

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

**Form 20-F**

(Mark One)

- REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**  
OR  
 **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the fiscal year ended December 31, 2019  
OR  
 **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
OR  
 **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
Date of event requiring this shell company report \_\_\_\_\_  
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)

David Zaccardelli  
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	Trading symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 8 ordinary shares, nominal value £0.05 per share	VRNA	The Nasdaq Stock Market LLC (Nasdaq Global Market)

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: 105,326,638 as of December 31, 2019**

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 pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. 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, or IFRS, as issued by the International Accounting Standards Board, or IASB. 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;
- the duration of our patent portfolio; and
- our ability to retain key personnel and recruit qualified personnel, as well as the successful transition of our chief executive officer and chief financial officer roles.

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. The consolidated financial and other data for the years ended December 31, 2019, 2018, and 2017 and as of December 31, 2019 and 2018 have been derived from our audited financial statements and the notes thereto included elsewhere in this Annual Report. Our audited financial statements and the notes thereto and other data for the years ended December 31, 2016 and 2015 and as of December 31, 2017, 2016, and 2015 are not included elsewhere in this Annual Report. Our historical results are not necessarily indicative of the results that should be expected in the future.

The restatement is due to a change in accounting policy relating to movements in the assumed contingent obligation (see note 2.17 to the financial statements).

	Year Ended December 31,				
	2019	2018	2017	Restated 2016	Restated 2015
	(£'000s)				
<b>Consolidated statement of comprehensive income data:</b>					
Research and development costs	(33,476)	(19,294)	(23,717)	(4,522)	(7,270)
General and administrative costs	(7,607)	(6,297)	(6,039)	(2,498)	(1,706)
Operating loss	(41,083)	(25,591)	(29,756)	(7,020)	(8,976)
Finance income	2,351	2,783	7,018	1,841	45
Finance expense	(474)	(1,325)	(2,465)	(670)	(64)
Loss before taxation	(39,206)	(24,133)	(25,203)	(5,849)	(8,995)
Taxation — credit	7,265	4,232	4,706	954	1,509
Loss for the year	(31,941)	(19,901)	(20,497)	(4,895)	(7,486)
Other comprehensive income / (loss):			—		
Exchange differences on translating foreign operations	(33)	38	(29)	43	4
Total comprehensive loss attributable to owners of the company	(31,974)	(19,863)	(20,526)	(4,852)	(7,482)
Loss per ordinary share — basic and diluted (pence)	(30.3)	(18.9)	(23.4)	(14.6)	(37.1)

## Year Ended December 31,

	2019	Restated 2018	Restated 2017	Restated 2016	Restated 2015
(£'000s)					
<b>Consolidated statement of financial position data:</b>					
Cash and cash equivalents	22,934	19,784	31,443	39,785	3,524
Short term investments	7,823	44,919	48,819	—	—
Total assets	45,135	74,745	89,988	46,627	7,840
Share premium	118,862	118,862	118,862	58,526	26,650
Total liabilities	11,270	11,327	9,623	11,674	2,407
Accumulated loss	100,627	68,633	48,770	28,244	23,392
Total equity	33,865	63,418	80,365	34,953	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 £31.9 million, £19.9 million and £20.5 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated loss of £100.6 million (2018: £68.6 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 chronic obstructive pulmonary disease, or COPD;
- conduct any clinical trials of ensifentrine for the treatment of cystic fibrosis, or 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 clinical trials of ensifentrine and, subject to regulatory review, our planned Phase 3 clinical trials of ensifentrine, 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 activities including product positioning studies, product manufacturing, medical affairs, 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, 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 not be sufficient to complete a Phase 3 program of ensifentrine for the maintenance treatment of COPD. We will require additional funds to complete our planned Phase 3 clinical trials and other studies, including any post-marketing studies, to support the commercial positioning of ensifentrine for the treatment of COPD, if regulatory approval is received. 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 costs, progress and results of our planned Phase 3 clinical trials for the maintenance treatment of COPD, subject to regulatory review;
- the costs, timing and outcome of the regulatory review of ensifentrine, including any post-marketing studies that could be required by regulatory authorities, if regulatory approval is received;
- the cost, progress and results of any other studies required to support the commercial positioning of ensifentrine for the treatment of COPD, if regulatory approval is received;
- 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 MDI formulations of ensifentrine for the maintenance treatment of COPD and potentially asthma and other respiratory diseases;
- 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 withdrawal of the United Kingdom 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, or public health emergencies, such as the novel coronavirus (COVID-19).

**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 a national referendum and enactment of legislation by the government of the United Kingdom, the United Kingdom formally withdrew from the EU on January 31, 2020 and entered into a transition period during which it will continue its ongoing and complex negotiations with the EU relating to the future trading relationship between the parties. Significant political and economic uncertainty remains about whether the terms of the relationship will differ materially from the terms before withdrawal, as well as about the possibility that a so-called "no deal" separation will occur if negotiations are not completed by the end of the transition period.

These developments 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. 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 United Kingdom's withdrawal from the EU has resulted in the relocation of the EMA from the United Kingdom to the Netherlands. This relocation 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 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, or the utility of data from these trials may be compromised, for a variety of reasons, including the following:

- delays in or failure to obtain regulatory agreement on appropriate Phase 3 trial design, including dose and frequency of administration;
- 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 15 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, thirteen patients have reported in aggregate sixteen serious adverse events (including a suicide); eleven of these serious adverse events were assessed as not related to study drug and five 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 FDA, the EMA or comparable foreign regulatory authorities may find that the dose or doses evaluated in Phase 3 clinical trials or the way in which double blinding was effected 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 publicly disclose top-line or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock after this offering.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

**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. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the district court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how these decisions, subsequent appeals, if any, and other efforts to challenge, repeal or replace the ACA or 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 2029 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), certain health care professionals beginning in 2022, 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. For example, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context; 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). In addition, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU.

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 extra-territorially 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. Moreover, for drugs and biologics administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such products. 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 MDI 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 liabilities 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 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 suppliers, 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, MDI, 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 the successful transition of our CEO and CFO roles, retaining our key personnel and recruiting additional qualified personnel.**

Our success depends upon the 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. On February 3, 2020 we announced the appointment of David Zaccardelli as chief executive officer with effect from February 1, 2020, following the retirement of Jan-Anders Karlsson, PhD. We also announced the appointment of Mark Hahn as chief financial officer with effect from March 1, 2020, as successor to Piers Morgan. We anticipate that we will experience a transitional period until our new chief executive officer and chief financial officer are fully integrated into their new roles and the transition may not be successful. Moreover, we cannot provide any assurance that the transition in leadership will not result in a disruption that adversely impacts our business and employee morale, or that successful working relationships between our other key management individuals and the new chief executive officer and chief financial officer will be developed.

Our other key management individuals include 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, 2019, our senior management, board of directors and greater than 5% shareholders and their respective affiliates, in the aggregate, owned approximately 61% 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 depositary 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 depositary 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 depositary 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 depositary 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 depositary, 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 depositary. However, the depositary 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 depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary 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. Following implementation of the changes in management announced on February 3, 2020 a majority of our executive officers are expected to be U.S. citizens or residents. 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, 2019, 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, 2019, 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, 2019. 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, 2019 were £0.3 million (2018: £0.3 million, 2017: £0.2 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 2020 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 — Operating and Capital Expenditure Requirements, Item 4.D. Property, Plant and Equipment, and Note 21 of our Annual Consolidated Financial Statements included elsewhere in this Annual Report.

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 single compound in clinical development or approved by the U.S. Food and Drug Administration, or FDA, nor the European Medicines Agency, or EMA, for the treatment of respiratory diseases that acts 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 has currently completed Phase 2 clinical development for the treatment of chronic obstructive pulmonary disease, or COPD, and we are preparing to meet with the FDA to discuss plans for Phase 3 clinical trials, which we expect to commence in the third quarter of 2020, subject to FDA feedback and to funding.

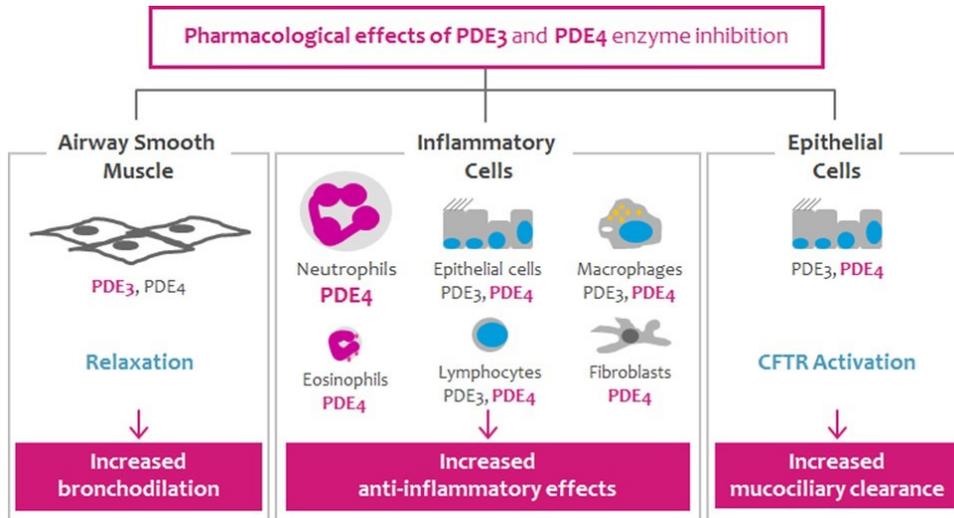
Successful Phase 1 and 2 studies have been completed with nebulized ensifentrine in healthy volunteers and in patients with cystic fibrosis, or CF, chronic asthma and allergic rhinitis, in addition to COPD. A Phase 2 study in COPD with ensifentrine formulated in a dry powder inhaler, or DPI, has been completed, with positive clinical results reported in August 2019. A Phase 2 study in COPD with ensifentrine formulated in a pressurized metered dose inhaler, or MDI, is ongoing with clinical results expected in the second half of 2020. We intend to 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 (roflumilast) with anti-inflammatory properties, although frequency of adverse events has limited its use in COPD patients. Clinicians have expressed desire to use this oral PDE4 inhibitor in more patients were it not for the adverse events. We believe this suggests that ensifentrine has potential to become an important treatment for COPD and other respiratory diseases if our late-stage clinical program demonstrates favorable efficacy, safety and tolerability results for the compound.

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 1.2 million patients in the United States alone) are uncontrolled, remaining symptomatic and at an increased risk of exacerbations. Existing anti-inflammatory therapies used in COPD, namely 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 a number of factors including allergens, infections, stress and certain drugs. Such exacerbations may occur even if patients are taking their medications, especially in those with more severe disease. We believe ensifentrine's bronchodilator and anti-inflammatory properties may be useful also in patients with asthma.

We have completed fifteen Phase 1 and Phase 2 clinical trials with ensifentrine, which have enrolled over 1,300 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 in a study or a trial occurred by chance alone.

In two Phase 2b clinical trials 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 reported COPD symptom scores. In addition, our clinical trials have also shown clinically meaningful and statistically significant 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 (branded as 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, if successfully developed and approved. 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. As a result, we believe it has potential to meet the need for a safe and effective dual bronchodilator/anti-inflammatory treatment regimen as an add-on to other therapies, for example, a LAMA. Furthermore, in the United States, approximately another three million COPD patients are treated with dual bronchodilator therapy (LAMA/LABA) with or without ICS.

In January 2020, we reported top-line results from our 4 week 416-patient Phase 2b dose-ranging clinical trial. This trial evaluated four doses of nebulized ensifentrine (0.375 mg, 0.75 mg, 1.5 mg and 3.0 mg) or placebo as an add-on treatment to tiotropium (Spiriva® Respimat®), a commonly used LAMA bronchodilator, in symptomatic patients with moderate-to-severe COPD who required additional treatment. The trial met its primary endpoint of improved lung function, with ensifentrine plus tiotropium producing a clinically and statistically significant dose-dependent improvement in FEV<sub>1</sub> at week 4, compared to placebo plus tiotropium. Additionally, clinically meaningful improvements in health-related quality of life (mean SGRQ-C) were observed on top of tiotropium. Ensifentrine was well tolerated at all doses with an adverse event profile similar to placebo. We believe that these data support dose selection for our planned Phase 3 program, which we anticipate initiating in the third quarter of 2020, subject to FDA feedback and funding.

In January 2019, we announced results from our exploratory pharmacological Phase 2 clinical trial evaluating nebulized ensifentrine administered twice daily on top of treatment with tiotropium and olodaterol. Although we did not meet the primary endpoint, treatment with ensifentrine showed statistically significant improvements in FEV<sub>1</sub>, including when measured over 24 hours, and after the second dose in the evening. We believe this 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.

Verona has completed a pilot Phase 2 study in CF patients, the results of which support the continued development of ensifentrine as a possible new treatment for CF patients. 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 DPI or a pressurized metered-dose inhaler, or MDI. 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, may 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 (which may take approximately 5 minutes) and required nebulizer device cleaning. Furthermore, nebulizers may be more appropriate for certain groups of patients who may struggle to use an inhaler effectively.

We also are developing ensifentrine in both DPI and MDI formulations for the maintenance treatment of COPD. In August 2019 we announced positive results from a Phase 2, two-part clinical trial evaluating a DPI formulation of ensifentrine in COPD patients. The trial showed clinically and statistically significant improvements in FEV<sub>1</sub> following one week of treatment, compared to placebo, with a dose-dependent improvement over the dose range of 0.15 mg, 500 mg, 1500 mg and 3 mg ensifentrine. Handheld DPI and MDI devices are the most common forms of drug delivery in non-hospitalized COPD patients, 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 MDI 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 MDI formulations for the treatment of asthma and other respiratory diseases.

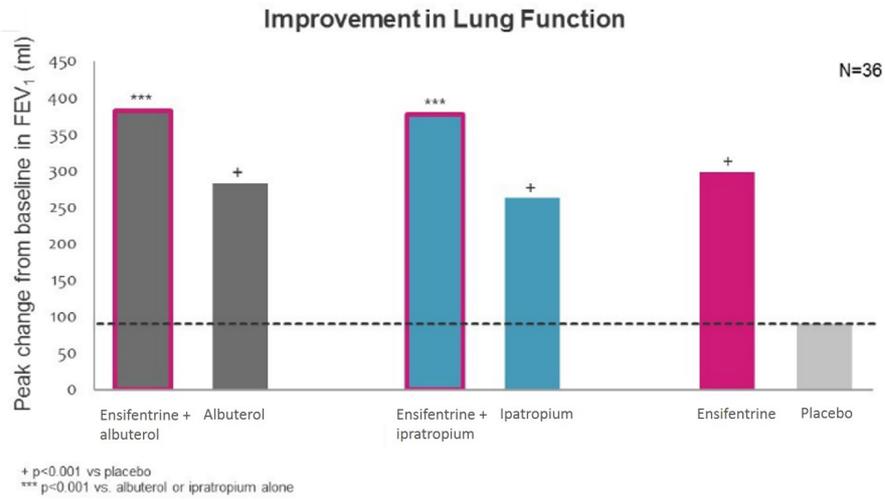
## **DEVELOPMENT OF ENSIFENTRINE**

### *Clinical development of ensifentrine in COPD*

We have completed six studies with a nebulized suspension formulation of ensifentrine and one study with a DPI formulation of ensifentrine in patients with moderate-to-severe COPD. A Phase 2 study with our MDI formulation of ensifentrine is ongoing. We anticipate reporting data from the single-dose portion of this trial (Part A) early in the second quarter of 2020, and reporting results from the second portion of the trial (Part B), which evaluates multiple doses of the MDI formulation of ensifentrine, in the second half of 2020.

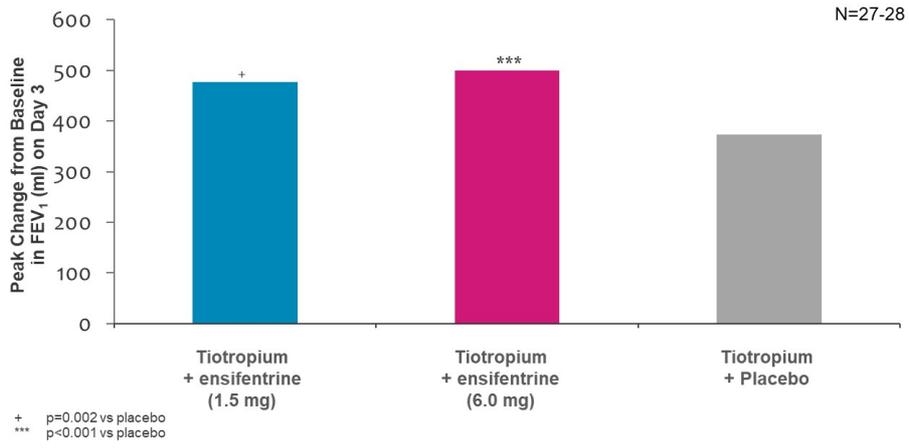
### **Clinical studies with nebulized formulation of ensifentrine**

Clinical trials we have conducted with nebulized ensifentrine include 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 MDI 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). Ensisentrine also resulted in an additive and significant reduction in lung volume and airway resistance.

