with contract research organizations ("CROs") to assist in the performance of our 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.

## ITEM 6: DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

### A. Executive Officers and Directors

The following table presents information about our executive officers, directors, and other key members of management, including their ages as of the date of this Annual Report:

Name	Age	Position
<b>Executive Officers</b>		
Jan-Anders Karlsson, Ph.D.	64	Chief Executive Officer and Director
Piers Morgan	52	Chief Financial Officer
Claire Poll	51	General Counsel
Kathleen Rickard, M.D.	60	Chief Medical Officer
<b>Other Key Management</b>		
Richard Hennings	49	Commercial Director
Desiree Luthman	59	Vice President, Regulatory Affairs
Tara Rheault	43	Vice President, R&D Operations and Global Project Management
Peter Spargo	57	Senior Vice President, Chemistry Manufacturing and Controls
<b>Non-Executive Directors</b>		
Ken Cunningham, M.D. <sup>(2)</sup>	66	Non-executive Director
David Ebsworth, Ph.D. <sup>(1,2,3)</sup>	64	Chairman of the Board
Rishi Gupta <sup>(2)</sup>	41	Non-executive Director
Mahendra Shah, Ph.D. <sup>(3)</sup>	74	Non-executive Director
Andrew Sinclair, Ph.D. <sup>(1)</sup>	47	Non-executive Director
Vikas Sinha <sup>(1)</sup>	55	Non-executive Director
Anders Ullman, Ph.D. <sup>(3)</sup>	63	Non-executive Director

(1) Audit and Risk Committee member

(2) Remuneration Committee member

(3) Governance Committee member

The following are brief biographies of our executive officers and directors:

**Jan-Anders Karlsson, Ph.D.** Dr. Karlsson has served as our Chief Executive Officer and on our board of directors since June 2012. Dr. Karlsson has over 30 years of experience in leadership experience in the pharmaceutical industry, with successes in drug discovery and development in both large pharmaceutical and biotech companies where he built entrepreneurial drug discovery and development cultures. Prior to joining Verona Pharma, Dr. Karlsson was the Chief Executive Officer of S\*BIO Pte Ltd, a biotechnology company in Singapore. Prior to S\*BIO, Dr. Karlsson was Executive Vice President and head of Pharma Global Research at Bayer HealthCare AG in Germany. Dr. Karlsson received an M.Sc. in pharmacy from Uppsala University and a Doctor of Medical Science (Ph.D.) in clinical experimental pharmacology from the University of Lund.

**Piers Morgan.** Mr. Morgan has served as our Chief Financial Officer since September 2016. From November 2015 to September 2016, Mr. Morgan was an independent consultant. From May 2014 to November 2015, Mr. Morgan was the Chief Executive Officer of C4X Discovery plc, a biotechnology company. Prior to C4X, Mr. Morgan co-founded uniQure N.V., a biotechnology company, in Amsterdam, where he served as Chief Financial Officer from December 2009 to May 2014. Mr. Morgan is a member of the Institute of Chartered Accountants in England and Wales and received an M.A. in law and management studies from the University of Cambridge.

**Kathleen Rickard, M.D.** Dr. Rickard has served as our Chief Medical Officer since February 2019. Prior to joining Verona Pharma, Dr. Rickard served in multiple roles, most recently at Aerocrine AB, a medical diagnostics product company, where she directed clinical and regulatory strategies. Prior to Aerocrine, Dr. Rickard was Vice President Clinical Development and Medical Affairs of GlaxoSmithKline's Respiratory Medicines Development Centre and, over a period of 15 years, held a number of other leadership positions in clinical development across GlaxoSmithKline's global respiratory franchise. Dr. Rickard received an M.D. from Hahnemann University Hospital, Philadelphia.



**Claire Poll.** Ms. Poll has served as General Counsel since September 2016. From September 2015 to August 2016, Ms. Poll served as an advisor to us on legal, general corporate and financing matters. She also served as an Executive Director on our board of directors from September 2006 until September 2015. Ms. Poll received a Bachelor of Laws from the University of Western Australia and a Diploma in Applied Finance and Investment from the Securities Institute of Australia.

**David Ebsworth, Ph.D.** Dr. Ebsworth has served as the Non-Executive Chairman of our board of directors since December 2014. From October 2009 to August 2014, Dr. Ebsworth served as Chief Executive Officer of Vifor Pharma, based in Zürich, the specialty pharma division of Galenica AG Group, a pharmaceutical wholesaler and retailer, and as a member of Galenica's Executive Committee. In 2012, Dr. Ebsworth was also named as Chief Executive Officer of Galenica and as Chairman of Galenica's Executive Committee, positions he held until August 2014. In his earlier career, Dr. Ebsworth worked with Bayer AG for over 19 years, heading the Canadian, North American and global pharmaceutical business. He also served as Chief Executive Officer of Oxford Glycosciences, a biotech company, listed on the London Stock Exchange and Nasdaq, which was acquired by Celltech plc (now part of UCB) in 2003. Dr. Ebsworth received a Ph.D. in industrial relations from the University of Surrey.

**Ken Cunningham, M.D.** Dr. Cunningham has served as a Non-Executive Director on our board of directors since September 2015. Dr. Cunningham has over 25 years' experience in the pharmaceutical industry including leadership roles at several companies focused on developing respiratory medicines. Between 2008 and 2010, he was at SkyePharma plc (now part of Vectura Group plc), initially as Chief Operating Officer and subsequently as Chief Executive Officer where he was involved in the late-stage development of flutiform for asthma. Earlier in his career, Dr. Cunningham held a variety of clinical development and commercial strategy roles at GlaxoWellcome plc and Warner-Lambert. Dr. Cunningham serves as the non-executive chairman of the board of directors of Abzena plc and of Medherant Ltd. Dr. Cunningham received a degree in medicine from St. Mary's, Imperial College, London University.

**Rishi Gupta.** Mr. Gupta has served as a Non-Executive Director on our board of directors since July 2016. Mr. Gupta was designated for appointment to our board of directors by OrbiMed Private Investments VI, LP, or OrbiMed, pursuant to our relationship agreement with OrbiMed. Since 2002, Mr. Gupta has held various positions at OrbiMed Advisors LLC, a global healthcare investment firm, where he is currently a Partner. Prior to that, he was a healthcare investment banker at Raymond James & Associates, served as manager of corporate development at Veritas Medicine and was a summer associate at Wachtell, Lipton. Mr. Gupta currently is a member of the board of directors of Avitide, Inc., Turnstone Biologics, Inc., Modis Therapeutics, Inc. and Attenua, Inc. Mr. Gupta received an A.B. in biochemical sciences from Harvard College and a J.D. from Yale Law School.

**Mahendra Shah, Ph.D.** Dr. Shah has served as a Non-Executive Director on our board of directors since July 2016. Dr. Shah was designated for appointment to our board of directors by funds affiliated with Vivo Capital pursuant to our relationship agreement with such funds. Dr. Shah is a successful pharmaceutical entrepreneur and executive and, since March 2010, has served as a Managing Director of Vivo Capital, a healthcare investment firm. He is also the founder and Executive Chair of Semnur Pharmaceuticals, Inc., a specialty pharmaceutical company. Dr. Shah serves as a member of the board of directors of Fortis Inc., Homology Medicines, Inc., Soleno Therapeutics, Inc., and several private companies in the biopharmaceutical and biotechnology industries. Dr. Shah received his Ph.D. in industrial pharmacy from St. John's University and a Master's Degree in Pharmacy from L.M. College of Pharmacy in Gujarat, India.

**Andrew Sinclair, Ph.D.** Dr. Sinclair has served as a Non-Executive Director on our board of directors since July 2016. Dr. Sinclair was designated for appointment to our board of directors by Abingworth Bioventures VI, LP, or Abingworth, pursuant to our relationship agreement with Abingworth. Since 2008, Dr. Sinclair has held various positions at Abingworth LLP, a life sciences investment group, where he is currently a Partner and Portfolio Manager. Dr. Sinclair is a member of the Institute of Chartered Accountants in England and Wales and received a Ph.D. in chemistry and genetic engineering at the BBSRC Institute of Plant Science, Norwich, and a B.Sc. in microbiology from King's College London.

**Vikas Sinha.** Mr. Sinha has served as a Non-Executive Director on our board of directors since September 2016. Mr. Sinha has over 20 years' experience working in executive finance roles in the life sciences industry. Since January 2018, Mr. Sinha has served as an Executive Partner of MPM Capital, Inc., a life sciences investment company. From 2005 to 2016, Mr. Sinha was the Chief Financial Officer of Alexion Pharmaceuticals, Inc., a biotechnology company, where he was responsible for finance, business development, strategy, investor relations and IT. Prior to joining Alexion, Mr. Sinha held various positions with Bayer AG in the United States, Japan, Germany and Canada, including Vice President and Chief Financial Officer of Bayer Pharmaceuticals Corporation in the United States and Vice President and Chief Financial Officer of Bayer Yakuin Ltd. in Japan. Mr. Sinha holds a master's degree in business administration from the Asian Institute of Management. He is also

a qualified Chartered Accountant from the Institute of Chartered Accountants of India and a Certified Public Accountant in the United States.

**Anders Ullman, M.D., Ph.D.** Dr. Ullman has served as a Non-Executive Director on our board of directors since September 2015. From 2016 to 2018, Dr. Ullman served as Head of the COPD Centre at Sahlgrenska University Hospital, Sweden. From 2013 to 2014, he was Executive Vice President and Head of Research and Development in the BioScience business unit of Baxter International Inc., a healthcare company, which became Baxalta Inc. From 2007 to 2013, Dr. Ullman was Executive Vice President, Head of Research and Development at Nycomed Pharma Private Limited (now part of Takeda Pharmaceuticals Company Limited), where he led the development and approval of Daxas, the PDE4 inhibitor used to prevent COPD exacerbations. Earlier in his career, he held a number of roles in AstraZeneca. Dr. Ullman serves on the board of directors of Pexa AB. Dr. Ullman received a M.D. and a Ph.D. in clinical pharmacology from the University of Gothenburg.

#### **Other Senior Management**

The following are brief biographies of other members of the senior management team that participate in leading ensifentrine's development.

**Richard Hennings.** Mr. Hennings has served as our Commercial Director since March 2017. From May 2016 to March 2017, Mr. Hennings was the Global Marketing Director for AstraZeneca UK Limited, a biopharmaceutical company. Since July 2015, Mr. Hennings has been a director of Hennings Consulting Ltd., where he consults with healthcare organizations on commercial strategy. From January 2012 to June 2015, Mr. Hennings held various positions at Gilead Sciences, Inc., a biopharmaceutical company, most recently as Commercial Director — EMEA Planning & Operations. Mr. Hennings received a bachelor's degree in applied chemistry from the University of Portsmouth.

**Desiree Luthman, DDS.** Dr. Luthman has served as our Vice President, Regulatory Affairs since June 2017. From 2015 to 2017, Dr. Luthman served as Senior Regulatory Director, Global Inflammation — Immunoncology Therapeutic Area at Sanofi S.A., a multinational pharmaceutical company. From 2013 to 2015, Dr. Luthman was a Director, Global Regulatory Strategy and Science at Bristol, Meyers & Squibb Company, a pharmaceutical company. Dr. Luthman received a doctorate in dentistry from the Karolinska Institute, Stockholm, Sweden.

**Tara Rheault, Ph.D.** Dr. Rheault has served as our Vice President, R&D and Global Project Management since January 2019. From August 2015 to January 2019, Dr. Rheault served as Senior Director, Strategic Drug Development at IQVIA, a multinational company serving the combined industries of health information technologies and clinical research, where she helped pharmaceutical companies develop integrated commercial and R&D strategies. Prior to IQVIA, from September 2002 to August 2015, Dr. Rheault served in various roles at GlaxoSmithKline, most recently as Clinical Leader within the respiratory therapy area. Dr. Rheault received a Ph.D. in organic chemistry from North Dakota State University and a Master in Public Health from the University of North Carolina.

**Peter Spargo, Ph.D.** Dr. Spargo has served as our Senior Vice President, Chemistry Manufacturing and Controls since May 2014. From January to October 2015, Dr. Spargo served as Senior Vice President, CMC at Spinifex Pharmaceuticals Inc., a biotechnology company, that was acquired by Novartis International AG. From 2011 to 2013, Dr. Spargo was Senior Vice President, CMC at Creabilis SA, a pharmaceutical company. Dr. Spargo received an M.A. in natural sciences and a Ph.D. in synthetic organic chemistry from Cambridge University.

#### **Family Relationships**

There are no family relationships among any of the members of our board of directors and executive officers.

## B. Compensation

### Executive Officer Remuneration

The following table sets forth the approximate remuneration paid during the year ended December 31, 2018, to our current executive officers, who are the members of our administrative, supervisory, and management bodies.

Name and Principal Position	Salary (£)	Bonus <sup>(1)</sup> (£)	Option Awards <sup>(2)</sup> (£)	All Other Compensation (£)	Total (£)
Jan-Anders Karlsson, Ph.D. Chief Executive Officer	300,000	225,000	999,939	22,493 <sup>(3)</sup>	1,547,432
Piers Morgan Chief Financial Officer	225,000	72,850	349,975	13,500 <sup>(3)</sup>	661,325
Kathleen Rickard Chief Medical Officer	—	39,170	—	—	39,170
Claire Poll General Counsel	176,000	55,450	249,981	8,304 <sup>(3)</sup>	489,735
<b>Total</b>	<b>701,000</b>	<b>392,470</b>	<b>1,599,895</b>	<b>44,297</b>	<b>2,737,662</b>

(1) Amount shown reflects bonuses awarded for achievement of performance goals or sign-on bonus in 2018.

(2) Amount shown represents the aggregate grant date fair value of option and restricted share units awards granted in 2018 measured using the Black Scholes model. For a description of the assumptions used in valuing these awards, see note 16 to our Annual Consolidated Financial Statements included elsewhere in this Annual Report.

(3) Amount shown represents health benefits payments and pension contributions made by us.

### Executive Officer Employment Agreements

#### Jan-Anders Karlsson, Ph.D.

We entered into an employment agreement with Dr. Karlsson on April 30, 2012, which was subsequently amended. This agreement, as amended, entitles Dr. Karlsson to receive an annual base salary of £300,000 or such higher rate as may be agreed in writing, and a target annual bonus opportunity of 66% of his annual base salary (potentially extending to up to 132%), with the amount of any such bonus based on annual performance criteria to be agreed between us and Dr. Karlsson. Dr. Karlsson is also entitled to participate in a workplace pension scheme that we contribute to on his behalf. See "— Pension, Retirement or Similar Benefits" below.

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. Karlsson at any time with immediate effect for cause or by giving written notice to Dr. Karlsson that we shall pay, in lieu of notice, his base salary during the 12 months following termination, a pro-rated full discretionary bonus and any other contractual benefits prevailing at the time when such notice is given. The employment agreement provides that, upon a change of control, Dr. Karlsson is entitled to receive his full discretionary bonus (without an obligation to purchase ordinary shares) and full accelerated vesting of any outstanding, unvested equity awards under our share and share option schemes. See "— Equity Compensation Arrangements" below. If payments to Dr. Karlsson would constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended, or the Code, and would be subject to the excise tax imposed by Section 4999 of the Code, then such payment would be reduced to either (i) the largest portion of the payment that would result in no portion of the payment being subject to the excise tax or (ii) the largest portion of the payment, whichever of (i) or (ii) would result in Dr. Karlsson's receipt, on an after-tax basis, of the greater amount of the payment. Additionally, in order to minimize the effect of the different rates of U.S. and U.K. income tax rates, Dr. Karlsson is entitled to receive a payment from us to leave him in a net after-tax position substantially equivalent to what he would experience if he were only subject to U.K. taxes during the period of his employment with us. Dr. Karlsson's employment agreement also contains restrictive covenants pursuant to which he has agreed to refrain from competing with us or soliciting our customers or prospective customers for a period of six months following his termination of employment.

#### Kathleen Rickard, M.D.

We entered into an offer letter with Dr. Rickard on December 13, 2018, pursuant to which she agreed to serve as our Chief Medical Officer, effective February 1, 2019. This agreement entitles Dr. Rickard to receive an annual base salary of \$390,000 and a target annual bonus opportunity of 40% of her annual base salary, with the

amount of any such bonus based on performance criteria for our company and her individual performance, as determined by the board of directors in its sole discretion. Dr. Rickard was also entitled to receive a sign-on bonus of \$50,000, payable on the date of the offer letter, and is entitled to receive a retention bonus of \$250,000, with \$125,000 payable on April 1, 2019 and \$125,000 payable on April 1, 2020, subject to Dr. Rickard being employed at the applicable date of payment and with the condition that each retention bonus payment is repayable if she resigns or is terminated for "Cause" within 12 months of payment. Subject to the approval of our board of directors and our share dealing policy, Dr. Rickard's offer letter also entitled her to receive a stock option to purchase 70,000 of our ADSs and to be issued 15,000 restricted stock units ("RSUs") with respect to ADSs under the terms of the Company's equity incentive plan, half of which vests in equal proportions on the first, second and third anniversary of the grant date and half in equal proportions on the first, second, third and fourth anniversary of the grant date, subject to accelerated vesting upon a change in control. The exercise price of the stock option to purchase ADSs will be determined according to the terms of the Company's equity incentive plan at the date of grant. The offer letter with Dr. Rickard also provides that she is entitled to participate in the Company's 401(k) plan and healthcare plans generally available from time to time to employees of the Company based in the U.S.

If Dr. Rickard's employment is terminated by us without "Cause" or by Dr. Rickard for "Good Reason" (as each such term is defined in her offer agreement), then, subject to her signing and not revoking a general release of claims, she is entitled to receive (i) four weeks of base salary continuation, (ii) four weeks of continued payment of premiums for continued medical coverage under COBRA, (iii) a pro-rated portion of the annual bonus that she otherwise would have earned in the year of termination based on actual performance in such year.

#### *Piers Morgan*

We entered into an employment agreement with Mr. Morgan on September 24, 2016, which was subsequently amended, pursuant to which he agreed to serve as our Chief Financial Officer, effective September 26, 2016. This agreement entitles Mr. Morgan to receive an annual base salary of £210,000, or such higher rate as may be agreed in writing, and a target annual bonus opportunity of 35% (potentially extending to up to 50%) of his salary, with the amount of any such bonus based on performance criteria for our company and his individual performance, as determined by our board of directors in its sole discretion. Within 12 months after receiving any such bonus payment, Mr. Morgan is expected to invest an amount equal to 25% of the bonus (net of income tax paid by Mr. Morgan) in our company through the purchase of our ordinary shares until he has invested an amount equal to £200,000. Pursuant to this agreement, on September 16, 2016, Mr. Morgan received an option to purchase 300,000 of our ordinary shares with an exercise price of £2.04 per ordinary share, which vests in equal proportions on the first, second and third anniversary of the grant date of September 26, 2016. Mr. Morgan is also entitled to participate in a workplace pension scheme that we contribute to on his behalf. See "— Pension, Retirement or Similar Benefits" below.

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. Morgan at any time with immediate effect for cause or by giving written notice to Mr. Morgan that we shall pay, in lieu of notice, his base salary during the six months following termination, a pro-rated full discretionary bonus and any other contractual benefits prevailing at the time when such notice is given. The employment agreement provides that, upon a change of control, Mr. Morgan is entitled to receive his full discretionary bonus (without an obligation to purchase ordinary shares) and full accelerated vesting of any outstanding, unvested equity awards under our share and share option schemes. If payments to Mr. Morgan would constitute a "parachute payment" within the meaning of Section 280G of the Code, and would be subject to the excise tax imposed by Section 4999 of the Code, then such payment would be reduced to either (i) the largest portion of the payment that would result in no portion of the payment being subject to the excise tax or (ii) the largest portion of the payment, whichever of (i) or (ii) would result in Mr. Morgan's receipt, on an after-tax basis, of the greater amount of the payment. Additionally, in order to minimize the effect of the different rates of U.S. and U.K. income tax rates, Mr. Morgan is entitled to receive a payment from us to leave him in a net after-tax position substantially equivalent to what he would experience if he were only subject to U.K. taxes during the period of his employment with us. Mr. Morgan's employment agreement also contains restrictive covenants pursuant to which he has agreed to refrain from competing with us or soliciting our customers or prospective customers for a period of six months following his termination of employment.

#### *Claire Poll*

We entered into an employment agreement with Ms. Poll on October 1, 2016 pursuant to which Ms. Poll agreed to serve as our General Counsel, effective September 1, 2016. This agreement, as amended, entitles Ms. Poll to receive an annual base salary of £170,000, or such higher rate as may be agreed in writing, and a target annual bonus opportunity of 35% of her annual base salary, with the amount of any such bonus based primarily on annual performance criteria to be agreed to between us and Ms. Poll. Pursuant to this agreement, on September 13, 2016, Ms. Poll received an option to purchase a total of 200,000 of our ordinary shares with an

exercise price of £1.89 per ordinary share, which vests in equal proportions on the first three anniversaries of the date of grant. Ms. Poll is also entitled to participate in a workplace pension scheme that we contribute to on her behalf. See "— Pension, Retirement or Similar Benefits" below.

Either party may terminate the employment agreement by giving the other party not less than six months' written notice, provided that we may terminate Ms. Poll at any time with immediate effect for cause or by giving written notice to Ms. Poll that we shall pay, in lieu of notice, her base salary during the six months following termination, a pro-rated full discretionary bonus and any other contractual benefits prevailing at the time when such notice is given. The employment agreement provides that, upon a change of control, Ms. Poll is entitled to receive her full discretionary bonus and full accelerated vesting of any outstanding, unvested equity awards under our share and share option schemes. If payments to Ms. Poll would constitute a "parachute payment" within the meaning of Section 280G of the Code, and would be subject to the excise tax imposed by Section 4999 of the Code, then such payment would be reduced to either (i) the largest portion of the payment that would result in no portion of the payment being subject to the excise tax or (ii) the largest portion of the payment, whichever of (i) or (ii) would result in Ms. Poll's receipt, on an after-tax basis, of the greater amount of the payment. Ms. Poll's employment agreement also contains restrictive covenants pursuant to which she has agreed to refrain from competing with us or soliciting our customers or prospective customers for a period of six months following her termination of employment.

### **Equity Compensation Arrangements**

In May 2017, we closed the initial public offering of our American Depositary Shares in the United States and a private placement of our ordinary shares in Europe, together the global offering. Prior to the global offering, we issued option grants under two option schemes, the Unapproved Share Option Scheme, or the Unapproved Scheme, adopted by our board of directors on September 18, 2006, and the EMI Option Scheme, or the EMI Scheme, adopted by our board of directors on July 24, 2012. Discussions in this section regarding the Unapproved Scheme or the EMI Scheme that refer to our board of directors include any designated committee of our board of directors. Since the adoption of the 2017 Incentive Award Plan, or the 2017 Incentive Plan, no further awards are being made under either the Unapproved Scheme or the EMI Scheme.

#### *EMI Option Scheme*

Under the EMI Scheme, eligible employees were granted tax-efficient options to purchase our ordinary shares. Options were granted to eligible employees who were contracted to work for us or a qualifying subsidiary for at least 25 hours a week, or, if less than 25 hours a week, for at least 75% of their working time. The options granted under the EMI Scheme are exercisable at a price and in accordance with a vesting schedule determined by our board of directors at the time of grant and expire 10 years from the date of grant.

#### *Unapproved Share Option Scheme*

Under the Unapproved Scheme, we granted non-tax-qualifying options to purchase our ordinary shares. Options were granted to employees, directors or consultants to acquire our ordinary shares at a price determined by our board of directors. In general, the options granted under the Unapproved Scheme are exercisable at a price and in accordance with the vesting period determined by our board of directors at the date of grant and expire 10 years from the date of grant.

#### *Certain Transactions*

Under the EMI Scheme and the Unapproved Scheme, if certain changes are made in, or events occur with respect to, our ordinary shares (including any capitalization, sub-division, reduction or other variation of our ordinary shares), any outstanding awards may be adjusted in terms of the number of ordinary shares subject to an option and the exercise price as our board of directors may determine appropriate on a fair and reasonable basis. In the event of certain corporate transactions, including a change of control, scheme of arrangement, merger, demerger or liquidation, the vesting and exercisability of all options will accelerate and, to the extent not exercised, will lapse within certain time periods defined in the applicable plan rules.

#### *Amendment and Termination*

Our board of directors may at any time amend the rules of the EMI Scheme or the Unapproved Scheme in any manner, except that no amendment may be made if, in the reasonable opinion of our board of directors, it would materially abrogate or adversely affect the subsisting rights of an option holder regarding existing options, unless the amendment is made either (i) with the written consent of the number of option holders that hold options to acquire 50% of the ordinary shares that would be delivered if all options granted and subsisting under the scheme, as applicable, were exercised; or (ii) by a resolution at a meeting of option holders passed by not less than 50% of the option holders holding options under the scheme, as applicable, who attend and vote either in person or by proxy. The EMI Scheme and the Unapproved Scheme are discretionary and may be suspended or

terminated by us at any time. Suspension or termination will not affect any options granted under the schemes to the extent that they are subsisting at the date of the suspension or termination.

### **2017 Incentive Plan**

Under the 2017 Incentive Plan, we may grant cash and equity-based incentive awards to eligible service providers in order to attract, retain and motivate the persons who make important contributions to us. The material terms of the 2017 Incentive Plan are summarized below. Except where the context indicates otherwise, references hereunder to our ordinary shares shall be deemed to include a number of ADSs equal to an ordinary share.

#### **Eligibility and Administration**

Our employees, consultants and directors, and employees and consultants of our subsidiaries, are eligible to receive awards under the 2017 Incentive Plan. The 2017 Incentive Plan is administered by our board of directors, which may delegate its duties and responsibilities to one or more committees of our board of directors and/or officers (referred to collectively as the plan administrator below), subject to the limitations imposed under the 2017 Incentive Plan, stock exchange rules and other applicable laws. The plan administrator has the authority to take all actions and make all determinations under the 2017 Incentive Plan, to interpret the 2017 Incentive Plan and award agreements and to adopt, amend and repeal rules for the administration of the 2017 Incentive Plan as it deems advisable. The plan administrator also has the authority to determine which eligible service providers receive awards, grant awards, set the terms and conditions of all awards under the 2017 Incentive Plan, including any vesting and vesting acceleration provisions, and designate whether such awards will cover our ordinary shares or ADSs, subject to the conditions and limitations in the 2017 Incentive Plan.

#### **Sub-Plan**

The 2017 Incentive Plan authorizes the administrator to establish one or more sub-plans. Immediately after the 2017 Incentive Plan was established, the administrator established a sub-plan. The sub-plan incorporated all of the terms of the 2017 Incentive Plan, except that only employees of ours (or our subsidiaries) were eligible to receive awards under the sub-plan. Awards under the sub-plan counted towards the total number of shares available for issuance under the 2017 Incentive Plan. The sub-plan is an "employees' share scheme" for the purposes of the UK Companies Act 2006.

#### **Shares Available for Awards**

An aggregate of 6,333,000 of our ordinary shares were initially made available for issuance under the 2017 Incentive Plan. The number of shares initially available for issuance will be increased by an annual increase on January 1 of each calendar year beginning in 2018 and ending in and including 2027 equal to the least of (A) 4% of our ordinary shares outstanding on the final day of the immediately preceding calendar year and (B) a smaller number of shares determined by our board of directors. As of January 1, 2019, the number of shares available for issuance was 7,473,568. Pursuant to the terms of the 2017 Incentive Plan, awards may be issued under the 2017 Incentive Plan covering ADSs in lieu of the number of our ordinary shares that such ADSs represent. No more than 5,000,000 shares may be issued under the 2017 Incentive Plan upon the exercise of incentive options. Shares issued under the 2017 Incentive Plan may be authorized but unissued shares, shares purchased on the open market, treasury shares or ADSs.

If an award under the 2017 Incentive Plan, the EMI Option Scheme, the Unapproved Share Option Scheme or any prior equity incentive plan, expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, any unused shares subject to the award will, as applicable, become or again be available for new grants under the 2017 Incentive Plan. Awards granted under the 2017 Incentive Plan in substitution for any options or other equity or equity-based awards granted by an entity before the entity's merger or consolidation with us or our acquisition of the entity's property or stock will not reduce the shares available for grant under the 2017 Incentive Plan, but will count against the maximum number of shares that may be issued upon the exercise of incentive options.

#### **Awards**

The 2017 Incentive Plan provides for the grant of options, share appreciation rights, or SARs, restricted shares, dividend equivalents, restricted share units, or RSUs, and other share or cash based awards. All awards under the 2017 Incentive Plan will be set forth in award agreements, which will detail the terms and conditions of awards, including any applicable vesting and payment terms and post-termination exercise limitations. A brief description of each award type follows.

**Options and SARs.** Options provide for the purchase of our ordinary shares in the future at an exercise price set on the grant date. SARs entitle their holder, upon exercise, to receive from us an amount equal to the

appreciation of the shares subject to the award between the grant date and the exercise date. The plan administrator will determine the number of shares covered by each option and SAR, the exercise price of each option and SAR and the conditions and limitations applicable to the exercise of each option and SAR.

**Restricted Shares and Restricted Share Units.** Restricted shares are an award of nontransferable ordinary shares that remain forfeitable unless and until specified conditions are met and which may be subject to a purchase price. RSUs are contractual promises to deliver our ordinary shares in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on our ordinary shares prior to the delivery of the underlying shares. The plan administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to restricted shares and RSUs will be determined by the plan administrator, subject to the conditions and limitations contained in the 2017 Incentive Plan.