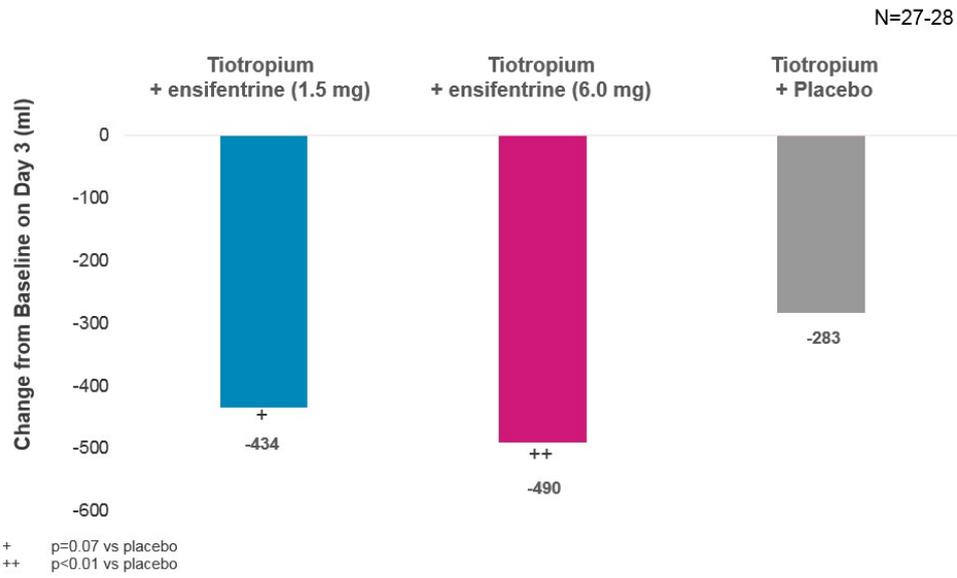


We conducted a Phase 2a crossover study in 30 patients with moderate-to-severe COPD to examine the effect of ensifentrine when added to a standard dose of a single bronchodilator (LAMA, tiotropium or Spiriva®) in the United Kingdom. Patients received tiotropium 18 µg once daily, plus ensifentrine 1.5 mg, ensifentrine 6 mg or placebo twice daily for three 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

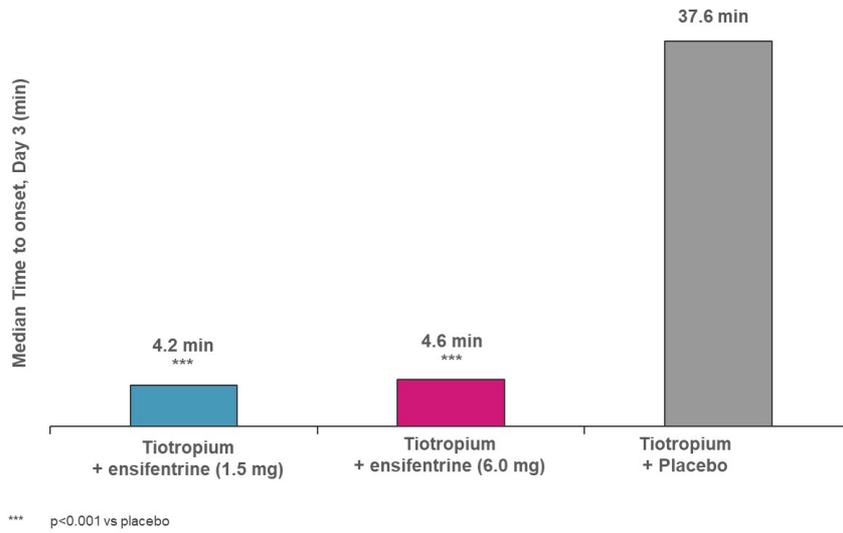


### Change in Residual Volume (ml)



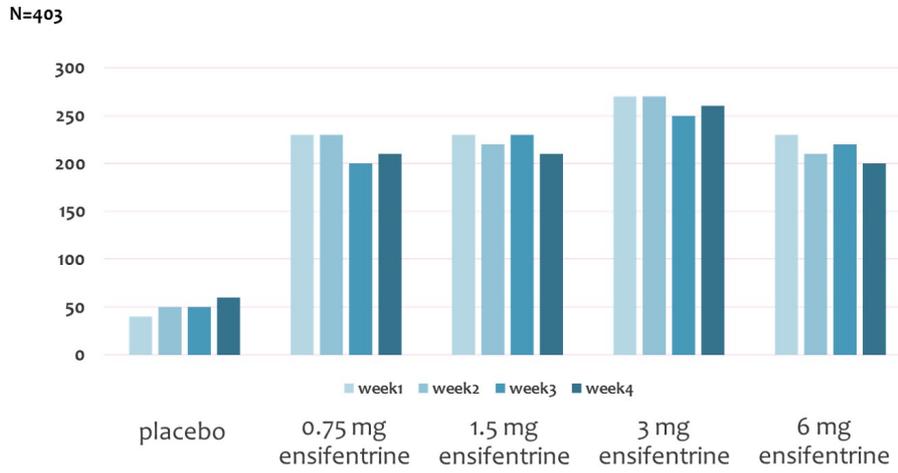
Median Time to Onset ( $\geq 10\%$  improvement in FEV<sub>1</sub>; mins) on Day 3

N=27-28

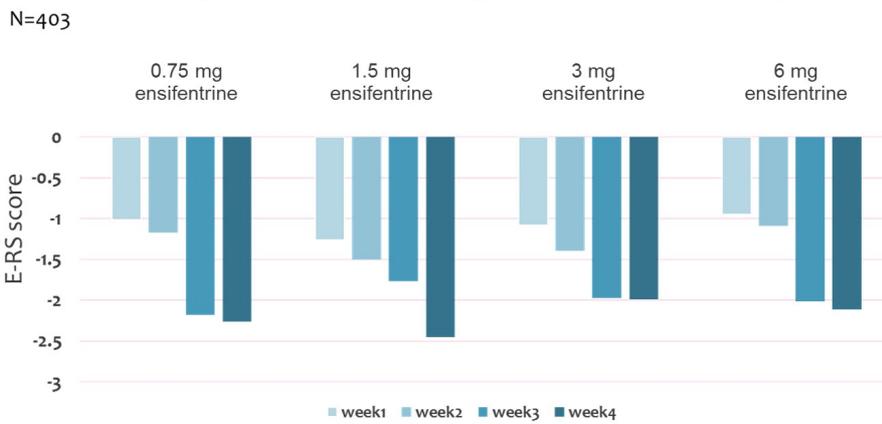


We conducted a Phase 2b parallel group study in 403 patients with COPD in Europe to examine the effect in patients without concomitant bronchodilator therapy. Patients received either placebo or ensifentrine at doses ranging from 0.75 mg to 6 mg twice daily over 4 weeks. Treatment with ensifentrine met 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 EXACT - Respiratory Symptoms (E-RS), a recognized daily patient-reported outcome measure for use in clinical studies of COPD, as well as 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, suggests 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)

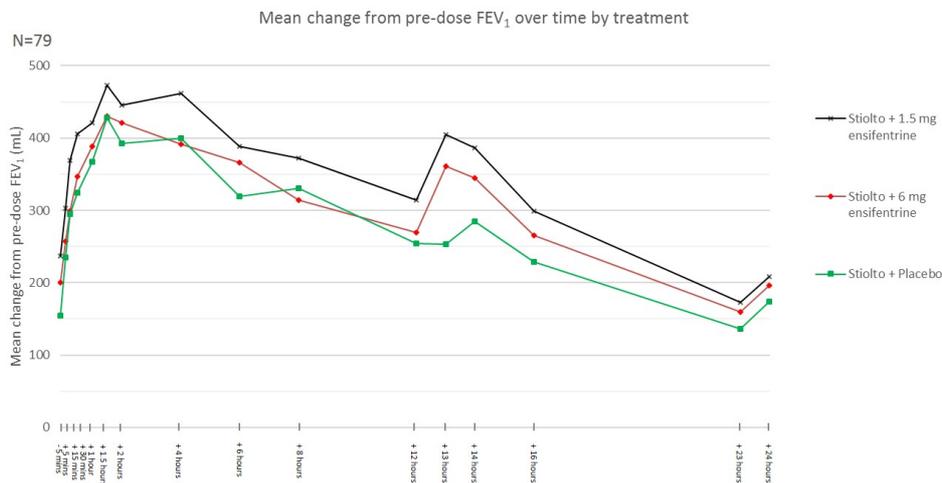


### Total score (0-40) E-RS: COPD by week (placebo corrected, p<0.02)



In January 2019, we announced top-line data from an exploratory Phase 2 three-way crossover pharmacological 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. 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 bronchodilator therapy". Although the primary endpoint of a statistically significant improvement in morning peak FEV<sub>1</sub> on the third day of dosing 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 added on top of Stiolto® Respimat® (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,  $p = 0.036$ ).

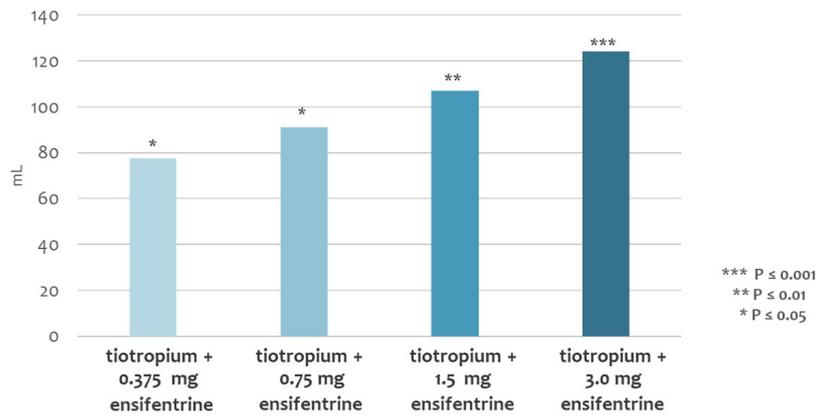


In January 2020, we reported top-line results from our 4 week 416-patient Phase 2b dose-ranging clinical trial. This trial evaluated four doses of nebulized ensifentrine (0.375 mg, 0.75 mg, 1.5 mg and 3.0 mg) or placebo as an add-on treatment to tiotropium (Spiriva® Respimat®), a commonly used LAMA bronchodilator, in symptomatic patients with moderate-to-severe COPD who required additional treatment.

The trial met its primary endpoint of improved lung function, with ensifentrine plus tiotropium producing a clinically and statistically significant dose-dependent improvement in peak FEV<sub>1</sub> at week 4, compared to placebo plus tiotropium. The improvements ranged from 78 mL for the 0.375 mg dose ( $p = 0.0368$ ) to 124 mL for the 3.0 mg dose ( $p = 0.0008$ ) and were maintained over the 4-week study period. Dose-dependent improvements in lung function were observed on both average FEV<sub>1</sub> AUC 0-4 hours and FEV<sub>1</sub> AUC 0-12 hours. There was also a statistically significant improvement in average FEV<sub>1</sub> AUC 0-12 hours of 87 mL for the 3.0 mg dose ( $p = 0.0111$ ), which we believe is supportive of twice daily dosing. Area Under the Curve over 0-12 hours post dose, or FEV<sub>1</sub> AUC<sub>(0-12hr)</sub>, was calculated using the trapezoidal rule, divided by the observation time (12 hours) to report in mL, a measure of the aggregate effect over 12 hours.

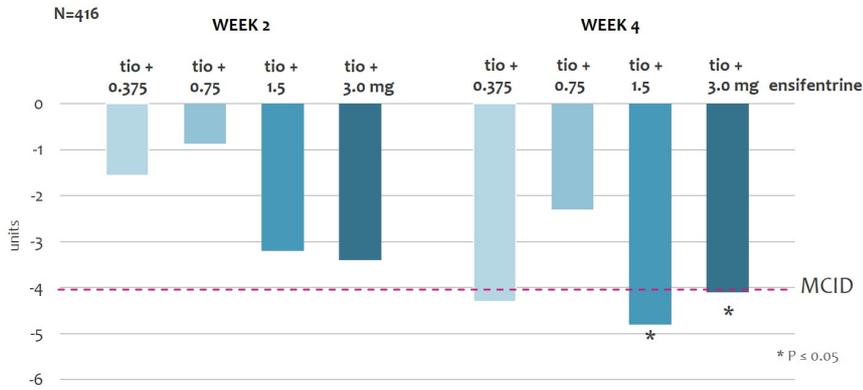
## Peak Change from Day 1 Baseline in FEV<sub>1</sub> (mL) at Week 4; placebo corrected

N=416



Additionally, clinically meaningful improvements in health-related quality of life as measured by St. George's Respiratory Questionnaire for COPD (mean SGRQ-C) were observed on top of tiotropium, exceeding the minimal clinically important difference ("MCID") of 4 units compared to placebo at week 4, with the two highest doses 1.5 mg and 3 mg also achieving statistical significance. The SGRQ-C is a validated instrument that measures impact on overall health, daily life, and perceived well-being in patients with COPD (i.e. change in frequency and severity of COPD symptoms, and impact on activities, social functioning and psychological disturbances related to airways disease).

## SGRQ-C Mean Change from Baseline; placebo corrected

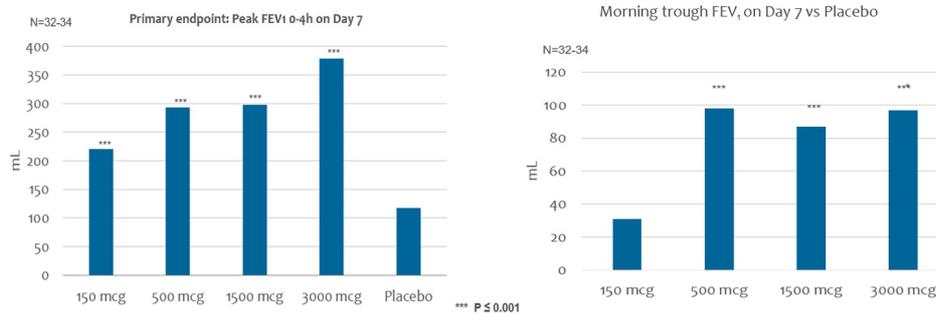


In the trial, ensifentrine was well tolerated at all doses with an adverse event profile similar to placebo. We believe that these data support dose selection for our planned Phase 3 program, which we anticipate initiating in the third quarter of 2020, subject to FDA feedback and funding.

## Clinical studies with handheld DPI and MDI formulations of ensifentrine

In August 2019, we announced results from our Phase 2 clinical trial evaluating a DPI formulation of ensifentrine for the maintenance treatment of patients with COPD. The magnitude of improvement in lung function, as measured by FEV<sub>1</sub> was highly statistically significant and we believe this supports twice daily dosing of ensifentrine for COPD treatment. Secondary lung function endpoints were also met, and ensifentrine was well tolerated at all dose levels. We believe that delivery of ensifentrine with a hand-held inhalation device, such as the DPI format, could substantially expand the clinical utility and commercial opportunity in COPD treatment.

### Change from Day 1 Baseline in Peak and Trough FEV<sub>1</sub> (mL) at Day 7



In June 2019, we announced the initiation of a Phase 2 dose-ranging trial to evaluate the pharmacokinetic, or PK profile, efficacy, and safety of a pressurized MDI formulation of ensifentrine in patients with moderate-to-severe COPD. We anticipate reporting data from the single-dose portion of this trial (Part A) early in the second quarter of 2020, and reporting results from the second portion of the trial (Part B), which evaluates multiple doses of the MDI formulation of ensifentrine, in the second half of 2020.

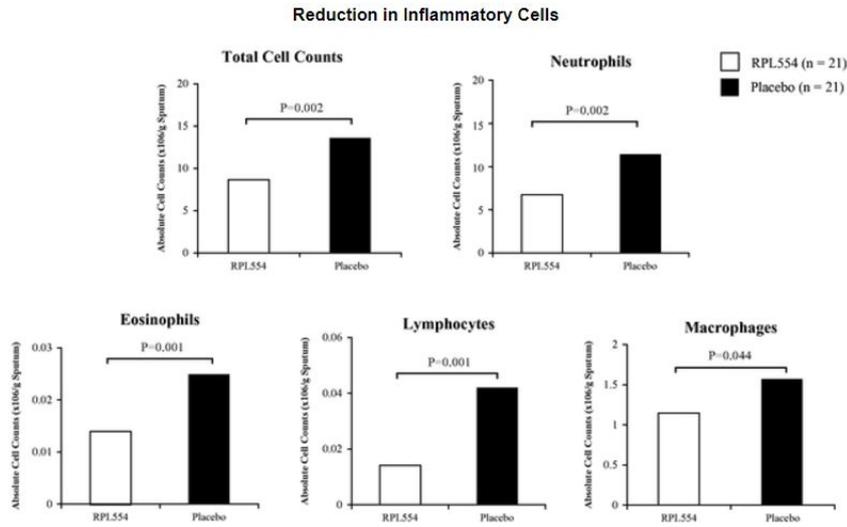
Ensifentrine has been observed to be well tolerated in our clinical studies performed to date when administered alone, and as an add-on therapy to commonly used bronchodilators at dose levels ranging from 0.4 mg to 24 mg. Dose-limiting toxicities have not been observed. To date across all studies and populations, 13 subjects have reported 16 serious adverse events, or SAEs. Of these events, only two were assessed as possibly related to ensifentrine, although relevant mitigating factors were subsequently considered. In our completed clinical trials adverse events were rare, with nature and incidence similar to placebo. In ECGs assessed in over 800 patients with COPD, and 24-hour Holter monitoring in over 400 patients, no meaningful effects were observed compared to placebo, except for a small, transient and not clinically meaningful increase in peak heart rate of approximately 3 beats per minute with the 6 mg dose of ensifentrine. Ensifentrine 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 ensifentrine was used alone. In our studies, the most common adverse events have been mild to moderate, and included headache, dizziness, cough, nasopharyngitis (throat irritation) and rash, which occurred with comparable frequency to placebo.

An End of Phase 2 Meeting with the FDA is planned to take place during the first half of 2020, to discuss our planned Phase 3 clinical trial design and program. We intend to use the data from all our completed studies, including data from our most recently completed Phase 2b trial to inform our future studies, including the design of our planned Phase 3 program for the maintenance treatment of COPD with nebulized ensifentrine.

Additional studies with ensifentrine 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 ensifentrine entered the bloodstream via the gastrointestinal tract. The low oral bioavailability of nebulized ensifentrine, as was 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 ensifentrine.

Ensifentrine has also 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. The results demonstrated that ensifentrine produced 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 the 1.5 mg and 6 mg doses, respectively. Ensifentrine elicited a statistically significant increase in average FEV<sub>1</sub> in treated patients for the 1.5 mg dose (all time points, p<0.01) and the 6 mg dose (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 the compound.

## 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. According to the World Health Organization, COPD is expected to become the third leading cause of death globally by 2030, with 384 million people worldwide suffering from the disease. It is estimated that there are 24 million people with COPD in the United States, of whom 16 million have been diagnosed. Of those diagnosed with COPD in the United States, 3 million suffer from severe or very severe forms of the disease. Total annual medical costs relating to COPD in the United States are projected to rise to \$49 billion in 2020. Global sales of drugs used for chronic maintenance therapy of COPD were \$13.6 billion in 2019, of which \$9.6 billion were in the US. 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.

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. Global sales of drugs used for the treatment of CF were \$3.5 billion in 2019, of which \$2.0 billion were in the US.

Asthma is widely seen as a result of chronic inflammation in the lungs. Worldwide 300 million people suffer from asthma with about 25 million diagnosed in the US alone. Global sales of drugs used for the treatment of asthma were \$16.5 billion in 2019, with \$9.7 billion in the US. 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. Annual sales of biologics in the United States for the treatment of asthma exceed \$1.0 billion. We see potential for ensifentrine as an inhaled product for such patients.

We may also explore the development of ensifentrine in MDI and/or DPI formulations for the treatment of asthma and other respiratory diseases.

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:

	Expanding Indications	Expanding Delivery	Supporting Trials			
			Pre-Clinical	Phase 1	Phase 2	Phase 3
Expanding Pipeline	COPD Maintenance (Home)	Nebulizer	[Progress bar: Pre-Clinical, Phase 1, Phase 2]			
	COPD Acute (Hospital)		[Progress bar: Pre-Clinical, Phase 1]			
	Cystic Fibrosis		[Progress bar: Pre-Clinical, Phase 1]			
	Severe Asthma		[Progress bar: Pre-Clinical, Phase 1]			
	COPD Maintenance (Home)	DPI	[Progress bar: Pre-Clinical, Phase 1, Phase 2]			
	COPD Maintenance (Home)	MDI	[Progress bar: Pre-Clinical, Phase 1, Phase 2]			

## 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 MDI 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 fifteen Phase 1 and 2 clinical trials for ensifentrine with over 1,300 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 EXACT - Respiratory Symptoms (E-RS), a recognized daily patient-reported outcome measure for use in clinical studies of COPD, as well as 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, suggests the involvement of an anti-inflammatory effect.

Our recently completed 4 week 416-patient Phase 2b dose-ranging clinical trial evaluated four doses of nebulized ensifentrine (0.375 mg, 0.75 mg, 1.5 mg and 3.0 mg) or placebo as an add-on treatment to tiotropium (Spiriva® Respimat®), a commonly used LAMA bronchodilator, in symptomatic patients with moderate-to-severe COPD who required additional treatment.

The trial met its primary endpoint of improved lung function, with ensifentrine plus tiotropium producing a clinically and statistically significant dose-dependent improvement in peak FEV<sub>1</sub> at week 4, compared to placebo plus tiotropium. The improvements ranged from 78 mL for the 0.375 mg dose ( $p = 0.0368$ ) to 124 mL for the 3.0 mg dose ( $p = 0.0008$ ) and were maintained over the 4-week study period. Dose-dependent improvements in lung function were observed on both average FEV<sub>1</sub> AUC 0-4 hours and FEV<sub>1</sub> AUC 0-12 hours. There was also a statistically significant improvement in average FEV<sub>1</sub> AUC 0-12 hours of 87 mL for the 3.0 mg dose ( $p = 0.0111$ ), which we believe is supportive of twice daily dosing. Area Under the Curve over 0-12 hours post dose, or FEV<sub>1</sub> AUC<sub>(0-12hr)</sub>, was calculated using the trapezoidal rule, divided by the observation time (12 hours) to report in mL, a measure of the aggregate effect over 12 hours.