**Other Share or Cash Based Awards.** Other share or cash based awards are awards of cash, fully-vested ordinary shares and other awards valued wholly or partially by referring to, or otherwise based on, our ordinary shares or other property. Other share or cash based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of compensation to which a participant is otherwise entitled. The plan administrator will determine the terms and conditions of other share or cash based awards, which may include any purchase price, performance goal, transfer restrictions and vesting conditions.

### **Performance Criteria**

The plan administrator may select performance criteria for an award to establish performance goals for a performance period. Performance criteria under the 2017 Incentive Plan may include, but are not limited to, the following: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including but not limited to gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on shareholders' equity; total shareholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to the company's performance or the performance of a subsidiary, division, business segment or business unit of the company or a subsidiary, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies. When determining performance goals, the plan administrator may provide for exclusion of the impact of an event or occurrence which the plan administrator determines should appropriately be excluded, including, without limitation, non-recurring charges or events, acquisitions or divestitures, changes in the corporate or capital structure, events unrelated to the business or outside of the control of management, foreign exchange considerations, and legal, regulatory, tax or accounting changes.

### **Certain Transactions**

In connection with certain corporate transactions and events affecting our ordinary shares, including a change in control, another similar corporate transaction or event, another unusual or nonrecurring transaction or event affecting us or its financial statements or change in any applicable laws or accounting principles, the plan administrator has broad discretion to take action under the 2017 Incentive Plan to prevent the dilution or enlargement of intended benefits, facilitate the transaction or event or give effect to the change in applicable laws or accounting principles. This includes canceling awards for cash or property, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares subject to outstanding awards and/or with respect to which awards may be granted under the 2017 Incentive Plan and replacing or terminating awards under the 2017 Incentive Plan. In addition, in the event

of certain non-reciprocal transactions with our shareholders, the plan administrator will make equitable adjustments to the 2017 Incentive Plan and outstanding awards as it deems appropriate to reflect the transaction. Pursuant to the terms of their individual employment agreements, awards granted under the 2017 Incentive Plan to certain of our executives may become fully vested and exercisable upon a change in control.

#### **Plan Amendment and Termination**

Our board of directors may amend or terminate the 2017 Incentive Plan at any time; however, no amendment, other than an amendment that increases the number of shares available under the 2017 Incentive Plan, may materially and adversely affect an award outstanding under the 2017 Incentive Plan without the consent of the affected participant and shareholder approval will be obtained for any amendment to the extent necessary to comply with applicable laws. Further, the plan administrator cannot, without the approval of our shareholders, amend any outstanding option or SAR to reduce its price per share or cancel any outstanding option or SAR in exchange for cash or another award under the 2017 Incentive Plan with an exercise price per share that is less than the exercise price per share of the original option or SAR. The 2017 Incentive Plan will remain in effect until the tenth anniversary of its effective date unless earlier terminated by our board of directors. No awards may be granted under the 2017 Incentive Plan after its termination.

#### **Non-U.S. Participants, Claw-Back Provisions, Transferability and Participant Payments**

The plan administrator may modify awards granted to participants who are non-U.S. nationals or employed outside the United States or establish sub-plans or procedures to address differences in laws, rules, regulations or customs of such foreign jurisdictions. All awards will be subject to any company claw-back policy as set forth in such claw-back policy or the applicable award agreement. Except as the plan administrator may determine or provide in an award agreement, awards under the 2017 Incentive Plan are generally non-transferrable, except by will or the laws of descent and distribution, or, subject to the plan administrator's consent, pursuant to a domestic relations order, and are generally exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2017 Incentive Plan, and exercise price obligations arising in connection with the exercise of options under the 2017 Incentive Plan, the plan administrator may, in its discretion, accept cash, wire transfer or check, our ordinary shares that meet specified conditions, a promissory note, a "market sell order," such other consideration as the plan administrator deems suitable or any combination of the foregoing.

#### **2018 Grants**

The following table summarizes the options that we granted to our directors and executive officers under the 2017 Incentive Plan in 2018:

<b>Name</b>	<b>Ordinary Shares Underlying Options</b>	<b>Exercise Price Per Share (£)</b>	<b>Grant Date</b>	<b>Expiration Date</b>
Jan-Anders Karlsson, Ph.D., M.D.	868,758	1.46	March 08, 2018	March 08, 2028
Piers Morgan	304,063	1.46	March 08, 2018	March 08, 2028
Claire Poll	217,186	1.46	March 08, 2018	March 08, 2028

The following table summarizes the RSUs that we granted on March 8, 2018, to our directors and executive officers under the 2017 Incentive Plan in 2018:

<b>Name</b>	<b>Restricted Share Units Granted</b>
Jan-Anders Karlsson, Ph.D., M.D.	136,986
Piers Morgan	47,944
Claire Poll	34,246

The options and RSUs vest as to 50% of the ordinary shares in three substantially equal annual installments following the grant date and as to 50% of the ordinary shares in four substantially equal annual installments following the grant date.



## 2017 Grants

The following table summarizes the options that we granted to our directors and executive officers under the 2017 Unapproved Scheme in 2017:

Name	Ordinary Shares Underlying Options	Exercise Price Per Share (£)	Grant Date	Expiration Date
Jan-Anders Karlsson, Ph.D., M.D.	1,385,598	1.32	April 26, 2017	April 26, 2027
Piers Morgan	802,690	1.32	April 26, 2017	April 26, 2027
Claire Poll	487,347	1.32	April 26, 2017	April 26, 2027
Vikas Sinha	120,384	1.32	April 26, 2017	April 26, 2027

The following table summarizes the RSUs that we granted on April 26, 2017, to our directors and executive officers under the 2017 Incentive Plan in 2017.

Name	Restricted Share Units Granted
Jan-Anders Karlsson, Ph.D., M.D.	346,395
Piers Morgan	200,669
Claire Poll	121,835

The options and RSUs (other than the options granted to Mr. Sinha) vest as to 50% of the ordinary shares in three substantially equal annual installments following the grant date and as to 50% of the ordinary shares in four substantially equal annual installments following the grant date. The options granted to Mr Sinha vest in three substantially equal annual installments following the grant date. This description relates to the options and RSUs granted in 2017 and 2018.

## Non-Employee Directors Remuneration

The following table sets forth the remuneration paid during 2018 to our current non-employee directors:

Name	Annual Fees (£)	Total (£)
David Ebsworth	108,000	108,000
Anders Ullman	56,000	56,000
Ken Cunningham	40,000	40,000
Rishi Gupta	30,000	30,000
Mahendra Shah	30,000	30,000
Vikas Sinha	42,000	42,000
Andrew Sinclair	30,000	30,000

## Non-Employee Director Service Contracts

The remuneration of the non-executive directors is determined by our board as a whole, based on a review of current practices in other companies. We have entered into service contracts with our directors for their services, which are subject to a three-month termination period.

## Pension, Retirement or Similar Benefits

We operate a defined contribution pension scheme which is available to all UK employees. The total amount set aside or accrued by us to provide pension, retirement or similar benefits to our current directors and our executive officers with respect to 2018 was £29,000, which represents contributions made by us in 2018 in respect of a defined contribution scheme in which Dr. Karlsson, Ms. Poll, and Mr. Morgan participated.

## C. Board Practices

### Composition of our Board of Directors

Our Board is comprised of eight members. In accordance with our Articles of Association, one third of our directors retire from office at every annual general meeting of shareholders. However, if the number of directors serving on our Board is not divisible by three, then the number nearest but not exceeding 33.3% shall retire from office at each annual general meeting of shareholders. Retiring directors are eligible for re-election and, if no other director is elected to fill his or her position and the director is willing, shall be re-elected by default.

The expiration of the current terms of the members of our board of directors and the period each member has served in that term are as follows:

Name	Year Current Term Began	Next year of re-election
Jan-Anders Karlsson, Ph.D.	2012	2020
David Ebsworth, Ph.D.	2018	2022
Ken Cunningham, M.D.	2015	2019
Rishi Gupta	2016	2021
Mahendra Shah, Ph.D.	2016	2020
Andrew Sinclair, Ph.D.	2016	2019
Vikas Sinha	2016	2021
Anders Ullman, M.D., Ph.D.	2018	2022

There are no arrangements or understanding between us and any of the members of our board of directors providing for benefits upon termination of their service.

### Committees of our Board of Directors

Our Board has three standing committees: an Audit and Risk Committee, a Remuneration Committee and a Nomination and Governance Committee.

#### ***Audit and Risk Committee of the Board***

The Audit and Risk Committee, which consists of Vikas Sinha, Dr. David Ebsworth and Dr. Andrew Sinclair, assists the Board in overseeing our accounting and financial reporting processes and the audits of our financial statements and monitoring UK Governance Code compliance and business risk. Mr. Sinha serves as Chairman of the Audit and Risk Committee. The Audit and Risk Committee consists of members of our Board who are financially literate and are also considered to be "audit committee financial experts" as defined by applicable SEC rules and have 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 the independent auditor;
- pre-approving the audit services and non-audit services to be provided by the 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 our Board on at least an annual basis;
- reviewing and discussing with the executive officers, our Board and the independent auditor our financial statements and our financial reporting process;
- considering and recommending to our Board whether the audited financial statements be approved; and
- monitoring our review and mitigation of corporate and operational risk.

The Audit and Risk Committee meets as often as one or more members of the Committee deem necessary, but in any event must meet at least four times per year. The Audit and Risk Committee must meet at least once per year with our independent auditor, without our executive officers being present.

#### ***Remuneration Committee of the Board***

The Remuneration Committee, which consists of Dr. Ken Cunningham, Dr. David Ebsworth and Rishi Gupta, assists the Board in determining directors' and executive officers' compensation. Dr Cunningham serves as Chairman of the Committee.

The Remuneration Committee's responsibilities include:

- identifying, reviewing and proposing policies relevant to the compensation of the Company's directors and executive officers;
- evaluating each executive officer's performance in light of such policies and reporting to the Board;
- analyzing the possible outcomes of the variable remuneration components and how they may affect the remuneration of the executive officers;
- recommending any equity long-term incentive component of each executive officer's compensation in line with the remuneration policy and reviewing our executive officer compensation and benefits policies generally;
- appointing and setting the terms of engagement for any remuneration consultants who advise the Committee and obtain benchmarking data with respect to the directors' and executive officers' compensation; and
- reviewing and assessing risks arising from our compensation policies and practices.

***Nomination and Governance Committee of the Board***

The Nomination and Governance Committee, which consists of Dr. David Ebsworth, Dr. Mahendra Shah and Dr. Anders Ullman, assists our Board in identifying individuals qualified to become executive and non-executive directors of our Company consistent with criteria established by our Board and in developing our corporate governance principles. Dr Ebsworth serves as Chairman of the Committee.

The Nomination and Governance Committee's responsibilities include:

- reviewing and evaluating the structure, size and composition of our Board and making recommendations with regard to any adjustments considered necessary;
- drawing up selection criteria and appointment procedures for Board members;
- identifying and nominating, for the approval of our Board, candidates to fill vacancies on the Board and its corresponding committees;
- keeping under review the leadership needs of the Company, both executive and non-executive, and planning the orderly succession of such appointments; and
- assessing the functioning of our Board and individual members and reporting the results of such assessment to the Board.

**D. Employees**

As of December 31, 2018, 2017 and 2016, we had 15, 15, and 11 employees, respectively, of which 11, 10, and 7 were based in the United Kingdom, respectively, and the remainder of which were based outside the United Kingdom. All of our employees were engaged in either administrative or research and development functions. None of our employees are covered by a collective bargaining agreement.

**E. Share Ownership**

For information regarding the share ownership of members of our board and executive officers and arrangements involving our employees in our share capital, see Item 6.B. Compensation, Item 7.A. Major Shareholders and Item 7.B. Related Party Transactions.

## ITEM 7: MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

### A. MAJOR SHAREHOLDERS

The following table sets forth information relating to the beneficial ownership of our ordinary shares as of December 31, 2018, by:

- each person, or group of affiliated persons, that beneficially owns 3% or more of our outstanding ordinary shares (including ordinary shares in the form of our ADSs);
- each member of our board of directors and each of our executive officers; and
- all board members and executive officers as a group.

The number of 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 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 December 31, 2018, 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.

The percentage of ordinary shares beneficially owned is computed on the basis of 105,326,637 of our ordinary shares outstanding as of December 31, 2018. Ordinary shares that a person has the right to acquire within 60 days of December 31, 2018 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. As of December 31, 2018, 55,408,460 ordinary shares, representing 53% of our issued and outstanding ordinary shares (including ordinary shares in the form of our ADSs), were held by 15 U.S. record holders. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Verona Pharma plc, 3 More London Riverside, London SE1 2RE UK.

Name and address of beneficial owner	Number of Shares Beneficially Owned	
	Number	Percentage
<b>3% or Greater Shareholders:</b>		
Novo A/S <sup>(1)</sup>	14,159,611	13.44%
Vivo Capital affiliates <sup>(2)</sup>	13,811,584	13.11%
OrbiMed Private Investments VI, LP <sup>(3)</sup>	11,871,112	11.27%
Growth Equity Opportunities Fund IV, LLC <sup>(4)</sup>	11,527,019	10.94%
Abingworth Bioventures VI, LP <sup>(5)</sup>	8,619,765	8.18%
venBio Select Advisor <sup>(6)</sup>	7,000,000	6.65%
Biodiscovery 4 FCPI <sup>(7)</sup>	6,652,398	6.32%
Tekla Capital affiliates <sup>(8)</sup>	5,296,845	5.03%
Aisling Capital IV, LP <sup>(9)</sup>	4,138,643	3.93%
Arix Bioscience Holdings Ltd affiliates <sup>(10)</sup>	3,916,493	3.72%
Canaccord Genuity Group, Inc. <sup>(11)</sup>	3,233,598	3.07%
Polar Capital Holdings plc <sup>(12)</sup>	4,550,000	4.32%
<b>Executive Officers and Directors:</b>		
Jan-Anders Karlsson, Ph.D. <sup>(13)</sup>	1,608,122	1.53%
Piers Morgan <sup>(14)</sup>	492,974	*
Kathleen Rickard, M.D.	—	—
Claire Poll <sup>(15)</sup>	512,297	*
Ken Cunningham, M.D.	—	—
David Ebsworth, Ph.D. <sup>(16)</sup>	152,703	*
Rishi Gupta	—	—
Mahendra Shah, Ph.D.	—	—
Andrew Sinclair, Ph.D.	—	—
Vikas Sinha <sup>(17)</sup>	62,350	*
Anders Ullman, Ph.D.	—	—
All executive officers and directors as a group (11 persons)	2,828,446	2.69%

<sup>(1)</sup> Consists of (a) 12,389,985 ordinary shares held directly by Novo A/S, or Novo, and (b) warrants to purchase 1,769,626 ordinary shares. The board of directors of Novo A/S, or the Novo Board, has shared investment and voting control over the securities held by Novo and may exercise such control only with the support of a majority of the Novo Board. As such, no individual member of the Novo Board is deemed to hold any beneficial ownership or reportable pecuniary interest in the securities held by Novo. Beneficial ownership information is based on information known to us and a Form TR-1 provided to us on June 6, 2017. Novo's mailing address is Tuborg Havnevej 19, Hellerup, G7 2900, Denmark.

<sup>(2)</sup> Consists of (a) 2,388,728 ordinary shares held directly by Vivo Ventures Fund VI, L.P., or Vivo VI, of which 1,126,760 are held in the form of ADSs, (b) warrants to purchase 370,871 ordinary shares held directly by Vivo VI, (c) warrants to purchase 2,717 ordinary shares held directly by Vivo Ventures VI Affiliates Fund, L.P., or Vivo Affiliates VI, (d) 9,554,917 ordinary shares held directly by Vivo Ventures Fund VII L.P., or Vivo VII, of which 4,507,040 are held in the form of ADSs, (e) warrants to purchase 1,462,477 ordinary shares held directly by Vivo VII, (f) warrants to purchase 31,874 ordinary shares held directly by Vivo Ventures VII Affiliates Fund, L.P., or Vivo Affiliates VII. Vivo Ventures VI, LLC, or Vivo Ventures VI, is the sole general partner of Vivo VI and Vivo Affiliates VI. Vivo Ventures VII, LLC, or Vivo Ventures VII, is the sole general partner of Vivo VII and Vivo Affiliates VII. Vivo Ventures VI and Vivo Ventures VII disclaim beneficial ownership of all shares held by Vivo VI, Vivo Affiliates VI, Vivo VII and Vivo Affiliates VII except to the extent of any pecuniary interest therein. The managing members of Vivo Ventures VI are Drs. Albert Cha, Edgar Engleman and Frank Kung, each of whom may be deemed to have shared voting and dispositive power of the shares held by Vivo VI and Vivo Affiliates VI. The managing members of Vivo Ventures VII are Drs. Albert Cha, Edgar Engleman, Frank Kung, Chen Yu and Mr. Shan Fu, each of whom may be deemed to have shared voting and dispositive power of the shares held by Vivo VII and Vivo Affiliates VII. Mahendra Shah, the Managing Director of Vivo Capital, is a member of our Board of Directors and disclaims beneficial ownership of these shares except to the extent of his pecuniary interest arising as a result of his employment by Vivo Capital. Beneficial ownership information is based on information known to us and Forms TR-1 provided to us on May 30, 2017. Vivo Capital's mailing address is 505 Hamilton Avenue, Suite 200, Palo Alto, CA 94301.

<sup>(3)</sup> Consists of (a) 10,003,174 ordinary shares held directly by OrbiMed Private Investments VI, LP, or OPI VI, of which 10,003,168 are held in the form of ADSs and (b) warrants to purchase 1,867,938 ordinary shares are held directly by OPI VI. OrbiMed Capital GP VI LLC, or GP VI, is the general partner of OPI VI. OrbiMed Advisors LLC, or Advisors, pursuant to its authority as the sole managing member of GP VI, the sole general partner of OPI VI, may be deemed to indirectly beneficially own the ordinary shares held by OPI VI. GP VI, pursuant to its authority as general partner or OPI VI, may be deemed to indirectly beneficially own the ordinary shares held by OPI VI. As a result, Advisors and GP VI share the power to direct the vote and to direct the disposition of the ordinary shares held by OPI VI. Advisors exercises this investment and voting power through a management committee comprised of Carl L. Gordon, Sven H. Borho and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the ordinary shares held by OPI VI. Beneficial ownership information is based on information known to us and a Schedule 13D/A filed

with the SEC on January 26, 2018. The mailing address of OPI VI, GP VI and Advisors is 601 Lexington Avenue, 54th Floor, New York, NY 10022.

- (4) Consists of (a) 9,757,393 ordinary shares held directly by Growth Equity Opportunities Fund IV, LLC, or GEO, of which 5,333,328 are held in the form of ADSs, and (c) warrants to purchase 1,769,626 ordinary shares held directly by GEO. New Enterprise Associates 15, L.P., or NEA 15, is the sole member of GEO. NEA Partners 15, L.P., NEA Partners 15, is the sole general partner of NEA 15. NEA 15 GP, LLC, or NEA 15 LLC, is the sole general partner of NEA Partners 15. Peter J. Barris, Forest Baskett, Anthony Florence, Jr., Krishnu Kolluri, David M. Mott, Scott D. Sandell, Peter Sonsini, Jon Sakoda, Ravia Viswanthan and Henry Weller are the managers of NEA 15 LLC. NEA 15, NEA Partners 15, NEA 15 LLC and the managers of NEA 15 LLC share voting and dispositive power with regard to the securities held by GEO. Each of NEA 15, NEA Partners 15 and NEA 15 LLC as well as each of the managers of NEA 15 LLC disclaims beneficial ownership of all shares held by GEO except to the extent of their actual pecuniary interest therein. Beneficial ownership information is based on information known to us and a Form TR-1 provided to us on May 8, 2017. GEO's mailing address is 1954 Greenspring Drive, Suite 600, Timonium, MD 21093-4135.
- (5) Consists of (a) 7,215,544 ordinary shares held directly by Abingworth Bioventures VI, LP, or Abingworth VI, all of which are held in the form of ADSs, and (b) warrants to purchase 1,404,221 ordinary shares held directly by Abingworth VI. Abingworth Bioventures VI GP LP, or Abingworth GP VI, serves as general partner of Abingworth VI. Abingworth General Partner VI LLP, or Abingworth General Partner VI, serves as general partner of Abingworth GP VI. Abingworth General Partner VI has delegated to Abingworth LLP, all investment and dispositive power over the securities held by Abingworth VI. An Abingworth LLP investment committee comprised of Stephen Bunting, Timothy Haines, Kurt von Emster and Genghis Lloyd-Harris approves investment and voting decisions of Abingworth VI by a majority vote, and no individual member has the sole control or voting power over the securities held by Abingworth VI. Abingworth GP VI, Abingworth General Partner VI, Abingworth LLP and each of Stephen Bunting, Timothy Haines, Kurt von Emster and Genghis Lloyd-Harris disclaim beneficial ownership of securities held by Abingworth VI, except to the extent, if any of their pecuniary interest therein. Andrew Sinclair is a Partner and Portfolio Manager at Abingworth LLP and a member of our board of directors. Dr. Sinclair does not have voting or dispositive power over any of the securities held by Abingworth VI. Beneficial ownership information is based on information known to us and a Form TR-1 provided to us on May 9, 2017. Abingworth VI's mailing address is 38 Jermyn Street, London SW1Y 6DN, United Kingdom.
- (6) Consists of 7,000,000 ordinary shares held in the form of ADSs by VenBio Select Advisor. This information is based on information known to us. The mailing address for VenBio Select Advisor is 120 W 45th St #2802, New York, NY 10036
- (7) Consists of (a) 1 ordinary share and 5,767,584 ordinary shares held in the form of ADSs by Biodiscovery 4 FCPI, or Biodiscovery, and (b) warrants to purchase 884,813 ordinary shares held directly by Biodiscovery. Biodiscovery is a fund under the management of Andera Partners and may be deemed to beneficially own the Biodiscovery shares. Beneficial ownership information is based on information known to us and a Schedule 13G filed on February 11, 2019. The mailing address for Biodiscovery is 347 rue Saint-Honoré 75001 Paris, France.
- (8) Consists of (a) 4,412,031 ordinary shares held directly by Tekla World Healthcare Fund, or Tekla World, of which 2,200,000 are held in the form of ADSs, (b) warrants to purchase 513,192 ordinary shares held directly by Tekla World, and (c) warrants to purchase 371,622 ordinary shares held directly by Tekla Life. Tekla Capital Management LLC, or Tekla Capital, is an investment adviser registered pursuant to Section 203 of the Investment Advisers Act of 1940 and is the investment adviser of Tekla World and Tekla Life, each of which is a registered investment company pursuant to Section 8 of the Investment Company Act of 1940. Each of Tekla Capital and Daniel R. Omstead, through his control of Tekla Capital, has sole power to dispose of the shares beneficially owned by Tekla World and Tekla Life. Neither Tekla Capital nor Daniel R. Omstead has the sole power to vote or direct the vote of the shares beneficially owned by Tekla World and Tekla Life, which power resides in each fund's Board of Trustees. Tekla Capital carries out the voting of the shares under written guidelines established by each fund's Board of Trustees. Beneficial ownership information is based on information known to us and a Schedule 13G filed with the SEC on February 12, 2019. Tekla Capital's mailing address is 100 Federal Street, 19th Floor, Boston, MA 02110.
- (9) Consists of (a) 3,548,768 ordinary shares held directly by Aisling Capital IV, LP, or Aisling, of which 2,074,080 are held in the form of ADSs, and (b) warrants to purchase 589,875 ordinary shares held directly by Aisling. This information is based on information known to us and a TR-1 provided to us on June 6, 2017. The mailing address of Aisling is Aisling Capital, 888 Seventh Avenue, 12th Floor, New York, NY 10106.
- (10) Consists of (a) 1,290,352 ordinary shares held directly by Arix Bioscience Holdings Ltd, or Arix, (b) warrants to purchase 516,141 ordinary shares held directly by Arix and (c) 2,110,000 ordinary shares held directly by Wales Life Sciences Investment Fund, or WLSIF. Arthurian Life Sciences Ltd, or Arthurian, is the general partner of WLSIF and a wholly owned subsidiary of Arix. Beneficial ownership information is based on information known to us and Forms TR-1 provided to us on August 3, 2016 and January 3, 2017. Arix's mailing address is 20 Berkeley Square, London W1J 6EQ, United Kingdom.
- (11) Canaccord Genuity Group Inc. is the beneficial owner of 3,233,598 ordinary shares held directly by Canaccord Genuity Wealth Management. This information is based on information known to us. The mailing address for Canaccord Genuity Group Inc. is 88 Wood Street, London, UK, EC2V 7QR.
- (12) Consists of 4,550,000 ordinary shares of which (a) 3,000,000 ordinary shares are held directly by Polar Biotechnology Fund, or PBF, (b) 800,000 are held by PBF in the form of ADSs and (c) 750,000 ordinary shares are held directly by Polar Capital Global Healthcare, or PCGH. PBF and PCGH are managed by Polar Capital Holdings plc, or PCH. Beneficial ownership information is based on information known to us. The mailing address of PBF, PCGH and PCH is 4 Matthew Parker Street, London, SW1H 9NP, United Kingdom.
- (13) Consists of (a) 193,545 ordinary shares and (b) 1,414,577 options to purchase ordinary shares that are, or will be within 60 days of December 31, 2018, immediately exercisable.
- (14) Consists of (a) 58,594 ordinary shares and (b) 434,380 options to purchase ordinary shares that are, or will be within 60 days of December 31, 2018, immediately exercisable.
- (15) Consists of (a) 95,000 ordinary shares and (b) 417,297 options to purchase ordinary shares that are or will be immediately exercisable within 60 days of December 31, 2018.
- (16) Consists of (a) 147,787 ordinary shares, and (b) warrants to purchase 4,916 ordinary shares.

(17) Consists of (a) 22,222 ordinary shares and (b) 40,128 options to purchase ordinary shares that are, or will be within 60 days of December 31, 2018, immediately exercisable

To our knowledge, other than as provided in the table above, our other filings with the SEC and this Annual Report, there has been no significant change in the percentage ownership held by any major shareholder since January 1, 2016.

The major shareholders listed above do not have voting rights with respect to their ordinary shares that are different from the voting rights of other holders of our ordinary shares.

#### **B. Related Party Transactions.**

The following is a description of related party transactions we have entered into since January 1, 2018 or currently in effect with any member of our board of directors and executive officers.

##### **Registration Rights Agreement**

In July 2016, we entered into a registration rights agreement that provides certain demand registration rights to Abingworth Bioventures VI, LP, or Abingworth, Growth Equity Opportunities Fund IV, LLC, OrbiMed Private Investments VI, LP, or OrbiMed, and Vivo Ventures Fund VII, L.P., Vivo Ventures VII Affiliates Fund, L.P., Vivo Ventures Fund VI, L.P., and Vivo Ventures Fund VI Affiliates Fund, L.P., or collectively, Vivo Capital, with respect to the ordinary shares and any ADSs held by them.

##### **Demand Registration Rights**

At any time, the holders of at least a majority of the registrable securities as defined in the registration rights agreement have the right to demand that we effect an underwritten public offering of their registrable securities pursuant to an effective registration statement under the Securities Act. These registration rights are subject to specified conditions and limitations including the right of the underwriters, if any, to limit the number of shares included in any such registration under specified circumstances. Upon such a request, we are required to use commercially reasonable efforts to effect the public offering.

##### **Expenses of Registration**

We will pay all expenses relating to any registration under the registration rights agreement, other than selling commission, discounts or brokerage fees and stock transfer taxes, subject to specified conditions and limitations.

##### **Termination of Registration Rights**

The registration rights granted under the registration rights agreement shall terminate upon the earlier to occur of (i) the fifth anniversary of the closing of the global offering and (ii) the date on which there are no registrable securities remaining pursuant to the registration rights agreement.

##### **Relationship Agreements**

In June 2016, we entered into relationship agreements with each of Vivo Capital, OrbiMed, and Abingworth, pursuant to which our relationship with such parties is regulated and their influence over our corporate actions and activities, and the outcome of general matters pertaining to us, are limited. Pursuant to the relationship agreements, we also agreed to appoint representatives designated by Vivo Capital, OrbiMed, and Abingworth to our board of directors, who are Dr. Mahendra Shah, Mr. Rishi Gupta, and Dr. Andrew Sinclair, respectively. The appointment rights under the relationship agreements will automatically terminate upon (i) Vivo Capital, OrbiMed or Abingworth (or any of their associates), as applicable, ceasing to beneficially hold 6.5% of our issued ordinary shares, or (ii) our ordinary shares ceasing to be admitted to AIM. In addition, each of the relationship agreements will automatically terminate upon the first date which Vivo Capital, OrbiMed, or Abingworth, as applicable, cease to have certain rights and obligations under the relationship agreements.

##### **Indemnification Agreements**

To the extent permitted by the U.K. Companies Act 2006, we are empowered to indemnify our directors against any liability they incur by reason of their directorship. We have also entered into a deed of indemnity with each of our directors and executive officers. In addition to such indemnification, we provide our directors and executive officers with directors' and officers' liability insurance.

##### **Agreements with Our Executive Officers and Directors**

We have entered into employment agreements with certain of our executive officers and service agreements with our non-employee directors. See Item 6B and note 8 of the financial statements.

##### **Other Transactions**

At December 31, 2018, there was a receivable of £126 thousand (2017: nil) due from one director and two key management personnel relating to tax due on RSUs that vested in the year ended December 31, 2018. This receivable was repaid, together with interest at a rate of 3.9% per annum, by March 6, 2019. The Company notes that the transaction that generated this receivable was potentially a breach of Section 402 of the Sarbanes-Oxley Act of 2002. See Item 3.D. Risk Factors-Risks Related to Our ADSs and Ordinary Shares. We may have inadvertently violated Section 13(k) of the Exchange Act (implementing Section 402 of the Sarbanes-Oxley Act of 2002) and may be subject to sanctions as a result.

**C. Interests of Experts and Counsel**

Not applicable.



## **ITEM 8: FINANCIAL INFORMATION**

### **A. Consolidated Statements and Other Financial Information.**

#### **Consolidated Financial Statements**

Our consolidated financial statements are appended at the end of this Annual Report, starting at page F-1, and are incorporated herein by reference.

#### **Legal Proceedings**

We are not subject to any material legal proceedings.

#### **Dividend Distribution Policy**

We have never paid or declared any cash dividends on our ordinary shares, and we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Under English law, among other things, we may only pay dividends if we have sufficient distributable reserves (on a non-consolidated basis), which are our accumulated realized profits that have not been previously distributed or capitalized less our accumulated realized losses, so far as such losses have not been previously written off in a reduction or reorganization of capital.

### **B. Significant Changes.**

There have been no significant changes since December 31, 2018.

## **ITEM 9: THE OFFER AND THE LISTING**

### **A. Offer and Listing Details.**

Our Ordinary Shares are listed on AIM, a market of the London Stock Exchange, under the symbol "VRP", and our ADSs are listed on The Nasdaq Global Market under the symbol "VRNA".

### **B. Plan of Distribution.**

Not applicable.

### **C. Markets.**

Our Ordinary Shares are listed on AIM, a market of the London Stock Exchange, and our ADSs are listed on The Nasdaq Global Market.

### **D. Selling Shareholders.**

Not applicable.

### **E. Dilution.**

Not applicable.

### **F. Expenses of the Issue.**

Not applicable.

## **ITEM 10: ADDITIONAL INFORMATION**

### **A. Share Capital.**

Not applicable.

### **B. Memorandum and Articles of Association.**

The information in response to this item is contained under the caption "Description of Share Capital and Articles of Association" in our final prospectus filed with the SEC on April 28, 2017 and is incorporated herein by reference.

### **C. Material Contracts.**

In addition to the contracts described elsewhere in this Annual Report, the following are summaries of each material contract to which we are a party for the two years preceding the date of this Annual Report.

## Underwriting Agreement

On April 26, 2017, we entered into an underwriting agreement with Jefferies LLC and Stifel, Nicolaus & Company, Incorporated, as representatives of the underwriters, on April 26, 2017, for the initial public offering of 5,768,000 American Depositary Shares in the United States and the private placement of 1,255,001 ordinary shares in Europe. Pursuant to the underwriting agreement, we paid underwriting discounts and commissions of \$0.9450 per ADS and £0.0924 per ordinary shares. The underwriting agreement contained customary representations and warranties. We also agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect of such liabilities.

## Lease

Our principal office is located at 3 More London Riverside, London SE1 2RE, United Kingdom, where we lease office space. We also lease office space in White Plains, New York. The office space in these two locations is held under four leases that terminate between August 2018 and January 2020 and under these leases we pay £0.3 million per year. We intend to add new facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

## 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 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 our Articles of Association on the right of non-residents to hold or vote shares.

## E. Taxation

The following is a description of certain material U.S. federal income tax consequences to the U.S. Holders described below of owning and disposing of our ordinary shares or ADSs. It is not a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire securities. This discussion applies only to a U.S. Holder that holds our ordinary shares or ADSs as a capital asset for tax purposes (generally, property held for investment). In addition, it does not describe all of the tax consequences that may be relevant in light of a U.S. Holder's particular circumstances, including state and local tax consequences, estate tax consequences, alternative minimum tax consequences, the potential application of the Medicare contribution tax, and tax consequences applicable to U.S. Holders subject to special rules, such as:

- banks, insurance companies, and certain other financial institutions;
  - U.S. expatriates and certain former citizens or long-term residents of the United States;
  - dealers or traders in securities who use a mark-to-market method of tax accounting;
  - persons holding our ordinary shares or ADSs as part of a hedging transaction, "straddle," wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to ordinary shares or ADSs;
  - persons whose "functional currency" for U.S. federal income tax purposes is not the U.S. dollar;
  - brokers, dealers or traders in securities, commodities or currencies;
  - tax-exempt entities or government organizations;
  - S corporations, partnerships, or other entities or arrangements classified as partnerships for U.S. federal income tax purposes;
  - regulated investment companies or real estate investment trusts;
  - persons who acquired our ordinary shares or ADSs pursuant to the exercise of any employee stock option or otherwise as compensation;
  - persons subject to special tax accounting rules as a result of any item of gross income with respect to ordinary shares or ADSs being taken into account in an applicable financial statement;
- persons that own or are deemed to own ten percent or more of our ordinary shares by vote or value; and
- persons holding our ordinary shares or ADSs in connection with a trade or business, permanent establishment, or fixed base outside the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds our ordinary shares or ADSs, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding our ordinary shares or ADSs and partners in such partnerships are encouraged to consult their tax advisers as to the particular U.S. federal income tax consequences of holding and disposing of our ordinary shares or ADSs.

The discussion is based on the Internal Revenue Code of 1986, as amended (the "Code"), administrative pronouncements, judicial decisions, final, temporary and proposed Treasury Regulations, and the income tax treaty between the United Kingdom and the United States (the "Treaty") all as of the date hereof, changes to any of which may affect the tax consequences described herein — possibly with retroactive effect.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of our ordinary shares or ADSs who is eligible for the benefits of the Treaty and is:

- (1) a citizen or individual resident of the United States;
- (2) 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; or
- (3) an estate or trust the income of which is subject to U.S. federal income taxation regardless of its source.

U.S. Holders are encouraged to consult their tax advisers concerning the U.S. federal, state, local and foreign tax consequences of owning and disposing of our ordinary shares or ADSs in their particular circumstances.

The discussion below assumes that the representations contained in the deposit agreement with respect to our ADSs are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. Generally, a holder of an ADS should be treated for U.S. federal income tax purposes as holding the ordinary shares represented by the ADS. Accordingly, no gain or loss will be recognized upon an exchange of ADSs for ordinary shares. The U.S. Treasury has expressed concerns that intermediaries in the chain of ownership between the holder of an ADS and the issuer of the security underlying the ADS may be taking actions that are inconsistent with the beneficial ownership of the underlying security. Accordingly the creditability of foreign taxes, if any, as described below, could be affected by actions taken by intermediaries in the chain of ownership between the holders of our ADSs and our company if as a result of such actions the holders of our ADSs are not properly treated as beneficial owners of the underlying ordinary shares.

#### ***Passive Foreign Investment Company ("PFIC") Rules***

Because we did not earn revenue from our business operations during the year ended December 31, 2018, and because our sole source of income currently is interest on bank accounts held by us, we believe we will likely be classified as a PFIC for the taxable year ended December 31, 2018. A non-U.S. corporation will be classified as a PFIC for any taxable year in which, after applying certain look-through rules, either:

- at least 75% of its gross income is passive income (such as interest income); or
- at least 50% of its gross assets (determined on the basis of a quarterly average) is attributable to assets that produce passive income or are held for the production of passive income.

We will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other corporation, the equity of which we own, directly or indirectly, 25% or more (by value).

A separate determination must be made after the close of each taxable year as to whether we are a PFIC for that year. As a result, our PFIC status may change. While it is possible we may not meet the PFIC test described above once we start generating substantial revenue from our business operations, the analysis is factual and it is possible we may continue to be a PFIC for future years. In particular, the total value of our assets for purposes of the asset test generally will be calculated using the market price of our ordinary shares or ADSs, which may fluctuate considerably. Fluctuations in the market price of our ordinary shares or ADSs may result in our being a PFIC for any taxable year.

If we are classified as a PFIC in any year with respect to which a U.S. Holder owns our ordinary shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns our ordinary shares or ADSs, regardless of whether we continue to meet the tests described above unless (1) we cease to be a PFIC and the U.S. Holder has made a "deemed sale" election under the PFIC rules, or (2) the U.S. Holder makes a QEF Election (defined below) with respect to taxable years in which we are a PFIC. If such election is made, the U.S. Holder will be deemed to have sold our ordinary shares or ADSs it holds at their fair market value and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, the ordinary shares or ADSs with respect to which such election was made will not be treated as shares in a PFIC and the U.S. Holder will not be subject to the rules described below with respect to any "excess

distribution" it receives from us or any gain from an actual sale or other disposition of our ordinary shares or ADSs. U.S. Holders should consult their tax advisors as to the possibility and consequences of making a deemed sale election if we cease to be a PFIC and such election becomes available.

For each taxable year we are treated as a PFIC with respect to a U.S. Holder, such holder will be subject to special tax rules with respect to any "excess distribution" it receives and any gain it recognizes from a sale or other disposition (including a pledge) of our ordinary shares or ADSs, unless such holder makes a QEF Election or a mark-to-market election as discussed below. Distributions that a U.S. Holder receives in a taxable year that are greater than 125% of the average annual distributions received during the shorter of the three preceding taxable years or such holder's holding period for our ordinary shares or ADSs will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over such holder's holding period for our ordinary shares or ADSs;
- the amount allocated to the current taxable year, and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or "excess distribution" cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of our ordinary shares or ADSs cannot be treated as capital, even if the U.S. Holder holds our ordinary shares or ADSs as capital assets.

If we are a PFIC, a U.S. Holder will generally be subject to similar rules with respect to distributions we receive from, and our dispositions of the stock of, any of our direct or indirect subsidiaries that also are PFICs, as if such distributions were indirectly received by, and/or dispositions were indirectly carried out by, such U.S. Holder. U.S. Holders should consult their tax advisors regarding the application of the PFIC rules to our subsidiaries.

U.S. Holders can avoid the interest charge on excess distributions or gain relating to our ordinary shares or ADSs by making a mark-to-market election with respect to our ordinary shares or ADSs, provided that our ordinary shares or ADSs are "marketable." Our ordinary shares or ADSs will be marketable if they are "regularly traded" on certain U.S. stock exchanges or on a foreign stock exchange that meets certain conditions. For these purposes, our ordinary shares or ADSs will be considered regularly traded during any calendar year during which they are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. Our ADSs are listed on the Nasdaq Global Market and our ordinary shares are traded on AIM, a market of the London Stock Exchange, each of, which is a qualified exchange for these purposes. Consequently, if our ADSs remain listed on the Nasdaq Global Market or our ordinary shares remain listed on AIM and, in each case, are regularly traded, and you are a holder of ADSs, we expect the mark-to-market election would be available to U.S. Holders of such ordinary shares or ADSs if we are a PFIC (which we believe likely for the current year). Each U.S. Holder should consult its tax advisor as to whether a mark-to-market election is available or advisable with respect to our ordinary shares or ADSs.

A U.S. Holder that makes a mark-to-market election must include in ordinary income for each year an amount equal to the excess, if any, of the fair market value of our ordinary shares or ADSs at the close of the taxable year over the U.S. Holder's adjusted tax basis in our ordinary shares or ADSs. An electing holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted basis in our ordinary shares or ADSs over the fair market value of our ordinary shares or ADSs at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains for prior years. Gains from an actual sale or other disposition of our ordinary shares or ADSs will be treated as ordinary income, and any losses incurred on a sale or other disposition of our ordinary shares or ADSs will be treated as an ordinary loss to the extent of any net mark-to-market gains for prior years. Once made, the election cannot be revoked without the consent of the U.S. Internal Revenue Service (the "IRS"), unless our ordinary shares or ADSs cease to be marketable.

However, a mark-to-market election generally cannot be made for equity interests in any lower-tier PFICs that we own, unless shares of such lower-tier PFIC are themselves "marketable." We believe that

Rhinopharma Limited will likely be treated as a lower-tier PFIC. As a result, even if a U.S. Holder validly makes a mark-to-market election with respect to our ordinary shares or ADSs, the U.S. Holder may continue to be subject to the PFIC rules (described above) with respect to its indirect interest in any of our investments that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. U.S. Holders should consult their tax

advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

Alternatively, a U.S. Holder can make an election, if we provide the necessary information, to treat us and each lower-tier PFIC as a qualified electing fund (a "QEF Election") in the first taxable year we (and our relevant subsidiaries) are treated as a PFIC with respect to the holder. If such election remains in place while we and any lower-tier PFIC subsidiaries are PFICs, we and our subsidiaries will not be treated as PFICs with respect to such U.S. Holder when we cease to be a PFIC. A U.S. Holder must make the QEF Election for each PFIC by attaching a separate properly completed IRS Form 8621 for each PFIC to the holder's timely filed U.S. federal income tax return. We will provide the information necessary for a U.S. Holder to make a QEF Election with respect to us and will cause each lower-tier PFIC which we control to provide such information with respect to such lower-tier PFIC.

If a U.S. Holder makes a QEF Election with respect to a PFIC, the holder will be currently taxable 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 classified as a PFIC. If a U.S. Holder makes a QEF Election with respect to us, any distributions paid by us out of our earnings and profits that were previously included in the holder's income under the QEF Election would not be taxable to the holder. A U.S. Holder will increase its tax basis in our ordinary shares or ADSs by an amount equal to any income included under the QEF Election and will decrease its tax basis by any amount distributed on our ordinary shares or ADSs that is not included in the holder's income. In addition, a U.S. Holder will recognize capital gain or loss on the disposition of our ordinary shares or ADSs in an amount equal to the difference between the amount realized and the holder's adjusted tax basis in our ordinary shares or ADSs. U.S. Holders should note that if they make QEF Elections with respect to us and lower-tier PFICs, they may be required to pay U.S. federal income tax with respect to our ordinary shares or ADSs for any taxable year significantly in excess of any cash distributions received on our ordinary shares or ADSs for such taxable year. U.S. Holders should consult their tax advisors regarding making QEF Elections in their particular circumstances.

Unless otherwise provided by the U.S. Treasury, each U.S. Holder of a PFIC is required to file an annual report containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file the annual report will cause the statute of limitations for such U.S. Holder's U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. Holder files the annual report, and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder's entire U.S. federal income tax return will remain open during such period. U.S. Holders should consult their tax advisors regarding the requirements of filing such information returns under these rules.

#### ***Taxation of Distributions***

Subject to the discussion above under "Passive Foreign Investment Company ("PFIC") Rules," distributions paid on our ordinary shares or ADSs, other than certain *pro rata* distributions of ordinary shares or ADSs, will generally 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). Because we do not calculate our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be taxable at preferential rates applicable to "qualified dividend income." However, the qualified dividend income treatment may not apply if we are treated as a PFIC with respect to the U.S. Holder. The amount of a dividend will include any amounts withheld by us in respect of United Kingdom income taxes. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will generally be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in foreign currency will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt. Such gain or loss would generally be treated as U.S.-source ordinary income or loss. The amount of any distribution of property other than cash (and other than certain *pro rata* distributions of ordinary shares or ADSs or rights to acquire ordinary shares or ADSs) will be the fair market value of such property on the date of distribution.

For foreign tax credit purposes, our dividends will generally be treated as passive category income. Subject to applicable limitations, some of which vary depending upon the U.S. Holder's particular circumstances, any United Kingdom income taxes withheld from dividends on our ordinary shares or ADSs at a rate not exceeding the rate provided by the Treaty will be creditable against the U.S. Holder's U.S. federal income tax liability. The rules governing foreign tax credits are complex and U.S. Holders should consult their tax advisers regarding the

credibility of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct foreign taxes, including any United Kingdom income tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

#### ***Sale or Other Taxable Disposition of Our Ordinary Shares and ADSs***

Subject to the discussion above under "Passive Foreign Investment ("PFIC") Company Rules," gain or loss realized on the sale or other taxable disposition of our ordinary shares or ADSs will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held our ordinary shares or ADSs for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in our ordinary shares or ADSs disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to limitations.

If the consideration received by a U.S. Holder is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if our ordinary shares or ADSs are treated as traded on an "established securities market" and the U.S. Holder is either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), such holder will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If a U.S. Holder is an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, such holder will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date.

**WE STRONGLY URGE INVESTORS IN OUR ORDINARY SHARES OR ADSs TO CONSULT THEIR TAX ADVISORS REGARDING THE IMPACT OF OUR PFIC STATUS ON THEIR INVESTMENT IN OUR ORDINARY SHARES OR ADSs AS WELL AS THE APPLICATION OF THE PFIC RULES TO SUCH INVESTMENT IN OUR ORDINARY SHARES OR ADSs.**

#### ***Information Reporting and Backup Withholding***

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (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 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 (and, under proposed regulations, certain entities) may be required to report information relating to our ordinary shares or ADSs, subject to certain exceptions (including an exception for ordinary shares or ADSs held in accounts maintained by certain U.S. financial institutions). U.S. Holders should consult their tax advisers regarding their reporting obligations with respect to their ownership and disposition of our ordinary shares or ADSs.

#### **F. Dividends and Paying Agents.**

Not applicable.

#### **G. Statement by Experts.**

Not applicable.

#### **H. Documents on Display.**

We maintain a corporate website at [www.veronapharma.com](http://www.veronapharma.com). We make available free of charge on our website our Reports on Form 6-K, our Annual Reports on Form 20-F, and any other reports that we file or furnish with the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this

Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

The SEC also maintains a website at [www.sec.gov](http://www.sec.gov) that contains reports, proxy and information statements and other information regarding issuers that file electronically, such as us, with the SEC.

References made in this Annual Report to any contract or certain other document are not necessarily complete and you should refer to the exhibits attached or incorporated by reference into this Annual Report for copies of the actual contract or document.

**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.

### ***Credit Risk***

We consider all of our material counterparties to be creditworthy. We consider the credit risk for each of our counterparties to be low and do not have a significant concentration of credit risk at any of our counterparties.

### ***Liquidity Risk***

We manage our liquidity risk by maintaining adequate cash reserves at banking facilities, and by continuously monitoring our cash forecasts, our actual cash flows and by matching the maturity profiles of financial assets and liabilities.

### ***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. Our financial position, as expressed in pounds sterling, are exposed to movements in foreign exchange rates against the U.S. dollar and the Euro. Our main trading currencies are pounds sterling, the U.S. dollar and the Euro. We are exposed to foreign currency risk as a result of operating transactions and the translation of foreign bank accounts. We monitor our exposure to foreign exchange risk. We have not entered into foreign exchange contracts to hedge against gains or losses from foreign exchange fluctuations.

### ***Interest rate Risk***

Interest rate risk reflects the risk that the value of a financial instrument will fluctuate as a result of a change in market interest rates on classes of financial assets and financial liabilities. We do not hold any derivative instruments to manage interest rate risk.

See note 3.1 of the financial statements for quantitative disclosures about market risk.

## **ITEM 12: DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

### **A. Debt Securities.**

Not applicable.

### **B. Warrants and Rights.**

Not applicable.

### **C. Other Securities.**

Not applicable.



## D. American Depositary Shares.

### Fees and Charges

Holders of our ADSs are required to pay the following fees under the terms of the deposit agreement:

<b>Service</b>	<b>Fee</b>
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 \$0.05 per ADS 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 \$0.05 per ADS cancelled
Distribution of cash dividends or other cash distributions (e.g., upon a sale of rights and other entitlements)	Up to \$0.05 per ADS 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 \$0.05 per ADS held
Distribution of securities other than ADSs or rights to purchase additional ADSs (e.g., upon a spin-off)	Up to \$0.05 per ADS held
ADS Services	Up to \$0.05 per ADS held on the applicable record date(s) established by the depositary

Holders of our ADSs are also 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 American Depositary Receipts; and
- the fees and expenses incurred by the depositary, the custodian, or any nominee in connection with the servicing or delivery of deposited property.

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 depository into the Depository Trust Company, or 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 event of refusal to pay the depository fees, the depository may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depository fees from any distribution to be made to the ADS holder. Note that the fees and charges holders of our ADSs may be required to pay may vary over time and may be changed by us and by the depository. Holders of our ADSs will receive prior notice of such changes. The depository may reimburse us for certain expenses incurred by us in respect of the ADS program, by making available a portion of the ADS fees charged in respect of the ADS program or otherwise, upon such terms and conditions as we and the depository agree from time to time.

## PART II

### ITEM 13: DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

### ITEM 14: MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

- A. None
- B. None
- C. None
- D. None
- E. Use of Proceeds.

In May 2017, we completed the initial public offering of our ADSs in the United States and a private placement of our ordinary shares in Europe, or the global offering. In the global offering we issued and sold 6,501,738 ADSs, including 733,738 ADSs issued and sold upon the partial exercises by the underwriters pursuant to their overallotment option to purchase additional ADSs, at a public offering price of \$13.50 per ADS, and 1,225,001 ordinary shares at an offering price of £1.32 per share. We received aggregate gross proceeds from the global offering of approximately \$89.9 million, and aggregate net proceeds of approximately \$80.8 million after deducting underwriting discounts and commissions of approximately \$6.3 million and offering expenses of approximately \$3.2 million. No payments for such expenses were made directly or indirectly to (i) any of our officers, members of our board of directors, or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

The offer and sale of the ADSs and ordinary shares in the global offering were registered under the Securities Act pursuant to a registration statement on Form F-1 (File No. 333-217124) to register ordinary shares, which was declared effective by the SEC on April 26, 2017, a registration statement on Form F-1 to register additional ordinary shares (File No. 333-217487), which was immediately effective upon filing on April 26, 2017, and a registration statement on Form F-6 (File No. 333-217353) to register the ADSs, which was declared effective by the SEC on April 26, 2017, or, collectively, the Registration Statements. Under the Registration Statements, we registered an aggregate offering price of approximately \$91.7 million of ordinary shares and 100,000,000 ADSs for a registered aggregate offering price of \$5.0 million.

There has been no material change in our planned use of the net proceeds from the global offering as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on April 28, 2017.

### ITEM 15: CONTROLS AND PROCEDURES

#### Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

#### Disclosure Controls and Procedures.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a- 15(e) and 15d- 15(e) under the Exchange Act), as of the end of the period covered by this Annual Report on Form 20-F. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

#### Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our 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, 2018, our internal control over financial reporting was effective.

#### Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the period covered by this Annual Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### ITEM 16A: AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Vikas Sinha, Dr. David Ebsworth and Dr. Andrew Sinclair each qualify as an audit committee financial expert as defined by the rules of the SEC and has the requisite financial sophistication under the applicable rules and regulations of Nasdaq. Mr. Sinha and Drs. Ebsworth and Sinclair are each independent as such term is defined in Rule 10A-3 under the Exchange Act and under the listing standards of Nasdaq.

#### ITEM 16B: CODE OF ETHICS

##### Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, that is applicable to all of our employees, executive officers, members of our board of directors, and consultants. The Code of Conduct is available on our website at [www.veronapharma.com](http://www.veronapharma.com). We will provide a copy of our Code of Conduct to any person without charge upon written request sent to:

Verona Pharma plc  
3 More London Riverside  
London SE1 2RE  
United Kingdom  
Attn: Secretary

We intend to satisfy the disclosure requirement under Item 16B(d) and (e) of Form 20-F regarding amendment to, or waiver from, a provision of our Code of Conduct, as well as Nasdaq's requirement to disclose waivers with respect to directors and executive officers, by posting such information in the "Investors" section of our website at [www.veronapharma.com](http://www.veronapharma.com). Our executive officers are responsible for administering the Code of Conduct. Amendment, alteration or termination of the Code of Conduct requires the approval of our board of directors.

#### ITEM 16C: PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table summarizes the fees of PricewaterhouseCoopers LLP, our independent registered public accounting firm, billed to us for each of the last two fiscal years for audit and other services:

Fee Category	2018	2017
	£'000s	£'000s
Audit Fees	114	117
Audit-Related Fees	68	333
Other Services	86	150
Total Fees	268	600

##### Audit-Related Fees

For the year ended December 31, 2018, audit related services include fees for quarterly interim reviews.

For the year ended December 31, 2017, audit related services include fees for quarterly interim reviews and assurance on information included in our registration statement for the initial public offering in the United States of our ADSs.

##### Tax Fees

We did not incur any tax fees for services from PricewaterhouseCoopers LLP in 2018 or 2017.

## **All Other Fees**

For the year ended December 31, 2018, other fees related to a review of our F-3 shelf registration statement.

For the year ended December 31, 2017, we incurred other services related to advice on compliance with Sarbanes-Oxley legislation.

## **Audit Committee Pre-Approval Policy and Procedures**

The Audit Committee has adopted a policy, or the Pre-Approval Policy, which sets forth the procedures and conditions pursuant to which audit and non-audit services proposed to be performed by the independent auditor may be pre-approved. The Pre-Approval Policy generally provides that we will not engage PricewaterhouseCoopers LLP to render any audit, audit-related, tax or permissible non-audit service unless the service is either (i) explicitly approved by the Audit Committee, or specific pre-approval, or (ii) entered into pursuant to the pre-approval policies and procedures described in the Pre-Approval Policy, or general pre-approval. Unless a type of service to be provided by PricewaterhouseCoopers LLP has received general pre-approval under the Pre-Approval Policy, it requires specific pre-approval by the Audit Committee or by a designated member of the Audit Committee to whom the committee has delegated the authority to grant pre-approvals. Any proposed services exceeding pre-approved cost levels or budgeted amounts will also require specific pre-approval. For both types of pre-approval, the Audit Committee will consider whether such services are consistent with the SEC's rules on auditor independence. The Audit Committee will also consider whether the independent auditor is best positioned to provide the most effective and efficient service, for reasons such as its familiarity with our business, people, culture, accounting systems, risk profile and other factors, and whether the service might enhance our ability to manage or control risk or improve audit quality. All such factors will be considered as a whole, and no one factor should necessarily be determinative. The Audit Committee may also review and generally pre-approve the services (and related fee levels or budgeted amounts) that may be provided by PricewaterhouseCoopers LLP without first obtaining specific pre-approval from the Audit Committee. The Audit Committee may revise the list of general pre-approved services from time to time, based on subsequent determinations.

## **ITEM 16D: EXEMPTIONS FORM THE LISTING STANDARDS FOR AUDIT COMMITTEES**

None

## **ITEM 16E: PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS**

None

## **ITEMS 16F: CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT**

There has been no change in our independent accountant during our two most recent fiscal years.

## **ITEM 16G: CORPORATE GOVERNANCE**

As a "foreign private issuer," as defined by the SEC, we are permitted to follow home country corporate governance practices, instead of certain corporate governance practices required by Nasdaq for domestic issuers, with certain exceptions. While we voluntarily follow most Nasdaq corporate governance rules, we follow U.K. corporate governance practices in lieu of Nasdaq corporate governance rules as follows:

- We do not 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, our articles of association provide alternative quorum requirements that are generally applicable to meetings of shareholders.
- We do not follow Nasdaq Rule 5605(b)(2), which requires that independent directors regularly meet in executive session, where only independent directors are present. Our independent directors may choose to meet in executive session at their discretion.

## **ITEM 16H: MINE SAFETY DISCLOSURE**

None

## **PART III**

## **ITEM 17: FINANCIAL STATEMENTS**

We have elected to provide financial statements pursuant to Item 18.

**ITEM 18: FINANCIAL STATEMENTS**

The financial statements are filed as part of this Annual Report beginning on page F-1.