- **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 for 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 that remain 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 compound's effect on FEV<sub>1</sub>, COPD symptoms, exacerbations and its duration of action. 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, namely bronchodilation and the 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. We believe that we have validated the dose and commercial positioning of ensifentrine in our comprehensive Phase 2 clinical trial program, and we plan to participate in an End of Phase 2 Meeting with the FDA to obtain guidance on our planned Phase 3 program, which we anticipate will include two large-scale pivotal studies. We expect to meet with the FDA for our End of Phase 2 Meeting in the first half of 2020, and initiate our Phase 3 clinical studies in the third quarter of 2020, subject to FDA feedback and to funding.
- 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, over a 24-hour period 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.** The ensifentrine suspension for nebulized administration has been presented in a glass vial with a flip, tear-up cap in clinical studies to date. 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. A unit dose plastic ampule presentation format for the ensifentrine nebulizer suspension has been under development, and we are positioning this for use in Phase 3 clinical trials.
- **Develop DPI and MDI formulations of ensifentrine.** In addition to our nebulized formulation of ensifentrine, we are developing ensifentrine in both DPI and MDI formulations for the maintenance treatment of COPD. We believe the development of DPI and MDI 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 have obtained favorable Phase 2 clinical trial results for our DPI formulation. We expect complete results from our Phase 2 MDI trial in the third quarter of 2020, and we are seeking partnerships with larger commercial-stage pharmaceutical and biotechnology companies to advance these programs further, including potential opportunities to explore the development of ensifentrine in these formulations for the treatment of asthma and other respiratory diseases.
- **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. Ensisfentrine demonstrated a statistically significant bronchodilator effect, a PK profile that is consistent with that observed in patients with COPD while being well tolerated.
- **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 liabilities 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 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 for the manufacture 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 MDI 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 United States. 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 3 million US COPD patients are currently treated with dual bronchodilatory therapy, and of these approximately 1.2 million 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 (Brovana® and Perforomist®) and long-acting anti-muscarinic bronchodilators (Yupelri® and Lonhala®Magnair®). However, neither class of drug provides an anti-inflammatory effect. We consider ensifentrine's current closest potential competitors in the DPI/MDI 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 that was approved in China in December 2019.

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 6, 2020 our patent portfolio consisted of ten issued US patents, four pending US patent applications, thirty-seven issued foreign patents and fifty pending foreign applications including one patent application made under the Patent Cooperation Treaty. 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 2040.

The patent portfolio relating to ensifentrine includes ten patent families:

- The first of these patent families relates to ensifentrine *per se*. As of February 6, 2020, 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 6, 2020, 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 6, 2020, 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 6, 2020, this patent family included granted patents in Australia, Europe, Japan, Russia and the United States (two patents) and patent applications in Canada, China, India, South Korea, Mexico and Thailand. 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 6, 2020, this patent family included a granted patent in the United States and patent applications in Australia, Canada, China, Europe, Israel, Japan, Mexico, New Zealand, the United States (continuation application) 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 cystic fibrosis). As of February 6, 2020, this patent family included a granted patents in Europe (two patents) and Russia and patent applications in Australia, Canada, Israel, Mexico, 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 6, 2020, this patent family included granted patents in Europe (two patents), Hong Kong (two patents), Israel, Russia, the United States, Singapore and South Africa and patent applications in Australia (parent and divisional applications), Brazil, Canada, China (parent and divisional applications), Europe (divisional application), Hong Kong (divisional application), Indonesia, India, Japan (parent and divisional applications), South Korea, Mexico, Malaysia, New Zealand, the Philippines, Thailand and the United States (continuation 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 6, 2020, this patent family included a granted European patent and patent applications in China, Hong Kong, 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 MDI. As of February 6, 2020, this patent family included a pending, unpublished PCT patent application and a pending, unpublished patent application in the United Kingdom. We expect patents in this family to expire in October 2039.
- The tenth of these patent families relates to a formulation comprising ensifentrine for DPI. As of February 6, 2020, this patent family included a pending, unpublished patent application in the United Kingdom. We expect patents in this family to expire in August 2040.

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. Pre-clinical testing may continue after the IND is effective. 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 27 Member States of the EU plus Norway, Iceland and Liechtenstein, and the United Kingdom until the end of the transition period on December 31, 2020 provided for in the Withdrawal Agreement between the EU and the United Kingdom) 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, 2019, we had 25 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 three leases that terminate in early 2022. We also lease office space at 434 West 33rd Street, New York City, New York, under a lease that terminates in 2021. 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 2021 and February 2022. 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 single compound in clinical development or approved by the U.S. Food and Drug Administration, or FDA, nor the European Medicines Agency, or EMA, for the treatment of respiratory diseases that acts 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 has currently completed Phase 2 clinical development for the treatment of chronic obstructive pulmonary disease, or COPD, and we are preparing to meet with the FDA to discuss plans for Phase 3 clinical trials, which we expect to commence in the third quarter of 2020, subject to FDA feedback and to funding.

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, or DPI, has been completed, with positive clinical results reported in August 2019. A Phase 2 study in COPD with ensifentrine formulated in a pressurized metered dose inhaler, or MDI, is ongoing with clinical results expected in the second half of 2020. We intend to 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 (roflumilast) with anti-inflammatory properties, although frequency of adverse events has limited its use in COPD patients. Clinicians have expressed desire to use this oral PDE4 inhibitor in more patients were it not for the adverse events. We believe this suggests that ensifentrine has potential to become an important treatment for COPD and other respiratory diseases if our late-stage clinical program demonstrates favorable efficacy, safety and tolerability results for the compound.

We have completed fifteen Phase 1 and Phase 2 clinical trials with ensifentrine, which have enrolled over 1,300 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 in a study or a trial occurred by chance alone.

In two Phase 2b clinical trials 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 reported COPD symptom scores. In addition, our clinical trials have also shown clinically meaningful and statistically significant 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 (branded as 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, if successfully developed and approved. 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. As a result, we believe it has potential to meet the need for a safe and effective dual bronchodilator/anti-inflammatory treatment regimen as an add-on to other therapies, for example, a LAMA. Verona has completed a pilot Phase 2 study in CF patients, the results of which support the continued development of ensifentrine as a possible new treatment for CF patients. 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 January 2020, we reported top-line results from our 4 week 416-patient Phase 2b dose-ranging clinical trial. This trial evaluated four doses of nebulized ensifentrine (0.375 mg, 0.75 mg, 1.5 mg and 3.0 mg) or placebo as an add-on treatment to tiotropium (Spiriva® Respimat®), a commonly used LAMA bronchodilator, in symptomatic patients with moderate-to-severe COPD who required additional treatment.

The trial met its primary endpoint of improved lung function, with ensifentrine plus tiotropium producing a clinically and statistically significant dose-dependent improvement in peak FEV<sub>1</sub> at week 4, compared to placebo plus tiotropium. The improvements ranged from 78 mL for the 0.375 mg dose (p=0.0368) to 124 mL for the 3.0 mg dose (p=0.0008) and were maintained over the 4-week study period. Dose-dependent improvements in lung function were observed on both average FEV<sub>1</sub> AUC 0-4 hours and FEV<sub>1</sub> AUC 0-12 hours. There was also a statistically significant improvement in average FEV<sub>1</sub> AUC 0-12 hours of 87 mL for the 3.0 mg dose (p=0.0111), which we believe is supportive of twice daily dosing. Area Under the Curve over 0-12 hours post dose, or FEV<sub>1</sub> AUC<sub>(0-12hr)</sub>, was calculated using the trapezoidal rule, divided by the observation time (12 hours) to report in mL, a measure of the aggregate effect over 12 hours.

Additionally, clinically meaningful improvements in health-related quality of life as measured by St. George's Respiratory Questionnaire for COPD (mean SGRQ-C) were observed on top of tiotropium, exceeding the minimal clinically important difference ("MCID") of 4 units compared to placebo at week 4, with the two highest doses 1.5 mg and 3 mg also achieving statistical significance. The SGRQ-C is a validated instrument that measures impact on overall health, daily life, and perceived well-being in patients with COPD (i.e. change in frequency and severity of COPD symptoms, and impact on activities, social functioning and psychological disturbances related to airways disease). Ensisentrine was well tolerated at all doses with an adverse event profile similar to placebo. We believe that these data support dose selection for our planned Phase 3 program, which we anticipate initiating in the third quarter of 2020, subject to FDA feedback and to funding.

We plan to meet with the FDA in the second quarter of 2020 for an End Of Phase 2 meeting, in which we intend to discuss our clinical data to date and determine the design of our Phase 3 clinical trials.

In August 2019, we announced results from our Phase 2 clinical trial evaluating a DPI formulation of ensifentrine for the maintenance treatment of patients with COPD. The magnitude of improvement in lung function, as measured by FEV<sub>1</sub> was highly statistically significant and we believe this supports twice daily dosing of ensifentrine for COPD treatment. Secondary lung function endpoints were also met, and ensifentrine was well tolerated at all dose levels. We believe that delivery of ensifentrine with a hand-held inhalation device, such as the DPI format, could substantially expand the clinical utility and commercial opportunity in COPD treatment.

In January 2019, we announced top-line data from an exploratory Phase 2 three-way crossover pharmacological 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. 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 bronchodilator therapy". Although the primary endpoint of a statistically significant improvement in morning peak FEV<sub>1</sub> on the third day of dosing 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 added on top of Stiolto® Respimat® (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).

In March 2018, 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. Patients in this study 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 EXACT - Respiratory Symptoms (E-RS), a recognized daily patient-reported outcome measure for use in clinical studies of COPD, as well as 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, suggests 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 the 1.5 mg and 6 mg doses, respectively. Ensifentrine elicited a statistically significant increase in average FEV<sub>1</sub> in treated patients for the 1.5 mg dose (all time points,  $p < 0.01$ ) and the 6 mg dose (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 the compound.

We do not have any approved products and, as a result, have not generated any revenue from product sales or otherwise. Ensifentrine 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, 2018 and 2019 we incurred net losses of £19.9 million and £32.0 million, respectively. As of December 31, 2019, we had an accumulated loss of £100.6 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 liabilities 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. 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 that we currently anticipate will be required for the completion of clinical development or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of our clinical development programs.

#### **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 for small or medium sized entities and are currently 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. The amount of such rebates is currently under review and may in future be subject to certain additional conditions and/or a cap. 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 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 Liability***

A significant management estimate relates to the probability, amount and timing of any payment relating to the assumed contingent liability 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 20 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 liability 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 2.19 to our Annual Consolidated Financial Statements for the year ended December 31, 2019 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.

## Results of Operations

A discussion of the year ended December 31, 2018, compared to the year ended December 31, 2017, has been reported previously in our Annual Report on Form 20-F for the year ended December 31, 2018, filed with the SEC on March 19, 2019, under the heading "Operating and Financial Review and Prospects."

### Comparison of Operations for the Years ended December 31, 2019, and 2018

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, 2019 at the noon buying rate of the Federal Reserve Bank of New York on December 31, 2019, which was £1.00 to \$1.3269. 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,					
	2019			2018		
	£'000s		\$'000s	£		£'000s
Research and development costs	£	(33,476)	\$	(44,419)	£	(19,294)
General and administrative costs		(7,607)		(10,094)		(6,297)
Operating loss		(41,083)		(54,513)		(25,591)
Finance income		2,351		3,120		2,783
Finance expense		(474)		(629)		(1,325)
Loss before taxation		(39,206)		(52,022)		(24,133)
Taxation — credit		7,265		9,640		4,232
Loss for the year		(31,941)		(42,382)		(19,901)
Other comprehensive (loss) / income						
Exchange differences on translating foreign operations		(33)		(44)		38
Total comprehensive loss attributable to owners of the company	£	(31,974)	\$	(42,426)	£	(19,863)

### **Comparison of Operations for the Years ended December 31, 2019 and 2018**

The operating loss for the year ended December 31, 2019 was £41.1 million (2018: £25.6 million) and the loss after tax for the year ended December 31, 2019 was £31.9 million (2018: £19.9 million).

#### *Research and Development Costs*

Research and development costs were £33.5 million for the year ended December 31, 2019 as compared to £19.3 million for the year ended December 31, 2018, an increase of £14.2 million. The cost of clinical trials increased by £12.7 million as there were two active trials in the year ended December 31, 2018, compared to four clinical trials in the year ended December 31, 2019. Pre-clinical costs increased by £0.3 million which was offset by a reduction in contract manufacturing and formulation development costs by £0.4 million. Personnel related costs increased by £1.3 million in the year ended December 31, 2019, compared to the prior year.

#### *General and Administrative Costs*

General and administrative costs were £7.6 million for the year ended December 31, 2019 as compared to £6.3 million for the year ended December 31, 2018, an increase of £1.3 million. The increase was primarily attributable to a £0.9 million increase in costs relating to commercial market research, a £0.3 million increase in personnel related costs and a £0.6 million increase in other overhead costs. This was offset by a £0.5 million decrease in share based payments.

#### *Finance Income and Expense*

Finance income was £2.4 million for the year ended December 31, 2019 and £2.8 million for the year ended December 31, 2018. The decrease was due to a loss in foreign exchange on cash and short term investments (recorded as a finance expense) compared to £1.9 million gain in the prior year. This was offset by a £1.6 million decrease in the fair value of the warrant liability in the year ended December 31, 2019 compared to an increase in the liability in the year ended December 31, 2018 (which is a non-cash item, recorded as a finance expense).

Finance expense was £0.5 million for the year ended December 31, 2019, as compared to £1.3 million for the year ended December 31, 2018. The movement was due to a decrease in the fair value of the warrant liability (recorded in finance income), compared to an increase of £1.2 million December 31, 2018, both non-cash items. In addition, there was a foreign exchange loss on cash and short-term investments in December 31, 2019 of £0.3 million. In the year ended December 31, 2018, there was a foreign exchange gain (recorded in finance income).

As at December 31, 2019, there was approximately £22.9 million in cash and cash equivalents (2018: £19.8 million) and £7.8 million in short-term investments (2018: £44.9 million).

#### *Taxation*

Taxation for the year ended December 31, 2019 amounted to a credit of £7.3 million as compared to a credit of £4.2 million for the year ended December 31, 2018, an increase in the credit amount of £3.1 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

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.

The Company has incurred recurring losses since inception, including net losses of £31.9 million, £19.9 million and £20.5 million for the years ended December 31, 2019, 2018 and 2017, respectively. In addition, as of December 31, 2019, the Company had an accumulated loss of £100.6 million. The Company expects to continue to generate operating losses for the foreseeable future. As of the issuance date of the annual consolidated financial statements, the Company expects that its cash and cash equivalents, would be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these annual consolidated financial statements. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

The Company intends to initiate its Phase 3 program for the maintenance treatment of COPD once it believes it has alignment with the FDA on its planned design for the Phase 3 clinical program. The Company will require significant additional funding to initiate and complete this Phase 3 program and will need to secure the required capital to fund the program. The Company will seek additional funding through public or private financings, debt financing, collaboration or licensing agreements and other arrangements. However, there is no guarantee that the Company will be successful in securing additional finance on acceptable terms, or at all, and should the Company be unable to raise sufficient additional funds it will be required to defer the initiation of Phase 3 clinical trials, until such funding can be obtained. This could also force the Company to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, or pursue alternative development strategies that differ significantly from its current strategy, which could have a material adverse effect on the Company's business, results of operations and financial condition.

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 summaries 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, 2019 at the noon buying rate of the Federal Reserve Bank of New York on December 31, 2019, which was £1.00 to \$1.3269. 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,					
	2019		2018			
	£'000s	\$'000s	£'000s			
Net cash used in operating activities	£	(33,820)	\$	(44,876)	£	(18,111)
Net cash generated from investing activities		37,799		50,155		5,281
Net cash used in financing activities		(426)		(565)		—
Net increase / (decrease) in cash and cash equivalents	£	3,553	\$	4,714	£	(12,830)

The increase in net cash used in operating activities to £33.8 million for the year ended December 31, 2019, from £18.1 million for the year ended December 31, 2018, was primarily due to an increase in operating activities of £15.5 million, which principally comprises the increase in clinical trial and other research expenditure amounting to £14.2 million together with an increase in General and Administrative expenditure of £1.3 million, each of which are described further above.

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 £37.8 million for the year ended December 31, 2019, compared to net cash generated from investing activities of £5.3 million for the year ended December 31, 2018. In 2019, 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 £0.4 million repayment of finance lease liabilities in financing activities for the year ended December 31, 2019, relating to payments for leased office space. There were no financing activities for the year ended December 31, 2018.

### **Operating and Capital Expenditure Requirements**

As of December 31, 2019, we had an accumulated loss of £100.6 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 Phase 3 clinical trials for ensifentrine for the maintenance treatment of COPD;
- continue the clinical development of our DPI and pMDI formulations of ensifentrine and research and develop other formulations of ensifentrine;
- initiate and conduct further clinical trials for ensifentrine for the treatment of acute COPD, 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.

The Company has incurred recurring losses since inception, including net losses of £31.9 million, £19.9 million and £20.5 million for the years ended December 31, 2019, 2018 and 2017, respectively. In addition, as of December 31, 2019, the Company had an accumulated loss of £101.1 million. The Company expects to continue to generate operating losses for the foreseeable future. As of the issuance date of the annual consolidated financial statements, the Company expects that its cash and cash equivalents, would be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these annual consolidated financial statements. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

The Company intends to initiate its Phase 3 program for the maintenance treatment of COPD once it believes it has alignment with the FDA on its planned design for the Phase 3 clinical program. The Company will require significant additional funding to initiate and complete this Phase 3 program and will need to secure the required capital to fund the program. The Company will seek additional funding through public or private financings, debt financing, collaboration or licensing agreements and other arrangements. However, there is no guarantee that the Company will be successful in securing additional finance on acceptable terms, or at all, and should the Company be unable to raise sufficient additional funds it will be required to defer the initiation of Phase 3 clinical trials, until such funding can be obtained. This could also force the Company to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, or pursue alternative development strategies that differ significantly from its current strategy, which could have a material adverse effect on the Company's business, results of operations and financial condition.

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 security holders' 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.

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.

### **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 Company has contractual commitments for office space, in London and New York. After the adoption of IFRS 16 these are recognized as right of use assets on the Consolidated Statement of Financial Position. As a result they are not disclosed as operating lease liabilities.

The Company has assumed contingent liability 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 liabilities 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, or 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 liabilities 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>		
David Zaccardelli, Pharm.D.	55	President, Chief Executive Officer and Director
Piers Morgan	53	Chief Financial Officer
Claire Poll	52	General Counsel
Kathleen Rickard, M.D.	61	Chief Medical Officer
<b>Other Key Management</b>		
Richard Hennings	50	Vice President and Commercial Head
Desiree Luthman	60	Vice President, Regulatory Affairs
Tara Rheault	44	Vice President, R&D Operations and Global Project Management
Peter Spargo	58	Senior Vice President, Chemistry Manufacturing and Controls
<b>Non-Executive Directors</b>		
Ken Cunningham, M.D. <sup>(2)</sup>	67	Non-executive Director
David Ebsworth, Ph.D. <sup>(1,2,3)</sup>	65	Chairman of the Board
Rishi Gupta <sup>(2)</sup>	42	Non-executive Director
Mahendra Shah, Ph.D. <sup>(3)</sup>	75	Non-executive Director
Andrew Sinclair, Ph.D. <sup>(1)</sup>	48	Non-executive Director
Vikas Sinha <sup>(1)</sup>	56	Non-executive Director
Anders Ullman, Ph.D. <sup>(3)</sup>	64	Non-executive Director
Martin Edwards, M.D.	64	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:

**David Zaccardelli, Pharma.D.** Dr. Zaccardelli has served as our President and Chief Executive Officer and on our board of directors since February 2020. From December 2018 until its acquisition by Swedish Orphan Biovitrum for up to \$915 million in November 2019, Dr. Zaccardelli served as President and CEO of Dova Pharmaceuticals, a US company developing therapeutics for rare diseases. Previously, he was Acting CEO of Cempra, from December 2016 until the company's merger with Melinta Therapeutics in November 2017. From 2004 until 2016, Dr Zaccardelli served in several senior management roles at United Therapeutics Corporation, including Chief Operating Officer, Chief Manufacturing Officer and Executive Vice President, Pharmaceutical Development and Operations. Prior to United Therapeutics, he founded and led a start-up company focused on contract research positions and held a variety of clinical research positions at Burroughs Wellcome & Co, Glaxo Wellcome, and Bausch & Lomb Pharmaceutical. Dr. Zaccardelli received a Pharm.D. from the University of Michigan.

**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 at Aerocrine AB, a medical diagnostics product company, including as Chief Medical Officer from April 2011 to January 2019, and as Chief Compliance Officer from April 2014 to January 2019. Prior to Aerocrine, Dr. Rickard was Vice President Clinical Development and Medical Affairs of the Respiratory Medicines Development Centre at GlaxoSmithKline, a pharmaceutical

company, 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 Holdings (US) LLC and of Medherant Ltd. Dr. Cunningham received a degree in medicine from St. Mary's, Imperial College, London University.

**Martin Edwards, M.D.** Dr. Edwards has served as a Non-Executive Director on our board of directors since April 2019. Since 2003, Dr. Edwards has held various positions at Novo Holdings, a life sciences investment firm, and most recently as part-time Senior Partner. Earlier in his career, he was Corporate VP and Global Head of Drug Development for Novo Nordisk, where he led all aspects of pre-clinical and clinical drug development. Dr. Edwards currently serves on the boards of directors of Kalvista Pharmaceuticals Inc, F2G Ltd, Harmony Biosciences Inc, Karus Therapeutics Ltd, Nuvelution Pharma Inc, and Vantia Therapeutics Ltd. Dr. Edwards trained in physiology and medicine at the University of Manchester. He is a Member of the Royal College of Physicians, a Member with distinction of the Royal College of General Practitioners, a Fellow of the Faculty of Pharmaceutical Medicine and holds a MBA from the University of Warwick.

**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., Attenua, Inc, EnLiven Therapeutics, Inc, and Pionyr Immunotherapeutics, 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. Dr. Shah serves as a member of the board of directors of Scilex Pharmaceuticals, Inc., Fortis Inc., Citrine Medicines, 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. Mr. Sinha is co-founder and Chief Financial Officer of ElevateBio, Inc., a holding company focused on building cell and gene therapy companies. He also serves as President and Chief Financial Officer of AlloVir, Inc., an ElevateBio portfolio 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 Yakuhin 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 Vice President and Commercial Head 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, 2019, 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 <sup>(3)</sup> (£)	Total (£)
David Zaccardelli President and Chief Executive Officer <sup>(4)</sup>	—	—	—	—	—
Piers Morgan Chief Financial Officer	243,000	59,535	179,413	14,580	496,528
Kathleen Rickard Chief Medical Officer	272,901	263,227	265,132	5,307	806,567
Claire Poll General Counsel	214,000	67,410	128,151	6,420	415,981
<b>Total</b>	<b>729,901</b>	<b>390,172</b>	<b>572,696</b>	<b>26,307</b>	<b>1,719,076</b>

<sup>(1)</sup> Amount shown reflect bonuses awarded for achievement of performance goals, including retention bonuses in 2019.

<sup>(2)</sup> Amount shown represents the aggregate grant date fair value of option and restricted share units awards granted in 2019 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.

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

<sup>(4)</sup> Dr. Zaccardelli was appointed as our President and Chief Executive Officer, effective as of February 1, 2020.

### Executive Officer Employment Agreements

David S. Zaccardelli, Pharm.D.

We entered into an employment agreement with Dr. Zaccardelli on February 1, 2020. This agreement entitles Dr. Zaccardelli to receive an annual base salary of \$750,000, which is payable in part in cash and in part in restricted stock units, or the Annual RSUs, and a target annual bonus opportunity of 50% of his annual base salary. The Annual RSUs vest in equal quarterly installments during the calendar year in which the grant occurs, subject to continued employment. Pursuant to his employment agreement, Dr. Zaccardelli is also entitled to receive (i) an award of restricted stock units, subject to approval at our annual general meeting of shareholders in 2020, equal to 4% of our outstanding ordinary shares and (ii) an additional award of restricted units if the Company raises additional equity capital during fiscal year 2020, which is intended to result in Dr. Zaccardelli's equity awards (other than the portion of his base salary payable in restricted stock units) being equal to 4% of our outstanding ordinary shares on the applicable date of issuance. These awards of restricted stock units will vest as to 25% on the first anniversary of Dr. Zaccardelli's employment commencement date and as to the remainder in quarterly installments thereafter over the following three years, subject to continued employment.

If Dr. Zaccardelli's employment is terminated by us without "Cause" or by Dr. Zaccardelli for "Good Reason" (as each such term is defined in his offer agreement), then, subject to his signing and not revoking a general release of claims, he is entitled to receive (i) 18 months (or 12 months if the termination occurs after the second anniversary of Mr. Zaccardelli's employment commencement date) of base salary continuation and continued payment of premiums for continued medical coverage under COBRA, (ii) an amount equal to 150% (or 100% if the termination occurs after the second anniversary of Dr. Zaccardelli's employment commencement date) of Dr. Zaccardelli's full annual discretionary bonus, calculated as though all applicable objectives have been achieved for the year of termination, (iii) payment of all accrued and unused paid time-off, and (iv) full accelerated vesting of any outstanding, unvested equity awards under our share and share option schemes (with any performance-vesting awards become vested based on target level attainment), provided that if such termination occurs prior to the first anniversary of Dr. Zaccardelli's employment commencement date, the awards will become vested as to the portion that would have otherwise vested on or prior to the first anniversary of Dr. Zaccardelli's employment commencement date.

If payments to Dr. Zaccardelli 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. Zaccardelli's receipt, on an after-tax basis, of the greater amount of the payment. Dr. Zaccardelli has also agreed to refrain from competing with us or soliciting our customers or prospective customers for a period of one year following his termination of employment.

*Jan-Anders Karlsson, Ph.D.*

We and Dr. Karlsson entered into a separation agreement, or the Karlsson Separation Agreement, pursuant to which we and Dr. Karlsson agreed that he would no longer serve as chief executive officer, director or officer, effective as of February 2, 2020, and that his employment with us will terminate effective as of February 28, 2020, or the Separation Date. Dr. Karlsson agreed to help transition his duties to Dr. Zaccardelli. Pursuant to the Karlsson Separation Agreement, Dr. Karlsson agreed to execute a general release of claims, or the Karlsson Settlement Agreement, and he is entitled to receive cash severance payments in the aggregate amount of £982,160, payments for continued medical and life insurance benefits until the first anniversary of the Separation Date and continued pension contributions until the first anniversary of the Separation Date, subject to his compliance with the terms of the Karlsson Separation Agreement, the Karlsson Settlement Agreement and his employment agreement. Additionally, equity awards will either be vested as of the Separation Date, will be forfeited as of the Separation Date, or will be unvested as of the Separation Date and will either vest according to the applicable vesting schedule, or will be forfeited as of February 28, 2021, unless an earlier change in control event occurs, Dr. Karlsson dies or we breach the terms of the Karlsson Separation Agreement or the Karlsson Settlement Agreement.

*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 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.

We and Mr. Morgan entered into a separation agreement, or the Morgan Settlement Agreement, pursuant to which we and Mr. Morgan agreed that his employment with us will terminate effective as of February 28, 2020, or the Separation Date. The Morgan Settlement Agreement contains a general release of claims in our favour. Pursuant to the Morgan Settlement Agreement, Mr. Morgan is entitled to cash severance payments in the aggregate amount of £276,550, payments for continued life insurance benefits for six months following the Separation Date and continued pension contributions for six months following the Separation Date, subject to his compliance with the terms of the Morgan Settlement Agreement and his employment agreement. Additionally, equity awards will either be vested as of the Separation Date, or will be forfeited as of the Separation Date.

#### *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.

#### *Mark W. Hahn*

We entered into an employment agreement with Mark Hahn on February 1, 2020 pursuant to which he agreed to commence employment with us on February 1, 2020 and serve as our Chief Financial Officer, effective March 1, 2020. This agreement entitles Mr. Hahn to receive an annual base salary of \$500,000, which is payable in part in cash and in part in restricted stock units, or the Hahn Annual RSUs, and a target annual bonus opportunity of 50% of his annual base salary. The Hahn Annual RSUs vest in equal quarterly installments during the calendar year in which the grant occurs, subject to continued employment. Pursuant to his employment agreement, and subject to approval at our annual general meeting of shareholders in 2020, Mr. Hahn is also entitled to receive (i) an award of restricted stock units equal to 3% of our outstanding ordinary shares, or the First RSU Award, and (ii) an additional award of restricted stock units during or prior to our first open trading window following the date

that is six months after his employment commencement date, or the Reference Date, equal to 1% of our outstanding ordinary shares, or the Second RSU Award. The First RSU Award and the Second RSU Award will vest as to 25% on the first anniversary of Mr. Hahn's employment commencement date or the Reference Date, respectively, and as to the remainder in quarterly installments thereafter over the following three years, subject to continued employment. In the event that the Company raises additional equity capital during fiscal year 2020, which is intended to result in Mr. Hahn's equity awards (other than the portion of his base salary payable in restricted stock units) being equal to 4% of our outstanding ordinary shares on the applicable date of issuance. These awards of restricted stock units will vest as to 75% of the award, on the same vesting schedule as the First RSU Award, and as to 25% of the award, on the same vesting schedule as the Second RSU Award, subject to continued employment.

If Mr. Hahn's employment is terminated by us without "Cause" or by Mr. Hahn for "Good Reason" (as each such term is defined in his offer agreement), then, subject to his signing and not revoking a general release of claims, he is entitled to receive (i) 18 months (or 12 months if the termination occurs after the second anniversary of Mr. Hahn's employment commencement date) of base salary continuation and continued payment of premiums for continued medical coverage under COBRA, (ii) an amount equal to 150% (or 100% if the termination occurs after the second anniversary of Mr. Hahn's employment commencement date) of Mr. Hahn's full annual discretionary bonus, calculated as though all applicable objectives have been achieved for the year of termination, (iii) payment of all accrued and unused paid time-off and (iv) full accelerated vesting of any outstanding, unvested equity awards under our share and share option schemes (with any performance-vesting awards become vested based on target level attainment), provided that if such termination occurs prior to the first anniversary of Mr. Hahn's employment commencement date, the awards will become vested as to the portion that would have otherwise vested on or prior to the first anniversary of Mr. Hahn's employment commencement date.

If payments to Mr. Hahn 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 Mr. Hahn's receipt, on an after-tax basis, of the greater amount of the payment. Mr. Hahn has also agreed to refrain from competing with us or soliciting our customers or prospective customers for a period of one year following his 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, 2020, the number of shares available for issuance was 5,499,058. 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.

## 2019 Grants

The following table summarizes the options that we granted to our directors and executive officers under the 2017 Incentive Plan in 2019:

Name	Ordinary Shares Underlying Options	Exercise Price Per Share (£)	Grant Date	Expiration Date
Kathleen Rickard	560,000	0.57	April 01, 2019	March 29, 2029
Piers Morgan	359,430	0.57	April 01, 2019	March 29, 2029
Claire Poll	256,735	0.57	April 01, 2019	March 29, 2029

The following table summarizes the RSUs that we granted on April 1, 2019, to our directors and executive officers under the 2017 Incentive Plan in 2019:

Name	Restricted Share Units Granted
Kathleen Rickard	120,000
Piers Morgan	93,247
Claire Poll	66,603

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.

### Non-Employee Directors Remuneration

The following table sets forth the remuneration paid during 2019 to our current non-employee directors:

Name	Fees (£)	Total (£)
David Ebsworth	108,000	108,000
Anders Ullman	30,000	30,000
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
Martin Edwards	22,500	22,500

### 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 2019 was £30,000, which represents contributions made by us in 2019 in respect of a defined contribution scheme in which Ms. Poll, Ms. Rickard, and Mr. Morgan participated.

## C. Board Practices

### Composition of our Board of Directors

Our Board is comprised of nine 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
David Zaccardelli, Pharma.D.	2020	2020
David Ebsworth, Ph.D.	2018	2021
Ken Cunningham, M.D.	2015	2022
Rishi Gupta	2016	2020
Mahendra Shah, Ph.D.	2016	2020
Andrew Sinclair, Ph.D.	2016	2022
Vikas Sinha	2016	2020
Anders Ullman, M.D., Ph.D.	2018	2021
Martin Edwards, M.D.	2019	2021

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, among other things:

- 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, among other things:

- 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, among other things:

- 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, 2019, 2018 and 2017, we had 24, 15, and 15 employees, respectively, of which 13, 11, and 10 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, 2019, 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, 2019, 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 105,326,638 of our ordinary shares outstanding as of December 31, 2019. Ordinary shares that a person has the right to acquire within 60 days of December 31, 2019 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, 2019, 56,045,857 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	13.22%
Vivo Capital affiliates <sup>(2)</sup>	13,811,584	12.88%
OrbiMed Private Investments VI, LP <sup>(3)</sup>	11,871,112	11.07%
Growth Equity Opportunities Fund IV, LLC <sup>(4)</sup>	11,527,019	10.76%
Abingworth Bioventures VI, LP <sup>(5)</sup>	8,619,765	8.08%
venBio Select Advisor <sup>(6)</sup>	7,000,000	6.65%
Polar Capital Holdings plc <sup>(7)</sup>	5,368,819	5.09%
Tekla Capital affiliates <sup>(8)</sup>	5,296,845	4.99%
Aisling Capital IV, LP <sup>(9)</sup>	4,138,643	3.91%
<b>Executive Officers and Directors:</b>		
David Zaccardelli, Pharm.D	—	—
Piers Morgan <sup>(10)</sup>	1,712,362	1.60%
Kathleen Rickard, M.D.	—	—
Claire Poll <sup>(11)</sup>	799,141	*
Ken Cunningham, M.D.	—	—
Martin Edwards	—	—
David Ebsworth, Ph.D. <sup>(12)</sup>	400,303	*
Rishi Gupta	—	—
Mahendra Shah, Ph.D.	—	—
Andrew Sinclair, Ph.D.	—	—
Vikas Sinha <sup>(13)</sup>	102,478	*
Anders Ullman, Ph.D.	—	—
All executive officers and directors as a group (12 persons)	3,014,284	2.83%

\* Less than 1%.

(1) 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 Schedule 13D filed with the SEC on April 2, 2019. Novo's mailing address is Tuborg Havnevej 19, Hellerup, G7 2900, Denmark

(2) 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.

(3) 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 5,300,000 ordinary shares of which (a) 4,500,000 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) warrants to purchase 68,819 ordinary shares held directly by PBF. PBF and PCGH are managed by Polar Capital Holdings plc, or PCH. Beneficial ownership information is based on a TR-1 provided to us on September 9, 2019 and information known to us.
- (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) 147,009 ordinary shares, (b) 238,420 ordinary shares issuable from restricted stock units that will vest within 60 days of December 31, 2019 and (c) 1,326,933 options to purchase ordinary shares that are, or will be within 60 days of December 31, 2019, immediately exercisable.
- (11) Consists of (a) 130,575 ordinary shares and (b) 668,566 options to purchase ordinary shares that are, or will be within 60 days of December 31, 2019, immediately exercisable.
- (12) Consists of (a) 395,387 ordinary shares and (b) warrants to purchase 4,916 ordinary shares.
- (13) Consists of (a) 22,222 ordinary shares and (b) options to purchase 80,256 ordinary shares that are or will be immediately exercisable within 60 days of December 31, 2019.

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, 2017.

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, 2019 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 6.B. Compensation and Note 8 of our Annual Consolidated Financial Statements included elsewhere in this Annual Report.

**Other Transactions**

At December 31, 2019, there was a receivable of £nil (2018: £126 thousand) 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.

In the year ended December 31, 2019, a director provided consultancy services for £26 thousand (2018: £26 thousand).

**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, 2019.

## **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.

A copy of our Articles of Association is attached as Exhibit 1.1 to this Annual Report. The information called for by this Item is set forth in Exhibit 2.5 to this Annual Report and is incorporated by reference into this Annual Report.

### C. Material Contracts.

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

#### 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 New York, New York. The office space in these two locations is held under four leases that terminate in 2020 and 2021. We pay £0.5 million per year under these leases. 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, 2019, 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, 2019. 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 creditability 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:

Service	Fee
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 depositary into the Depositary 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 depositary fees, the depositary may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees from any distribution to be made to the ADS holder. 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 depositary. Holders of our ADSs will receive prior notice of such changes. The depositary 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 depositary agree from time to time.

**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. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of December 31, 2019, our disclosure controls and procedures were effective.

**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, 2019, our internal control over financial reporting was effective.

#### **Attestation Report of the Registered Public Accounting Firm**

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for “emerging growth companies.”

#### **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, including our principal executive, principal financial and principal accounting 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:

<b>Fee Category</b>	<b>2019</b>	<b>2018</b>
	<b>£'000s</b>	<b>£'000s</b>
Audit Fees	148	114
Audit-Related Fees	52	68
Other Services	67	86
<b>Total Fees</b>	<b>267</b>	<b>268</b>

**Audit-Related Fees**

For the years ended December 31, 2019 and 2018, audit related services include fees for quarterly interim reviews.

**Tax Fees**

We did not incur any tax fees for services from PricewaterhouseCoopers LLP in 2019 or 2018.

**All Other Fees**

For the year ended December 31, 2019 other fees related to advice relating to fund raising.

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

**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 required under this Item 18 are filed as part of this Annual Report beginning on page F-1. The audit report of PricewaterhouseCoopers LLP, independent registered public accounting firm, is included herein preceding the financial statements.

**ITEM 19: EXHIBITS**

Exhibit Number	Exhibit Description	Form	Incorporated by Reference to Filings Indicated			
			File No.	Exhibit No.	Filing date	Filed / Furnished
<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="#">2.5</a>	<a href="#">Description of Securities</a>					*
<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>	20-F	001-38067	4.3	3/19/2019	
<a href="#">4.3.1</a>	<a href="#">Renewal Agreement to Lease by and between the Verona Pharma plc and Regus Management (UK) Limited dated November 8, 2017</a>	20-F	001-38067	4.3.1	3/19/2019	
<a href="#">4.3.2</a>	<a href="#">Renewal Agreement to Lease by and between the Verona Pharma plc and Regus Management (UK) Limited dated April 3, 2018</a>	20-F	001-38067	4.3.2	3/19/2019	
<a href="#">4.3.3</a>	<a href="#">Renewal Agreement to Lease by and between the Verona Pharma plc and Regus Management (UK) Limited dated September 16, 2017#1</a>					*
<a href="#">4.3.4</a>	<a href="#">Renewal Agreement to Lease by and between the Verona Pharma plc and Regus Management (UK) Limited dated September 16, 2017#2</a>					*

<a href="#">4.3.5</a>	<a href="#">Renewal Agreement to Lease by and between the Verona Pharma plc and Regus Management (UK) Limited dated September 16, 2017#3</a>					*
<a href="#">4.3.6</a>	<a href="#">Renewal Agreement to Lease by and between the Verona Pharma Inc. and Regus Management Group LLC dated July 16, 2019</a>					*
<a href="#">4.4#</a>	<a href="#">EMI Option Scheme</a>	F-1	333-217124	10.4	4/3/2017	
<a href="#">4.5#</a>	<a href="#">Unapproved Share Option Scheme, as amended</a>	F-1	333-217124	10.5	4/3/2017	
<a href="#">4.6#</a>	<a href="#">2017 Incentive Award Plan and forms of award agreements thereunder</a>	20-F	001-38067	4.6	2/27/2018	
<a href="#">4.7#</a>	<a href="#">Employment Agreement, dated January 28, 2020, between Verona Pharma Inc. and David Zaccardelli, Pharm. D.</a>					*
<a href="#">4.8#</a>	<a href="#">Employment Agreement, dated December 21, 2019, between Verona Pharma plc and Kathleen Rickard</a>	20-F	001-38067	4.3.2	3/19/2019	
<a href="#">4.9#</a>	<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	
<a href="#">4.10#</a>	<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	
<a href="#">4.11</a>	<a href="#">Form of Indemnification Agreement for board members</a>	F-1/A	333-217124	10.11.1	4/18/2017	
<a href="#">4.12</a>	<a href="#">Form of Indemnification Agreement for executive officers</a>	F-1/A	333-217124	10.11.2	4/18/2017	
<a href="#">4.13</a>	<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	
<a href="#">4.14</a>	<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	
<a href="#">4.15</a>	<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	
<a href="#">8.1</a>	<a href="#">List of Subsidiaries</a>	F-1	333-217124	21.1	4/3/2017	
<a href="#">12.1</a>	<a href="#">Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer</a>					*
<a href="#">12.2</a>	<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="#"><u>101.INS</u></a>	<a href="#"><u>XBRL Instance Document</u></a>	*
<a href="#"><u>101.SCH</u></a>	<a href="#"><u>XBRL Taxonomy Extension Schema Document</u></a>	*
<a href="#"><u>101.CAL</u></a>	<a href="#"><u>XBRL Taxonomy Extension Calculation Linkbase Document</u></a>	*
<a href="#"><u>101.LAB</u></a>	<a href="#"><u>XBRL Taxonomy Extension Label Linkbase Document</u></a>	*
<a href="#"><u>101.PRE</u></a>	<a href="#"><u>XBRL Taxonomy Extension Presentation Linkbase Document</u></a>	*
<a href="#"><u>101.DEF</u></a>	<a href="#"><u>XBRL Taxonomy Extension Definition Linkbase Document</u></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/ David Zaccardelli

Name: David Zaccardelli, Pharm. D  
Title: Chief Executive Officer

Date: February 27, 2020

## 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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

### ***Change in Accounting Principle***

As discussed in Note 2.17 to the consolidated financial statements, the Company changed the manner in which it accounts for its contingent liability in 2019.