**ITEM 19: EXHIBITS**

Exhibit Number	Exhibit Description	Form	Incorporated by Reference to Filings Indicated			Filed / Furnished
			File No.	Exhibit No.	Filing date	
<a href="#">1.1</a>	<a href="#">Articles of Association, as amended and as currently in effect</a>	F-1	333-217124	3.1	4/3/2017	
<a href="#">2.1</a>	<a href="#">Deposit Agreement</a>	20-F	001-38067	2.1	2/27/2018	
<a href="#">2.2</a>	<a href="#">Form of American Depositary Receipt (included in Exhibit 2.1)</a>	20-F	001-38067	2.2	2/27/2018	
<a href="#">2.3</a>	<a href="#">Form of Warrant issued to each of the investors named in Schedule A thereto</a>	F-1	333-217124	4.3	4/3/2017	
<a href="#">2.4</a>	<a href="#">Warrant Instrument issued to NPlus1 Singer LLP</a>	F-1	333-217124	4.4	4/3/2017	
<a href="#">4.1</a>	<a href="#">Registration Rights Agreement, dated July 29, 2016, by and among Verona Pharma plc and the investors set forth therein</a>	F-1	333-217124	10.1	4/3/2017	
<a href="#">4.2†</a>	<a href="#">Intellectual Property Assignment and Licence Agreement between Vernalis Development Limited and Rhinopharma Limited, as predecessor to Verona Pharma plc, dated February 7, 2005</a>	F-1	333-217124	10.2	4/3/2017	
<a href="#">4.3</a>	<a href="#">Renewal Agreement to Lease by and between the Verona Pharma plc and Regus Management (UK) Limited dated October 19, 2017</a>					*

4.3.1	<a href="#">Renewal Agreement to Lease by and between the Verona Pharma plc and Regus Management (UK) Limited dated November 8, 2017</a>					*
4.3.2	<a href="#">Renewal Agreement to Lease by and between the Verona Pharma plc and Regus Management (UK) Limited dated April 3, 2018</a>					*
4.4#	<a href="#">EMI Option Scheme</a>	F-1	333-217124	10.4	4/3/2017	
4.5#	<a href="#">Unapproved Share Option Scheme, as amended</a>	F-1	333-217124	10.5	4/3/2017	
4.6#	<a href="#">2017 Incentive Award Plan and forms of award agreements thereunder</a>	20-F	001-38067	4.6	2/27/2018	
4.7#	<a href="#">Employment Agreement, dated April 30, 2012, as amended, between Verona Pharma plc and Jan-Anders Karlsson</a>	F-1	333-217124	10.6	4/3/2017	
4.8#	<a href="#">Employment Agreement, dated December 21, 2019, between Verona Pharma plc and Kathleen Rickard</a>					*
4.9#	<a href="#">Employment Agreement, dated September 24, 2016, between Verona Pharma plc and Piers John Morgan</a>	F-1	333-217124	10.8	4/3/2017	
4.10#	<a href="#">Employment Agreement, dated October 1, 2016, between Verona Pharma plc and Claire Poll</a>	F-1	333-217124	10.9	4/3/2017	
4.11	<a href="#">Form of Indemnification Agreement for board members</a>	F-1/A	333-217124	10.11.1	4/18/2017	
4.12	<a href="#">Form of Indemnification Agreement for executive officers</a>	F-1/A	333-217124	10.11.2	4/18/2017	
4.13	<a href="#">Relationship Agreement relating to Verona Pharma plc, dated July 29, 2016, by and among the Verona Pharma plc, OrbiMed Private Investments VI, LP and NPlus1 Singer Advisory LLP</a>	F-1	333-217124	10.12	4/3/2017	
4.14	<a href="#">Relationship Agreement relating to Verona Pharma plc, dated July 29, 2016, by and among the Verona Pharma plc, Abingworth Bioventures VI LP and NPlus1 Singer Advisory LLP</a>	F-1	333-217124	10.13	4/3/2017	
4.15	<a href="#">Relationship Agreement relating to Verona Pharma plc, dated July 29, 2016, by and among the Verona Pharma plc, Vivo Ventures Fund VII, L.P., Vivo Ventures VII Affiliates Fund, L.P., Vivo Ventures Fund VI, L.P., Vivo Ventures VI Affiliates Fund, L.P. and NPlus1 Singer Advisory LLP</a>	F-1	333-217124	10.14	4/3/2017	
8.1	<a href="#">List of Subsidiaries</a>	F-1	333-217124	21.1	4/3/2017	
12.1	<a href="#">Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer</a>					*
12.2	<a href="#">Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer</a>					*

<a href="#">13.1</a>	<a href="#">Section 1350 Certification of Chief Executive Officer</a>	**
<a href="#">13.2</a>	<a href="#">Section 1350 Certification of Chief Financial Officer</a>	**
<a href="#">15.1</a>	<a href="#">Consent of PricewaterhouseCoopers LLP</a>	*
<a href="#">101.INS</a>	<a href="#">XBRL Instance Document</a>	*
<a href="#">101.SCH</a>	<a href="#">XBRL Taxonomy Extension Schema Document</a>	*
<a href="#">101.CAL</a>	<a href="#">XBRL Taxonomy Extension Calculation Linkbase Document</a>	*
<a href="#">101.LAB</a>	<a href="#">XBRL Taxonomy Extension Label Linkbase Document</a>	*
<a href="#">101.PRE</a>	<a href="#">XBRL Taxonomy Extension Presentation Linkbase Document</a>	*
<a href="#">101.DEF</a>	<a href="#">XBRL Taxonomy Extension Definition Linkbase Document</a>	*

\* Filed herewith.

\*\* Furnished herewith.

# Indicates management contract or compensatory plan.

† Confidential treatment granted as to portions of the exhibit. Confidential materials omitted and filed separately with the SEC.



## SIGNATURES

The registrant 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.

VERONA PHARMA PLC

By: /s/ Jan-Anders Karlsson

Name: Jan-Anders Karlsson, Ph.D.

Title: Chief Executive Officer

Date: March 19, 2019

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

### Consolidated financial statements

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## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Verona Pharma Plc

### ***Opinion on the Financial Statements***

We have audited the accompanying consolidated statements of financial position of Verona Pharma plc and its subsidiaries (the "Company") as of December 31, 2018 and 2017 and the related consolidated statements of comprehensive income, of changes in equity and of cash flows for each of the three years in the period ended December 31, 2018 including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

### ***Basis for Opinion***

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements 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 consolidated 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 such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP  
Reading, United Kingdom  
March 19, 2019

We have served as the Company's auditor since 2015.

VERONA PHARMA PLC  
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION  
AS OF DECEMBER 31, 2018 AND 2017

	Notes	As of December 31, 2018 £'000s	As of December 31, 2017 £'000s
<b>ASSETS</b>			
<b>Non-current assets:</b>			
Goodwill	11	441	441
Intangible assets	12	2,134	1,969
Property, plant and equipment	13	21	16
<b>Total non-current assets</b>		<b>2,596</b>	<b>2,426</b>
<b>Current assets:</b>			
Prepayments and other receivables	14	2,463	1,810
Current tax receivable		4,499	5,006
Short term investments		44,919	48,819
Cash and cash equivalents		19,784	31,443
<b>Total current assets</b>		<b>71,665</b>	<b>87,078</b>
<b>Total assets</b>		<b>74,261</b>	<b>89,504</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Capital and reserves attributable to equity holders:</b>			
Share capital	15	5,266	5,251
Share premium		118,862	118,862
Share-based payment reserve		7,923	5,022
Accumulated loss		(69,117)	(49,254)
<b>Total equity</b>		<b>62,934</b>	<b>79,881</b>
<b>Current liabilities:</b>			
Derivative financial instrument	17	2,492	1,273
Trade and other payables	18	7,733	7,154
Tax payable—U.S. Operations		—	169
<b>Total current liabilities</b>		<b>10,225</b>	<b>8,596</b>
<b>Non-current liabilities:</b>			
Assumed contingent obligation	19	996	875
Deferred income		106	152
<b>Total non-current liabilities</b>		<b>1,102</b>	<b>1,027</b>
<b>Total equity and liabilities</b>		<b>74,261</b>	<b>89,504</b>

The accompanying notes form an integral part of these consolidated financial statements.

**VERONA PHARMA PLC**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**  
**FOR THE YEARS ENDED DECEMBER 31, 2018, 2017 AND 2016**

	Notes	Year ended December 31, 2018	Year ended December 31, 2017	Year Ended December 31, 2016
		£'000s	£'000s	£'000s
Research and development costs		(19,294)	(23,717)	(4,522)
General and administrative costs		(6,297)	(6,039)	(2,498)
<b>Operating loss</b>	7	<b>(25,591)</b>	<b>(29,756)</b>	<b>(7,020)</b>
Finance income	9	2,783	7,018	1,841
Finance expense	9	(1,325)	(2,465)	(794)
<b>Loss before taxation</b>		<b>(24,133)</b>	<b>(25,203)</b>	<b>(5,973)</b>
Taxation — credit	10	4,232	4,706	954
<b>Loss for the year</b>		<b>(19,901)</b>	<b>(20,497)</b>	<b>(5,019)</b>
<b>Other comprehensive income / (loss):</b>				
<b>Items that might be subsequently reclassified to profit or loss</b>				
Exchange differences on translating foreign operations		38	(29)	43
<b>Total comprehensive loss attributable to owners of the Company</b>		<b>(19,863)</b>	<b>(20,526)</b>	<b>(4,976)</b>
Loss per ordinary share — basic and diluted (pence)	5	(18.9)	(23.4)	(15.0)

The accompanying notes form an integral part of these consolidated financial statements.

**VERONA PHARMA PLC**  
**CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**  
**FOR THE YEARS ENDED DECEMBER 31, 2018, 2017 AND 2016**

	Share Capital	Share Premium	Share-based Payment Reserve	Total Accumulated Losses	Total Equity
	£'000s	£'000s	£'000s	£'000s	£'000s
<b>Balance at January 1, 2016</b>	1,010	26,650	1,526	(23,752)	5,434
Loss for the year	—	—	—	(5,019)	(5,019)
Other comprehensive income for the year:					
Exchange differences on translating foreign operations	—	—	—	43	43
Total comprehensive loss for the year	—	—	—	(4,976)	(4,976)
New share capital issued	1,556	34,151	—	—	35,707
Transaction costs on share capital issued	—	(2,325)	—	—	(2,325)
Share options exercised during the year	2	50	—	—	52
Share-based payments	—	—	577	—	577
<b>Balance at December 31, 2016</b>	2,568	58,526	2,103	(28,728)	34,469
<b>Balance at January 1, 2017</b>	2,568	58,526	2,103	(28,728)	34,469
Loss for the year	—	—	—	(20,497)	(20,497)
Other comprehensive loss for the year:					
Exchange differences on translating foreign operations	—	—	—	(29)	(29)
Total comprehensive loss for the year	—	—	—	(20,526)	(20,526)
New share capital issued	2,677	67,648	—	—	70,325
Transaction costs on share capital issued	—	(7,453)	—	—	(7,453)
Share options exercised during the year	6	141	—	—	147
Share-based payments	—	—	2,919	—	2,919
<b>Balance at December 31, 2017</b>	5,251	118,862	5,022	(49,254)	79,881
<b>Balance at January 1, 2018</b>	5,251	118,862	5,022	(49,254)	79,881
Loss for the year	—	—	—	(19,901)	(19,901)
Other comprehensive income for the year:					
Exchange differences on translating foreign operations	—	—	—	38	38
Total comprehensive loss for the year	—	—	—	(19,863)	(19,863)
New share capital issued	15	—	—	—	15
Share-based payments	—	—	2,901	—	2,901
<b>Balance at December 31, 2018</b>	5,266	118,862	7,923	(69,117)	62,934

The currency translation reserve for 2018, 2017, and 2016, is not considered material and as such is not presented in a separate reserve but is included in the total accumulated losses reserve.

**VERONA PHARMA PLC**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**FOR THE YEARS ENDED DECEMBER 31, 2018, 2017 AND 2016**

	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
	£'000s	£'000s	£'000s
<b>Cash used in operating activities:</b>			
Loss before taxation	(24,133)	(25,203)	(5,973)
Finance income	(2,783)	(7,018)	(1,841)
Finance expense	1,325	2,465	794
Share-based payment charge	2,901	2,919	577
Increase in prepayments and other receivables	(640)	(161)	(1,809)
Increase in trade and other payables	531	5,363	1,068
Depreciation of property, plant and equipment	8	7	10
Loss on disposal of property plant and equipment	—	—	3
Amortization of intangible assets	90	116	52
<b>Cash used in operating activities</b>	<b>(22,701)</b>	<b>(21,512)</b>	<b>(7,119)</b>
Cash inflow from taxation	4,590	816	1,533
<b>Net cash used in operating activities</b>	<b>(18,111)</b>	<b>(20,696)</b>	<b>(5,586)</b>
<b>Cash flow from investing activities:</b>			
Interest received	883	128	87
Purchase of plant and equipment	(13)	(9)	(13)
Payment for patents and computer software	(255)	(208)	(115)
Purchase of short term investments	(59,700)	(54,465)	—
Maturity of short term investments	64,366	5,085	—
<b>Net cash generated from / (used in) investing activities</b>	<b>5,281</b>	<b>(49,469)</b>	<b>(41)</b>
<b>Cash flow from financing activities:</b>			
Gross proceeds from issue of shares and warrants	—	—	44,750
Gross proceeds from the April 2017 Global Offering	—	70,032	—
Transaction costs on issue of shares and warrants	—	—	(2,910)
Transaction costs on April 2017 Global Offering	—	(6,786)	(636)
<b>Net cash generated from financing activities</b>	<b>—</b>	<b>63,246</b>	<b>41,204</b>
<b>Net (decrease) / increase in cash and cash equivalents</b>	<b>(12,830)</b>	<b>(6,919)</b>	<b>35,577</b>
Cash and cash equivalents at the beginning of the year	31,443	39,785	3,524
Effect of exchange rates on cash and cash equivalents	1,171	(1,423)	684
<b>Cash and cash equivalents at the end of the year</b>	<b>19,784</b>	<b>31,443</b>	<b>39,785</b>

**VERONA PHARMA PLC  
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE THREE YEARS ENDED DECEMBER 31, 2018**

**1. General information**

Verona Pharma plc and its subsidiaries (the "Company") are a clinical-stage biopharmaceutical group focused on developing and commercializing innovative therapeutics for the treatment of respiratory diseases with significant unmet medical needs.

The Company is a public limited company, which is dual listed on the AIM, a market of the London Stock Exchange, and The Nasdaq Global Market. The company is incorporated and domiciled in the United Kingdom. The address of the registered office is 1 Central Square, Cardiff, CF10 1FS, United Kingdom.

The Company has two subsidiaries, Verona Pharma Inc. and Rhinopharma Limited ("Rhinopharma"), both of which are wholly owned.

On February 10, 2017, the Company effected a 50-for-1 consolidation of its shares. All references to ordinary shares, options and warrants, as well as share, per share and related information in these consolidated financial statements have been adjusted to reflect the consolidation as if it had occurred at the beginning of the earliest period presented.

On April 26, 2017, the Company announced the closing of its global offering of an aggregate of 47,399,001 new ordinary shares, consisting of the initial public offering in the United States of 5,768,000 American Depositary Shares ("ADSs") at a price of \$13.50 per ADS and the private placement in Europe of 1,255,001 ordinary shares at a price of £1.32 per ordinary share, for gross proceeds of \$80 million (the "Global Offering"). Each ADS offered represents eight ordinary shares of the Company. The ordinary shares offered were allotted and issued in a concurrent private placement in Europe and other countries outside of the United States and Canada.

In addition, the Chairman of Verona Pharma's board of directors, Dr. David Ebsworth, and an existing shareholder agreed to subscribe for 254,099 new ordinary shares at a price of £1.32 per ordinary share in a shareholder private placement separate from the Global Offering (the "Shareholder Private Placement"), contingent on and concurrent with the Global Offering and generating additional gross proceeds of £0.3 million.

On May 15 and May 23, 2017, pursuant to the Global Offering, the underwriters purchased an additional 733,738 ADSs, representing 5,869,904 ordinary shares, at a price of \$13.50 per ADS, for additional gross proceeds of \$9.9 million bringing the total gross proceeds in the Global Offering to \$89.9 million (£70.0 million). Including the Shareholder Private Placement, the total gross proceeds of the capital raising amounted to \$90.3 million (£70.3 million).

The ADSs trade on The Nasdaq Global Market under the symbol "VRNA" and Verona Pharma's ordinary shares trade on AIM under the symbol "VRP".



**VERONA PHARMA PLC  
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)  
FOR THE THREE YEARS ENDED DECEMBER 31, 2018**

**2. Accounting policies**

A summary of the principal accounting policies, all of which have been applied consistently throughout the year, is set out below.

**2.1 Basis of preparation**

The consolidated financial statements of the Company have been prepared in accordance with International Financial Reporting Standards ("IFRSs") as issued by the International Accounting Standards Board and IFRS Interpretations Committee applicable to companies reporting under IFRS.

The consolidated financial statements have been prepared under the historical cost convention, with the exception of derivative financial instruments which have been measured at fair value.

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Company's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in note 4.

**Going concern**

During the year ended December 31, 2018, the Company had a loss of £19.9 million (2017: £20.5 million). As of December 31, 2018, the Company had net assets of £62.9 million (2017: £79.9 million) of which £64.7 million (2017: £80.3 million) was cash and cash equivalents and short term investments.

The operation of the Company is currently being financed from funds that the Company raised from share placings. In April and May 2017, the Company raised \$90.3 million (£70.3 million) from the Global Offering and the Shareholder Private Placement. On July 29, 2016, the Company raised gross proceeds of £44.7 million from a placing, subscription and open offer (the "July 2016 Placement"). These funds are being used primarily to support the development of ensifentrine in chronic obstructive pulmonary disease ("COPD") and other chronic respiratory diseases, as well as corporate and general administrative expenditures.

The Directors believe that the Company has sufficient funds to complete the current clinical trials, to cover corporate and general administration costs and for it to comply with all commitments for at least 12 months from the end of the reporting date and, accordingly, are satisfied that the going concern basis remains appropriate for the preparation of these consolidated financial statements.

**Business combination**

The Company applies the acquisition method to account for business combinations. The consideration transferred for the acquisition of a subsidiary is the fair value of the assets transferred, the liabilities incurred to the former owners of the acquiree and the equity interests issued by the Company. The consideration transferred includes the fair value of any asset or liability resulting from a contingent consideration arrangement and the fair value of any pre-existing equity interest in the subsidiary. The excess of the cost of acquisition over the fair value of the Company's share of the identifiable net assets acquired is recorded as goodwill. Goodwill arising on acquisitions is capitalized and is subject to an impairment review, both annually and when there are indications that the carrying value may not be recoverable.

Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date. Acquisition-related costs are expensed as incurred and included in administrative expenses.

**Basis of consolidation**

These consolidated financial statements include the financial statements of Verona Pharma plc and its wholly owned subsidiaries Verona Pharma, Inc. and Rhinopharma. The acquisition method of accounting was used to account for the acquisition of Rhinopharma.

Inter-company transactions, balances and unrealized gains on transactions between group companies are eliminated.

Verona Pharma Inc. and Rhinopharma adopt the same accounting policies as the Company.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**Accounting policies (Continued)**

**2.2 Foreign currency translation**

Items included in the Company's consolidated 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 pounds sterling ("£"), which is the functional and presentational currency of the Company.

Transactions in foreign currencies are recorded using the rate of exchange ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are translated using the rate of exchange ruling at the balance sheet date and the gains or losses on translation are included in the Consolidated Statement of Comprehensive Income. Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the original transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined.

The assets and liabilities of foreign operations are translated into pounds sterling at the rate of exchange ruling at the balance sheet date. Income and expenses are translated at weighted average exchange rates for the period. The exchange differences arising on translation for consolidation are recognized in Other Comprehensive Income.

**2.3 Cash and cash equivalents**

Cash and cash equivalents includes cash in hand, deposits held at call with banks and other short-term highly liquid investments with original maturities of three months or less.

**2.4 Deferred taxation**

Deferred tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the balance sheet date and expected to apply when the related deferred tax is realized or the deferred liability is settled.

Deferred tax assets are recognized to the extent that it is probable that the future taxable profit will be available against which the temporary differences can be utilized.

**2.5 Research and development costs**

Capitalization of expenditure on product development commences from the point at which technical feasibility and commercial viability of the product can be demonstrated and the Company is satisfied that it is probable that future economic benefits will result from the product once completed. No such costs have been capitalized to date, given the early stage of the Company's product candidate development.

Expenditure on research and development activities that do not meet the above criteria is charged to the Consolidated Statement of Comprehensive Income as incurred.

**2.6 Property, plant and equipment**

Property, plant and equipment are stated at cost, net of depreciation and any provision for impairment. Cost includes the original purchase price of the asset and the costs attributable to bringing the asset to its working condition for its intended use. Depreciation is calculated so as to write off the cost less their estimated residual values, on a straight-line basis over the expected useful economic lives of the assets concerned. The principal annual periods used for this purpose are:

Computer hardware	3 years
Office equipment	5 years

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**Accounting policies (Continued)**

**2.7 Intangible assets and goodwill**

(a) Goodwill

Goodwill arises on the acquisition of subsidiaries and represents the excess of the consideration transferred over the fair value of the identifiable net assets acquired.

(b) Patents

Patent costs associated with the preparation, filing, and obtaining of patents are capitalized and amortized on a straight-line basis over the estimated useful lives of the patents of ten years.

(c) Computer software

Amortization is calculated so as to write off the cost less estimated residual values, on a straight-line basis over the expected useful economic life of two years.

(d) In-process research & development ("IP R&D")

IP R&D assets acquired through business combinations which, at the time of acquisition, have not reached technical feasibility are recognized at fair value. The amounts are capitalized and are not amortized but are subject to impairment testing until completion, abandonment of the projects or when the research findings are commercialized through a revenue generating project. The Company determines whether intangible assets (including goodwill) are impaired on an annual basis or where there is an impairment indicator and this requires the estimation of the higher of fair value less costs of disposal and value in use. Upon successful completion or commercialization of the relevant project, IP R&D will be reclassified to developed technology. The Company will make a determination as to the then useful life of the developed technology, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. In case of abandonment the asset will be impaired.

**2.8 Impairment of intangible assets, goodwill and non-financial assets**

Goodwill and intangible assets that have an indefinite useful life and intangible assets not ready to use are not subject to amortization. These assets are tested annually for impairment or more frequently if impairment indicators exist. Non-financial assets that are subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value (less costs of disposal) and value in use.

For the purpose of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows, which are largely independent of the cash flows from other assets or group of assets (cash generating units "CGUs").

Goodwill is allocated to CGUs for the purpose of impairment testing. The allocation is made to those CGUs or groups of CGUs that are expected to benefit from the business combination in which the goodwill arose. The units or group of units are identified at the lowest level at which goodwill is monitored for internal management purposes, being the operating segments.

The Company is a single cash generating unit. Goodwill that arose on the acquisition of Rhinopharma has been thus allocated to this single CGU. IP R&D is tested for impairment at this level as well, since it is the lowest level at which independent cash flows can be identified.

Non-financial assets, other than goodwill, that have been previously impaired are reviewed for possible reversal of the impairment at each subsequent reporting date.

**2.9 Employee Benefits**

(a) Pension

The Company operates a defined contribution pension scheme for UK employees. Contributions payable for the year are charged to the Consolidated Statement of Comprehensive Income. The contributions are recognized as

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**Accounting policies (Continued)**

employee benefit expense when they are due. Differences between contributions payable in the year and contributions actually paid are shown as either accruals or prepayments in the Consolidated Statement of Financial Position. The Company has no further payment obligation once the contributions have been paid.

**(b) Bonus plans**

The Company recognizes a liability and an expense for bonus plans if contractually obligated or if there is a past practice that has created a constructive obligation.

**2.10 Share-based payments**

The Company operates a number of equity-settled, share-based compensation schemes. The fair value of share-based payments under such schemes is expensed on a straight-line basis over the vesting period, based on the Company's estimate of shares that will eventually vest.

Where equity settled transactions are entered into with third party service providers, fair value is determined by reference to the value of the services provided in lieu of payment. The expense is measured based on the services received at the date of receipt of those services and is charged to the Consolidated Statement of Comprehensive Income over the period for which the services are received and a corresponding credit is made to reserves. For other equity-settled transactions fair value is determined using the Black-Scholes model and requires several assumptions and estimates as disclosed in note 16.

**2.11 Provisions**

Provisions are recognized when the Company has a present legal or constructive obligation as a result of past events, it is probable that an outflow of resources will be required to settle the obligation, and the amount can be reliably estimated. Provisions are measured at the present value of the expenditures expected to be required to settle the obligation using a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the obligation.

**2.12 Assumed contingent obligation related to the business combinations**

On September 19, 2006, the Company acquired Rhinopharma for a total consideration of £1.52 million payable in ordinary shares. In addition, the Company assumed certain contingent obligations owed by Rhinopharma to Vernalis Pharmaceuticals Limited ("Vernalis"), which was subsequently acquired by Ligand Pharmaceuticals, Inc. ("Ligand"), under an assignment and license agreement (the "assumed contingent consideration") following the sale of IP by Vernalis to Rhinopharma. In October 2018, Vernalis was acquired by, and became a wholly owned subsidiary of, Ligand Pharmaceuticals, Inc., or Ligand). The Company refers to the assignment and license agreement as the Ligand Agreement and now refers to Vernalis as Ligand.

Pursuant to the agreement Ligand (i) assigned to the Company all of its rights to certain patents and patent applications relating to ensifentrine and related compounds (the "Ligand Patents") and (ii) granted to the Company an exclusive, worldwide, royalty-bearing license under certain Ligand know-how to develop, manufacture and commercialize products (the "Licensed Products") developed using Ligand Patents, Ligand know-how and the physical stock of certain compounds.

The assumed contingent obligation comprises (a) a milestone payment on obtaining the first approval of any regulatory authority for the commercialization of a Licensed Product; (b) low to mid-single digit royalties based on the future sales performance of all Licensed Products; and (c) a portion equal to a mid-twenty percent of any consideration received from any sub-licensees for the Ligand Patents and for Ligand know-how. On the date of acquisition the fair value of the assumed contingent obligation was estimated as the expected value of the milestone payment, royalty payments and sub-license payments, based on an assessment of the probability of success using standard market probabilities for respiratory drug development. The risk-weighted value of the assumed contingent arrangement was then discounted back to its net present value applying an effective interest rate of 12%. The initial fair value of the assumed contingent obligation as of December 31, 2006, was deemed to be insignificant at the date of the acquisition, so it was not recorded.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**Accounting policies (Continued)**

The amount of royalties payable under the agreement is based on the future sales performance of certain products, and so the total amount payable is unlimited. The level of sales that may be achieved under the agreement is difficult to predict and subject to estimate, which is inherently uncertain. The value of this assumed contingent obligation is measured at amortized cost using the effective interest rate method, and is re-measured for changes in estimated cash flows, when the probability of success changes. The assumed contingent obligation is accounted for as a liability, and any adjustments made to the value of the liability will be recognized in the Consolidated Statement of Comprehensive Income for the period.

**2.13 Government and other grants**

The Company may receive government, regional or charitable grants to support its research efforts in defined projects where these grants provide for reimbursement of approved costs incurred as defined in the respective grants. Income in respect of such grants would include contributions towards the costs of research and development. Income would be recognized when costs under each grant are incurred in accordance with the terms and conditions of the grant and the collectability of the receivable is reasonably assured. Government, regional and charitable grants relating to costs would be deferred and recognized in the Consolidated Statement of Comprehensive Income over the period necessary to match them with the costs they are intended to compensate. When the cash in relation to recognized government, regional or charitable grants is not yet received the amount is included as a receivable on the Consolidated Statement of Financial Position.

Where the grant income is directly related to the specific items of expenditure incurred, the income would be netted against such expenditure. Where the grant income is not a specific reimbursement of expenditure incurred, the Company would include such income under "Other income" in the Consolidated Statement of Comprehensive Income.

**2.14 Financial instruments — initial recognition and subsequent measurement**

The Company classifies a financial instrument, or its component parts, as a financial liability, a financial asset or an equity instrument in accordance with the substance of the contractual arrangement and the definitions of a financial liability, a financial asset and an equity instrument.

The Company evaluates the terms of the financial instrument to determine whether it contains an asset, a liability or an equity component. Such components shall be classified separately as financial assets, financial liabilities or equity instruments.

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

(a) Financial assets, initial recognition and measurement and subsequent measurement

All financial assets not recorded at fair value through profit or loss, such as receivables and deposits, are recognized initially at fair value plus transaction costs. Financial assets carried at fair value through profit or loss are initially recognized at fair value, and transaction costs are expensed in the income statement.

The measurement of financial assets depends on their classification. Financial assets such as receivables and deposits are subsequently measured at amortized cost using the effective interest method, less loss allowance. The Company does not hold any financial assets at fair value through profit or loss or fair value through other comprehensive income.

(b) Financial liabilities, initial recognition and measurement and subsequent measurement

Financial liabilities are classified as measured at amortized cost or FVTPL.

A financial liability is classified as at FVTPL if it is a derivative. Financial liabilities at FVTPL are measured at fair value and net gains and losses, including any interest expense, are recognized in profit or loss.

Other financial liabilities are subsequently measured at amortized cost using the effective interest method. Interest expense and foreign exchange gains and losses are recognized in profit or loss. Any gain or loss on derecognition is also recognized in profit or loss.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**Accounting policies (Continued)**

The Company's financial liabilities include trade and other payables and derivative financial instruments.

(c) Derivative financial instruments

Derivatives are initially recognized at fair value on the date a derivative contract is entered into and are subsequently re-measured at fair value at the end of each reporting date. The Company holds only one type of derivative financial instrument, the warrants, as explained in Note 2.15.

The full fair value of the derivative is classified as a non-current liability when the warrants are exercisable in more than 12 months and as a current liability when the warrants are exercisable in less than 12 months.

Changes in fair value of a derivative financial liability when related to a financing arrangement are recognized in the Consolidated Statement of Comprehensive Income within Finance income or Finance expense. Fair value gains or losses on derivatives used for non-financing arrangements are recognized in other operating income or expense.

**2.15 Warrants**

Warrants issued by the Company to investors as part of a share subscription are compound financial instruments where the warrant meets the definition of a financial liability.

The financial liability component is initially measured at fair value in the Consolidated Statement of Financial Position. Equity is measured at the residual between the subscription price for the entire instrument and the liability component. The financial liability component is remeasured depending on its classification. Equity is not remeasured.

**2.16 Short Term Investments**

Short term investments include fixed term deposits held at banks with original maturities of more than three months but less than a year. They are classified as loans and receivables and are measured at amortized cost using the effective interest method.

**2.17 Transaction costs**

Qualifying transaction costs might be incurred in anticipation of an issuance of equity instruments and may cross reporting periods. The entity defers these costs on the balance sheet until the equity instrument is recognized. Deferred costs are subsequently reclassified as a deduction from equity when the equity instruments are recognized, as the costs are directly attributable to the equity transaction. If the equity instruments are not subsequently issued, the transaction costs are expensed. Any costs not directly attributable to the equity transaction are expensed.

Transaction costs that relate to the issue of a compound financial instrument are allocated to the liability and equity components of the instrument in proportion to the allocation of proceeds. Where the liability component is held at fair value through profit or loss, the transaction costs are expensed to the Consolidated Statement of Comprehensive Income. For liabilities held at amortized cost, transaction costs are deducted from the liability and subsequently amortized. The amount of transaction costs accounted for as a deduction from equity in the period is disclosed separately in accordance with International Accounting Standard ("IAS") 1.

**2.18 New standards, amendments and interpretations adopted by the Company**

The following amendments have been adopted by the Company for the first time for the financial year beginning on or after January 1, 2018:

- IFRS 9 "Financial instruments"
- IFRS 15 "Revenue from contracts with customers"

IFRS 9 had no material impact on the accounting or measurement of any of the financial instruments the Company currently holds.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**Accounting policies (Continued)**

IFRS 15 had no impact on the financial statements of the Company as it is not currently revenue generating.