### ***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  
February 27, 2020

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

VERONA PHARMA PLC  
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION  
AS OF DECEMBER 31, 2019 AND 2018

	Notes	As of December 31, 2019 £'000s	Restated As of December 31, 2018 £'000s
<b>ASSETS</b>			
<b>Non-current assets:</b>			
Goodwill	11	441	441
Intangible assets	12	2,757	2,618
Property, plant and equipment	13	43	21
Right-of-use assets	14	971	—
<b>Total non-current assets</b>		<u>4,212</u>	<u>3,080</u>
<b>Current assets:</b>			
Prepayments and other receivables	15	2,770	2,463
Current tax receivable		7,396	4,499
Short term investments		7,823	44,919
Cash and cash equivalents		22,934	19,784
<b>Total current assets</b>		<u>40,923</u>	<u>71,665</u>
<b>Total assets</b>		<u>45,135</u>	<u>74,745</u>
<b>EQUITY AND LIABILITIES</b>			
<b>Capital and reserves attributable to equity holders:</b>			
Share capital	16	5,266	5,266
Share premium		118,862	118,862
Share-based payment reserve		10,364	7,923
Accumulated loss		(100,627)	(68,633)
<b>Total equity</b>		<u>33,865</u>	<u>63,418</u>
<b>Current liabilities:</b>			
Derivative financial instrument	18	895	2,492
Lease liability	14	460	—
Trade and other payables	19	8,261	7,733
<b>Total current liabilities</b>		<u>9,616</u>	<u>10,225</u>
<b>Non-current liabilities:</b>			
Assumed contingent liability	20	1,103	996
Non-current lease liability	14	491	—
Deferred income		60	106
<b>Total non-current liabilities</b>		<u>1,654</u>	<u>1,102</u>
<b>Total equity and liabilities</b>		<u>45,135</u>	<u>74,745</u>

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, 2019, 2018 AND 2017

	Notes	Year ended December 31, 2019	Year ended December 31, 2018	Year Ended December 31, 2017
		£'000s	£'000s	£'000s
Research and development costs		(33,476)	(19,294)	(23,717)
General and administrative costs		(7,607)	(6,297)	(6,039)
<b>Operating loss</b>	7	<b>(41,083)</b>	<b>(25,591)</b>	<b>(29,756)</b>
Finance income	9	2,351	2,783	7,018
Finance expense	9	(474)	(1,325)	(2,465)
<b>Loss before taxation</b>		<b>(39,206)</b>	<b>(24,133)</b>	<b>(25,203)</b>
Taxation — credit	10	7,265	4,232	4,706
<b>Loss for the year</b>		<b>(31,941)</b>	<b>(19,901)</b>	<b>(20,497)</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		(33)	38	(29)
<b>Total comprehensive loss attributable to owners of the Company</b>		<b>(31,974)</b>	<b>(19,863)</b>	<b>(20,526)</b>
Loss per ordinary share — basic and diluted (pence)	5	(30.3)	(18.9)	(23.4)

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, 2019, 2018 AND 2017

	Share Capital	Share Premium	Share-based Payment Reserve	Total Accumulated Losses	Total Equity
	£'000s	£'000s	£'000s	£'000s	£'000s
<b>Balance at January 1, 2017, as previously reported</b>	2,568	58,526	2,103	(28,728)	34,469
Impact of change in accounting policy	—	—	—	484	484
<b>Balance at January 1, 2017 (Restated)</b>	2,568	58,526	2,103	(28,244)	34,953
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 (Restated)</b>	5,251	118,862	5,022	(48,770)	80,365
<b>Balance at January 1, 2018 (Restated)</b>	5,251	118,862	5,022	(48,770)	80,365
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 (Restated)</b>	5,266	118,862	7,923	(68,633)	63,418
<b>Balance at January 1, 2019</b>	5,266	118,862	7,923	(68,633)	63,418
Impact of change in accounting policy	—	—	—	(20)	(20)
<b>Adjusted Balance at January 1, 2019</b>	5,266	118,862	7,923	(68,653)	63,398
Loss for the year	—	—	—	(31,941)	(31,941)
Other comprehensive loss for the year:					
Exchange differences on translating foreign operations	—	—	—	(33)	(33)
Total comprehensive loss for the year	—	—	—	(31,974)	(31,974)
Share-based payments	—	—	2,441	—	2,441
<b>Balance at December 31, 2019</b>	5,266	118,862	10,364	(100,627)	33,865

The currency translation reserve for 2019, 2018, and 2017, 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, 2019, 2018 AND 2017

	Year ended December 31, 2019	Year ended December 31, 2018	Year ended December 31, 2017
	£'000s	£'000s	£'000s
<b>Cash used in operating activities:</b>			
Loss before taxation	(39,206)	(24,133)	(25,203)
Finance income	(2,351)	(2,783)	(7,018)
Finance expense	474	1,325	2,465
Share-based payment charge	2,441	2,901	2,919
Increase in prepayments and other receivables	(484)	(640)	(161)
Increase in trade and other payables	449	531	5,363
Depreciation of property, plant, equipment and right of use asset	398	8	7
Unrealised FX gains/ losses	(8)	—	—
Amortization of intangible assets	106	90	116
<b>Cash used in operating activities</b>	<b>(38,181)</b>	<b>(22,701)</b>	<b>(21,512)</b>
Cash inflow from taxation	4,361	4,590	816
<b>Net cash used in operating activities</b>	<b>(33,820)</b>	<b>(18,111)</b>	<b>(20,696)</b>
<b>Cash flow from investing activities:</b>			
Interest received	887	883	128
Purchase of plant and equipment	(38)	(13)	(9)
Payment for patents and computer software	(244)	(255)	(208)
Purchase of short term investments	(7,940)	(59,700)	(54,465)
Maturity of short term investments	45,134	64,366	5,085
<b>Net cash generated from / (used in) investing activities</b>	<b>37,799</b>	<b>5,281</b>	<b>(49,469)</b>
<b>Cash flow used in financing activities:</b>			
Gross proceeds from the April 2017 Global Offering	—	—	70,032
Transaction costs on April 2017 Global Offering	—	—	(6,786)
Repayment of finance lease liabilities	(426)	—	—
<b>Net cash (used in) / generated from financing activities</b>	<b>(426)</b>	<b>—</b>	<b>63,246</b>
<b>Net increase / (decrease) in cash and cash equivalents</b>	<b>3,553</b>	<b>(12,830)</b>	<b>(6,919)</b>
Cash and cash equivalents at the beginning of the year	19,784	31,443	39,785
Effect of exchange rates on cash and cash equivalents	(403)	1,171	(1,423)
<b>Cash and cash equivalents at the end of the year</b>	<b>22,934</b>	<b>19,784</b>	<b>31,443</b>

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2019**

**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 ("Nasdaq"). 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.

The Company listed its American Depositary Shares ("ADS") on Nasdaq in April 2017 ("the 2017 Global Offering").

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

## 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 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 disclosed in note 4.

### Going concern

The Company has incurred recurring losses since inception, including net losses of £31.9 million, £19.9 million and £20.5 million for the years ended December 31, 2019, 2018 and 2017, respectively. In addition, as of December 31, 2019, the Company had an accumulated loss of £100.6 million. The Company expects to continue to generate operating losses for the foreseeable future. As of the issuance date of the annual consolidated financial statements, the Company expects that its cash and cash equivalents, would be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these annual consolidated financial statements. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

The Company intends to initiate its Phase 3 program for the maintenance treatment of COPD once it believes it has alignment with the FDA on its planned design for the Phase 3 clinical program. The Company will require significant additional funding to initiate and complete this Phase 3 program and will need to secure the required capital to fund the program. The Company will seek additional funding through public or private financings, debt financing, collaboration or licensing agreements and other arrangements. However, there is no guarantee that the Company will be successful in securing additional finance on acceptable terms, or at all, and should the Company be unable to raise sufficient additional funds it will be required to defer the initiation of Phase 3 clinical trials, until such funding can be obtained. This could also force the Company to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, or pursue alternative development strategies that differ significantly from its current strategy, which could have a material adverse effect on the Company's business, results of operations and financial condition.

### 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. 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.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2019**  
**Accounting policies (Continued)**

**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.

**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.

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

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2019**  
**Accounting policies (Continued)**

**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 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

**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 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")

The IP R&D asset acquired through a business combination, that had not reached technical feasibility, was initially recognized at fair value. Subsequent movements in the assumed contingent liability (see 2.12) that relate to changes in estimated cashflows or probabilities of success are recognized as additions to the IP R&D asset that it relates to. There were no changes in estimated cashflows or probabilities of success in the years ended 31 December, 2019, or 2018.

This is a change in accounting policy as prior to January 1, 2019, movements in the assumed contingent liability were taken to the Statement of Comprehensive Income (see note 2.17). As a result of the change in accounting policy £484 thousand was restated from Accumulated Loss to the IP R&D asset.

The asset is subject to impairment testing until completion, abandonment of the project or when the research findings are commercialized through a revenue generating project. The Company determines whether intangible assets are impaired on an annual basis or when there is an indication of impairment.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2019**  
**Accounting policies (Continued)**

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

The Company holds intangible assets relating to acquired IP R&D, patent costs and goodwill. Goodwill and intangible assets are tested annually for impairment or if there is an indication of impairment. The Company is a single cash generating unit ("CGU") so all intangibles are allocated to the Company as one CGU.

As at 31 December, 2019, and 2018 the Company carried out impairment reviews with reference to its market capitalization. At points during the year ended 31 December 2019, the Company's market capitalization was less than its net assets. As a result, the Company carried out an impairment review by forecasting expected sales of ensifentrine, delivered by nebulizer for the maintenance treatment of chronic COPD, and associated costs. This cashflow forecast was then discounted to its net present value to demonstrate that the value in use of the ensifentrine was greater than the Company's net assets. The Company was required to make various estimates and assumptions as inputs for this model including, but not limited to:

- market size and product acceptance by clinicians, patients and reimbursement bodies;
- gross and net selling price;
- costs of manufacturing, product distribution and marketing support;
- costs of the Company's overhead;
- size and make up of a sales force;
- probabilities of success; and
- discount rate.

**2.9 Employee Benefits**

(a) Pension

The Company operates defined contribution pension schemes for its employees. Contributions payable for the year are charged to the Consolidated Statement of Comprehensive Income. The Company has no further liability 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 liability.

**2.10 Share-based payments**

The Company operates a number of equity-settled, share-based compensation schemes. The fair value of share based payments is determined using the Black-Scholes model and requires several assumptions and estimates as disclosed in note 17.

The fair value of share-based payments under these schemes is expensed on a straight-line basis over the share based payments' vesting periods, based on the Company's estimate of shares that will eventually vest.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2019**  
**Accounting policies (Continued)**

**2.11 Provisions**

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

**2.12 Assumed contingent liability related to the business combination**

In 2006 the Company acquired Rhinopharma and assumed contingent liabilities owed to Vernalis Pharmaceuticals Limited which was subsequently acquired by Ligand Pharmaceuticals, Inc. ("Ligand"). The Company refers to the assignment and license agreement as the Ligand Agreement.

Ligand assigned to the Company all of its rights to certain patents and patent applications relating to ensifentrine and related compounds (the "Ligand Patents") and 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 liability comprises a milestone payment on obtaining the first approval of any regulatory authority for the commercialization of a Licensed Product, low to mid-single digit royalties based on the future sales performance of all Licensed Products and a portion equal to a mid-twenty percent of any consideration received from any sublicensees for the Ligand Patents and for Ligand know-how.

The liability was initially recognized at fair value and subsequently measured at amortized cost. The assumed contingent liability is estimated as the expected value of the milestone payment and royalty payments. This expected value is based on estimated future royalties payable, derived from sales forecasts, and an assessment of the probability of success using standard market probabilities for respiratory drug development. The risk-weighted value of the assumed contingent arrangement is discounted back to its net present value applying an effective interest rate of 12%.

Royalties payable are based on the future sales performance so the amount payable is unlimited. Sales that may be achieved are difficult to predict and subject to estimate, which is inherently uncertain.

The assumed contingent liability is accounted for as a liability and its value is measured at amortized cost using the effective interest rate method, and is re-measured for changes in estimated cash flows or when the probability of success changes.

Remeasurements relating to changes in estimated cash flows and probabilities of success are recognized in the IP R&D asset it relates to ("see 2.7"). This is a change in accounting policy for the year ended December 1, 2019 (see 2.17). The unwind of the discount is recognized in finance expense.

**2.13 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.

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

The Company has no financial assets recorded at fair value through profit or loss ("FVPTL"). All assets are initially recognized initially at fair value plus transaction costs and subsequently measured at amortized cost using the effective interest method.

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

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

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2019**  
**Accounting policies (Continued)**

The Company's warrants are classified as FVTPL and fair value gains and losses are recognized in profit or loss.

Other financial liabilities are initially recognized at fair value and 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.

The Company's financial liabilities include trade and other payables, the Company's warrants and the assumed contingent liability.

(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 one type of derivative financial instrument, the warrants, as explained in Note 2.14.

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.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2019**  
**Accounting policies (Continued)**

**2.14 Derivative financial instrument - 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. Equity is not remeasured.

**2.15 Short Term Investments**

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

**2.16 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").

**2.17 Changes in accounting policy**

**Accounting for the assumed contingent liability**

As discussed in note 2.12, in 2006 the Company acquired Rhinopharma and assumed contingent liabilities owed to Vernalis Pharmaceuticals Limited which was subsequently acquired by Ligand Pharmaceuticals, Inc. ("Ligand").

Ligand assigned to the Company all of its rights to certain patents and patent applications relating to ensifentrine and related compounds and an exclusive, worldwide, royalty-bearing license to develop, manufacture and commercialize products. The assumed contingent liability comprises a milestone payment on obtaining the first approval of any regulatory authority and royalties based on the future sales of ensifentrine.

The initial fair value of the assumed contingent liability was estimated as the expected value of the milestone payment and royalty payments. This expected value is based on estimated future royalties payable, derived from sales forecasts, an assessment of the probability of success using standard market probabilities for respiratory drug development discounted to net present value applying an effective interest rate of 12%.

The assumed contingent liability is accounted for as a liability and its value is measured at amortized cost using the effective interest rate method, and is re-measured for changes in estimated cash flows or when the probability of success changes.

Up to the year ended December 31, 2018, movements in the liability relating to re-measurements of cash flows or changes in the probabilities of success were taken to the Consolidated Statement of Comprehensive Income. During the year ended December 31, 2019, the Company reviewed the accounting for this item and has determined that these movements in the liability will now be recognized in the cost of the corresponding asset. The corresponding asset is the intangible IP R&D asset.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2019**  
**Accounting policies (Continued)**

The Company believes that this change in accounting policy results in the Consolidated Financial Statements providing a more relevant and reliable view of its financial position and performance because without an adjustment to the IP R&D asset on the re-measurement of the liability, the cost of the asset would not be fairly reflected on the Consolidated Statement of Financial Position. The Consolidated Statement of Financial Position more faithfully represents the financial position of the Company if the intangible asset is adjusted by any re-measurement of the liability for changes in estimated cash flows, to give a fairer reflection of the cost of the intangible asset.

The Company has reviewed the International Financial Reporting Interpretations Committee ("IFRIC") discussion of accounting for variable payments made for the purchase of an intangible asset that is not part of a business combination that concluded that it was too broad for it to address within the confines of existing IFRS standards. As a result, practice in this area is mixed and many pharmaceutical companies follow a cost accumulation model. The Company also noted that adjusting the cost of the asset when a liability is remeasured for changes in estimated cash flows is consistent with the guidance in IFRIC 1 for decommissioning liabilities and IFRS 16 for lease liabilities.

There were no such re-measurements of the liability in the years ended December 31, 2019, 2018 and 2017. Movements in the liability in these periods related to the unwinding of the discount and movements in exchange rates.

IAS 8 requires opening balance of each affected component of equity to be adjusted for the earliest prior period presented and the other comparative amounts disclosed for each prior period presented as if the new accounting policy had always been applied.

The impact to the Group, therefore, is the restatement of £484 thousand from Accumulated Loss to the IP R&D asset, which relates to re-measurements recorded prior to January 1, 2017. As there were no re-measurements in the years ended December 31, 2019, 2018 and 2017 the £484 thousand adjustment is the same at each reporting period.

The following table is a summary of the restatement:

Financial statement line item	As reported	Adjustment for the change in accounting policy	As adjusted
<b>January 1, 2017</b>	<b>£'000s</b>	<b>£'000s</b>	<b>£'000s</b>
Accumulated loss	28,728	(484)	28,244
Intangible assets - IP R&D	1,469	484	1,953

This adjustment also increases non-current assets, total assets and total equity by £484 thousand in each of the years presented.

#### **Adoption of IFRS 16**

IFRS 16 'Leases' is effective for accounting periods beginning on or after January 1, 2019 and replaces 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 adoption of IFRS 16 resulted in the Group recognizing lease liabilities within current liabilities, and corresponding right-of-use assets.

The Group's principal lease arrangements are for office space. The Group has adopted IFRS 16 retrospectively with the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings at January 1, 2019. The standard permits a choice on initial adoption, on a lease-by-lease basis, to measure the right-of-use asset at either its carrying amount as if IFRS 16 had been applied since the commencement of the lease, or an amount equal to the lease liability, adjusted for any accrued or prepaid lease payments as at the time of adoption. The Group has elected to measure the right-of-use asset at its carrying value as if IFRS 16 had been applied since the commencement of the lease, with the result of a £20 thousand reduction in opening total accumulated losses.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2019**  
**Accounting policies (Continued)**

Initial adoption resulted in the recognition of right-of-use assets of £326 thousand and lease liabilities of £316 thousand.

	£'000s
Lease commitments (including prepayments) disclosed as at December 31, 2018	600
Less: adjustments relating to prepaid lease payments	(28)
Lease commitments as at December 31, 2018	572
Discounted using the group's incremental borrowing rate	526
Less: short-term leases recognized on a straight-line basis as expense	(210)
<b>Lease liability recognized as at January 1, 2019</b>	<b>316</b>

In applying IFRS 16 for the first time, the group has used the following practical expedients permitted by the standard:

- the use of a single discount rate of 8% to a portfolio of leases with reasonably similar characteristics;
- accounting for leases with a remaining lease term of less than 12 months as at January 1, 2019, as short-term leases; and
- the use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease.