**2.19 New standards, amendments and interpretations issued but not effective for the financial year beginning January 1, 2018 and not early adopted**

New standards and amendments to standards and interpretations have been issued but are not yet effective for annual periods beginning after January 1, 2018 (noted below), and have not been adopted in preparing these consolidated financial statements.

IFRS 16 "Leases" (effective for annual periods beginning on or after January 1, 2019)

IFRS 16 is effective for accounting periods beginning on or after January 1, 2019 and will replace IAS 17 "Leases". It eliminates the classification of leases as either operating leases or finance leases and, instead, introduces a single lessee accounting model.

The Group will recognize new assets and liabilities for its operating leases of office leases (see Note 20). The nature of expenses related to those leases will now change because the Group will recognize a depreciation charge for right-of-use assets and interest expense on lease liabilities. Previously, the Group recognized operating lease expense on a straight-line basis over the term of the lease, and recognize assets and liabilities only to the extent that there was a timing difference between actual lease payments and the expense recognized. Instead, the Group will include the payments due under the lease in its lease liability. Based on the information currently available, using the modified retrospective method, the Group estimates that it will recognize additional lease liabilities of £316 thousand and assets of £325 thousand as of January 1, 2019. There will be no material impact on other lines in the financial statements.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**

### 3. Financial Instruments

#### 3.1 Financial Risk Factors

The Company's activities have exposed it to a variety of financial risks: market risk (including currency risk and interest rate risk), credit risk, and liquidity risk. The Company's overall risk management program is focused on preservation of capital and the unpredictability of financial markets and has sought to minimize potential adverse effects on the Company's financial performance and position.

(a) Currency risk

Foreign currency risk reflects the risk that the Company's net assets will be negatively impacted due to fluctuations in exchange rates. The Company has not entered into foreign exchange contracts to hedge against gains or losses from foreign exchange fluctuations.

The summary quantitative data about the Company's exposure to currency risk is as follows. Figures are the pounds sterling values of balances in each currency:

	December 31, 2018		December 31, 2017	
	USD	EUR	USD	EUR
	£'000s	£'000s	£'000s	£'000s
Cash and cash equivalents	8,470	21	16,806	301
Short term Investments	25,069	—	19,718	—
Trade and other payables	4,329	532	276	403

#### Sensitivity Analysis

A reasonably possible strengthening (weakening) of the Euro, U.S. dollar, or pounds sterling against all other currencies as of December 31, 2018 and 2017 would have affected the measurement of the financial instruments denominated in a foreign currency and affected equity and profit and loss by the amounts shown below. This analysis assumes that all other variables remain constant.

	Profit or loss and equity	
	Strengthening	Weakening
	£'000s	£'000s
<b>December 31, 2018</b>		
EUR (5% movement)	(26)	26
USD (5% Movement)	1,461	(1,461)
<b>December 31, 2017</b>		
EUR (5% movement)	35	(35)
USD (5% Movement)	1,840	(1,840)

Foreign currency denominated trade payables are short term in nature (generally 30 to 45 days). The Company has a U.S. operation, the net assets of which are exposed to foreign currency translation risk.

(b) Credit risk

Credit risk reflects the risk that the Company may be unable to recover contractual receivables. As the Company is still in the development stage no policies are currently required to mitigate this risk.

For banks and financial institutions, only independently rated parties with a minimum rating of "B+" are accepted. The Directors recognize that this is an area in which they may need to develop specific policies should the Company become exposed to further financial risks as the business develops.

As of December 31, 2018, and December 31, 2017, cash and cash equivalents and short term investments were placed at the following banks:



**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**Financial Instruments (continued)**

<b>Cash and Cash Equivalents</b>	<b>Year ended</b>	<b>Credit rating</b>	<b>Year ended</b>	<b>Credit rating</b>
	<b>December 31, 2018</b>		<b>December 31, 2017</b>	
	<b>£'000</b>		<b>£'000</b>	
<b>Banks</b>				
Royal Bank of Scotland	150	A1	16,623	A2
Lloyds Bank	15,862	Aa3	13,448	Aa3
Standard Chartered	—	A1	1,242	A1
Citibank	3,135	A1	—	—
Barclays	449	A2	—	—
Wells Fargo	188	Aa1	130	Aa1
Total	<u>19,784</u>		<u>31,443</u>	

<b>Short Term Investments</b>	<b>Year ended</b>	<b>Credit rating</b>	<b>Year ended</b>	<b>Credit rating</b>
	<b>December 31, 2018</b>		<b>December 31, 2017</b>	
	<b>£'000</b>		<b>£'000</b>	
<b>Banks</b>				
Royal Bank of Scotland	9,186	A1	15,316	A2
Lloyds Bank	1,567	Aa3	11,036	Aa3
Standard Chartered	15,450	A1	22,467	A1
Citibank	7,053	A1	—	—
Barclays	11,663	A2	—	—
Total	<u>44,919</u>		<u>48,819</u>	

(c) Management of capital

The Company considers capital to be its equity reserves. At the current stage of the Company's life cycle, the Company's objective in managing its capital is to ensure funds raised meet the research and operating requirements until the next development stage of the Company's suite of projects.

The Company ensures it is meeting its objectives by reviewing its Key Performance Indicators to ensure the research activities are progressing in line with expectations, costs are controlled and unused funds are placed on deposit to conserve resources and increase returns on surplus cash held.

(d) Interest rate risk

As of December 31, 2018, the Company had cash deposits of £19.8 million (2017: £31.4 million) and short term investments of £44.9 million (2017: £48.8 million). The rates of interest received during 2018 ranged between 0.0% and 2.87%. A 0.25% increase in interest rates would not have a material impact on finance income. The Company's exposure to interest rate risk, which is the risk that the interest received will fluctuate as a result of changes in market interest rates on classes of financial assets and financial liabilities, was as follows:

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**Financial Instruments (continued)**

	December 31, 2018		December 31, 2017	
	Floating interest rate	Fixed Interest rate	Floating interest rate	Fixed Interest rate
	£'000s	£'000s	£'000s	£'000s
<b>Financial asset</b>				
Cash deposits	15,082	4,702	25,720	5,723
Short Term Investments	—	44,919	—	48,819
<b>Total</b>	<u>15,082</u>	<u>49,621</u>	<u>25,720</u>	<u>54,542</u>

(e) Liquidity risk

The Company prepares periodic working capital forecasts for the foreseeable future, allowing an assessment of the cash requirements of the Company, to manage liquidity risk. The following table provides an analysis of the Company's financial liabilities. The carrying value of all balances is equal to their fair value. The Company's maturity analysis for the derivative financial instrument from the issue of warrants is given in note 17.

	LESS THAN 1 YEAR	BETWEEN 1 AND 2 YEARS	BETWEEN 2 AND 5 YEARS	OVER 5 YEARS <sup>(1)</sup>
	£'000s	£'000s	£'000s	£'000s
<b>At December 31, 2018</b>				
Trade payables	2,839	—	—	—
Other payables	12	—	—	—
Accruals	4,882	—	—	—
Contingent obligation	—	—	—	1,807
<b>Total</b>	<u>7,733</u>	<u>—</u>	<u>—</u>	<u>1,807</u>

(1) This table includes the undiscounted amount of the assumed contingent obligation. See note 19.

	LESS THAN 1 YEAR	BETWEEN 1 AND 2 YEARS	BETWEEN 2 AND 5 YEARS	OVER 5 YEARS <sup>(1)</sup>
	£'000s	£'000s	£'000s	£'000s
<b>At December 31, 2017</b>				
Trade payables	1,214	—	—	—
Other payables	74	—	—	—
Accruals	5,866	—	—	—
Contingent obligation	—	—	—	1,807
<b>Total</b>	<u>7,154</u>	<u>—</u>	<u>—</u>	<u>1,807</u>

(1) This table includes the undiscounted amount of the assumed contingent obligation. See note 19.

**3.2 Fair value estimation**

The carrying amounts of cash and cash equivalents, receivables, accounts payable and accrued liabilities approximate to fair value due to their short-term nature. The carrying amount of the assumed contingent liability approximates to fair value as the underlying assumptions are currently similar.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**Financial Instruments (continued)**

For financial instruments that are measured in the Consolidated Statement of Financial Position at fair value, IFRS 7 requires disclosure of fair value measurements by level of the following fair value measurement hierarchy:

- Quoted prices (unadjusted) in active markets for identical assets or liabilities (level 1);
- Inputs other than quoted prices included within level 1 that are observable for the asset or liability, either directly or indirectly (level 2); and
- Inputs for the asset or liability that are not based on observable market data (level 3).

For the year ended December 31, 2018, and 2017, fair value adjustments to financial instruments through profit and loss resulted in the recognition of finance loss of £1.2 million in 2018 and a finance income of £6.7 million in 2017.

The fair value of financial instruments that are not traded in an active market is determined by using valuation techniques. These valuation techniques maximize the use of observable market data where it is available and rely as little as possible on entity specific estimates. If all significant inputs required to ascertain the fair value of an instrument are observable, the instrument is included in level 2. If one or more of the significant inputs are not based on observable market data, the instrument is included in level 3.

	<b>Level 3</b>	<b>Total</b>
	<b>£'000s</b>	<b>£'000s</b>
<b>At December 31, 2018</b>		
Derivative financial instrument	2,492	2,492
<b>Total</b>	<b>2,492</b>	<b>2,492</b>

Movements in Level 3 items during the years ended December 31, 2018, and 2017 are as follows:

<b>Derivative financial instrument</b>	<b>2018</b>	<b>2017</b>
	<b>£'000s</b>	<b>£'000s</b>
<b>At January 1</b>	1,273	7,923
Fair value adjustments recognized in profit and loss	1,219	(6,650)
<b>At December 31</b>	<b>2,492</b>	<b>1,273</b>

Further details relating to the derivative financial instrument are set out in notes 4 and 17 of these financial statements.

In determining the fair value of the derivative financial instrument, the Company applied the Black Scholes model; key inputs include the share price at reporting date, estimations on timelines, volatility and risk-free rates. These assumptions and the impact of changes in these assumptions, where material, are disclosed in note 17.

### 3.3 Change in liabilities arising from financing activities

The Company has provided a reconciliation so that changes in liabilities arising from financing activities, including both changes arising from cash flows and non-cash changes can be evaluated.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**Financial Instruments (continued)**

	2018 Derivative financial instrument
	£'000s
At January 1	1,273
Fair value adjustments - non cash	1,219
At December 31	2,492

See note 17 for information relating to the derivative financial instrument.

#### 4. Critical accounting estimates and judgments

The preparation of financial statements in conformity with IFRS requires the use of accounting estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. Although these estimates are based on management's best knowledge of current events and actions, actual results ultimately may differ from those estimates. IFRS also requires management to exercise its judgment in the process of applying the Company's accounting policies.

The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are as follows:

(a) Assumed contingent obligation

The Company has a material obligation for the future payment of royalties and milestones associated with contractual obligations on ensifentrine, a development product acquired as part of the acquisition of Rhinopharma. The estimation of the fair value of the assumed contingent obligation on acquisition requires the selection of an appropriate valuation model, consideration as to the inputs necessary for the valuation model chosen, the estimation of the likelihood that the regulatory approval milestone will be achieved and estimates of the future cash flows and their timing (for further detail see note 17). The estimates for the assumed contingent obligation are based on a discounted cash flow model. Key estimates included in the fair value calculation of deferred consideration are:

- development, regulatory and marketing risks associated with progressing the product to market approval in key target territories;
- market size and product acceptance by clinicians, patients and reimbursement bodies;
- gross and net selling price;
- costs of manufacturing, product distribution and marketing support;
- launch of competitive products; and
- discount rate and time to crystallization of contingent consideration.

When there is a change in the expected cash flows, the assumed contingent obligation is re-measured with the change in value going through the Consolidated Statement of Comprehensive Income. Cash flow estimates are revised when the probability of success changes. The assumed contingent obligation is measured at amortized cost with the discount unwinding in the Consolidated Statement of Comprehensive Income throughout the year. Actual outcomes could differ significantly from the estimates made.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**Critical accounting estimates and judgments (continued)**

The value of the assumed contingent obligation as of December 31, 2018 amounted to £1.0 million. (2017: £0.9 million). The increase in value of the assumed contingent obligation during 2018 amounted to £0.1 million (2017: £0.1 million) and the movement relates to unwinding the discount on the liability and retranslating for changes in U.S. dollar exchange rates. The expense relating to the unwinding of the discount was recorded in finance expense. There was no change in the year to the probability of success and consequently cash flow estimates were not revised.

The discount percentage applied is 12%.

(b) Valuation of the July 2016 warrants

Pursuant to the July 2016 Placement, the Company issued 31,115,926 units to new and existing investors at the placing price of £1.4365 per unit. Each unit comprises one ordinary share and one warrant. The warrants entitle the investors to subscribe for in aggregate a maximum of 12,401,262 ordinary shares.

In accordance with IAS 32 and the Company's accounting policy, as disclosed in note 2.15, the Company classified the warrants as a derivative financial liability to be presented on the Company's Consolidated Statement of Financial Position.

The fair value of these warrants is determined by applying the Black-Scholes model. Assumptions are made on inputs such as time to maturity, the share price, volatility and risk free rate in order to determine the fair value per warrant. For further details see note 17.

(c) Recognition of research and development expenditure

The Company incurs research and development expenditure from third parties. The Company recognizes this expenditure in line with the management's best estimation of the stage of completion of each research and development project. This includes the calculation of accrued costs at each period end to account for expenditure that has been incurred. This requires management to estimate full costs to complete for each project and also to estimate its current stage of completion. Costs relating to clinical research organization expenses in the year were £14.0 million. The related accruals and prepayments were £3.4 million and £0.7 million, respectively.

(d) Transaction costs related to the Global Offering

In 2017, the Company incurred various transaction costs relating to the Global Offering, including commissions, professional advisor fees, financial advice, listing fees and other costs. When management judged them to be incremental costs directly attributable to the transaction they were accounted for as a deduction from equity. Otherwise the costs were expensed to the Consolidated Income Statement as incurred.

## 5. Earnings per share

Basic loss per ordinary share of 18.9p (2017: 23.4p and 2016: 15.0p) for the Company is calculated by dividing the loss for the year ended December 31, 2018 by the weighted average number of ordinary shares in issue of 105,110,504 as of December 31, 2018 (2017: 87,748,031 and 2016: 33,499,413). Potential ordinary shares are not treated as dilutive as the entity is loss making and such shares would be anti-dilutive.

## 6. Segmental reporting

The Company's activities are covered by one operating and reporting segment: Drug Development. There have been no changes to management's assessment of the operating and reporting segment of the Company during the year.

All non-current assets are based in the United Kingdom.

VERONA PHARMA PLC  
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)  
FOR THE THREE YEARS ENDED DECEMBER 31, 2018

7. Operating loss

	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
	£'000s	£'000s	£'000s
<b>Operating Loss is stated after charging / (crediting):</b>			
<b>Research and development costs:</b>			
Employee benefits (note 8)	3,360	3,435	2,037
Amortization of patents (note 12)	85	111	51
Legal, professional consulting and listing fees	161	331	—
Other research and development expenses	15,688	19,840	2,434
Total research and development costs	19,294	23,717	4,522
<b>General and administrative costs:</b>			
Employee benefits (note 8)	3,240	2,857	865
Legal, professional consulting and listing fees	1,296	2,045	884
Amortization of computer software (note 12)	5	5	1
Loss on disposal of property, plant and equipment (note 13)	—	—	3
Depreciation of property, plant and equipment (note 13)	8	7	10
Operating lease charge — land and buildings	384	294	169
(Gain) / Loss on variations in foreign exchange rate	(9)	36	139
Other general and administrative expenses	1,373	795	427
Total general and administrative costs	6,297	6,039	2,498
Operating loss	25,591	29,756	7,020

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**

**8. Directors' emoluments and staff costs**

	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
The average number of employees (excluding directors) of the Company during the year:			
Research and Development	7	7	5
General and Administrative	7	5	2
Total	<u>14</u>	<u>12</u>	<u>7</u>
	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
	£'000s	£'000s	£'000s
<b>Aggregate emoluments of directors:</b>			
Salaries and other short-term employee benefits	830	897	951
Social security costs	94	103	118
Incremental payment for additional services	27	—	44
Other pension costs	10	17	19
Total directors' emoluments	961	1,017	1,132
Share-based payment charge	1,337	1,037	257
Directors' emoluments including share-based payment charge	<u>2,298</u>	<u>2,054</u>	<u>1,389</u>
	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
	£'000s	£'000s	£'000s
<b>Aggregate executive officers costs:</b>			
Wages and salaries	857	864	512
Social security costs	83	81	22
Incremental payment for additional services	—	—	—
Share-based payment charge	769	1,332	235
Other pension costs	19	17	2
Total executive officers costs	<u>1,728</u>	<u>2,294</u>	<u>771</u>
	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
	£'000s	£'000s	£'000s
<b>Aggregate other staff costs:</b>			
Wages and salaries	1,622	1,272	515
Social security costs	150	101	76
Incremental payment for additional services	—	—	58
Share-based payment charge	795	550	84
Other pension costs	34	21	9
Total other staff costs	<u>2,601</u>	<u>1,944</u>	<u>742</u>

The Company considers key management personnel to comprise directors and executive officers.

The Company operates a defined contribution pension scheme for U.K. employees and executive directors. The total pension cost during the year ended December 31, 2018 was £63 thousand (2017: £55 thousand and 2016: £30 thousand). There were no prepaid or accrued contributions to the scheme at December 31, 2018 (2017 and 2016: £nil).

VERONA PHARMA PLC  
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)  
FOR THE THREE YEARS ENDED DECEMBER 31, 2018

9. Finance income and expense

	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
	£'000s	£'000s	£'000s
<b>Finance income:</b>			
Interest received on cash balances	861	345	86
Foreign exchange gain on translating foreign currency denominated balances	1,922	—	687
Fair value adjustment on derivative financial instruments (note 17)	—	6,650	1,068
Other Income	—	23	—
Total finance income	<u>2,783</u>	<u>7,018</u>	<u>1,841</u>
	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
	£'000s	£'000s	£'000s
<b>Finance expense:</b>			
Fair value adjustment on derivative financial instruments (note 17)	1,219	—	—
Transaction costs allocated to the issue of warrants (note 17)	—	—	586
Foreign exchange loss on translating foreign currency denominated balances	—	2,392	—
Remeasurement of assumed contingent arrangement	—	—	122
Unwinding of discount factor related to the assumed contingent arrangement (note 19)	106	73	86
Total finance expense	<u>1,325</u>	<u>2,465</u>	<u>794</u>



**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**

**10. Taxation**

	Year ended December 31, 2018	Year ended December 31, 2017	Year ended December 31, 2016
	£'000s	£'000s	£'000s
<b>Analysis of tax credit for the year</b>			
Current tax:			
U.K. tax credit	(4,290)	(5,006)	(1,067)
U.S. tax charge	30	306	129
Adjustment in respect of prior periods	28	(6)	(16)
<b>Total tax credit</b>	<b>(4,232)</b>	<b>(4,706)</b>	<b>(954)</b>

The difference between the total tax shown above and the amount calculated by applying the standard rate of tax to the loss before tax is as follows:

<b>Factors affecting the tax credit for the year</b>			
Loss on ordinary activities before taxation	(24,133)	(25,203)	(5,973)
Multiplied by standard rate of corporation tax of 19% (2017: 19.25% and 2016: 20%)	(4,585)	(4,852)	(1,195)
Effects of:			
Non-deductible expenses	540	675	292
Fair value adjustment on derivative financial instruments	232	(1,280)	(214)
Research and development incentive	(1,846)	(2,116)	(427)
Temporary differences not recognized	(3)	(2)	(4)
Difference in overseas tax rates	8	136	56
Tax losses carried forward not recognized	1,394	2,739	554
Adjustment in respect of prior periods	28	(6)	(16)
<b>Total tax credit</b>	<b>(4,232)</b>	<b>(4,706)</b>	<b>(954)</b>

U.K. corporation tax is charged at 19% (2017: 19.25% and 2016: 20.00%) and U.S. federal and state tax at 27.6% (2017 and 2016: 35%).

The following tables represent deferred tax balances recognized in the Consolidated Statement of Financial Position. There were no movements in either the deferred tax asset or the deferred tax liability.

	As at December 31, 2018	As at December 31, 2017
	£'000s	£'000s
Deferred tax assets	250	250
Deferred tax liabilities	(250)	(250)
<b>Net balances</b>	<b>—</b>	<b>—</b>

The deferred tax liability relates to the difference between the accounting and tax bases of the IP R&D intangible asset. A deferred tax asset relating to UK tax losses has been recognized and offset against the liability.

**Factors that may affect future tax charges**

The Company has U.K. tax losses available for offset against future profits in the United Kingdom. However an additional deferred tax asset has not been recognized in respect of such items due to uncertainty of future profit streams. As of December 31, 2018, the unrecognized deferred tax asset at 17% is estimated to be £6.65 million (2017: £5.43 million at 17%).

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**

**11. Goodwill**

	As of December 31, 2018	As of December 31, 2017
	£'000s	£'000s
Goodwill at January 1 and December 31	441	441

Goodwill represents the excess of the purchase price over the fair value of the net assets acquired in connection with the acquisition of Rhinopharma in September 2006. Goodwill is not amortized, but is tested annually for impairment.

Recognizing that the Company is still in its pre-revenue phase and that the research projects are not yet ready for commercial use, the Company assesses the recoverable amount of the CGU containing the IP R&D and goodwill with reference to the Company's market capitalization as of December 31, 2018, the date of testing of IP R&D and goodwill impairment. The market capitalization of the Company was approximately £92.2 million as of December 31, 2018, (2017: £109.7 million) compared to the Company's net assets of £62.9 million (2017: £79.9 million). Therefore, no impairment was recognized.

**12. Intangible assets**

	IP R&D	Computer software	Patents	Total
	£'000s	£'000s	£'000s	£'000s
<b>Cost</b>				
At January 1, 2017	1,469	6	592	2,067
Additions	—	5	203	208
Disposals	—	—	(68)	(68)
At December 31, 2017	1,469	11	727	2,207
<b>Accumulated amortization</b>				
At January 1, 2017	—	1	189	190
Charge for year	—	5	111	116
Disposals	—	—	(68)	(68)
At December 31, 2017	—	6	232	238
<b>Net book value</b>				
At December 31, 2017	1,469	5	495	1,969

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**Intangible assets (continued)**

	IP R&D	Computer software	Patents	Total
	£'000s	£'000s	£'000s	£'000s
<b>Cost</b>				
At January 1, 2018	1,469	11	727	2,207
Additions	—	4	251	255
Disposals	—	—	(6)	(6)
At December 31, 2018	1,469	15	972	2,456
<b>Accumulated amortization</b>				
At January 1, 2018	—	6	232	238
Charge for year	—	5	85	90
Disposals	—	—	(6)	(6)
At December 31, 2018	—	11	311	322
<b>Net book value</b>				
At December 31, 2018	1,469	4	661	2,134

Intangible assets comprise patents, computer software and an IP R&D asset that arose on the acquisition of Rhinopharma and investment in patents to protect ensifentrine.

IP R&D is currently not amortized and is reviewed for impairment on an annual basis, together with goodwill, or where there is an indication that the assets might be impaired until the asset is brought into use.

Patents are amortized over a period of ten years and are regularly reviewed for impairment to ensure the carrying amount exceeds the recoverable amount in accordance with note 2.8.

Recognizing that the Company is still in its pre-revenue phase and that the research projects are not yet ready for commercial use, the Company assesses the recoverable amount of the CGU containing the IP R&D and goodwill with reference to the Company's market capitalization as of December 31, 2018, the date of testing of IP R&D and goodwill impairment. The market capitalization of the Company was approximately £92.2 million as of December 31, 2018, (2017: £109.7 million) compared to the Company's net assets of £62.9 million (2017: £79.9 million). Therefore, no impairment was recognized.

The Company notes that after the reduction in the share price since December 31, 2018, and as at February 21, 2019, the market value of the Company was £6.6 million less than the net book value as of 31 December 2018. The Company judges that the decline in the share price was a reaction to recent clinical trial results and was driven by relatively low trading volumes. The Company believes that the trial data was encouraging and notes that this has not resulted in a significant change in development plans, timelines, potential market share or pricing.

VERONA PHARMA PLC  
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)  
FOR THE THREE YEARS ENDED DECEMBER 31, 2018

13. Property, plant and equipment

	Computer hardware £'000s	Total £'000s
<b>Cost</b>		
At January 1, 2017	17	17
Additions	9	9
At December 31, 2017	26	26
<b>Accumulated depreciation</b>		
At January 1, 2017	3	3
Charge for the year	7	7
At December 31, 2017	10	10
<b>Net book value</b>		
At December 31, 2017	16	16

	Computer hardware £'000s	Total £'000s
<b>Cost</b>		
At January 1, 2018	26	26
Additions	13	13
At December 31, 2018	39	39
<b>Accumulated depreciation</b>		
At January 1, 2018	10	10
Charge for the year	8	8
At December 31, 2018	18	18
<b>Net book value</b>		
At December 31, 2018	21	21

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**

**14. Prepayments and other receivables**

	<b>As of December 31, 2018</b>	<b>As of December 31, 2017</b>
	<b>£'000s</b>	<b>£'000s</b>
Prepayments	1,362	1,138
Other receivables	1,101	672
<b>Total prepayments and other receivables</b>	<b>2,463</b>	<b>1,810</b>

The prepayments balance includes prepayments for insurance and clinical activities.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**

## 15. Share Capital

The movements in the Company's share capital are summarized below:

Date	Description	Number of shares	Share Capital amounts in £'000s
<b>January 1, 2017</b>		<b>51,361,063</b>	<b>2,568</b>
May 2, 2017	Issuance of shares	47,653,100	2,383
May 18, 2017	Issuance of shares	5,539,080	277
May 26, 2017	Issuance of shares	330,824	17
September 13, 2017	Exercise of options	133,333	6
<b>As at December 31, 2017</b>		<b>105,017,400</b>	<b>5,251</b>
August 9, 2018	Vesting of RSUs	58,112	3
September 20, 2018	Vesting of RSUs	251,125	12
<b>As at December 31, 2018</b>		<b>105,326,637</b>	<b>5,266</b>

The total number of authorized ordinary shares, with a nominal value of £0.05 each, is 200,000,000 (share capital of £10,000,000). All 105,326,637 ordinary shares at December 31, 2018 are allotted, unrestricted, called up and fully paid.

As at December 31, 2018, the number of ordinary shares in issue was 105,326,637. All new ordinary shares rank pari passu with existing ordinary shares.

During 2018, the Company issued 309,237 ordinary shares upon vesting of employee restricted share units.

On April 26, 2017, the Company announced the closing of the Global Offering of an aggregate of 47,399,001 new ordinary shares, comprising 5,768,000 ADSs at a price of \$13.50 per ADS and 1,255,001 ordinary shares at a price of £1.32 per ordinary share. During May 2017, the underwriters purchased an additional 733,738 ADSs, representing 5,869,904 ordinary shares, at a price of \$13.50 per ADS. The total gross proceeds in the Global Offering amounted to \$89.9 million (£70.0 million).

In addition, the Chairman of Verona Pharma's board of directors, Dr. David Ebsworth, and an existing shareholder agreed to subscribe for 254,099 new ordinary shares at a price of £1.32 per ordinary share in the Shareholder Private Placement, contingent on and concurrent with the Global Offering and generating gross proceeds of £0.3 million.

Where there is a time and foreign exchange difference between proceeds from a share issue becoming due and being received, the movement is taken to Finance income or Finance expense as appropriate. In respect of the Global Offering and Shareholder Private Placement, the Company recorded a finance expense of £439 thousand arising from movements in exchange rates on funds receivable, offset by a saving on commission payable of £31 thousand, for a net finance expense of £408 thousand.

On September 13, 2017, the company issued 133,333 new shares upon exercise of share options at 110p per share, resulting in proceeds of £147 thousand to the Company.

On February 8, 2017, the board of directors of the Company approved a share consolidation where every 50 existing ordinary shares of £0.001 were consolidated into one ordinary share of £0.05.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**

**16. Share-based payments charge**

In accordance with IFRS 2 "Share Based Payments," the cost of equity-settled transactions is measured by reference to their fair value at the date at which they are granted. Where equity-settled transactions were entered into with third party service providers, fair value is determined by reference to the value of the services provided. For other equity-settled transactions fair value is determined using the Black-Scholes model. The cost of equity-settled transactions is recognized over the period until the award vests. No expense is recognized for awards that do not ultimately vest. At each reporting date, the cumulative expense recognized for equity-based transactions reflects the extent to which the vesting period has expired and the number of awards that, in the opinion of the Directors at that date, will ultimately vest.

The costs of equity-settled share-based payments to employees are recognized in the Statement of Comprehensive Income, together with a corresponding increase in equity during the vesting period. During the twelve months ended December 31, 2018, the Company recognized a share-based payment expense of £2.90 million (2017: £2.92 million). The charge is included within both general and administrative costs as well as in research and development costs and represents the current year's allocation of the expense for relevant share options.

The Company granted share options under an Unapproved Share Option Scheme (the "Unapproved Scheme"). Under the Unapproved Scheme, options were granted to employees, directors and consultants to acquire shares at a price to be determined by the Directors. In general, options granted prior to December 31, 2016 were granted at a premium to the share price at the date of grant and vested over a period of three years from the date of grant, one third vesting on the first anniversary of grant, a further third vesting on the second anniversary of grant and the remainder vesting on the third anniversary of grant.

Options granted since January 1, 2017 generally vest over three or four years from the date of the grant using two different methods. The first method is one third vesting over one year, the second third vesting over two years and the final third vesting over three years. The second method is one quarter vesting over one year, the second quarter vesting over two years, the third quarter vesting over three years and the final quarter vesting over four years. The vesting period is defined as the period between the date of grant and the date when the options become exercisable. The options are exercisable during a period ending ten years after the date of grant.

Options were issued to advisors under the Unapproved Scheme. Such options generally vested immediately and were exercisable between one and two years after grant.

In 2016, the Company issued options under its tax efficient EMI Option Scheme (the "EMI Scheme"). Under the EMI Scheme, options were granted to employees and directors who were contracted to work at least 25 hours a week for the Company or for at least 75% of their working time. The options granted under the EMI Scheme are exercisable at a price that is above the share price at the date of the grant and in accordance with a vesting schedule determined by the Directors at the time of grant and have an exercise period of ten years from the date of grant.

Under its 2017 Incentive Award Plan, the Company grants RSUs to employees and directors. The RSUs vest over a period of three or four years from the date of the grant using two different methods. The first method is one third vesting over one year, the second third vesting over two years and the final third vesting over three years. The second method is one quarter vesting over one year, the second quarter vesting over two years, the third quarter vesting over three years and the final quarter vesting over four years.

In the year ended December 31, 2018, under the 2017 Incentive Award Plan, the Company granted 2,090,847 (2017: 4,656,828 ) share options and 273,390 RSUs (2017: 1,052,236 ). The total fair values of the options and RSUs were estimated using the Black-Scholes option-pricing model for equity-settled transactions and amounted to £2.32 million (2017: £5.33 million). The cost is amortized over the vesting period of the options and RSUs on a straight-line basis.

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**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**16. Share-based payments charge (Continued)**

The following assumptions were used for the Black-Scholes valuation of share options and RSUs granted in 2017 and 2018. For the options granted under the Unapproved Scheme the table indicates the ranges used in determining the fair-market values, aligning with the various dates of the underlying grants. The volatility is calculated using historic weekly averages of the Company's share price over a period that is in line with the expected life of the options and RSUs.

<b>Issued in 2017</b>	<b>Unapproved Scheme</b>	<b>Restricted Stock Units</b>
Options granted	4,656,828	1,052,236
Risk-free interest rate	0.29% - 0.62%	0.42%-0.62%
Expected life of options	5.5 – 7.0 years	5.5 – 7.0 years
Annualized volatility	71.3% - 73.3%	71.3% - 73.3%
Dividend rate	0.00%	0.00%
Vesting period	1 to 4 years	1 to 4 years

<b>Issued in 2018</b>	<b>Unapproved Scheme</b>	<b>Restricted Stock Units</b>
Options granted	2,090,847	273,390
Risk-free interest rate	1.08% - 1.22%	1.08% - 1.22%
Expected life of options	5.5 - 7 years	5.5 - 7 years
Annualized volatility	69.88% -71.35%	69.88% -71.35%
Dividend rate	0.00%	0.00%
Vesting period	1 to 4 years	1 to 4 years

The Company had the following share options movements in the year ended December 31, 2018:

<b>Year of issue</b>	<b>Exercise price (£)</b>	<b>At January 1, 2018</b>	<b>Options granted</b>	<b>Options forfeited</b>	<b>Options expired</b>	<b>At December 31, 2018</b>	<b>Expiry date</b>
2012	2.50 - 7.50	99,993	—	—	—	99,993	June 1, 2022
2013	2	99,990	—	—	—	99,990	April 15, 2023
2013	2.00	159,999	—	—	—	159,999	July 29, 2023
2014	1.75	109,998	—	—	—	109,998	May 15, 2024
2014	1.75	49,998	—	—	—	49,998	May 15, 2024 *
2014	1.10 - 1.75	66,667	—	—	(66,667)	—	August 6, 2018 **
2015	1.25	41,997	—	—	—	41,997	January 29, 2025 *
2015	1.25	549,999	—	—	—	549,999	January 29, 2025
2016	2	260,000	—	(20,000)	—	240,000	February 2, 2026
2016	2.00	21,996	—	—	—	21,996	February 2, 2026 *
2016	1.80	809,996	—	(133,332)	—	676,664	August 3, 2026
2016	1.89	299,997	—	—	—	299,997	September 13, 2026
2016	2.04	300,000	—	—	—	300,000	September 16, 2026
2017	1.32 - 1.525	4,656,828	—	(563,664)	—	4,093,164	April 26, 2027
2018	1.46	—	2,090,847	(82,528)	—	2,008,319	March 8, 2028
<b>Total</b>		<b>7,527,458</b>	<b>2,090,847</b>	<b>(799,524)</b>	<b>(66,667)</b>	<b>8,752,114</b>	

\* Options granted under the EMI Scheme.

\*\* Valued based on fair value of services received.



**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**16. Share-based payments charge (Continued)**

The Company had the following RSU movements in the year ended December 31, 2018:

Year of issue	Exercise price (£)	At January 1, 2018	Units granted	Units vested	Units forfeited	At December 31, 2018	Expiry date
2017	n/a	1,052,236	—	(309,237)	(13,012)	729,987	April 26, 2027
2018	n/a	—	273,390	—	(140,904)	132,486	March 8, 2028
<b>Total</b>		<b>1,052,236</b>	<b>273,390</b>	<b>(309,237)</b>	<b>(153,916)</b>	<b>862,473</b>	

Outstanding and exercisable share options by scheme as of December 31, 2018:

Plan	Outstanding	Exercisable	Weighted average exercise price in £ for Outstanding	Weighted average exercise price in £ for Exercisable
Unapproved	8,538,130	3,336,232	1.49	1.57
EMI	213,984	206,652	3.06	3.09
<b>Total</b>	<b>8,752,114</b>	<b>3,542,884</b>	<b>1.53</b>	<b>1.66</b>

As of December 31, 2018 there were no restricted share options exercisable (2017: nil) and there is no exercise price for restricted share options.

The options outstanding at December 31, 2018 had a weighted average remaining contractual life of 8 years (2017: 8.6 years). For 2017 and 2018, the number of options granted and expired and the weighted average exercise price of options were as follows:

	Number of options	Weighted average exercise price (£)
<b>At January 1, 2017</b>	<b>3,037,296</b>	<b>1.87</b>
Options granted in 2017:		
Employees	3,150,846	1.32
Directors	1,505,982	1.32
Options exercised in the year	(133,333)	1.10
Options expired in the year	(33,333)	1.90
<b>At December 31, 2017</b>	<b>7,527,458</b>	<b>1.53</b>
<b>Exercisable at December 31, 2017</b>	<b>797,333</b>	<b>2.04</b>

	Number of options	Weighted average exercise price (£)
<b>At January 1, 2018</b>	<b>7,527,458</b>	<b>1.53</b>
Options granted in 2018:		
Employees	1,222,089	1.46
Directors	868,758	1.46
Options forfeited in the year	(799,524)	1.43
Options expired in the year	(66,667)	1.75
<b>At December 31, 2018</b>	<b>8,752,114</b>	<b>1.53</b>
<b>Exercisable at December 31, 2018</b>	<b>3,542,884</b>	<b>1.66</b>

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**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**16. Share-based payments charge (Continued)**

The following table shows the number of RSUs issued in 2017. There were no RSUs forfeited, canceled or vested in 2017. The fair value of each unvested RSU at grant date was £1.32.

	Number of RSUs
<b>At January 1, 2017</b>	—
Granted:	
Employees	705,841
Directors	346,395
<b>At December 31, 2017</b>	<b>1,052,236</b>

The following table shows the number of RSUs issued, exercised and forfeited in 2018. The fair value of each unvested RSU granted in 2018 was £1.46.

	Number of RSUs
<b>At January 1, 2018</b>	1,052,236
Granted:	
Employees	136,404
Directors	136,986
RSUs vested in the year	(309,237)
RSUs forfeited in the year	(153,916)
<b>At December 31, 2018</b>	<b>862,473</b>

**17. Derivative financial instrument**

Pursuant to the July 2016 Placement, on July 29, 2016, the Company issued 31,115,926 units to new and existing investors at the placing price of £1.4365 per unit. Each unit comprises one ordinary share and one warrant.

The warrant holders can subscribe for 0.4 of an ordinary share at a per share exercise price of 120% of the placing price or £1.7238. The warrant holders can opt for a cashless exercise of their warrants, whereby the warrant holders can choose to exchange the warrants held for reduced number of warrants exercisable at nil consideration. The reduced number of warrants is calculated based on a formula considering the share price and the exercise price of the warrants. The warrants are therefore classified as a derivative financial liability, since their exercise could result in a variable number of shares to be issued.

The warrants entitled the investors to subscribe for in aggregate a maximum of 12,401,262 shares. The warrants can be exercised on the "Commencement Date" which is defined as the earlier of the consummation of the Global Offering (being May 2, 2017) or the first anniversary of the grant, and the exercise period shall end on the fifth anniversary of the commencement date (being May 2, 2022).

The ordinary shares and warrants were accounted for as a compound financial instrument. The warrants component of the instrument issued at the July 2016 Placement was classified as a derivative financial liability and was initially measured at fair value of £9.0 million. The residual amount of proceeds totaling £35.7 million was recognized within equity. Subsequently the financial liability was re-measured at the reporting date at fair value through profit or loss.

The total of transaction costs the Company incurred for the above transactions amounted to £2.9 million of which £0.6 million was allocated to the warrants and the remaining £2.3 million was presented as a reduction to share premium, by reference to the proceeds allocated to each component. The amount assigned to the financial liability of the warrants was subsequently presented as finance expense in the Consolidated Statement of Comprehensive Income.

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**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**  
**Derivative financial instrument (Continued)**

In the year ended December 31, 2018, no warrants were forfeited (2017: 45,108).

The table below presents the assumptions in applying the Black-Scholes model to determine the fair value of the warrants.

	As of December 31, 2018	As of December 31, 2017
Shares available to be issued under warrants	12,401,262	12,401,262
Exercise price	£ 1.7238	£ 1.7238
Risk-free interest rate	0.760%	0.420%
Expected term to exercise	3.40 years	1.79 years
Annualized volatility	60.72%	47.35%
Dividend rate	0.00%	0.00%

The figures disclosed above relating to the issue of the shares and warrants have been retrospectively adjusted to reflect the 50-for-1 share consolidation in 2017 as described in note 1. The original number of units issued to new and existing investors was 1,555,796,345 units at a placing price of 2.873 pence per unit and an exercise price of 3.4476 pence per share. This entitled the investors to subscribe for in aggregate a maximum of 622,318,538 shares.

As per the reporting date, the Company updated the underlying assumptions and calculated a fair value of these warrants amounting to £2.5 million. The variance of 1.2 million is recorded as finance expense in the Consolidated Statement of Comprehensive Income.

	Derivative financial instrument	Derivative financial instrument
	2018	2017
	£'000s	£'000s
<b>At January 1</b>	1,273	7,923
Fair value adjustments recognized in profit or loss	1,219	(6,650)
<b>At December 31</b>	<b>2,492</b>	<b>1,273</b>

For the amount recognized at December 31, 2018, the effect when the following parameter deviates up or down is presented in the below table.

	Volatility (up / down 10% pts)
	£'000s
Variable up	3,262
<b>Base case, reported fair value</b>	<b>2,492</b>
Variable down	1,738

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**

**18. Trade and other payables**

	As of December 31, 2018	As of December 31, 2017
	£'000s	£'000s
Trade payables	2,839	1,214
Other payables	12	74
Accruals	4,882	5,866
Total trade and other payables	<u>7,733</u>	<u>7,154</u>

**19. Assumed contingent obligation related to the business combination**

The value of the assumed contingent obligation as of December 31, 2018 amounts to £996 thousand (2017: £875 thousand). The increase in value of the assumed contingent obligation during 2018 amounted to £121 thousand (2017: £73 thousand ) and the unwinding of the discount on the liability was recorded in finance expense. Periodic re-measurement is triggered by changes in the probability of success. The discount percentage applied is 12%. In 2018 there were no events that triggered remeasurement.

	2018	2017
	£'000s	£'000s
January 1, 2018	875	802
Impact of changes in foreign exchange rates	15	(23)
Unwinding of discount factor	106	96
December 31, 2018	<u>996</u>	<u>875</u>

For the amount recognized December 31, 2018 of £121 thousand (2017: £73 thousand) the effect if underlying assumptions were to deviate up or down is presented in the following table (assuming the probability of success does not change):

	Discount rate (up / down 1 % pt)	Revenue (up / down 10 % pts)
	£'000s	£'000s
Variable up	954	1,026
<b>Base case, reported fair value</b>	<b>996</b>	<b>996</b>
Variable down	1,040	966

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2018**

## 20. Financial commitments

As of December 31, 2018, and 2017, the Company was committed to making the following payments under non-cancellable operating leases related to its facilities.

	<u>Land and Buildings</u>	<u>Land and Buildings</u>
	<u>2018</u>	<u>2017</u>
	<u>£'000s</u>	<u>£'000s</u>
Operating lease obligations:		
Within one year	572	291
Between one and five years	<u>28</u>	<u>277</u>
Total	<u>600</u>	<u>568</u>

## 21. Related parties transactions and other shareholder matters

### (i) Related party transactions

The Directors have authority and responsibility for planning, directing and controlling the activities of the Company and they therefore comprise key management personnel as defined by IAS 24, ("Related Party Disclosures").

### (ii) Other shareholder matters

The Company has entered into the following arrangements with parties who are significant shareholders of the Company, though they are not classed as related parties.

The Company entered into relationship agreements with Vivo Ventures Fund VII, L.P., Vivo Ventures VII Affiliates Fund, L.P., Vivo Ventures Fund VI, L.P., Vivo Ventures VI Affiliates Fund, L.P. (collectively, "Vivo Capital"), Orbimed Private Investments VI L.P. ("Orbimed"), Abingworth Bioventures VI L.P. ("Abingworth"), and Arix Bioscience plc ("Arix") and Arthurian Life Sciences SPV GP Limited, ("Arthurian"). As agreed in these relationship agreements, the above parties invested in the Company as part of the July 2016 Placement, and the Company agreed to appoint representatives designated by Vivo Capital, OrbiMed, Abingworth, and Arix and Arthurian, to the board of directors, who are Dr. Mahendra Shah, Mr. Rishi Gupta, and Dr. Andrew Sinclair and who was, prior to the termination of the appointment rights in the Arix and Arthurian relationship agreement described below, Dr. Ken Cunningham, respectively.

The appointment rights within the relationship agreement with Arix and Arthurian terminated on closing of the Global Offering on April 26, 2017. Dr Cunningham agreed to continue to serve on the Company's board of directors as an independent director. The respective appointment rights under the remaining relationship agreements will automatically terminate upon (i) Vivo Capital, OrbiMed or Abingworth (or any of their associates), as applicable, ceasing to beneficially hold 6.5% of the issued ordinary shares, or (ii) the ordinary shares ceasing to be admitted to AIM.

The Company also entered into a management rights agreement with Novo A/S under which Novo A/S was entitled to appoint an observer to the Board. The appointment rights within the management rights agreement terminated on closing of the Global Offering on April 26, 2017.

Dr. Jan-Anders Karlsson, Chief Executive Officer of the Company, purchased 3,250 ordinary shares for £5 thousand from the market in the year ended December 31, 2018 (2017: £nil).

Dr. David Ebsworth, Chairman of the Company, purchased 12,000 ordinary shares for £14 thousand from the market in the year ended December 31, 2018 (2017: £28 thousand).

During the year ended December 31, 2017, Vikas Sinha, a Non-Executive Director, purchased of £234 thousand of our ordinary shares, in the form of ADSs, as part of the Global Offering.

At December 31, 2018, there was a receivable of £126 thousand (2017: nil) due from one director and two key management personnel relating to tax due on RSUs that vested in the year ended December 31, 2018. This receivable was repaid, together with interest at a rate of 3.9% per annum, by March 6, 2019.

In the year ended December 31, 2018, a director provided consultancy services for £26 thousand (2017: £nil).

Agreement Date : 19 October 2017      Confirmation No : R-380019

### Business Centre Details

LONDON, London Bridge - More London

Sales Manager      Max Chapman

### Client Details

Company Name      VERONA PHARMA PLC

Phone      02032834000

Email      piers.morgan@veronapharma.com

### Office Payment Details (exc.VAT and exc. services)

Office Number	Number of people	Price per Office
145A	6	£ 11,000.00
151	1	£ 2,858.00

Service Provision :	Start Date	1 January 2018	End Date	31 January 2020
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All agreements end on the last calendar day of the month.

### Terms and Conditions

We are IW Group Services (UK) Limited [the Provider], please click the link below for terms and conditions.

By signing our service Agreement, you agree to provide information and sign relevant documents to allow the Provider to claim any relief on business rates which at the Provider's risk is already included in your service fee with reference to the Business Centre within 2 working days of such request. The Provider has appointed Gerald Eve LLP Rating Payment Management Services to administer such information.



[Download the terms and conditions](#)



[Download the house rules](#)



This website is secure. Your personal details are protected at all times.



[Print Agreement](#)

## **1. This Agreement**

1.1 Nature of this agreement: This agreement is the commercial equivalent of an agreement for accommodation(s) in a hotel. The whole of the Centre remains in the Provider's possession and control. THE CLIENT ACCEPTS THAT THIS AGREEMENT CREATES NO TENANCY INTEREST, LEASEHOLD ESTATE OR OTHER REAL PROPERTY INTEREST IN THE CLIENT'S FAVOUR WITH RESPECT TO THE ACCOMMODATION(S). The Provider is giving the Client the right to share with the Provider the use of the Centre on these terms and conditions, as supplemented by the House Rules, so that the Provider can provide the services to the Client. This Agreement is personal to the Client and cannot be transferred to anyone else without prior consent from the Provider unless such transfer is required by law. The Provider will not unreasonably withhold its consent to assignment to a parent, subsidiary or affiliate of Client provided that Client and assignee execute the Provider's form of Assignment of License Agreement which will require assignee to assume all Client obligations and will not release the Client. This agreement is composed of the front page describing the accommodation(s), the present terms and conditions, the House Rules and the Service Price Guide (where available).

1.2 Comply with House Rules: The Client must comply with any House Rules which the Provider imposes generally on users of the Centre. The House Rules vary from country to country and from Centre to Centre and these can be requested locally.

1.3 AUTOMATIC RENEWAL: THIS AGREEMENT LASTS FOR THE PERIOD STATED IN IT AND THEN **WILL BE EXTENDED AUTOMATICALLY FOR SUCCESSIVE PERIODS EQUAL TO THE CURRENT TERM BUT NO LESS THAN 3 MONTHS** (UNLESS LEGAL RENEWAL TERM LIMITS APPLY) UNTIL TERMINATED BY THE CLIENT OR BY THE PROVIDER PURSUANT TO SECTION 1.4. ALL PERIODS SHALL RUN TO THE LAST DAY OF THE MONTH IN WHICH THEY WOULD OTHERWISE EXPIRE. THE FEES ON ANY RENEWAL WILL BE AT THE THEN PREVAILING MARKET RATE. THIS CLAUSE DOES NOT APPLY TO MONTH TO MONTH AGREEMENTS.

1.4 **CANCELLATION:** EITHER THE PROVIDER OR THE CLIENT CAN TERMINATE THIS AGREEMENT AT THE END DATE STATED IN IT, OR AT THE END OF ANY EXTENSION OR RENEWAL PERIOD, BY GIVING AT LEAST THREE MONTHS WRITTEN NOTICE TO THE OTHER. HOWEVER, IF THIS AGREEMENT, EXTENSION OR RENEWAL IS FOR THREE MONTHS OR LESS AND EITHER THE PROVIDER OR THE CLIENT WISHES TO TERMINATE IT, THE NOTICE PERIOD IS TWO MONTHS IF THIS AGREEMENT, EXTENSION OR RENEWAL IS FOR TWO MONTHS OR LESS, NOTICE MUST BE GIVEN WITHIN ONE WEEK OF THE START DATE OF THE CURRENT TERM. IF THE CLIENT IS ON A MONTH TO MONTH AGREEMENT EITHER PARTY MAY TERMINATE THIS AGREEMENT BY GIVING NO LESS THAN ONE MONTHS' NOTICE TO THE OTHER (EFFECTIVE FROM THE START OF ANY CALENDAR MONTH).

1.5 Ending this agreement immediately: To the maximum extent permitted by applicable law, the Provider may put an end to this agreement immediately by giving the Client notice and without need to follow any additional procedure if (a) the Client becomes insolvent, bankrupt, goes into liquidation or becomes unable to pay its debts as they fall due, or (b) the Client is in breach of one of its obligations which cannot be put right or which the Provider have given the Client notice to put right and which the Client has failed to put right within fourteen (14) days of that notice, or (c) its conduct, or that of someone at the Centre with its permission or invitation, is incompatible with ordinary office use and (i) such conduct is repeated despite the Client having been given a warning or (ii) such conduct is material enough (in the Provider's opinion) to warrant immediate termination.

If the Provider puts an end to this agreement for any of these reasons it does not put an end to any outstanding obligations, including additional services used, requested or required under the agreement and the monthly office fee for the remainder of the period for which this agreement would have lasted if the Provider had not ended it.

1.6 If the Centre is no longer available: In the event that the Provider is permanently unable to provide the services and accommodation(s) at the Centre stated in this agreement then this agreement will end and the Client will only have to pay monthly office fees up to the date it ends and for the additional services the Client has used. The Provider will try to find suitable alternative accommodation(s) for the Client at another Provider Centre.

1.7 When this agreement ends the Client is to vacate the accommodation(s) immediately, leaving the accommodation(s) in the same condition as it was when the Client took it. Upon the Client's departure or if the Client, at its option, chooses to relocate to different rooms within the Centre, the Provider will charge an Office Restoration Service fee to cover normal cleaning and testing and to return the accommodation(s) to its original state. This fee will differ by country and is listed in the House Rules. The Provider reserves the right to charge additional reasonable fees for any repairs needed above and beyond normal wear and tear. If the Client leaves any property in the Centre the Provider may dispose of it at the Client's cost in any way the Provider chooses without owing the Client any responsibility for it or any proceeds of sale. If the Client continues to use the accommodation(s) when

this agreement has ended the Client is responsible for any loss, claim or liability the Provider incurs as a result of the Client's failure to vacate on time. The Provider may, at its discretion, permit the Client an extension subject to a surcharge on the monthly office fee.

1.8 Employees: While this agreement is in force and for a period of six months after it ends, neither the Provider nor the Client may knowingly solicit or offer employment to any of the other's staff employed in the Centre. This obligation applies to any employee employed at the Centre up to that employee's termination of employment, and for three months thereafter. It is stipulated that the breaching party shall pay the non-breaching party the equivalent of six months' salary for any employee concerned. Nothing in this clause shall prevent either party from employing an individual who responds in good faith and independently to an advertisement which is made to the public at large.

1.9 Notices: All formal notices must be in writing, which may include by email, to the address first written above.

1.10 Confidentiality: The terms of this agreement are confidential. Neither the Provider nor the Client must disclose them without the other's consent unless required to do so by law or an official authority. This obligation continues for a period of 3 years after this agreement ends.

1.11 Applicable law: This agreement is interpreted and enforced in accordance with the law of the place where the relevant Centre is located. All dispute resolution proceedings will be conducted in the country, state or province where the Centre is located. If any provision of these terms and conditions is held void or unenforceable under the applicable law, the other provisions shall remain in force. In the case of Japan all agreements will be interpreted and enforced by the Tokyo District Court, and in the case of France, any dispute regarding this agreement will be settled by the relevant courts of the Paris jurisdiction.

## **2. Services and Obligations**

2.1 Office accommodation(s): The Provider is to provide the number of serviced office accommodation(s) for which the Client has agreed to pay in the Centre stated in this agreement. This agreement lists the accommodation(s) the Provider has initially allocated for the Client's use. The Client will have a non-exclusive right to the rooms allocated to it. Occasionally the Provider may need to allocate different accommodation(s), but these accommodation(s) will be of reasonably equivalent size and the Provider will notify the Client with respect to such different accommodation(s) in advance.

2.2 Office Services: The Provider is to provide during normal opening hours the services, if requested, described in the relevant service description (which is available on request). If the Provider decides that a request for any particular service is excessive, it reserves the right to charge an additional fee.

2.3 THE PROVIDER'S IT: WHILST THE PROVIDER HAS INTERNET SECURITY PROTOCOLS, THE PROVIDER DOES NOT MAKE ANY REPRESENTATIONS AS TO THE SECURITY OF THE PROVIDER'S NETWORK (OR THE INTERNET) OR OF ANY INFORMATION THAT THE CLIENT PLACES ON IT. The Client should adopt whatever security measures (such as encryption) it believes are appropriate to its circumstances. The Provider cannot guarantee that a particular degree of availability will be attained in connection with the Client's use of the Provider's network (or the internet). The Client's sole and exclusive remedy shall be the remedy of such failure by the Provider within a reasonable time after written notice.

## **3. Providing the Services**

3.1 Access to the accommodation(s): The Provider may need to enter the Client's accommodation(s) and may do so at any time. However, unless there is an emergency or the Client has given notice to terminate, the Provider will attempt to notify the Client verbally or electronically in advance when the Provider needs access to carry out testing, repair or works other than routine inspection, cleaning and maintenance. The Provider will also endeavour to respect reasonable security procedures to protect the confidentiality of the Client's business.

3.2 Availability at the start of this agreement: If for any reason the Provider cannot provide the accommodation(s) stated in this agreement by the date when this agreement is due to start it has no liability to the Client for any loss or damages but the Client may cancel this agreement without penalty. The Provider will not charge the Client the monthly office fee for accommodation(s) the Client cannot use until it becomes available. The Provider may delay the start date of this agreement provided it provides to the Client alternative accommodation(s) that shall be at least of equivalent size to the accommodation(s) stated in this agreement.



#### **4. Accommodation(s)**

4.1 The Client must not alter any part of its accommodation and must take good care of all parts of the centre, its equipment, fixtures, fittings and furnishings which the Client uses. The Client is liable for any damage caused by it or those in the Centre with the Client's permission or at the Client's invitation whether express or implied, including but not limited to all employees, contractors, agents or other persons present on the premises.

4.2 Office equipment: The Client must not install any cabling, IT or telecom connections without the Provider's consent, which the Provider may refuse at its absolute discretion.

As a condition to the Provider's consent, the Client must permit the Provider to oversee any installations (for example IT or electrical systems) and to verify that such installations do not interfere with the use of the accommodation(s) by other Clients or the Provider or any landlord of the building.

4.3 Insurance: It is the Client's responsibility to arrange insurance for its own property which it brings in to the Centre and for its own liability to its employees and to third parties. The Provider strongly recommends that the Client put such insurance in place.

#### **5. Use**

5.1 The Client must only use the accommodation(s) for office purposes. Office use of a "retail" or "medical" nature, involving frequent visits by members of the public, is not permitted.

5.2 The Client must not carry on a business that competes with the Provider's business of providing serviced office accommodation(s) or its ancillary services.

5.3 The Client's name and address: The Client may only carry on that business in its name or some other name that the Provider previously agrees.

5.4 Use of the Centre Address: The Client may use the Centre address as its business address. Any other uses are prohibited without the Provider's prior written consent.

#### **6. Compliance**

6.1 Comply with the law: The Client and the Provider must comply with all relevant laws and regulations in the conduct of its business in relation to this agreement. The Client must do nothing illegal in connection with its use of the Business Centre. The Client must not do anything that may interfere with the use of the Centre by the Provider or by others, (including but not limited to political campaigning or immoral activity), cause any nuisance or annoyance, increase the insurance premiums the Provider has to pay, or cause loss or damage to the Provider (including damage to reputation) or to the owner of any interest in the building which contains the Centre the Client is using. Both the Client and the Provider shall comply at all times with all relevant anti-bribery and anti-corruption laws. 6.2 If the Provider has been advised by any government authority or other legislative body that it has reasonable suspicion that the Client is conducting criminal activities from the Centre then the Provider shall be entitled to terminate this agreement with immediate effect. The Provider confirms that in providing the services it has not employed or used any labour in contravention of the requirements of any anti-slavery laws.

6.3 The Client acknowledges that (a) the terms of this clause are a material inducement in the Provider's execution of this agreement and (b) any violation by the Client of this clause shall constitute a material default by the Client hereunder, entitling the Provider to terminate this agreement, without further notice or procedure.

6.4 The Provider may collect and process personal data from and of the Client to administer contractual relationship, ensure compliance with applicable laws and regulations, and enable the Provider to provide its services and to manage its business. The Client acknowledges and accepts that such personal data may be transferred or made accessible to all entities of the Provider's group, wherever located, for the purposes of providing the services herein.

#### **7. The Provider's Liability**

7.1 The extent of the Provider's liability: To the maximum extent permitted by applicable law, the Provider is not liable to the Client in respect of any loss or damage the Client suffers in connection with this agreement, with the services or with the Client's accommodation(s) unless the Provider has acted deliberately or negligently in causing that loss or damage. The Provider is not liable for any loss as a result of the Provider's failure to provide a service as a result of mechanical breakdown, strike, termination of the Provider's interest in the building containing the Centre or otherwise unless the Provider does so deliberately or is negligent. In no event shall the Provider be liable for any loss or damage until the Client provides the Provider written notice and gives the Provider a reasonable time to put it right. If the Provider is liable for failing to provide the Client with any service under this

agreement then subject to the exclusions and limits set out immediately below the Provider will pay any actual and reasonable expenses the Client has incurred in obtaining that service from an alternative source. If the Client believes the Provider has failed to deliver a service consistent with these terms and conditions the Client shall provide the Provider written notice of such failure and give the Provider a reasonable period to put it right.