The Company is applying IFRS 16's low-value and short-term exemptions. The adoption of IFRS 16 has had no impact on the Group's net cash flows, although a presentation change has been reflected in 2019 whereby cash outflows of £426 thousand are now presented as financing, instead of operating. General and administrative costs are £123 thousand lower than if IFRS 16 not been adopted, as depreciation of the right of use asset is less than the lease costs. There is a £50 thousand increase in finance expense from the presentation of a portion of lease costs as interest costs. There is no significant impact on overall loss before tax and loss per share.

At the time of adoption it was not reasonably certain that the Company would extend the leases. However, in the period the Company determined that this was the case and agreed extensions. As a result it recognized an additional liability and right-of-use asset of £1,047 thousand.

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

The following standard has been adopted by the Company for the first time for the financial year beginning on or after January 1, 2019:

- IFRS 16 "Leases"

The Company adopted IFRS 16 on January 1, 2019, and, as a consequence, changed its accounting policies. See note 2.17.

#### **2.19 New standards, amendments and interpretations issued but not effective for the financial year beginning January 1, 2019 and not early adopted**

There are no IFRS standards or interpretations not yet effective that would be expected to have a material impact on the Group.

### 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 data about the Company's exposure to currency risk is as follows. Figures are the pound sterling values of balances in each currency:

	December 31, 2019			December 31, 2018		
	GBP	USD	EUR	GBP	USD	EUR
	£'000s	£'000s	£'000s	£'000s	£'000s	£'000s
Cash and cash equivalents	18,517	4,399	18	11,293	8,470	21
Short term Investments	6,316	1,507	—	19,850	25,069	—
Trade and other payables	3,226	4,306	728	2,872	4,329	532

##### Sensitivity Analysis

A reasonably possible strengthening or weakening of the Euro or U.S. dollar against pounds sterling as of December 31, 2019 and 2018 would have affected the measurement of the financial instruments denominated in a foreign currency (excluding the assumed contingent liability).

The following table shows how a movement in a currency would give rise to a profit or (loss) and a corresponding entry in equity.

	Profit or loss and equity	
	Strengthening	Weakening
	£'000s	£'000s
<b>December 31, 2019</b>		
EUR (5% movement)	(36)	36
USD (5% Movement)	80	(80)
<b>December 31, 2018</b>		
EUR (5% movement)	(26)	26
USD (5% Movement)	1,461	(1,461)

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.

Estimated cashflows relating to the assumed contingent liability are predominantly denominated in US dollars. In the years ended December 31, 2019, and 2018, movements in foreign exchange rates were not material and no sensitivity analysis is therefore provided.

##### (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, 2019, and December 31, 2018, cash and cash equivalents and short term investments were placed at the following banks:

Cash and Cash Equivalents	Year ended	Credit rating	Year ended	Credit rating
	December 31, 2019		December 31, 2018	
	£'000		£'000	
<b>Banks</b>				
Royal Bank of Scotland	1	A1	150	A1
Lloyds Bank	8,355	Aa3	15,862	Aa3
Citibank	6,529	Aa3	3,135	A1
Barclays	1,968	A1	449	A2
Wells Fargo	111	Aa1	188	Aa1
Close Brothers	5,970	Aa3	—	—
<b>Total</b>	<b>22,934</b>		<b>19,784</b>	

Short Term Investments	Year ended	Credit rating	Year ended	Credit rating
	December 31, 2019		December 31, 2018	
	£'000		£'000	
<b>Banks</b>				
Royal Bank of Scotland	5,616	A1	9,186	A1
Lloyds Bank	—	Aa3	1,567	Aa3
Standard Chartered	—	A1	15,450	A1
Citibank	—	Aa3	7,053	A1
Barclays	2,207	A1	11,663	A2
<b>Total</b>	<b>7,823</b>		<b>44,919</b>	

(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, 2019, the Company had cash deposits of £22.9 million (2018: £19.8 million) and short term investments of £7.8 million (2018: £44.9 million). The rates of interest received during 2019 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:

	December 31, 2019		December 31, 2018	
	Floating interest rate	Fixed interest rate	Floating interest rate	Fixed interest rate
	£'000s	£'000s	£'000s	£'000s
<b>Financial asset</b>				
Cash deposits	10,006	12,928	15,082	4,702
Short Term Investments	—	7,823	—	44,919
<b>Total</b>	<b>10,006</b>	<b>20,751</b>	<b>15,082</b>	<b>49,621</b>

(e) Liquidity risk

The Company periodically prepares 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 approximates to their fair value. The Company's maturity analysis for the derivative financial instrument from the issue of warrants is given in note 18.

	LESS THAN 1 YEAR	BETWEEN 1 AND 2 YEARS	BETWEEN 2 AND 5 YEARS	OVER 5 YEARS
	£'000s	£'000s	£'000s	£'000s
	<b>At December 31, 2019</b>			
Trade payables	1,455	—	—	—
Accruals	6,806	—	—	—
Lease liability	476	557	—	—
Assumed contingent liability <sup>(1)</sup>	—	—	—	1,807
<b>Total</b>	<b>8,737</b>	<b>557</b>	<b>—</b>	<b>1,807</b>

• This table includes the undiscounted amount of the assumed contingent liability. See note 20.

	LESS THAN 1 YEAR	BETWEEN 1 AND 2 YEARS	BETWEEN 2 AND 5 YEARS	OVER 5 YEARS
	£'000s	£'000s	£'000s	£'000s
	<b>At December 31, 2018</b>			
Trade payables	2,839	—	—	—
Other payables	12	—	—	—
Accruals	4,882	—	—	—
Assumed contingent liability <sup>(1)</sup>	—	—	—	1,807
<b>Total</b>	<b>7,733</b>	<b>—</b>	<b>—</b>	<b>1,807</b>

(1) This table includes the undiscounted amount of the assumed contingent liability. See note 20.

### 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.

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, 2019, and 2018, fair value adjustments to financial instruments measure at fair value through profit and loss resulted in the recognition of finance income of £1.6 million in 2019 and a finance loss of £1.2 million in 2018.

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.

	Level 3	Total
	£'000s	£'000s
<b>At December 31, 2019</b>		
Derivative financial instrument	895	895
<b>Total</b>	<b>895</b>	<b>895</b>

Movements in Level 3 items during the years ended December 31, 2019, and 2018 are as follows:

<b>Derivative financial instrument</b>	2019	2018
	£'000s	£'000s
<b>At January 1</b>	2,492	1,273
Fair value adjustments recognized in profit and loss	(1,597)	1,219
<b>At December 31</b>	<b>895</b>	<b>2,492</b>

Further details relating to the derivative financial instrument are set out in notes 4 and 18 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 18.

**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.

	2019 Derivative financial instrument
	£'000s
At January 1	2,492
Fair value adjustments - non cash	(1,597)
At December 31	<u>895</u>

See note 18 for information relating to the derivative financial instrument.

	2019 Lease liability
	£'000s
At January 1	316
Capitalization of rental leases - non cash	1,061
Payment of lease liability - cash	(426)
At December 31	<u>951</u>

See note 14 and note 2.17 for information relating to the capitalized leases.

**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 liability**

The Company has a material liability for the future payment of royalties and milestones associated with contractual liabilities on ensifentrine, acquired as part of the acquisition of Rhinopharma. The estimation of the amounts and timing of future cashflows requires the forecast of royalties payable and the estimation of the likelihood that the regulatory approval milestone will be achieved (see notes 2.12 and 20). The estimates for the assumed contingent liability are based on a discounted cash flow model. Key estimates included the 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;

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**Critical accounting estimates and judgments (continued)**

- launch of competitive products;
- probabilities of success; and
- time to crystallization of contingent consideration.

When there is a change in the expected cash flows or probabilities of success, the assumed contingent liability is re-measured with the change in value recognized in the IP R&D asset it relates to. This is a change in accounting policy for the year ended December 1, 2019 (see 2.17). The assumed contingent liability is measured at amortized cost with the discount unwinding in finance expense throughout the year. Actual outcomes could differ significantly from the estimates made.

The Company has judged that the probabilities of success will change when it moves from one stage of clinical development to another. Management have determined that, for the purposes of assessing probabilities of success, the Company will move from Phase 2 to Phase 3 after an End of Phase 2 Meeting with the Food and Drug Administration ("FDA") in the US that provides confidence over ensifentrine's historical development program and planned Phase 3 program. A remeasurement of the liability at this time is likely to result in a significant increase in both the liability and the corresponding IP R&D asset. The Company has previously announced that it expects to meet with the FDA in the first half of 2020. The Company notes that there is no guarantee that the meeting will take place in the timeframe anticipated or that there will be a successful outcome.

Should the probabilities of success and estimates of cash flows change there will be a material increase in the assumed contingent liability and corresponding IP R&D asset. The amount will be dependent on feedback from the FDA and the probabilities of success applied. Should the Company determine that it has moved from Phase 2 to Phase 3 then the value of the liability could increase by between £15 million and £30 million; the increase in the value of the liability will give rise to an approximately equivalent increase in the value of the IP R&D asset, as described further in Note 2.7.

The value of the assumed contingent liability as of December 31, 2019 amounted to £1.1 million. (2018: £1.0 million).

**(b) Valuation of the Derivative Financial Liability**

In July 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 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 2.14, 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 term, volatility and risk free rate in order to determine the fair value per warrant. For further details see note 18.

**5. Earnings per share**

Basic loss per ordinary share of 30.3p (2018: 18.9p and 2017: 23.4p) for the Company is calculated by dividing the loss for the year ended December 31, 2019 by the weighted average number of ordinary shares in issue of 105,326,638 as of December 31, 2019 (2018: 105,110,504 and 2017: 87,748,031). 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.

## 7. Operating loss

	Year ended December 31, 2019	Year ended December 31, 2018	Year ended December 31, 2017
	£'000s	£'000s	£'000s
<b>Operating Loss is stated after charging / (crediting):</b>			
<b>Research and development costs:</b>			
Employee benefits (note 8)	4,688	3,360	3,435
Amortization of patents (note 12)	102	85	111
Legal, professional consulting and listing fees	537	161	331
Other research and development expenses	28,149	15,688	19,840
Total research and development costs	33,476	19,294	23,717
<b>General and administrative costs:</b>			
Employee benefits (note 8)	3,093	3,240	2,857
Legal, professional consulting and listing fees	2,155	1,296	2,045
Amortization of computer software (note 12)	4	5	5
Depreciation of property, plant and equipment (note 13)	16	8	7
Depreciation of right-of-use assets (note 14)	382	—	—
Operating lease charge — land and buildings	—	384	294
Loss / (gain) on variations in foreign exchange rate	345	(9)	36
Other general and administrative expenses	1,612	1,373	795
Total general and administrative costs	7,607	6,297	6,039
Operating loss	41,083	25,591	29,756

**8. Directors' emoluments and staff costs**

	Year ended December 31, 2019	Year ended December 31, 2018	Year ended December 31, 2017
The average number of employees (excluding directors) of the Company during the year:			
Research and development	13	7	7
General and administrative	9	7	5
Total	<u>22</u>	<u>14</u>	<u>12</u>
	Year ended December 31, 2019	Year ended December 31, 2018	Year ended December 31, 2017
	£'000s	£'000s	£'000s
<b>Aggregate emoluments of directors:</b>			
Salaries and other short-term employee benefits	850	830	897
Social security costs	112	94	103
Incremental payment for additional services	26	26	—
Other pension costs	10	10	17
Total directors' emoluments	<u>998</u>	<u>960</u>	<u>1,017</u>
Share-based payment charge	925	1,337	1,037
Directors' emoluments including share-based payment charge	<u>1,923</u>	<u>2,297</u>	<u>2,054</u>
	Year ended December 31, 2019	Year ended December 31, 2018	Year ended December 31, 2017
	£'000s	£'000s	£'000s
<b>Aggregate executive officers costs:</b>			
Wages and salaries	1,150	857	864
Social security costs	98	83	81
Share-based payment charge	751	769	1,332
Other pension costs	21	19	17
Total executive officers costs	<u>2,020</u>	<u>1,728</u>	<u>2,294</u>
	Year ended December 31, 2019	Year ended December 31, 2018	Year ended December 31, 2017
	£'000s	£'000s	£'000s
<b>Aggregate other staff costs:</b>			
Wages and salaries	2,788	1,622	1,272
Social security costs	265	150	101
Share-based payment charge	765	795	550
Other pension costs	46	34	21
Total other staff costs	<u>3,864</u>	<u>2,601</u>	<u>1,944</u>

The Company considers key management personnel to comprise directors and executive officers.

The Company operates defined contribution pension schemes for its employees and executive director. The total pension cost during the year ended December 31, 2019 was £77 thousand (2018: £63 thousand and 2017: £55 thousand). There were no prepaid or accrued contributions to the scheme at December 31, 2019 (2018 and 2017: £nil).

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9. Finance income and expense

	Year ended December 31, 2019	Year ended December 31, 2018	Year ended December 31, 2017
	£'000s	£'000s	£'000s
<b>Finance income:</b>			
Interest received on cash balances	754	861	345
Foreign exchange gain on translating foreign currency denominated balances	—	1,922	—
Fair value adjustment on derivative financial instruments (note 18)	1,597	—	6,650
Other Income	—	—	23
Total finance income	<u>2,351</u>	<u>2,783</u>	<u>7,018</u>
	Year ended December 31, 2019	Year ended December 31, 2018	Year ended December 31, 2017
	£'000s	£'000s	£'000s
<b>Finance expense:</b>			
Fair value adjustment on derivative financial instruments (note 18)	—	1,219	—
Interest on discounted lease liability	50	—	—
Foreign exchange loss on translating foreign currency denominated balances	305	—	2,392
Unwinding of discount factor related to the assumed contingent arrangement (note 20)	119	106	73
Total finance expense	<u>474</u>	<u>1,325</u>	<u>2,465</u>

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 FOR THE THREE YEARS ENDED DECEMBER 31, 2019

## 10. Taxation

	Year ended December 31, 2019	Year ended December 31, 2018	Year ended December 31, 2017
	£'000s	£'000s	£'000s
<b>Analysis of tax credit for the year</b>			
Current tax:			
U.K. tax credit	(7,250)	(4,290)	(5,006)
U.S. tax charge	56	30	306
Adjustment in respect of prior periods	(71)	28	(6)
<b>Total tax credit</b>	<b>(7,265)</b>	<b>(4,232)</b>	<b>(4,706)</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	(39,206)	(24,133)	(25,203)
Multiplied by standard rate of corporation tax of 19% (2018: 19% and 2017: 19.25%)	(7,449)	(4,585)	(4,852)
Effects of:			
Non-deductible expenses	515	540	675
Fair value adjustment on derivative financial instruments	(303)	232	(1,280)
Research and development incentive	(3,119)	(1,846)	(2,116)
Temporary differences not recognized	(6)	(3)	(2)
Difference in overseas tax rates	16	8	136
Tax losses carried forward not recognized	3,152	1,394	2,739
Adjustment in respect of prior periods	(71)	28	(6)
<b>Total tax credit</b>	<b>(7,265)</b>	<b>(4,232)</b>	<b>(4,706)</b>

U.K. corporation tax is charged at 19% (2018: 19.00% and 2017: 19.25%) and U.S. federal and state tax at 27.6% (2018: 27.6% and 2017: 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, 2019	As at December 31, 2018
	£'000s	£'000s
Deferred tax assets	332	250
Deferred tax liabilities	(332)	(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, 2019, the unrecognized deferred tax asset at 17% is estimated to be £9.27 million (2018: £6.65 million at 17%).

**11. Goodwill**

	As of December 31, 2019	As of December 31, 2018
	£'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.

The Company has one CGU so goodwill is tested for impairment together with its intangible assets. It was tested with reference to the Company's market capitalization as of December 31, 2019, the date of testing of IP R&D and goodwill impairment. The market capitalization of the Company was approximately £65.3 million as of December 31, 2019, (2018: 92.2 million) compared to the Company's net assets of £33.9 million (2018: £63.4 million). Therefore, no impairment was required.

The Company notes that after the reduction in its share price since December 31, 2018, and before the increase by December 31, 2019, at various points in the three months to March 31, 2019, the market value of the Company was less than its net book value. The Company therefore carried out an impairment review as at March 31, 2019. From market research the Company assessed, among other inputs, potential patient numbers from likely physician prescribing patterns, price points, the time from possible launch to peak sales, script rejection, attrition rates and probability of success. The Company also carried out a sensitivity analysis on key assumptions and assessed that a reasonable change in these assumptions would not lead to the value in use falling below net book value. Consequently, management determined that the Company's value in use exceeded the carrying value of the Company's assets and that no impairment was required.

At various other points in the year ended December 31, 2019, the market value of the Company was less than its net book value. Consequently, management re-performed the impairment review quarterly, and identified no changes to market conditions, the competitive landscape, market research insights or other factors that would change its conclusions. As a result, management determined that the Company's value in use exceeded the carrying value of the Company's assets and that no impairment was required at those dates.

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 Intangible assets (continued)

12. Intangible assets

	IP R&D	Computer software	Patents	Total
	£'000s	£'000s	£'000s	£'000s
<b>Cost</b>				
At January 1, 2018 (Restated)	1,953	11	727	2,691
Additions	—	4	251	255
Disposals	—	—	(6)	(6)
At December 31, 2018 (Restated)	<u>1,953</u>	<u>15</u>	<u>972</u>	<u>2,940</u>
<b>Accumulated amortization</b>				
At January 1, 2018	—	6	232	238
Charge for year	—	5	85	90
Disposals	—	—	(6)	(6)
At December 31, 2018	<u>—</u>	<u>11</u>	<u>311</u>	<u>322</u>
<b>Net book value</b>				
At December 31, 2018 (Restated)	<u><u>1,953</u></u>	<u><u>4</u></u>	<u><u>661</u></u>	<u><u>2,618</u></u>

	IP R&D	Computer software	Patents	Total
	£'000s	£'000s	£'000s	£'000s
<b>Cost</b>				
At January 1, 2019	1,953	15	972	2,940
Additions	—	3	242	245
At December 31, 2019	<u>1,953</u>	<u>18</u>	<u>1,214</u>	<u>3,185</u>
<b>Accumulated amortization</b>				
At January 1, 2019	—	11	311	322
Charge for year	—	4	102	106
At December 31, 2019	<u>—</u>	<u>15</u>	<u>413</u>	<u>428</u>
<b>Net book value</b>				
At December 31, 2019	<u><u>1,953</u></u>	<u><u>3</u></u>	<u><u>801</u></u>	<u><u>2,757</u></u>

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.

The IP R&D asset acquired through the business combination was initially recognized at fair value. Subsequent movements in the assumed contingent liability that relate to changes in estimated cash flows or probabilities of success are recognized as additions to the IP R&D asset that it relates to. This is a change in accounting policy (see note 2.17). The asset is not amortized and is tested annually for impairment.

Patents are amortized over a period of ten years and are tested annually for impairment.

Intangible assets are tested for impairment with goodwill, as the Company has only one CGU. See note 11 for information about the impairment review.

## 13. Property, plant and equipment

	Computer hardware	Total
	£'000s	£'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

	Computer hardware	Total
	£'000s	£'000s
<b>Cost</b>		
At January 1, 2019	39	39
Additions	38	38
At December 31, 2019	77	77
<b>Accumulated depreciation</b>		
At January 1, 2019	18	18
Charge for the year	16	16
At December 31, 2019	34	34
<b>Net book value</b>		
At December 31, 2019	43	43

#### 14. Right-of-use assets - property leases

The right-of-use asset relates to rented office space in London and New York where the Company generally enters in to leases for terms of less than three years. Before the adoption of IFRS 16 these leases were classified as operating leases.

The Consolidated Statement of Financial Position shows the following amounts relating to leases:

	Year ended December 31, 2019	As of January 1, 2019*
	£'000s	£'000s
<b>Right-of-use assets</b>		
Right-of-use assets	971	326
	<u>971</u>	<u>326</u>
<b>Lease liabilities</b>		
Current	(460)	(316)
Non Current	(491)	—
	<u>(951)</u>	<u>(316)</u>

Additions to the right-of-use assets were £1,047,000 and were recognized when the Company was reasonably certain to extend the leases. The additions related to both of the Company's office locations, both of which agreements have similar terms and conditions.

To calculate the value of the lease liabilities the Company applied a discount rate of 8%.

The leases end in 2021 and 2022 and include options to extend them. The Company has determined it is not yet reasonably certain to operate the option to extend the leases and so has recognized lease payments only to these points in its calculation of the lease liabilities.

The right-of-use lease assets are depreciated over the term of the leases.

The Consolidated Statement of Comprehensive Income includes the following amounts relating to leases:

	Year ended December 31, 2019	Year ended December 31, 2018
	£'000s	£'000s
<b>Depreciation charge of right-of-use assets</b>		
Right-of-use assets	(382)	—
	<u>(382)</u>	<u>—</u>
Interest expense (including finance cost)	50	—
Expense relating to short-term leases (included in general and administrative expenses)	78	—

The total cash outflow for leases in 2019 was £492,000.

**15. Prepayments and other receivables**

	As of December 31, 2019	As of December 31, 2018
	£'000s	£'000s
Prepayments	1,309	1,362
Other receivables	1,461	1,101
<b>Total prepayments and other receivables</b>	<b>2,770</b>	<b>2,463</b>

The prepayments balance includes prepayments for insurance and clinical activities.

**16. 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, 2018</b>		<b>105,017,401</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>105,326,638</b>	<b>5,266</b>
<b>As at December 31, 2019</b>		<b>105,326,638</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 105,326,638 ordinary shares at December 31, 2019 are allotted, unrestricted, called up and fully paid. All issued shares rank pari passu.

During 2018, the Company issued 309,237 ordinary shares upon vesting of employee restricted share units.

## 17. Share-based payments charge

The Company operates various share based payment incentive schemes for its staff.

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, 2019, the Company recognized a share-based payment expense of £2.44 million (2018: £2.90 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 operates an Unapproved Share Option Scheme under which options were issued before 31 December 2016. The Company also operates a tax efficient EMI Option Scheme under which options were issued before 31 December 2016. In 2017 the Company commenced the 2017 Incentive Award Plan under which the Company grants share options and Restricted Stock Units ("RSUs") to employees and directors.

Since 2017 options are issued with an exercise price at the share price the evening before the date of issue. They vest over terms of one to four years.

RSUs also vest over terms of one to four years. In the year ended December 31, 2019, the Company modified the terms of all the RSUs issued prior January 1, 2019, to include a market based performance condition. The Company's share price must be maintained above £2 for thirty days for the RSUs to vest, in addition to the existing service condition. The RSUs vest after a five year term irrespective of whether the £2 market condition was met. This modification did not result in an increase in the fair value of the RSUs. The RSUs issued in the year ended December 31, 2019, also include the same market condition and five year term.

In the year ended December 31, 2019, under the 2017 Incentive Award Plan, the Company granted 5,569,050 (2018: 2,090,847) share options and 740,496 RSUs (2018: 273,390). 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 £2.25 million (2018: £2.32 million). The cost is amortized over the vesting period of the options and RSUs on a straight-line basis. The following assumptions were used for the Black-Scholes valuation of share options and RSUs granted in 2018 and 2019. 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 historical weekly averages of the Company's share price over a period that is in line with the expected life of the options and RSUs.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2019**  
**17. Share-based payments charge (Continued)**

<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
<b>Issued in 2019</b>	<b>Unapproved Scheme</b>	<b>Restricted Stock Units</b>
Options granted	5,569,050	740,496
Risk-free interest rate	0.39% - 0.82%	0.76% - 0.82%
Expected life of options	5.5 - 7 years	5.5 - 7 years
Annualized volatility	67.98% - 69.71%	63.82% - 69.71%
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, 2019:

<b>Year of issue</b>	<b>Exercise price (£)</b>	<b>At January 1, 2019</b>	<b>Options granted</b>	<b>Options forfeited</b>	<b>Options expired</b>	<b>At December 31, 2019</b>	<b>Expiry date</b>
2012	2.50 - 7.50	99,993	—	—	—	99,993	June 1, 2022
2013	2	99,990	—	—	(19,998)	79,992	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 *
2015	1.25	41,997	—	—	—	41,997	January 29, 2025 *
2015	1.25	549,999	—	—	—	549,999	January 29, 2025
2016	2	240,000	—	—	—	240,000	February 2, 2026
2016	2.00	21,996	—	—	—	21,996	February 2, 2026 *
2016	1.80	676,664	—	—	—	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	4,093,164	—	—	—	4,093,164	April 26, 2027
2018	1.46	2,008,319	—	(34,614)	—	1,973,705	March 8, 2028
2019	570.00	—	3,903,050	(87,356)	—	3,815,694	March 29, 2029
2019	595.00	—	346,000	—	—	346,000	June 11, 2029
2019	457.00	—	100,000	—	—	100,000	August 22, 2029
2019	0.436	—	720,000	—	—	720,000	November 6, 2029
2019	445.00	—	500,000	—	—	500,000	November 26, 2029
<b>Total</b>		8,752,114	5,569,050	(121,970)	(19,998)	14,179,196	

\* Options granted under the EMI Scheme.



**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2019**  
**17. Share-based payments charge (Continued)**

	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>

The following table shows the number of RSUs issued in 2019. There were no RSUs forfeited, canceled or vested in 2019. The fair value of each unvested RSU granted in 2019 was £0.57.

	Number of RSUs
<b>At January 1, 2019</b>	862,473
Granted:	
Employees	474,072
Directors	266,424
RSUs vested in the year	—
RSUs forfeited in the year	—
<b>At December 31, 2019</b>	<b>1,602,969</b>

**18. Derivative financial instrument**

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 £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 until May 2, 2022.

In the year ended December 31, 2019, no warrants were forfeited (2018: nil).

The table below presents the assumptions in applying the Black-Scholes model to determine the fair value of the warrants.

	As of December 31, 2019	As of December 31, 2018
Shares available to be issued under warrants	12,401,262	12,401,262
Exercise price	£ 1.7238	£ 1.7238
Risk-free interest rate	0.540%	0.760%
Expected term to exercise	2.34 years	3.34 years
Annualized volatility	65.56%	60.72%
Dividend rate	0.00%	0.00%

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2019**  
**18. Derivative financial instrument (Continued)**

As per the reporting date, the Company updated the underlying assumptions and calculated a fair value of these warrants amounting to £0.9 million. The variance of £(1.6) million is recorded as finance income in the Consolidated Statement of Comprehensive Income.

	Derivative financial instrument	Derivative financial instrument
	2019	2018
	£'000s	£'000s
<b>At January 1</b>	2,492	1,273
Fair value adjustments recognized in profit or loss	(1,597)	1,219
<b>At December 31</b>	<b>895</b>	<b>2,492</b>

For the amount recognized at December 31, 2019, the effect when the following parameter deviates up or down is presented in the below table.

	Volatility (up / down 10% pts)
	£'000s
Variable up	1,306
<b>Base case, reported fair value</b>	<b>895</b>
Variable down	535

**19. Trade and other payables**

	As of December 31, 2019	As of December 31, 2018
	£'000s	£'000s
Trade payables	1,455	2,839
Other payables	—	12
Accruals	6,806	4,882
<b>Total trade and other payables</b>	<b>8,261</b>	<b>7,733</b>

**20. Assumed contingent liability related to the business combination**

The value of the assumed contingent liability as of December 31, 2019 is £1.1 million (2018: £1.0 million). The increase in value of the assumed contingent liability during 2019 amounted to £0.1 million (2018: £0.1 million).

The assumed contingent liability relates to the acquisition, in 2006, of rights to certain patents and patent applications relating to ensifentrine and related compounds under which the Company is obliged to pay royalties to Ligand (see 2.12).

The assumed contingent liability is measured at the expected value of the milestone payment and royalty payments. This expected value is based on estimated future royalties payable, derived from sales forecasts, and an assessment of the probability of success using standard market probabilities for respiratory drug development. The risk-weighted value of the assumed contingent arrangement is discounted back to its net present value applying an effective interest rate of 12%.

The assumed contingent liability is accounted for as a liability and its value is measured at amortized cost using the effective interest rate method, and is re-measured for changes in estimated cash flows or when the probability of success changes.

**VERONA PHARMA PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 2019**

Re-measurements relating to changes in estimated cash flows and probabilities of success are recognized in the IP R&D asset it relates to ("see 2.7"). This is a change in accounting policy for the year ended December 1, 2019 (see 2.17). The unwind of the discount is recognized in finance expense.

The Company considers that probabilities of success will change when it moves from one stage of clinical development to another. See note 4 for a further discussion of this.

	2019	2018
	£'000s	£'000s
January 1	996	875
Impact of changes in foreign exchange rates	(12)	15
Unwinding of discount factor	119	106
December 31	<u>1,103</u>	<u>996</u>

There is no material difference between the fair value and carrying value of the financial liability.

For the amount recognized as at December 31, 2019, of £1,103 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	1,067	1,135
<b>Base case, reported fair value</b>	<b>1,103</b>	<b>1,103</b>
Variable down	1,141	1,071

## 22. 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").

Directors and key management personnel remuneration is disclosed in note 8.

### (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") and Abingworth Bioventures VI L.P. ("Abingworth"). 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 and Abingworth to the board of directors, who are Dr. Mahendra Shah, Mr. Rishi Gupta, and Dr. Andrew Sinclair.

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.

Piers Morgan, Chief Financial Officer of the Company, and his spouse purchased 88,415 ordinary shares in total for £53 thousand from the market in the year ended December 31, 2019 (2018: £nil).

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. There was no similar transaction as at December 31, 2019.

Dr. David Ebsworth, Chairman of the Company, purchased 247,600 ordinary shares for £124 thousand from the market in the year ended December 31, 2019 (2018: £14 thousand).

At December 31, 2018, there was a receivable of £126 thousand 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. There was no such balance as at December 31, 2019.

In the year ended December 31, 2019, a director provided consultancy services for £26 thousand (2018: £26 thousand).

## 22. Events after the reporting date

On February 3, 2020, the Company announced the appointment of David Zaccardelli as chief executive officer with effect from February 1, 2020, following the retirement of Jan-Anders Karlsson, PhD. The Company also announced the appointment of Mark Hahn as chief financial officer with effect from March 1, 2020, as successor to Piers Morgan.

## DESCRIPTION OF SECURITIES

### **DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION**

*Set forth below is a summary of certain information concerning the share capital of Verona Pharma plc (the "Company," "we," "us," and "our") as well as a description of certain provisions of our articles of association and relevant provisions of English law. Because the following is only a summary, it does not contain all of the information that may be important to you. The summary includes certain references to and descriptions of material provisions of our articles of association and English law in effect as of the date of the Company's Annual Report on Form 20-F for the year ended December 31, 2019 (the "Annual Report"). The summary below does not purport to be complete and is qualified in its entirety by reference to applicable English law and our articles of association, which have been publicly filed with the Securities and Exchange Commission.*

#### **General**

We were incorporated as a public limited company with the legal name Isis Resources plc under the laws of England and Wales on February 24, 2005 with the company number 5375156. In September 2006, we acquired Rhinopharma Limited, a company incorporated under the laws of the province of British Columbia, Canada and changed our name to Verona Pharma plc. Our registered office is One Central Square, Cardiff, CF10 1FS. The principal legislation under which we operate and our shares are issued is the Companies Act 2006.

#### **Articles of Association**

Set forth below is a summary of relevant information concerning our share capital and material provisions of our Articles of Association and applicable UK law.

#### **Ordinary Shares**

In accordance with the Articles, the following summarizes the rights of holders of our ordinary shares:

- each holder of our ordinary shares is entitled to one vote per ordinary share on all matters to be voted on by shareholders generally;
- the holders of the ordinary shares shall be entitled to receive notice of, attend, speak and vote at our general meetings; and
- holders of our ordinary shares are entitled to receive such dividends as are recommended by our directors and declared by our shareholders.

#### **Registered Shares**

We are required by the Companies Act 2006 to keep a register of our shareholders. Under English law, the ordinary shares are deemed to be issued when the name of the shareholder is entered in our share register. The share register therefore is prima facie evidence of the identity of our shareholders, and the shares that they hold. The share register generally provides limited, or no, information regarding the ultimate beneficial owners of our ordinary shares. Our share register is maintained by our registrar, Computershare Investor Services plc.

Holders of our ADSs will not be treated as one of our shareholders and their names will therefore not be entered in our share register. The depositary, the custodian or their nominees will be the holder of the shares underlying our ADSs. For discussion on our ADSs and ADS holder rights see "Description of American Depository Shares" below. Holders of our ADSs have a right to receive the ordinary shares underlying their ADSs as discussed in "Description of American Depository Shares" below.

Under the Companies Act 2006, we must enter an allotment of shares in our share register as soon as practicable and in any event within two months of the allotment. We also are required by the Companies Act 2006 to register a transfer of shares (or give the transferee notice of and reasons for refusal) as soon as practicable and in any event within two months of receiving notice of the transfer.

We, any of our shareholders or any other affected person may apply to the court for rectification of the share register if:

- the name of any person, without sufficient cause, is wrongly entered in or omitted from our register of members; or
- there is a default or unnecessary delay in entering on the register the fact of any person having ceased to be a member or on which we have a lien, provided that such refusal does not prevent dealings in the shares taking place on an open and proper basis.

### ***Preemptive Rights***

English law generally provides shareholders with preemptive rights when new shares are issued for cash; however, it is possible for the articles of association, or shareholders in general meeting, to exclude preemptive rights. Such an exclusion of preemptive rights may be for a maximum period of up to five years from the date of adoption of the articles of association, if the exclusion is contained in the articles of association, or from the date of the shareholder resolution, if the exclusion is by shareholder resolution. In either case, this exclusion would need to be renewed by our shareholders upon its expiration (i.e., at least every five years). On May 28, 2019, our shareholders approved the exclusion of preemptive rights up to an aggregate nominal amount of £5,266,331 which shall expire on June 1, 2021 unless renewed sooner.

### ***Shares and Rights Attaching to Them***

#### *Objects*

The objects of our company are unrestricted.

#### *Share Rights*

Subject to any special rights attaching to shares already in issue, our shares may be issued with or have attached to them any preferred, deferred or other special rights or privileges or be subject to such restrictions as we may resolve by ordinary resolution of the shareholders or decision of our board.

#### *Voting Rights*

Without prejudice to any special rights, privileges or restrictions as to voting rights attached to any shares forming part of our share capital from time to time, the voting rights attaching to shares are as follows:

- on a show of hands, every shareholder who (being an individual) is present in person and (being a corporation) is present by a duly authorized representative shall have one vote;
- on a show of hands, each proxy present in person has one vote for and one vote against a resolution if the proxy has been duly appointed by more than one shareholder and the proxy has been instructed by one or more of those shareholders to vote for the resolution and by one or more other of those shareholders to vote against it;
- on a show of hands, each proxy present in person has one vote for and one vote against a resolution if the proxy has been duly appointed by more than one shareholder entitled to vote on the resolution and either: (1) the proxy has been instructed by one or more of those shareholders to vote for the resolution and has been given any discretion by one or more other of those shareholders to vote and the proxy exercises that discretion to vote against it; or (2) the proxy has been instructed by one or more of those shareholders to vote against the resolution and has been given any discretion by one or more other of those shareholders to vote and the proxy exercises that discretion to vote for it; and
- on a poll every shareholder who is present in person or by proxy shall have one vote for each share of which he is the holder.

At any general meeting a resolution put to the vote of the meeting shall be decided on a show of hands unless a poll is demanded. Subject to the provisions of the Companies Act 2006, as described in "Differences in Corporate Law - Voting Rights" below, a poll may be demanded by:

- the chairman of the meeting;
- at least five shareholders present in person or by proxy and entitled to vote;
- any shareholder(s) present in person or by proxy and representing in the aggregate not less than one-tenth of the total voting rights of all shareholders having the right to attend and vote at the meeting (excluding the shares held in treasury); or
- any shareholder(s) present in person or by proxy and holding shares conferring a right to attend and vote at the meeting on which there have been paid up sums in the aggregate equal to not less than one-tenth of the total sums paid up on all shares conferring that right (excluding the shares held in treasury).

#### *Restrictions on Voting*

No shareholder shall be entitled to vote at any general meeting or at any separate class meeting in respect of any

share held by him unless all calls or other sums payable by him in respect of that share have been paid.

The board may from time to time make calls upon the shareholders in respect of any money unpaid on their shares and each shareholder shall (subject to at least 14 days' notice specifying the time or times and place of payment) pay at the time or times so specified the amount called on his shares.

#### *Dividends*

We may by ordinary resolution of shareholders declare dividends out of profits available for distribution in accordance with the respective rights of shareholders but no such dividend shall exceed the amount recommended by the directors. The board may from time to time pay shareholders such interim dividends as appear to the board to be justified by our profits and, if at any time, our share capital is divided into different classes the board may pay such interim dividends in respect of those shares which confer on the holders thereof deferred or non-preferential rights with regard to dividends.

Subject to any special rights attaching to or the terms of issue of any share, all dividends shall be declared and paid according to the amounts paid up on the shares and shall be apportioned and paid pro rata according to the amounts paid up on the shares during any part or parts of the period in respect of which the dividend is paid.

No dividend or other moneys payable by us on or in respect of any share shall bear interest against us. Any dividend unclaimed after a period of 12 years from the date such dividend became due for payment shall, if the Board so resolved, be forfeited and shall revert to us.

Dividends may be declared or paid in any currency and the board may decide the rate of exchange for any currency conversions that may be required, and how any costs involved are to be met, in relation to the currency of any dividend.

Any general meeting declaring a dividend may by ordinary resolution of shareholders, upon the recommendation of the board, direct payment or satisfaction of such dividend wholly or in part by the distribution of specific assets other than cash, and in particular of paid up shares or debentures of any other company. The directors may, if authorized by ordinary resolution of shareholders, offer any holders of ordinary shares the right to elect to receive in lieu of a dividend an allotment of ordinary shares credited as fully paid up, subject to such exclusions as the Board may deem necessary or desirable.

No shareholder shall be entitled to receive any dividend or other distribution in respect of any share held by him unless all calls or other sums payable by him in respect of that share have been paid.

#### *Change of Control*

There is no specific provision in our articles of association that would have the effect of delaying, deferring or preventing a change of control.

#### *Distributions on Winding Up*

On a winding up, the liquidator may, with the consent by a special resolution of shareholders and any other resolution of the shareholders (excluding us to the extent we are a shareholder by virtue only of our holding of

shares as treasury shares) in proportion to their shareholdings in specie or in kind or sanction of the court required by the Companies Act 2006 and/or the Insolvency Act 1986, divide amongst the shareholders the whole or any part of our assets (whether they shall consist of property of the same kind or not) and may set such values as he deems fair upon any property to be divided and may determine how such division shall be carried out as between the shareholders or different classes of shareholder. The liquidator may vest the whole or any part of such assets in trustees upon such trusts for the benefit of the shareholders as the liquidator shall think fit, but no shareholder shall be compelled to accept any shares or other assets upon which there is any liability or potential liability.

#### *Variation of Rights*

All or any of the rights and restrictions attached to any class of shares issued may be altered, added to or revoked with the consent in writing of the holders of not less than three-fourths in nominal value of the issued shares of that class (excluding any shares held as treasury shares) or by special resolution passed at a separate general meeting of the holders of such shares, subject to the Companies Act 2006 and the terms of their issue. The Companies Act 2006 provides a right to object to the variation of the share capital by the shareholders who did not vote in favor of the variation. Should an aggregate of 15% of the shareholders of the issued shares in question apply to the court to have the variation cancelled, the variation shall have no effect unless and until it is confirmed by the court.

#### *Alteration to Share Capital*

We may, by ordinary resolution of shareholders, consolidate and divide all or any of our share capital into shares of larger amount than our existing shares, or sub-divide our shares or any of them into shares of a smaller amount. We may, by special resolution of shareholders, confirmed by the court, reduce our share capital or any capital redemption reserve or any share premium account in any manner authorized by the Companies Act 2006. We may redeem or purchase all or any of our shares as described in "-Other U.K. Law Considerations - Purchase of Own Shares."