7.2 EXCLUSION OF CONSEQUENTIAL LOSSES, ETC.: THE PROVIDER WILL NOT IN ANY CIRCUMSTANCES HAVE ANY LIABILITY FOR LOSS OF BUSINESS, LOSS OF PROFITS, LOSS OF ANTICIPATED SAVINGS, LOSS OF OR DAMAGE TO DATA, THIRD PARTY CLAIMS OR ANY CONSEQUENTIAL LOSS UNLESS the Provider OTHERWISE AGREES IN WRITING. THE PROVIDER STRONGLY ADVISES THE CLIENT TO INSURE AGAINST ALL SUCH POTENTIAL LOSS, DAMAGE, EXPENSE OR LIABILITY.

7.3 Financial limits to the Provider's liability: In all cases, the Provider's liability to the Client is subject to the following limits:

- Without limit for personal injury or death;
- Up to a maximum of £1 million / USD\$2 million / €1.3 million (or local equivalent) for any one event or series of connected events for damage to the Client's personal property;
- Up to a maximum equal to 125% of the total fees paid between the date the Client moved into its accommodation(s) and the date on which the claim in question arises or £50,000 / USD\$100,000 / €66,000 (or local equivalent) whichever is the higher, in respect of any other loss or damage.

#### **8. Fees**

8.1 Taxes and duty charges: The Client agrees to pay promptly (i) all sales, use, excise, consumption and any other taxes and license fees which it is required to pay to any governmental authority (and, at the Provider's request, will provide to the Provider evidence of such payment) and (ii) any taxes paid by the Provider to any governmental authority that are attributable to the accommodation(s), including, without limitation, any gross receipts, rent and occupancy taxes, tangible personal property taxes, stamp tax or other documentary taxes and fees.

8.2 Service Retainer/Deposit: The Client will be required to pay a service retainer/deposit equivalent to two months' of the monthly office fee (plus VAT/Tax where applicable) upon entering into this agreement unless a different amount is specified on the front of this agreement. This will be held by the Provider without generating interest as security for performance of all the Client's obligations under this agreement. The service retainer/deposit or any balance will be returned to the Client when the Client has settled its account which includes deducting outstanding fees and other costs due to the Provider.

8.3 The Provider may require the Client to pay an increased retainer if outstanding fees exceed the service retainer/deposit held and/or the Client frequently fails to pay the Provider when due.

8.4 Payment: The Provider is continually striving to reduce its environmental impact and supports its clients in doing the same. Therefore the Provider will send all invoices electronically (where allowed by law) and the Client will make payments via an automated method such as Direct Debit or Credit Card, wherever local banking systems permit unless another form of payment is offered to the Client as a qualified and current Key Account.

8.5 Late payment: If the Client does not pay fees when due, a fee will be charged on all overdue balances. This fee will differ by country and is listed in the House Rules. If the Client disputes any part of an invoice the Client must pay the amount not in dispute by the due date or be subject to late fees. The Provider also reserves the right to withhold services (including for the avoidance of doubt, denying the Client access to its accommodation(s)) while there are any outstanding fees and/or interest or the Client is in breach of this agreement.

8.6 Insufficient Funds: The Client will pay a fee for any returned cheque or any other declined payments due to insufficient funds. This fee will differ by country and is listed in the House Rules.

8.7 If this agreement is for a term of more than 12 months, the Provider will increase the monthly office fee on each anniversary of the start date. This increase will be by the local Consumer Price Index or such other broadly equivalent index where a consumer price index is not available locally. If there is a negative index rate, prices will not be decreased. Renewals are calculated separately from annual indexation increases. Month to Month agreements will use the above stated index or the current month to month office price, whichever is the greater.

8.8 Standard services: The monthly office fee and any recurring services requested by the Client are payable monthly in advance. Unless otherwise agreed in writing, these recurring services will be



provided by the Provider at the specified rates for the duration of this Agreement (including any renewal). Specific due dates will differ by country and are listed in the House Rules. Where a daily rate applies, the charge for any such month will be 30 times the daily fee. For a period of less than a month the fee will be applied on a daily basis.

8.9 Pay-as-you-use and Additional Variable Services: Fees for pay-as-you-use services, plus applicable taxes, in accordance with the Provider's published rates which may change from time to time, are invoiced in arrears and payable the month following the calendar month in which the additional services were provided. Specific due dates will differ by country and are listed in the House Rules.

8.10 Discounts, Promotions and Offers: If the Client benefited from a special discount, promotion or offer, the Provider may discontinue that discount, promotion or offer without notice if the Client materially breaches these terms and conditions.

*Global Terms & Conditions, Iveber, Jan-17*

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## Verona Pharma

December 13, 2018

Kathleen Rickard, MD  
7012 Wildlife Trail,  
Raleigh, NC 27613

Re: Offer of Employment

Dear Kathy:

On behalf of Verona Pharma, Inc. (the “Company” or “Verona Pharma”), I am pleased to offer you the position of Chief Medical Officer of Verona Pharma plc, the Company’s parent company (the “Parent”). This offer letter agreement (the “Agreement”) sets forth the terms of employment the Company is offering you. If you accept this offer, we anticipate that your first day of employment will be February 1, 2019 (“Commencement Date”).

1. **DUTIES.** As the Parent’s Chief Medical Officer, your primary duties will be as set out in the Job Description in Exhibit A. You will report to the Chief Executive Officer (the “Manager”) of the Parent. You shall devote your full time and attention to the business affairs of the Company, and will attend the Company’s office in New York City as is reasonably required to fulfil your duties and undertake domestic and international travel as required.

2. **BASE SALARY.** You will receive an annual base salary of \$390,000 for all hours worked, less payroll deductions and withholdings, earned and payable in substantially equal installments in accordance with the Company’s payroll policy from time to time in effect.

3. **BONUS.**

(a) **Sign-on bonus.** You will receive a sign-on bonus of \$50,000, payable on signing of this Agreement.

(b) **Retention bonus.** You will receive a retention bonus of \$250,000, with \$125,000 payable on April 1, 2019 and \$125,000 payable on April 1, 2020, subject to you being employed on the date of payment. Each bonus payment will be repayable if you resign or are terminated for cause within 12 months of payment.

(c) **Annual discretionary bonus.** You will be eligible to participate in the Company’s annual bonus plan, with a target discretionary bonus of 40% of your base salary, subject to the terms of such plan and on such other terms and conditions as may be determined by the Company. You must be employed on the date of payment of the bonus in order to be eligible for the bonus.

Verona Pharma, Inc.

E-mail: [info@veronapharma.com](mailto:info@veronapharma.com) • Website: [www.veronapharma.com](http://www.veronapharma.com)

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4. **STOCK OPTIONS.** Subject to the approval of the board of directors of the Parent, and as soon as reasonably practicable after the Commencement Date having regard to the Parent's Share Dealing Policy, you will be granted, pursuant to, and subject to, Parent's equity incentive plan, an option to subscribe for a total of 70,000 American Depositary Shares ("ADSs") and 15,000 Restricted Stock Units with respect to the ADSs in the capital of Parent (together the "Stock Option"). The definitive terms of the Stock Option will be governed by the equity incentive plan, which requires, as a condition of the grant, that you enter into a written option agreement, which will contain the definitive terms of the Stock Option. The Stock Option shall vest 50% in equal proportions over three years from the date of grant and 50% in equal proportions over four years from the date of grant, or earlier in the event of a change in control of Parent (as defined in the equity incentive plan or option agreement), in each case subject to your continued employment through such date or such change in control.

5. **BENEFITS.** You will be entitled to participate in the Company's 401(k) plan and healthcare plan generally available from time to time to employees of the Company, subject to the terms of such plans. In addition, the Company will procure short-term disability insurance for you in accordance with New York state law, and you will be entitled to participate at your own expense in the Company's life insurance plan at up to \$250,000, with cover of \$40,000 provided by the Company. You will be entitled to 25 days of paid time off per year, earned and accrued on a pro rata basis throughout the year, provided that except with the prior written approval of the Manager, you may carry over five days of accrued but unused time into the first quarter of the subsequent year. You will not be paid for any accrued but unused time upon termination of employment.

6. **EXPENSES.** You shall be entitled to reimbursement for all ordinary and reasonable out-of-pocket business expenses which are reasonably incurred by you in furtherance of the Company's business and in accordance with the standard policies of the Company and Parent, provided that you produce to the Company such evidence of actual payment as the Company may require.

7. **SEVERANCE BENEFITS.**

(a) **Termination By The Company Without Cause or Termination by the Employee for Good Reason.** If this Agreement is terminated by the Company without Cause (as defined below) or by the Employee for Good Reason (as defined below), and if you sign an agreement acceptable to the Company that (i) waives any rights you may otherwise have against the Company and Parent, (ii) releases the Company and Parent from any actions, suits, claims, proceedings and demands you may have relating to the period of your employment with the Company and/or the termination of your employment, and (iii) contains certain other obligations which will be set forth at the time of the termination, the Company shall provide you with the following severance benefits: (1) continuation of your base salary less payroll deductions and withholding for a period of four (4) weeks; (2) continued payment, or reimbursement, as the case may be, of your COBRA premiums at the rate in effect upon termination for a period of four (4) weeks; and (3) a pro-rated portion of the annual bonus you otherwise would have earned for the year in which termination occurs, if any, based upon actual performance for such year.

(b) Termination By The Company With Cause, By Reason of Death or Disability or By Resignation. If this Agreement is terminated by the Company at any time with Cause, by reason of your death or disability, or if you terminate your employment with the Company under this Agreement, you shall not be entitled to any severance pay, severance benefits, accelerated vesting or any compensation or benefits from the Company whatsoever.

(c) Definitions:

A. Cause. "Cause" for purposes of this Agreement shall mean if you: (1) shall have committed any felony or any other act involving fraud, theft, misappropriation, dishonesty, or embezzlement; (2) shall have committed intentional acts that materially impair the goodwill or business of the Company or Parent or cause material damage to Company's or Parent's property, goodwill, or business; (3) shall have refused to, or willfully failed to, perform your material duties hereunder; or (4) shall have violated any written policies or procedures of the Company or Parent.

B. Good Reason. "Good Reason" for purposes of this Agreement shall mean if (i) the Company moves or relocates the Employee and the Employee is unable to achieve on reasonable terms approximately equivalent living circumstances to his situation in the New York metropolitan area, (ii) the Employee is demoted or assigned duties of less seniority than his duties under this Agreement, or (iii) the Company decreases by 15% or more the Employee's base salary and target bonus under this Agreement. In order for the Employee to terminate his Employment for "Good Reason" under this paragraph, immediately after becoming aware of the breach or other event giving rise to the Employee's right to terminate, the Employee must have provided the Company with written notice of his right to terminate pursuant to this paragraph and the Company must have failed to cure the breach or other event so specified, if curable, within thirty days after receiving such notice.

C. Release Requirement and Timing of Severance Payments. In order to receive the severance benefits under paragraph (a) above, as applicable, you must sign and tender the release as described above not later than sixty (60) days following your last day of employment, or such earlier date as required by the Company, and if you fail or refuse to do so, you shall forfeit the right to such termination compensation as would otherwise be due and payable. If the severance payments are otherwise subject to Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), they shall begin on the first pay period following the date that is sixty (60) days after your employment terminates and shall otherwise begin on the first pay period after the release becomes effective (with the initial salary continuation payment to include any unpaid salary continuation payments from the date your employment terminated), subject to your executing and tendering the release on the terms as set forth in the immediately preceding sentence. The pro-rated bonus, if any, shall be paid when such bonus would have been paid absent the termination of your employment and in all cases in the calendar year following the fiscal year to which the bonus relates.

8. COMPANY POLICIES AND CONFIDENTIALITY AGREEMENT. As an employee of the Company, you will be expected to abide by all of the applicable policies and procedures of the Company and Parent. As a condition of your employment, you agree to sign and to abide by the terms of a Protective Agreement with the Company, which is attached hereto as Exhibit B.

9. NEW YORK WAGE THEFT PREVENTION ACT NOTICE. Attached as Exhibit C a notice containing certain information regarding your pay as required by the New York Wage Theft Prevention Act.

10. AT-WILL EMPLOYMENT. As an employee of the Company, you may terminate your employment at any time and for any reason whatsoever simply by notifying the Company. Similarly, the Company may terminate your employment at any time and for any reason whatsoever, with or without cause or advance notice. Your at-will employment relationship with the Company cannot be changed except in writing signed by the Manager.

11. ENTIRE AGREEMENT. This Agreement, including Exhibit A, constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company with respect to the terms and conditions of your employment specified herein. If you enter into this Agreement, you are doing so voluntarily, and without reliance upon any promise, warranty or representation, written or oral, other than those expressly contained herein. This Agreement supersedes any other such promises, warranties, representations or agreements. This Agreement may not be amended or modified except by a written instrument signed by you and the CEO.

12. GOVERNING LAW. This Agreement will be governed by and construed in accordance with the laws of the State of New York.

13. DISPUTE RESOLUTION. To ensure the timely and economical resolution of disputes that arise in connection with your employment with the Company, you and the Company agree that any and all disputes, claims, or causes of action arising from or relating to the enforcement, breach, performance or interpretation of this Agreement, your employment, or the termination of your employment, shall be resolved to the fullest extent permitted by law by final, binding and confidential arbitration, by a single arbitrator, in New York, New York, conducted by Judicial Arbitration and Mediation Services, Inc. ("JAMS") under the applicable JAMS employment rules. By agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof in the State of New York. In reaching his or her decision, the arbitrator shall have no authority (a) to authorize or require the parties to engage in discovery (provided, however, that the arbitrator may schedule the time by which the parties must exchange copies of the exhibits that, and the names of the witnesses whom, the parties intend to present at the hearing) (b) to interpret or enforce the Protective Agreement (which shall not be covered by the dispute resolutions contained in this paragraph), (c) to change or modify any provision of this Agreement, (d) to base any part of his or her decision on the common law principle of constructive termination, or (e) to award punitive damages or any other damages not measured by the prevailing party's actual damages and may not make any ruling, finding or award that does not conform to this Agreement. Each party shall bear his, her or its own legal fees, costs and expenses of arbitration and one-half (1/2) of the costs of the arbitrator.

14. SECTION 409A. You and the Company intend that the payments and benefits provided for in this letter either be exempt from Section 409A of the Code, or be provided for in a manner that complies with Section 409A of the Code, and any ambiguity herein shall be



interpreted so as to be consistent with the intent of this Section 14. In no event whatsoever shall the Company be liable for any additional tax, interest or penalty that may be imposed on you by Section 409A of the Code or damages for failing to comply with Section 409A of the Code. Notwithstanding anything contained herein to the contrary, all payments and benefits under Section 7 above shall be paid or provided only at the time of a termination of your employment that constitutes a "separation from service" from the Company within the meaning of Section 409A of the Code and the regulations and guidance promulgated thereunder (determined after applying the presumptions set forth in Treas. Reg. Section 1.409A-1(h)(1)). Further, if you are a "specified employee" as such term is defined under Section 409A of the Code and the regulations and guidance promulgated thereunder, any payments described in Section 7 above shall be delayed for a period of six (6) months following your separation of employment to the extent and up to an amount necessary to ensure such payments are not subject to the penalties and interest under Section 409A of the Code. In addition, (i) in-kind benefits and reimbursements provided under this Agreement during any calendar year shall not affect in-kind benefits or reimbursements to be provided in any other calendar year, other than an arrangement providing for the reimbursement of medical expenses referred to in Section 105(b) of the Code, and are not subject to liquidation or exchange for another benefit and (ii) reimbursement requests must be timely submitted by you and, if timely submitted, reimbursement payments shall be promptly made to you following such submission, but in no event later than December 31<sup>st</sup> of the calendar year following the calendar year in which the expense was incurred. In no event shall you be entitled to any reimbursement payments after December 31<sup>st</sup> of the calendar year following the calendar year in which the expense was incurred. The reimbursement provisions in this Section 14 shall only apply to in-kind benefits and reimbursements that would result in taxable compensation income to you.

15. AUTHORIZATION TO WORK AND BACKGROUND CHECK. Your employment with the Company is contingent upon satisfactory results from any pre-employment background checks that we may deem necessary, including, but not limited to, a credit check, criminal background check, drug screening and confirmation of your legal authorization to work in the United States. Our offer is also contingent upon you not being subject to any limitation, obligation or agreement, whether imposed by contract, statute or otherwise, that would preclude your employment by the Company or in any way restrict your ability to perform your duties as an employee. If you have provided the Company with any false information with respect to your employment history, educational background or other credentials, the offer of employment contained herein shall be withdrawn or, if you have already been hired, your employment shall be immediately terminated.

If you choose to accept this Agreement under the terms described above, please sign below and return this letter to me no later than December 21, 2018.

We look forward to your favorable reply, and to a productive and enjoyable work relationship.

Very truly yours,

Verona Pharma, Inc.

\_\_\_\_\_  
Name: Jan-Anders Karlsson

Position: Director

Accepted and Agreed to by:

\_\_\_\_\_  
Employee Name: Kathleen Rickard

Date: \_\_\_\_\_





# Verona Pharma

## Exhibit A

### Chief Medical Officer Position Description

#### POSITION SUMMARY

The Chief Medical Officer will, as a strategic partner to the Chief Executive Officer, develop, lead and drive the clinical development and overall R&D strategy of Verona Pharma's current and future pipeline. This person will serve as a key member of the Executive Management Committee and will actively participate in strategic planning, partnering discussions, and presentations to the Board of Directors.

The CMO is responsible for strategy and effectiveness of the clinical development programs, ensuring that they meet key milestones and quality and safety standards required by medical and regulatory agencies. He/she will provide leadership to clinical operations, medical affairs, biostatistics and data management, and drug safety/pharmacovigilance. The CMO will work closely with peers to develop and implement Verona Pharma's product portfolio strategy with the ambition to be capable of bringing products to regulatory filings and product approval. In the process, ensuring that development goals set for the product portfolio are achieved in a timely manner and within budget. Represent Verona Pharma to medical and scientific audiences, KOLs, and medical and regulatory groups, addressing the medical and scientific aspects of the company's product portfolio.

Together with the leadership team, the CMO is responsible for product strategy, planning and implementation, and for investments in Verona Pharma's product portfolio meeting key yearly goals. The Company has a strategic relationship with a CRO and the CMO is responsible for managing this relationship. The CMO must be a strong leader with demonstrated operational excellence in a very hands-on and get it done environment.

The position requires strong relationships to be built with other members of the Verona Pharma management team, key members of the Board and KOL/investigators, consultants and advisors.

#### ESSENTIAL FUNCTIONS

##### Executive Management and Strategy

- Develop Verona Pharma's clinical, operational and financial strategy together with the CEO and executive team and regularly assess the Company's performance.
  - Provide medical vision and clinical leadership for the strategy and plan to advance Verona Pharma's clinical portfolio to registration and beyond
  - Develop required tools, systems, staff and external relationships to be able conduct all
-

aspects of the clinical development and registration of the company's products to the highest industry standard and regularly provide information to the CEO and executive leadership and make recommendations on strategy, planning and implementation of operations.

- Oversee long-term budget planning and cost management for own function, in relation to corporate strategy.
- Act as the primary spokesperson for the Company with key opinion leaders at medical and scientific conferences and advisory boards, building and maintaining relationships consistent with the Company's development and commercial objectives.
- Working with the CEO and the executive team on media, shareholder and investor programs as required.
- Working with the CEO and executive team to appraise business development opportunities, undertake due diligence activities.

#### Key Roles/Functions

- Responsible for the development of strategic plans for long term clinical development activities, resourcing, implementation and budget within the clinical organization including activities to be performed in-house or through third-party relationships.
  - Responsible for global clinical research organization, the effective execution of the clinical trials programs and clinical project management leading to full registration and regulatory approval of Verona Pharma's products.
  - May represent the Clinical Research line function on multidisciplinary project teams
  - Ensure clinical development programs meet quality and safety standards required by medical and regulatory agencies, providing leadership to medical affairs and drug safety/pharmacovigilance.
  - Collaborates with colleagues in discovery research and preclinical development line functions to move product candidates for entry into clinical investigations.
  - May work with marketing and business development to evaluate product candidates, determine product indications and design post-marketing studies, as appropriate.
  - Represent the Company with regulatory and medical agencies, globally addressing the scientific and medical/health aspects of our product portfolio.
  - Responsible for the safety of Verona Pharma's products and the most senior advisor for medical and health related matters.
  - Responsible for managing the interaction with IQVIA and related external vendors as well as interactions with various groups within the company and external to the business in the execution of clinical research activities.
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- Budget responsibility and participate in corporate short and mid-term budget preparations.
  - Establish, promote and ensure the team performs to the highest standards in global safety management, and quality assurance.
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Exhibit B

Protective Agreement

(attached)

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Exhibit C

New York Wage Theft Prevention Act Notice

(attached)

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## 1. This Agreement

1.1 Nature of this agreement: This agreement is the commercial equivalent of an agreement for accommodation(s) in a hotel. The whole of the Centre remains in the Provider's possession and control. THE CLIENT ACCEPTS THAT THIS AGREEMENT CREATES NO TENANCY INTEREST, LEASEHOLD ESTATE OR OTHER REAL PROPERTY INTEREST IN THE CLIENT'S FAVOUR WITH RESPECT TO THE ACCOMMODATION(S). The Provider is giving the Client the right to share with the Provider the use of the Centre on these terms and conditions, as supplemented by the House Rules, so that the Provider can provide the services to the Client. This Agreement is personal to the Client and cannot be transferred to anyone else without prior consent from the Provider. The Provider will not unreasonably withhold its consent to assignment to a parent, subsidiary or affiliate of Client provided that Client and assignee execute the Provider's form of Assignment of License Agreement which will require assignee to assume all Client obligations and will not release the Client. This agreement is composed of the front page describing the accommodation(s), the present terms and conditions, the House Rules and the Service Price Guide (where available).

1.2 Comply with House Rules: The Client must comply with any House Rules which the Provider imposes generally on users of the Centre. The House Rules vary from country to country and from Centre to Centre and these can be requested locally.

1.3 AUTOMATIC RENEWAL: THIS AGREEMENT LASTS FOR THE PERIOD STATED IN IT AND THEN WILL BE EXTENDED AUTOMATICALLY FOR SUCCESSIVE PERIODS EQUAL TO THE CURRENT TERM BUT NO LESS THAN 3 MONTHS (UNLESS LEGAL RENEWAL TERM LIMITS APPLY) UNTIL TERMINATED BY THE CLIENT OR BY THE PROVIDER PURSUANT TO SECTION 1.4. ALL PERIODS SHALL RUN TO THE LAST DAY OF THE MONTH IN WHICH THEY WOULD OTHERWISE EXPIRE. THE FEES ON ANY RENEWAL WILL BE AT THE THEN PREVAILING MARKET RATE.

1.4 CANCELLATION: EITHER THE PROVIDER OR THE CLIENT CAN TERMINATE THIS AGREEMENT AT THE END DATE STATED IN IT, OR AT THE END OF ANY EXTENSION OR RENEWAL PERIOD, BY GIVING AT LEAST THREE MONTHS WRITTEN NOTICE TO THE OTHER. HOWEVER, IF THIS AGREEMENT, EXTENSION OR RENEWAL IS FOR THREE MONTHS OR LESS AND EITHER THE PROVIDER OR THE CLIENT WISHES TO TERMINATE IT, THE NOTICE PERIOD IS TWO MONTHS OR (IF TWO MONTHS OR SHORTER) ONE WEEK LESS THAN THE PERIOD STATED IN THIS AGREEMENT.

1.5 Ending this agreement immediately: To the maximum extent permitted by applicable law, the Provider may put an end to this agreement immediately by giving the Client notice and without need to follow any additional procedure if (a) the Client becomes insolvent, bankrupt, goes into liquidation or becomes unable to pay its debts as they fall due, or (b) the Client is in breach of one of its obligations which cannot be put right or which the Provider have given the Client notice to put right and which the Client has failed to put right within fourteen (14) days of that notice, or (c) its conduct, or that of someone at the Centre with its permission or invitation, is incompatible with ordinary office use.

If the Provider puts an end to this agreement for any of these reasons it does not put an end to any outstanding obligations, including additional services used and the monthly office fee for the remainder of the period for which this agreement would have lasted if the Provider had not ended it.

1.6 If the Centre is no longer available: In the event that the Provider is permanently unable to provide the services and accommodation(s) at the Centre stated in this agreement then this agreement will end and the Client will only have to pay monthly office fees up to the date it ends and for the additional services the Client has used. The Provider will try to find suitable alternative accommodation(s) for the Client at another the Provider Centre.

1.7 When this agreement ends the Client is to vacate the accommodation(s) immediately, leaving the accommodation(s) in the same condition as it was when the Client took it. Upon the Client's departure or if the Client, at its option, chooses to relocate to different rooms within the Centre, the Provider will charge an Office Restoration Service fee to cover normal cleaning and testing and to return the accommodation(s) to its original state. This fee will differ by country and is listed in the House Rules. The Provider reserves the right to charge additional reasonable fees for any repairs needed above and beyond normal wear and tear. If the Client leaves any property in the Centre the Provider may dispose of it at the Client's cost in any way the Provider chooses without owing the Client any responsibility for it or any proceeds of sale. When a Client vacates its accommodation(s) invariably the Provider continues to receive the Client's mail, faxes, telephone calls and visitors. In order to professionally manage the redirection of the Client's calls, mail, faxes and visitors the Provider charges a one-time Business Continuity Service. This service lasts for three months after the end of the date of this agreement. If in the event that during the Client's stay there are no calls, mail, faxes or visitors this service will not be applied. This fee is located in the house rules.

If the Client continues to use the accommodation(s) when this agreement has ended the Client is responsible for any loss, claim or liability the Provider incurs as a result of the Client's failure to vacate on time. The Provider may, at its discretion, permit the Client an extension subject to a surcharge on the monthly office fee.

1.8 Employees: While this agreement is in force and for a period of six months after it ends, neither the Provider nor the Client may knowingly solicit or offer employment to any of the other's staff employed in the Centre. This obligation applies to any employee employed at the Centre up to that employee's termination of employment, and for three months thereafter. It is stipulated that the breaching party shall pay the non-breaching party the equivalent of one year's salary for any employee concerned. Nothing in this clause shall prevent either party from employing an individual who responds in good faith and independently to an advertisement which is made to the public at large.

1.9 Client Representation of the Provider Employees: Throughout the duration of this agreement, Client agrees that neither Client, nor any of Client's partners, members, officers or employees will represent, or otherwise provide legal counsel to, any of the Provider's current or former employees in any dispute with, or legal proceeding against, the Provider, or any of the Provider's affiliates, members, officers or employees.

1.10 Notices: All formal notices must be in writing to the address first written above.

1.11 Confidentiality: The terms of this agreement are confidential. Neither the Provider nor the Client must disclose them without the other's consent unless required to do so by law or an official authority. This obligation continues after this agreement ends.

1.12 Applicable law: This agreement is interpreted and enforced in accordance with the law of the place where the relevant Centre is located. All dispute resolution proceedings will be conducted in the country, state or province where the Centre is located. If any provision of these terms and conditions is held void or unenforceable under the applicable law, the other provisions shall remain in force. In the case of Japan all agreements will be interpreted and enforced by the Tokyo District Court, and in the case of France, any dispute regarding this agreement will be settled by the relevant courts of the Paris jurisdiction.

1.13 Enforcing this agreement: The Client must pay any reasonable and proper costs including legal fees that the Provider incurs in enforcing this agreement except that the Provider and the Client will bear their own arbitration costs in the event of arbitration.

## 2. Services and Obligations

2.1 Office accommodation(s): the Provider is to provide the number of serviced office accommodation(s) for which the Client has agreed to pay in the Centre stated in this agreement. This agreement lists the accommodation(s) the Provider has initially allocated for the Client's use. The Client will have a non-exclusive right to the rooms allocated to it. Occasionally the Provider may need to allocate different accommodation(s), but these accommodation(s) will be of reasonably equivalent size and the Provider will notify the Client with respect to such different accommodation(s) in advance.

2.2 Office Services: the Provider is to provide during normal opening hours the services, if requested, described in the relevant service description (which is available on request). If the Provider decides that a request for any particular service is excessive, it reserves the right to charge an additional fee.

2.3 the Provider IT: THE PROVIDER DOES NOT MAKE ANY REPRESENTATIONS AS TO THE SECURITY OF THE PROVIDER'S NETWORK (OR THE INTERNET) OR OF ANY INFORMATION THAT THE CLIENT PLACES ON IT. The Client should adopt whatever security measures (such as encryption) it believes are appropriate to its circumstances. The Provider cannot guarantee that a particular degree of availability will be attained in connection with the Client's use of the Provider's network (or the internet). The Client's sole and exclusive remedy shall be the remedy of such failure by the Provider within a reasonable time after written notice.

## 3. Providing the Services

3.1 Access to the accommodation(s): the Provider may need to enter the Client's accommodation(s) and may do so at any time. However, unless there is an emergency or the Client has given notice to terminate, the Provider will attempt to notify the Client verbally or electronically in advance when the Provider needs access to carry out testing, repair or works other than routine inspection, cleaning and maintenance. The Provider will also endeavour to respect reasonable security procedures to protect the confidentiality of the Client's business.

3.2 Availability at the start of this agreement: If for any reason the Provider cannot provide the accommodation(s) stated in this agreement by the date when this agreement is due to start it has no liability to the Client for any loss or damages but the Client may cancel this agreement without penalty. The Provider will not charge the Client the monthly office fee for accommodation(s) the Client cannot use until it becomes available. The Provider may delay the start date of this agreement provided it provides to the Client alternative



accommodation(s) that shall be at least of equivalent size to the accommodation(s) stated in this agreement.

#### 4. Accommodation(s)

4.1 The Client must not alter any part of its accommodation and must take good care of all parts of the centre, its equipment, fixtures, fittings and furnishings which the Client uses. The Client is liable for any damage caused by it or those in the Centre with the Client's permission or at the Client's invitation whether express or implied, including but not limited to all employees, contractors, agents or other persons present on the premises.

4.2 Office equipment: The Client must not install any cabling, IT or telecom connections without the Provider's consent, which the Provider may refuse at its absolute discretion.

As a condition to the Provider's consent, the Client must permit the Provider to oversee any installations (for example IT or electrical systems) and to verify that such installations do not interfere with the use of the accommodation(s) by other Clients or the Provider or any landlord of the building.

4.3 Insurance: It is the Client's responsibility to arrange insurance for its own property which it brings in to the Centre and for its own liability to its employees and to third parties. The Provider strongly recommends that the Client put such insurance in place.

#### 5. Use

5.1 The Client must only use the accommodation(s) for office purposes. Office use of a "retail" or "medical" nature, involving frequent visits by members of the public, is not permitted.

5.2 The Client must not carry on a business that competes with the Provider's business of providing serviced office accommodation(s) or its ancillary services.

5.3 The Client's name and address: The Client may only carry on that business in its name or some other name that the Provider previously agrees.

5.4 Use of the Centre Address: The Client may use the Centre address as its business address. Any other uses are prohibited without the Provider's prior written consent.

#### 6. Compliance

6.1 Comply with the law: The Client must comply with all relevant laws and regulations in the conduct of its business. The Client must do nothing illegal in connection with its use of the Business Centre. The Client must not do anything that may interfere with the use of the Centre by the Provider or by others, cause any nuisance or annoyance, increase the insurance premiums the Provider has to pay, or cause loss or damage to the Provider (including damage to reputation) or to the owner of any interest in the building which contains the Centre the Client is using. The Client acknowledges that (a) the terms of the foregoing sentence are a material inducement in the Provider's execution of this agreement and (b) any violation by the Client of the foregoing sentence shall constitute a material default by the Client hereunder, entitling the Provider to terminate this agreement, without further notice or procedure.

6.2 The Client acknowledges and accepts that its personal data may be transferred or made accessible to all entities of the Provider, wherever located, for the purposes of providing the services herein.

#### 7. The Provider's Liability

7.1. The extent of the Provider's liability: To the maximum extent permitted by applicable law, the Provider is not liable to the Client in respect of any loss or damage the Client suffers in connection with this agreement, with the services or with the Client's accommodation(s) unless the Provider has acted deliberately or negligently in causing that loss or damage. The Provider is not liable for any loss as a result of the Provider's failure to provide a service as a result of mechanical breakdown, strike, termination of the Provider's interest in the building containing the Centre or otherwise unless the Provider does so deliberately or is negligent. In no event shall the Provider be liable for any loss or damage until the Client provides the Provider written notice and gives the Provider a reasonable time to put it right. If the Provider is liable for failing to provide the Client with any service under this agreement then subject to the exclusions and limits set out immediately below the Provider will pay any actual and reasonable expenses the Client has incurred in obtaining that service from an alternative source. If the Client believes the Provider has failed to deliver a service consistent with these terms and conditions the Client shall provide the Provider written notice of such failure and give the Provider a reasonable period to put it right.

**7.2. EXCLUSION OF CONSEQUENTIAL LOSSES, ETC.: the Provider WILL NOT IN ANY CIRCUMSTANCES HAVE ANY LIABILITY FOR LOSS OF BUSINESS, LOSS OF PROFITS, LOSS OF ANTICIPATED SAVINGS, LOSS OF OR DAMAGE TO DATA, THIRD PARTY CLAIMS OR ANY CONSEQUENTIAL LOSS UNLESS the Provider OTHERWISE AGREES IN WRITING, the Provider STRONGLY ADVISES THE CLIENT TO INSURE AGAINST ALL SUCH POTENTIAL LOSS, DAMAGE, EXPENSE OR LIABILITY.**

7.3. Financial limits to the Provider's liability: In all cases, the Provider's liability to the Client is subject to the following limits:

- Without limit for personal injury or death;

- Up to a maximum of £1 million / USD\$2 million / €1.3 million (or local equivalent) for any one event or series of connected events for damage to the Client's personal property except in Turkey where it will be up to a maximum of the monthly office fee over the current term;
- Up to a maximum equal to 125% of the total fees paid between the date the Client moved into its accommodation(s) and the date on which the claim in question arises or £50,000 / USD\$100,000 / €66,000 (or local equivalent) whichever is the higher, in respect of any other loss or damage except in Turkey where it will be up to a maximum of the monthly office fee over the current term.

#### 8. Fees

8.1 Taxes and duty charges: The Client agrees to pay promptly (i) all sales, use, excise, consumption and any other taxes and license fees which it is required to pay to any governmental authority (and, at the Provider's request, will provide to the Provider evidence of such payment) and (ii) any taxes paid by the Provider to any governmental authority that are attributable to the accommodation(s), including, without limitation, any gross receipts, rent and occupancy taxes, tangible personal property taxes, stamp tax or other documentary taxes and fees.

8.2 Service Retainer/Deposit: The Client will be required to pay a service retainer/deposit equivalent to two months' of the monthly office fee (plus VAT/Tax where applicable) upon entering into this agreement unless a greater amount is specified on the front of this agreement. This will be held by the Provider without generating interest as security for performance of all the Client's obligations under this agreement. The service retainer/deposit or any balance after deducting outstanding fees, the Business Continuity and Office Restoration Service and other costs due to the Provider, will be returned to the Client after the Client has requested for the return of the retainer/deposit in writing, settled its account with the Provider and funds have been cleared.

8.3 The Provider may require the Client to pay an increased retainer if outstanding fees exceed the service retainer/deposit held and/or the Client frequently fails to pay the Provider when due.

8.4 The Client will be charged an office set up fee per occupant. Fee amounts are located in the House Rules which can be requested at any time.

8.5 Payment: the Provider is continually striving to reduce its environmental impact and supports its clients in doing the same. Therefore the Provider will send all invoices electronically (where allowed by law) and the Client will make payments via an automated method such as Direct Debit or Credit Card, wherever local banking systems permit unless another form of payment is offered to the Client as a qualified and current Key Account. All amounts payable by the Client under this agreement may be assigned to other members of the Provider's group.

8.6 Late payment: If the Client does not pay fees when due, a fee will be charged on all overdue balances. This fee will differ by country and is listed in the House Rules. If the Client disputes any part of an invoice the Client must pay the amount not in dispute by the due date or be subject to late fees. The Provider also reserves the right to withhold services (including for the avoidance of doubt, denying the Client access to its accommodation(s)) while there are any outstanding fees and/or interest or the Client is in breach of this agreement.

8.7 Insufficient Funds: The Client will pay a fee for any returned cheque or any other declined payments due to insufficient funds. This fee will differ by country and is listed in the House Rules.

8.8 The Provider will increase the monthly office fee each and every anniversary of the start date of this agreement by a percentage amount equal to the increase in the All Items Retail Prices Index, or such other broadly equivalent index which the Provider substitutes provided that if the foregoing increase is not permitted by applicable law, then the monthly office fee shall be increased as specified in the House Rules. This will only apply to agreements that have an original start and end date constituting more than a 12 month term. Renewals will be renewed as per clause 1.3 above and only those renewals with a start and end date constituting a term of over 12 months will have the same increase applied.

8.9 Standard services: The monthly office fee and any recurring services requested by the Client are payable monthly in advance. Unless otherwise agreed in writing, these recurring services will be provided by the Provider at the specified rates for the duration of this Agreement (including any renewal). Specific due dates will differ by country and are listed in the House Rules. Where a daily rate applies, the charge for any such month will be 30 times the daily fee. For a period of less than a month the fee will be applied on a daily basis.

8.10 Pay-as-you-use and Additional Variable Services: Fees for pay-as-you-use services, plus applicable taxes, in accordance with the Provider's published rates which may change from time to time, are invoiced in arrears and payable the month following the calendar

month in which the additional services were provided. Specific due dates will differ by country and are listed in the House Rules.

8.11 Discounts, Promotions and Offers: If the Client benefited from a special discount, promotion or offer, the Provider may discontinue that discount, promotion or offer without notice if the Client breaches these terms and conditions or becomes past due on two or more occasions.

*Global Terms & Conditions, Iveber, Aug-14*

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This agreement provides the key information you need to move ahead with your office. You can accept the agreement by clicking the blue button at the bottom of the page, or alternatively if you have any questions or need any assistance then please call our helpline on +44 (0)800 756 2911

Agreement Date : 3 April 2018      Confirmation No : 32768-699454

Business Centre Details		Client Details	
<b>LONDON, London Bridge - More London</b>		<b>Company Name</b>	Verona Pharm PLC
<b>Address</b>	3 More London Riverside London Greater London SE1 2RE United Kingdom	<b>Contact Name</b>	Paula Siu
		<b>Address</b>	3 more london London SE1 2RE United Kingdom

Office Payment Details (exc.VAT and exc. services)					
Office Number	Price per Person per Day	Discount on Initial Term	Discounted Price per Person per Day	x People	Discounted Price per Office per Day
143	£ 58.08	11.393 %	£ 51.46	4	£ 205.83
<b>Total Average Monthly Price per Person per Month</b>					<b>£ 1,543.75</b>
<b>Total Monthly Price</b>					<b>£ 6,175.00</b>

<b>Service Provision :</b>	<b>Start Date</b>	4 April 2018	<b>End Date</b>	31 January 2020
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- Invoices/Fees are charged on a monthly basis which is calculated based on a 30-day month
- All agreements end on the last calendar day of the month.
- A refundable deposit equivalent to 2 x monthly office fee will be payable.

**Terms and Conditions**

We are IW Group Services (UK) Limited, the "Provider". This Agreement incorporates our terms of business set out on attached Terms and Conditions, attached House Rules and Service Price Guide (where available) which you confirm you have read and understood. We both agree to comply with those terms and our obligations as set out in them. This agreement is binding from the agreement date and may not be terminated once it is made, except in accordance with its terms. Note that the Agreement does not come to an end automatically. See "Cancellation" section of your terms and conditions

By signing our service Agreement, you agree to provide information and sign relevant documents to allow the Provider to claim any relief on business rates which at the Provider's risk is already included in your service fee with reference to the Business Centre within 2 working days of such request. The Provider has appointed Gerald Eve LLP Rating Payment Management Services to administer such information.

I accept the terms and conditions

[Download the terms and conditions](#)

[Download the house rules](#)

**Confirm by typing your name in the box below**

<b>Name :</b> <input type="text" value="Piers Morgan"/> on behalf of Verona Pharm PLC	<b>Signed on</b> 3 April 2018
I confirm these details are correct to the best of my knowledge	

This website is secure. Your personal details are protected at all times.

[Print Agreement](#)

If you need assistance call our Helpline on +44 (0)800 756 2911

## **1. This Agreement**

1.1 Nature of this agreement: This agreement is the commercial equivalent of an agreement for accommodation(s) in a hotel. The whole of the Centre remains in the Provider's possession and control. THE CLIENT ACCEPTS THAT THIS AGREEMENT CREATES NO TENANCY INTEREST, LEASEHOLD ESTATE OR OTHER REAL PROPERTY INTEREST IN THE CLIENT'S FAVOUR WITH RESPECT TO THE ACCOMMODATION(S). The Provider is giving the Client the right to share with the Provider the use of the Centre on these terms and conditions, as supplemented by the House Rules, so that the Provider can provide the services to the Client. This Agreement is personal to the Client and cannot be transferred to anyone else without prior consent from the Provider unless such transfer is required by law. The Provider will not unreasonably withhold its consent to assignment to a parent, subsidiary or affiliate of Client provided that Client and assignee execute the Provider's form of Assignment of License Agreement which will require assignee to assume all Client obligations and will not release the Client. This agreement is composed of the front page describing the accommodation(s), the present terms and conditions, the House Rules and the Service Price Guide (where available).

1.2 Comply with House Rules: The Client must comply with any House Rules which the Provider imposes generally on users of the Centre. The House Rules vary from country to country and from Centre to Centre and these can be requested locally.

1.3 AUTOMATIC RENEWAL: THIS AGREEMENT LASTS FOR THE PERIOD STATED IN IT AND THEN **WILL BE EXTENDED AUTOMATICALLY FOR SUCCESSIVE PERIODS EQUAL TO THE CURRENT TERM BUT NO LESS THAN 3 MONTHS** (UNLESS LEGAL RENEWAL TERM LIMITS APPLY) UNTIL TERMINATED BY THE CLIENT OR BY THE PROVIDER PURSUANT TO SECTION 1.4. ALL PERIODS SHALL RUN TO THE LAST DAY OF THE MONTH IN WHICH THEY WOULD OTHERWISE EXPIRE. THE FEES ON ANY RENEWAL WILL BE AT THE THEN PREVAILING MARKET RATE. THIS CLAUSE DOES NOT APPLY TO MONTH TO MONTH AGREEMENTS.

1.4 **CANCELLATION:** EITHER THE PROVIDER OR THE CLIENT CAN TERMINATE THIS AGREEMENT AT THE END DATE STATED IN IT, OR AT THE END OF ANY EXTENSION OR RENEWAL PERIOD, BY GIVING AT LEAST THREE MONTHS WRITTEN NOTICE TO THE OTHER. HOWEVER, IF THIS AGREEMENT, EXTENSION OR RENEWAL IS FOR THREE MONTHS OR LESS AND EITHER THE PROVIDER OR THE CLIENT WISHES TO TERMINATE IT, THE NOTICE PERIOD IS TWO MONTHS IF THIS AGREEMENT, EXTENSION OR RENEWAL IS FOR TWO MONTHS OR LESS, NOTICE MUST BE GIVEN WITHIN ONE WEEK OF THE START DATE OF THE CURRENT TERM. IF THE CLIENT IS ON A MONTH TO MONTH AGREEMENT EITHER PARTY MAY TERMINATE THIS AGREEMENT BY GIVING NO LESS THAN ONE MONTH'S NOTICE TO THE OTHER (EFFECTIVE FROM THE START OF ANY CALENDAR MONTH).

1.5 Ending this agreement immediately: To the maximum extent permitted by applicable law, the Provider may put an end to this agreement immediately by giving the Client notice and without need to follow any additional procedure if (a) the Client becomes insolvent, bankrupt, goes into liquidation or becomes unable to pay its debts as they fall due, or (b) the Client is in breach of one of its obligations which cannot be put right or which the Provider have given the Client notice to put right and which the Client has failed to put right within fourteen (14) days of that notice, or (c) its conduct, or that of someone at the Centre with its permission or invitation, is incompatible with ordinary office use and (i) such conduct is repeated despite the Client having been given a warning or (ii) such conduct is material enough (in the Provider's opinion) to warrant immediate termination.

If the Provider puts an end to this agreement for any of these reasons it does not put an end to any outstanding obligations, including additional services used, requested or required under the agreement and the monthly office fee for the remainder of the period for which this agreement would have lasted if the Provider had not ended it.

1.6 If the Centre is no longer available: In the event that the Provider is permanently unable to provide the services and accommodation(s) at the Centre stated in this agreement then this agreement will end and the Client will only have to pay monthly office fees up to the date it ends and for the additional services the Client has used. The Provider will try to find suitable alternative accommodation(s) for the Client at another Provider Centre.

1.7 When this agreement ends the Client is to vacate the accommodation(s) immediately, leaving the accommodation(s) in the same condition as it was when the Client took it. Upon the Client's departure or if the Client, at its option, chooses to relocate to different rooms within the Centre, the Provider will charge an Office Restoration Service fee to cover normal cleaning and testing and to return the accommodation(s) to its original state. This fee will differ by country and is listed in the House Rules. The Provider reserves the right to charge additional reasonable fees for any repairs needed above and beyond normal wear and tear. If the Client leaves any property in the Centre the Provider may dispose of it at the Client's cost in any way the Provider chooses without owing the Client any responsibility for it or any proceeds of sale. If the Client continues to use the accommodation(s) when

this agreement has ended the Client is responsible for any loss, claim or liability the Provider incurs as a result of the Client's failure to vacate on time. The Provider may, at its discretion, permit the Client an extension subject to a surcharge on the monthly office fee.

1.8 Employees: While this agreement is in force and for a period of six months after it ends, neither the Provider nor the Client may knowingly solicit or offer employment to any of the other's staff employed in the Centre. This obligation applies to any employee employed at the Centre up to that employee's termination of employment, and for three months thereafter. It is stipulated that the breaching party shall pay the non-breaching party the equivalent of six months' salary for any employee concerned. Nothing in this clause shall prevent either party from employing an individual who responds in good faith and independently to an advertisement which is made to the public at large.

1.9 Notices: All formal notices must be in writing, which may include by email, to the address first written above.

1.10 Confidentiality: The terms of this agreement are confidential. Neither the Provider nor the Client must disclose them without the other's consent unless required to do so by law or an official authority. This obligation continues for a period of 3 years after this agreement ends.

1.11 Applicable law: This agreement is interpreted and enforced in accordance with the law of the place where the relevant Centre is located. All dispute resolution proceedings will be conducted in the country, state or province where the Centre is located. If any provision of these terms and conditions is held void or unenforceable under the applicable law, the other provisions shall remain in force. In the case of Japan all agreements will be interpreted and enforced by the Tokyo District Court, and in the case of France, any dispute regarding this agreement will be settled by the relevant courts of the Paris jurisdiction.

## **2. Services and Obligations**

2.1 Office accommodation(s): The Provider is to provide the number of serviced office accommodation(s) for which the Client has agreed to pay in the Centre stated in this agreement. This agreement lists the accommodation(s) the Provider has initially allocated for the Client's use. The Client will have a non-exclusive right to the rooms allocated to it. Occasionally the Provider may need to allocate different accommodation(s), but these accommodation(s) will be of reasonably equivalent size and the Provider will notify the Client with respect to such different accommodation(s) in advance.

2.2 Office Services: The Provider is to provide during normal opening hours the services, if requested, described in the relevant service description (which is available on request). If the Provider decides that a request for any particular service is excessive, it reserves the right to charge an additional fee.

2.3 THE PROVIDER'S IT: WHILST THE PROVIDER HAS INTERNET SECURITY PROTOCOLS, THE PROVIDER DOES NOT MAKE ANY REPRESENTATIONS AS TO THE SECURITY OF THE PROVIDER'S NETWORK (OR THE INTERNET) OR OF ANY INFORMATION THAT THE CLIENT PLACES ON IT. The Client should adopt whatever security measures (such as encryption) it believes are appropriate to its circumstances. The Provider cannot guarantee that a particular degree of availability will be attained in connection with the Client's use of the Provider's network (or the internet). The Client's sole and exclusive remedy shall be the remedy of such failure by the Provider within a reasonable time after written notice.

## **3. Providing the Services**

3.1 Access to the accommodation(s): The Provider may need to enter the Client's accommodation(s) and may do so at any time. However, unless there is an emergency or the Client has given notice to terminate, the Provider will attempt to notify the Client verbally or electronically in advance when the Provider needs access to carry out testing, repair or works other than routine inspection, cleaning and maintenance. The Provider will also endeavour to respect reasonable security procedures to protect the confidentiality of the Client's business.

3.2 Availability at the start of this agreement: If for any reason the Provider cannot provide the accommodation(s) stated in this agreement by the date when this agreement is due to start it has no liability to the Client for any loss or damages but the Client may cancel this agreement without penalty. The Provider will not charge the Client the monthly office fee for accommodation(s) the Client cannot use until it becomes available. The Provider may delay the start date of this agreement provided it provides to the Client alternative accommodation(s) that shall be at least of equivalent size to the accommodation(s) stated in this agreement.



#### **4. Accommodation(s)**

4.1 The Client must not alter any part of its accommodation and must take good care of all parts of the centre, its equipment, fixtures, fittings and furnishings which the Client uses. The Client is liable for any damage caused by it or those in the Centre with the Client's permission or at the Client's invitation whether express or implied, including but not limited to all employees, contractors, agents or other persons present on the premises.

4.2 Office equipment: The Client must not install any cabling, IT or telecom connections without the Provider's consent, which the Provider may refuse at its absolute discretion.

As a condition to the Provider's consent, the Client must permit the Provider to oversee any installations (for example IT or electrical systems) and to verify that such installations do not interfere with the use of the accommodation(s) by other Clients or the Provider or any landlord of the building.

4.3 Insurance: It is the Client's responsibility to arrange insurance for its own property which it brings in to the Centre and for its own liability to its employees and to third parties. The Provider strongly recommends that the Client put such insurance in place.

#### **5. Use**

5.1 The Client must only use the accommodation(s) for office purposes. Office use of a "retail" or "medical" nature, involving frequent visits by members of the public, is not permitted.

5.2 The Client must not carry on a business that competes with the Provider's business of providing serviced office accommodation(s) or its ancillary services.

5.3 The Client's name and address: The Client may only carry on that business in its name or some other name that the Provider previously agrees.

5.4 Use of the Centre Address: The Client may use the Centre address as its business address. Any other uses are prohibited without the Provider's prior written consent.

#### **6. Compliance**

6.1 Comply with the law: The Client and the Provider must comply with all relevant laws and regulations in the conduct of its business in relation to this agreement. The Client must do nothing illegal in connection with its use of the Business Centre. The Client must not do anything that may interfere with the use of the Centre by the Provider or by others, (including but not limited to political campaigning or immoral activity), cause any nuisance or annoyance, increase the insurance premiums the Provider has to pay, or cause loss or damage to the Provider (including damage to reputation) or to the owner of any interest in the building which contains the Centre the Client is using. Both the Client and the Provider shall comply at all times with all relevant anti-bribery and anti-corruption laws. 6.2 If the Provider has been advised by any government authority or other legislative body that it has reasonable suspicion that the Client is conducting criminal activities from the Centre then the Provider shall be entitled to terminate this agreement with immediate effect. The Provider confirms that in providing the services it has not employed or used any labour in contravention of the requirements of any anti-slavery laws.

6.3 The Client acknowledges that (a) the terms of this clause are a material inducement in the Provider's execution of this agreement and (b) any violation by the Client of this clause shall constitute a material default by the Client hereunder, entitling the Provider to terminate this agreement, without further notice or procedure.

6.4 The Provider may collect and process personal data from and of the Client to administer contractual relationship, ensure compliance with applicable laws and regulations, and enable the Provider to provide its services and to manage its business. The Client acknowledges and accepts that such personal data may be transferred or made accessible to all entities of the Provider's group, wherever located, for the purposes of providing the services herein.

#### **7. The Provider's Liability**

7.1 The extent of the Provider's liability: To the maximum extent permitted by applicable law, the Provider is not liable to the Client in respect of any loss or damage the Client suffers in connection with this agreement, with the services or with the Client's accommodation(s) unless the Provider has acted deliberately or negligently in causing that loss or damage. The Provider is not liable for any loss as a result of the Provider's failure to provide a service as a result of mechanical breakdown, strike, termination of the Provider's interest in the building containing the Centre or otherwise unless the Provider does so deliberately or is negligent. In no event shall the Provider be liable for any loss or damage until the Client provides the Provider written notice and gives the Provider a reasonable time to put it right. If the Provider is liable for failing to provide the Client with any service under this

agreement then subject to the exclusions and limits set out immediately below the Provider will pay any actual and reasonable expenses the Client has incurred in obtaining that service from an alternative source. If the Client believes the Provider has failed to deliver a service consistent with these terms and conditions the Client shall provide the Provider written notice of such failure and give the Provider a reasonable period to put it right.

7.2 EXCLUSION OF CONSEQUENTIAL LOSSES, ETC.: THE PROVIDER WILL NOT IN ANY CIRCUMSTANCES HAVE ANY LIABILITY FOR LOSS OF BUSINESS, LOSS OF PROFITS, LOSS OF ANTICIPATED SAVINGS, LOSS OF OR DAMAGE TO DATA, THIRD PARTY CLAIMS OR ANY CONSEQUENTIAL LOSS UNLESS the Provider OTHERWISE AGREES IN WRITING. THE PROVIDER STRONGLY ADVISES THE CLIENT TO INSURE AGAINST ALL SUCH POTENTIAL LOSS, DAMAGE, EXPENSE OR LIABILITY.

7.3 Financial limits to the Provider's liability: In all cases, the Provider's liability to the Client is subject to the following limits:

- Without limit for personal injury or death;
- Up to a maximum of £1 million / USD\$2 million / €1.3 million (or local equivalent) for any one event or series of connected events for damage to the Client's personal property;
- Up to a maximum equal to 125% of the total fees paid between the date the Client moved into its accommodation(s) and the date on which the claim in question arises or £50,000 / USD\$100,000 / €66,000 (or local equivalent) whichever is the higher, in respect of any other loss or damage.

#### **8. Fees**

8.1 Taxes and duty charges: The Client agrees to pay promptly (i) all sales, use, excise, consumption and any other taxes and license fees which it is required to pay to any governmental authority (and, at the Provider's request, will provide to the Provider evidence of such payment) and (ii) any taxes paid by the Provider to any governmental authority that are attributable to the accommodation(s), including, without limitation, any gross receipts, rent and occupancy taxes, tangible personal property taxes, stamp tax or other documentary taxes and fees.

8.2 Service Retainer/Deposit: The Client will be required to pay a service retainer/deposit equivalent to two months' of the monthly office fee (plus VAT/Tax where applicable) upon entering into this agreement unless a different amount is specified on the front of this agreement. This will be held by the Provider without generating interest as security for performance of all the Client's obligations under this agreement. The service retainer/deposit or any balance will be returned to the Client when the Client has settled its account which includes deducting outstanding fees and other costs due to the Provider.

8.3 The Provider may require the Client to pay an increased retainer if outstanding fees exceed the service retainer/deposit held and/or the Client frequently fails to pay the Provider when due.

8.4 Payment: The Provider is continually striving to reduce its environmental impact and supports its clients in doing the same. Therefore the Provider will send all invoices electronically (where allowed by law) and the Client will make payments via an automated method such as Direct Debit or Credit Card, wherever local banking systems permit unless another form of payment is offered to the Client as a qualified and current Key Account.

8.5 Late payment: If the Client does not pay fees when due, a fee will be charged on all overdue balances. This fee will differ by country and is listed in the House Rules. If the Client disputes any part of an invoice the Client must pay the amount not in dispute by the due date or be subject to late fees. The Provider also reserves the right to withhold services (including for the avoidance of doubt, denying the Client access to its accommodation(s)) while there are any outstanding fees and/or interest or the Client is in breach of this agreement.

8.6 Insufficient Funds: The Client will pay a fee for any returned cheque or any other declined payments due to insufficient funds. This fee will differ by country and is listed in the House Rules.

8.7 If this agreement is for a term of more than 12 months, the Provider will increase the monthly office fee on each anniversary of the start date. This increase will be by the local Consumer Price Index or such other broadly equivalent index where a consumer price index is not available locally. If there is a negative index rate, prices will not be decreased. Renewals are calculated separately from annual indexation increases. Month to Month agreements will use the above stated index or the current month to month office price, whichever is the greater.

8.8 Standard services: The monthly office fee and any recurring services requested by the Client are payable monthly in advance. Unless otherwise agreed in writing, these recurring services will be

provided by the Provider at the specified rates for the duration of this Agreement (including any renewal). Specific due dates will differ by country and are listed in the House Rules. Where a daily rate applies, the charge for any such month will be 30 times the daily fee. For a period of less than a month the fee will be applied on a daily basis.

8.9 Pay-as-you-use and Additional Variable Services: Fees for pay-as-you-use services, plus applicable taxes, in accordance with the Provider's published rates which may change from time to time, are invoiced in arrears and payable the month following the calendar month in which the additional services were provided. Specific due dates will differ by country and are listed in the House Rules.

8.10 Discounts, Promotions and Offers: If the Client benefited from a special discount, promotion or offer, the Provider may discontinue that discount, promotion or offer without notice if the Client materially breaches these terms and conditions.

*Global Terms & Conditions, Iveber, Jan-17*

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I, Jan-Anders Karlsson, Ph.D., certify that:

1. I have reviewed this annual report on Form 20-F of Verona Pharma 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 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 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: March 19, 2019

By: /s/ Jan-Anders Karlsson  
Jan-Anders Karlsson, Ph.D.  
Chief Executive Officer  
(Principal Executive Officer)

I, Piers Morgan, certify that:

1. I have reviewed this annual report on Form 20-F of Verona Pharma 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 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 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: March 19, 2019

By: /s/ Piers Morgan  
Piers Morgan  
Chief Financial Officer  
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jan-Anders Karlsson, Ph.D., Chief Executive Officer of Verona Pharma plc (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The Annual Report on Form 20-F of the Company for the period ended December 31, 2018 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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: March 19, 2019

/s/ Jan-Anders Karlsson  
Jan-Anders Karlsson, Ph.D.  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Piers Morgan, Chief Financial Officer of Verona Pharma plc. (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The Annual Report on Form 20-F of the Company for the period ended December 31, 2018 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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: March 19, 2019

/s/ Piers Morgan  
Piers Morgan  
Chief Financial Officer  
(Principal Financial Officer)

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form F-3 (No. 333-225107) and Form S-8 (333-217521) of Verona Pharma plc of our report dated March 19, 2019 relating to the financial statements, which appears in this Form 20-F.

/s/ PricewaterhouseCoopers LLP

Reading, United Kingdom

March 19, 2019