#### *Preemption Rights*

In certain circumstances, our shareholders may have statutory preemption rights under the Companies Act 2006 in respect of the allotment of new shares as described in "- Preemptive Rights" and "- Differences in Corporate Law - Preemptive Rights" below.

#### **Transfer of Shares**

Any certificated shareholder may transfer all or any of his shares by an instrument of transfer in the usual common form or in any other manner which is permitted by the Companies Act 2006 and approved by the board. Any written instrument of transfer shall be signed by or on behalf of the transferor and (in the case of a partly paid share) the transferee.

All transfers of uncertificated shares shall be made in accordance with and subject to the provisions of the Uncertificated Securities Regulations 2001 and the facilities and requirements of its relevant system. The Uncertificated Securities Regulations 2001 permit shares to be issued and held in uncertificated form and transferred by means of a computer-based system.

The board may decline to register any transfer of any share:

- which is not a fully paid share;
- to a person known to be a minor, bankrupt or person who is mentally disordered or a patient for the purpose of any statute relating to mental health;
- to an entity which is not a natural or legal person;
- unless any written instrument of transfer, duly stamped, is lodged with us at our registered office or such other place as the board may appoint accompanied by the certificate for the shares to which it relates;
- unless there is provided such evidence as the board may reasonably require to show the right of the transferor to make the transfer and if the instrument of transfer is executed by some other person on his behalf, the authority of that person to do so;
- where the transfer is in respect of more than one class of share; and
- in the case of a transfer to joint holders, the number of joint holders to whom the share is to be transferred exceeds four.

If the board declines to register a transfer it shall, as soon as practicable and in any event within two months after the date on which the transfer is lodged, send to the transferee notice of the refusal, together with reasons for the refusal.

### **CREST**

To be traded on AIM, securities must be able to be transferred and settled through the CREST system. CREST is a computerized paperless share transfer and settlement system which allows securities to be transferred by electronic means, without the need for a written instrument of transfer. The Articles of Association are consistent with CREST membership and, amongst other things, allow for the holding and transfer of shares in uncertificated form.

### **Shareholder Meetings**

#### *Annual General Meetings*

In accordance with the Companies Act 2006, we are required in each year to hold an annual general meeting in addition to any other general meetings in that year and to specify the meeting as such in the notice convening it. The annual general meeting shall be convened whenever and wherever the board sees fit, subject to the requirements of the Companies Act 2006, as described in "- Differences in Corporate Law - Annual General Meeting" and "- Differences in Corporate Law - Notice of General Meetings" below.

The arrangements for the calling of general meetings are described in "- Differences in Corporate Law - Notice of General Meetings" below.

#### *Quorum of General Meetings*

No business shall be transacted at any general meeting unless a quorum is present. At least two shareholders

present in person or by proxy and entitled to vote shall be a quorum for all purposes.

#### *Class Meetings*

The provisions in the Articles of Association relating to general meetings apply to every separate general meeting of the holders of a class of shares except that:

- the quorum for such class meeting shall be two holders in person or by proxy representing not less than one-third in nominal value of the issued shares of the class (excluding any shares held in treasury);
- at the class meeting, a holder of shares of the class present in person or by proxy may demand a poll and shall on a poll be entitled to one vote for every share of the class held by him; and
- if at any adjourned meeting of such holders a quorum is not present at the meeting, one holder of shares of the class present in person or by proxy at an adjourned meeting constitutes a quorum.

#### **Directors**

##### *Number of Directors*

We may not have less than two directors on the board of directors. We may, by ordinary resolution of the shareholders, vary the minimum and maximum number of directors from time to time.

##### *Appointment of Directors*

Subject to the provisions of the Articles of Association, we may, by ordinary resolution of the shareholders, elect any person to be a director, either to fill a casual vacancy or as an addition to the existing board. However, any person that is not a director retiring from the existing board must be recommended by a shareholder not less than seven and not more than 21 days before the day of the appointment in order to be eligible for election.

Without prejudice to the power to appoint any person to be a director by shareholder resolution, the board has power to appoint any person to be a director, either to fill a casual vacancy or as an addition to the existing board but so that the total number of directors does not exceed the maximum number fixed by or in accordance with the Articles of Association.

Any director appointed by the board will hold office only until the earlier to occur of the close of the next following annual general meeting and someone being appointed in his stead at that meeting. Such a director is eligible for re-election at that meeting but shall not be taken into account in determining the directors or the number of directors who are to retire by rotation at such meeting.

##### *Rotation of Directors*

At every annual general meeting, one-third of the directors or, if their number is not a multiple of three, then the

number nearest to and not exceeding one-third, shall retire from office.

The directors to retire on each occasion shall be those subject to retirement by rotation who have been longest in office since their last election, but as between persons who became or were re-elected directors on the same day those to retire shall (unless they otherwise agree amongst themselves) be determined by lot.

A director who retires at the annual general meeting shall be eligible for re-election.

The shareholders may, at the meeting at which a director retires, fill the vacated office by electing a person and in default the retiring director shall, if willing to continue to act, be deemed to have been re-elected, unless at such meeting it is expressly resolved not to fill such vacated office or unless a resolution for the re-election of such director shall have been put to the meeting and lost.

#### *Directors' Interests*

The directors may authorize, to the fullest extent permitted by law, any matter proposed to them which would otherwise result in a director infringing his duty to avoid a situation in which he has, or can have, a direct or indirect interest that conflicts, or possibly may conflict, with our interests. A director shall not, save as otherwise agreed by him, be accountable to us for any benefit which he derives from any matter authorized by the directors and any contract, transaction or arrangement relating thereto shall not be liable to be avoided on the grounds of any such benefit.

Subject to the requirements under sections 175, 177 and 182 of the Companies Act 2006, a director who is any way, whether directly or indirectly, interested in a proposed or existing transaction or arrangement with us shall declare the nature of his interest at a meeting of the directors.

In the case of interests arising where a director is in any way, directly or indirectly, interested in (a) a proposed transaction or arrangement with us or (b) a transaction or arrangement that has been entered into by us and save as otherwise provided by the Articles of Association, such director shall not vote at a meeting of the board or of a committee of the board on any resolution concerning such matter in which he has a material interest (otherwise than by virtue of his interest in shares, debentures or other securities of, or otherwise in or through, us) unless his interest or duty arises only because the case falls within one or more of the following paragraphs:

- the resolution relates to the giving of any security, guarantee or indemnity to the director in respect of money lent or obligations incurred by the director at the request of or for the benefit of us or our subsidiaries;
- the resolution relates to the giving to a third party of a security or indemnity in respect of a debt or obligation of ours or any of our subsidiaries for which the director or a person connected with him has assumed responsibility in whole or part under a guarantee or indemnity or by the giving of security;
- his interest arises by virtue of any offer of shares or debentures or other securities by us or our subsidiaries for subscription or purchase in which offer the director is or may be entitled to participate as a holder of securities or in the director is interested as a participant in the underwriting or sub-underwriting thereof;
- the resolution relates in any way to any other company in which he is interested, directly

or indirectly and whether as an officer or shareholder or otherwise howsoever, provided that he and any persons connected with him do not to his knowledge hold an interest in shares representing one per cent or more of any class of the equity share capital of such company or of the voting rights available to shareholder of such company;

- the resolution relates in any way to an arrangement in whole or in part for the benefit of our employees or any employees of our subsidiaries which does not award him as such any privilege or benefit not generally awarded to the employees to whom such arrangement relates;
- the resolution relates to the adoption, modification or operation of a superannuation fund or retirement, death or disability benefits scheme or employees' share scheme under which he may benefit and which has been approved by or is subject to and conditional upon approval by the U.K. tax authorities for taxation purposes and which does not award him any privilege or benefit not awarded to the employee to whom the scheme relates; or
- the resolution relates in any way to the purchase or maintenance for the directors of insurance against any liability which by virtue of any rule of law would otherwise attach to all or any of them in respect of any negligence, default, breach of duty or breach of trust in relation to us or any of our subsidiaries.

A director shall not be counted in the quorum present at a meeting in relation to a resolution on which he is not entitled to vote.

If a question arises at a meeting of the board or of a committee of the board as to the right of a director to vote or be counted in the quorum, and such question is not resolved by his voluntarily agreeing to abstain from voting or not to be counted in the quorum, the question shall be determined by a majority of votes of the remaining directors present at the meeting or if there is an equality of votes, the Chairman shall have a second or casting vote and his ruling in relation to any director other than himself shall be final and conclusive except in a case where the nature or extent of the interest of the director concerned has not been fairly disclosed.

#### *Directors' Fees and Remuneration*

Each of the directors shall be paid a fee at such rate as may from time to time be determined by the board (or for the avoidance of doubt any duly authorized committee of the board) provided that the aggregate of all such fees so paid to directors shall not exceed £500,000 per annum, or such higher amount as may from time to time be determined by ordinary resolution of shareholders.

Each director may be paid his traveling, hotel and incidental expenses of attending and returning from meetings of the board or committees of the board or general meetings or separate meetings of the holders class of shares or of debentures and shall be paid all expenses properly incurred by him in the conduct of our business or in the discharge of his duties as a director. Any director who, by request, performs special or extra services which in the opinion of the board go beyond the ordinary duties of a director may be paid such extra remuneration as the board may determine.

An executive director shall receive such remuneration as the board may determine, and either in addition to or in lieu of his remuneration as a director as detailed above.

#### *Borrowing Powers*

The board may exercise all the powers to borrow money and to mortgage or charge our undertaking, property and assets (present or future) and uncalled capital or any part thereof and to issue debentures and other securities, whether outright or as collateral security for any debt, liability or obligation of us or of any third party.

#### *Indemnity*

Every director, alternate director, other officer or auditor of our group may be indemnified against all costs, charges, expenses, losses and liabilities incurred by him in connection with any negligence, default, breach of duty or breach of trust by him in relation to us or in relation to the actual or purported execution or discharge of his duties or the exercise or purported exercise of his powers or otherwise in relation to such members of our group.

#### **Other U.K. Law Considerations**

##### *Notification of Voting Rights*

A shareholder in a public company incorporated in the United Kingdom whose shares are admitted to trading on AIM is required pursuant to Rule 5 of the Disclosure and Transparency Rules of the U.K. Financial Conduct Authority to notify us of the percentage of his voting rights if the percentage of voting rights which he holds as a shareholder or through his direct or indirect holding of financial instruments (or a combination of such holdings) reaches, exceeds or falls below 3%, 4%, 5%, and each 1% threshold thereafter up to 100% as a result of an acquisition or disposal of shares or financial instruments.

##### *Mandatory Purchases and Acquisitions*

Pursuant to Sections 979 to 991 of the Companies Act 2006, where a takeover offer has been made for us and the offeror has acquired or unconditionally contracted to acquire not less than 90% in value of the shares to which the offer relates and not less than 90% of the voting rights carried by those shares, the offeror may give notice to the holder of any shares to which the offer relates which the offeror has not acquired or unconditionally contracted to acquire that he wishes to acquire, and is entitled to so acquire, those shares on the same terms as the general offer. The offeror would do so by sending a notice to the outstanding minority shareholders telling them that it will compulsorily acquire their shares. Such notice must be sent within three months of the last day on which the offer can be accepted in the prescribed manner. The squeeze-out of the minority shareholders can be completed at the end of six weeks from the date the notice has been given, subject to the minority shareholders failing to successfully lodge an application to the court to prevent such squeeze-out any time prior to the end of those six weeks following which the offeror can execute a transfer of the outstanding shares in its favor and pay the consideration to us, which would hold the consideration on trust for the outstanding minority shareholders. The consideration offered to the outstanding minority shareholders whose shares are compulsorily acquired under the Companies Act 2006 must, in general, be the same as the consideration that was available under the takeover offer.

##### *Sell Out*

The Companies Act 2006 also gives our minority shareholders a right to be bought out in certain circumstances by an offeror who has made a takeover offer for all of our shares. The holder of shares to which the offer relates, and who has not otherwise accepted the offer, may require the offeror to acquire his shares if, prior to the expiry of the acceptance period for such offer, (i) the offeror has acquired or unconditionally agreed to acquire not less than 90% in value of the voting shares, and (ii) not less than 90% of the voting rights carried by those shares. The offeror may impose a time limit on the rights of minority shareholders to be bought out that is not less than three months after the end of the acceptance period. If a shareholder exercises his rights to be bought out, the offeror is required to acquire those shares on the terms of this offer or on such other terms as may be agreed.

#### *Disclosure of Interest in Shares*

Pursuant to Part 22 of the Companies Act 2006, we are empowered by notice in writing to any person whom we know or have reasonable cause to believe to be interested in our shares, or at any time during the three years immediately preceding the date on which the notice is issued has been so interested, within a reasonable time to disclose to us particulars of that person's interest and (so far as is within his knowledge) particulars of any other interest that subsists or subsisted in those shares.

Under the Articles of Association, if a person defaults in supplying us with the required particulars in relation to the shares in question, or default shares within the prescribed period, the directors may by notice direct that:

§ in respect of the default shares, the relevant member shall not be entitled to attend or vote (either in person or by proxy) at any general meeting or of a general meeting of the holders of a class of shares or upon any poll or to exercise any right conferred by the default shares;

§ where the default shares represent at least 0.25% of their class, (a) any dividend or other money payable in respect of the default shares shall be retained by us without liability to pay interest, and/or (b) no transfers by the relevant member of any default shares may be registered (unless the member himself is not in default and the member proves to the satisfaction of the Board that no person in default as regards supplying such information is interested in any of the default shares); and/or

§ any shares held by the relevant member in uncertificated form shall be converted into certificated form and that member shall not after that be entitled to convert all or any shares held by him into uncertificated form (unless the member himself is not in default as regards supplying the information required and the member proves to the satisfaction of the board that, after due and careful inquiry, the member is satisfied that none of the shares he is proposing to convert into uncertificated form is a default share).

#### *Purchase of Own Shares*

Under English law, a limited company may only purchase its own shares out of the distributable profits of the company or the proceeds of a fresh issue of shares made for the purpose of financing the purchase, provided that they are not restricted from doing so by their articles. A limited company may not purchase its own shares if, as a result of the purchase, there would no longer be any issued shares of the company other than redeemable shares or shares held as treasury shares. Shares must be fully paid in order to be repurchased.

Subject to the above, we may purchase our own shares in the manner prescribed below. We may make a market purchase of our own fully paid shares pursuant to an ordinary resolution of shareholders. The resolution authorizing the purchase must:

- specify the maximum number of shares authorized to be acquired;
- determine the maximum and minimum prices that may be paid for the shares; and
- specify a date, not being later than five years after the passing of the resolution, on which the authority to purchase is to expire.

We may purchase our own fully paid shares otherwise than on a recognized investment exchange pursuant to a purchase contract authorized by resolution of shareholders before the purchase takes place. Any authority will not be effective if any shareholder from whom we propose to purchase shares votes on the resolution and the resolution would not have been passed if he had not done so. The resolution authorizing the purchase must specify a date, not being later than five years after the passing of the resolution, on which the authority to purchase is to expire.

#### *Distributions and Dividends*

Under the Companies Act 2006, before a company can lawfully make a distribution or dividend, it must ensure that it has sufficient distributable reserves (on a non-consolidated basis). The basic rule is that a company's profits available for the purpose of making a distribution are its accumulated, realized profits, so far as not previously utilized by distribution or capitalization, less its accumulated, realized losses, so far as not previously written off in a reduction or reorganization of capital duly made. The requirement to have sufficient distributable reserves before a distribution or dividend can be paid applies to us and to each of our subsidiaries that has been incorporated under English law.

It is not sufficient that we, as a public company, have made a distributable profit for the purpose of making a distribution. An additional capital maintenance requirement is imposed on us to ensure that the net worth of the company is at least equal to the amount of its capital. A public company can only make a distribution:

- if, at the time that the distribution is made, the amount of its net assets (that is, the total excess of assets over liabilities) is not less than the total of its called up share capital and undistributable reserves; and
- if, and to the extent that, the distribution itself, at the time that it is made, does not reduce the amount of the net assets to less than that total.

#### *City Code on Takeovers and Mergers*

As a public company incorporated in England and Wales with our registered office in England and Wales which has shares admitted to AIM, we are subject to the U.K. City Code on Takeovers and Mergers, or the City Code, which is issued and administered by the U.K. Panel on Takeovers and Mergers, or the Panel. The City Code provides a framework within which takeovers of companies subject to it are conducted. In particular, the City Code contains certain rules in respect of mandatory offers. Under Rule 9 of the City Code, if a person:

- acquires an interest in our shares which, when taken together with shares in which he or persons acting in concert with him are interested, carries 30% or more of the voting

rights of our shares; or

- who, together with persons acting in concert with him, is interested in shares that in the aggregate carry not less than 30% and not more than 50% of the voting rights of our shares, and such persons, or any person acting in concert with him, acquires additional interests in shares that increase the percentage of shares carrying voting rights in which that person is interested,

the acquirer and depending on the circumstances, its concert parties, would be required (except with the consent of the Panel) to make a cash offer for our outstanding shares at a price not less than the highest price paid for any interests in the shares by the acquirer or its concert parties during the previous 12 months.

### Differences in Corporate Law

*The applicable provisions of the Companies Act 2006 differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the Companies Act 2006 applicable to us and the General Corporation Law of the State of Delaware relating to shareholders' rights and protections. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and English law.*

	England and Wales	Delaware
Number of Directors	Under the Companies Act 2006, a public limited company must have at least two directors and the number of directors may be fixed by or in the manner provided in a company's articles of association.	Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws.
Removal of Directors	Under the Companies Act 2006, shareholders may remove a director without cause by an ordinary resolution (which is passed by a simple majority of those voting in person or by proxy at a general meeting) irrespective of any provisions of any service contract the director has with the company, provided 28 clear days' notice of the resolution has been given to the company and its shareholders. On receipt of notice of an intended resolution to remove a director, the company must forthwith send a copy of the notice to the director concerned. Certain other procedural requirements under the Companies Act 2006 must also be followed such as allowing the director to make representations against his or her removal either at the meeting or in writing.	Under Delaware law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (a) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board of directors is classified, shareholders may effect such removal only for cause, or (b) in the case of a corporation having cumulative voting, if less than the entire board of directors is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

Vacancies on the Board of Directors	Under English law, the procedure by which directors, other than a company's initial directors, are appointed is generally set out in a company's articles of association, provided that where two or more persons are appointed as directors of a public limited company by resolution of the shareholders, resolutions appointing each director must be voted on individually.	Under Delaware law, vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) or by a sole remaining director unless (a) otherwise provided in the certificate of incorporation or by-laws of the corporation or (b) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case a majority of the other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.
Annual General Meeting	Under the Companies Act 2006, a public limited company must hold an annual general meeting in each six-month period following the company's annual accounting reference date.	Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.
General Meeting	Under the Companies Act 2006, a general meeting of the shareholders of a public limited company may be called by the directors.	Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.
Notice of General Meetings	Shareholders holding at least 5% of the paid-up capital of the company carrying voting rights at general meetings (excluding any paid up capital held as treasury shares) can require the directors to call a general meeting and, if the directors fail to do so within a certain period, may themselves convene a general meeting.  Under the Companies Act 2006, 21 clear days' notice must be given for an annual general meeting and any resolutions to be proposed at the meeting. Subject to a company's articles of association providing for a longer period, at least 14 clear days' notice is required for any other general meeting. In addition, certain matters, such as the removal of directors or auditors, require special notice, which is 28 clear days' notice. The shareholders of a company may in all cases consent to a shorter notice period, the proportion of shareholders' consent required being 100% of those entitled to attend and vote in the case of an annual general meeting and, in the case of any other general meeting, a majority in number of the members having a right to attend and vote at the meeting, being a majority who together hold not less than 95% in nominal value of the shares giving a right to attend and vote at the meeting.	Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.
Proxy	Under the Companies Act 2006, at any meeting of shareholders, a shareholder may designate another person to attend, speak and vote at the meeting on their behalf by proxy.	Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer

period. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Pre-emptive Rights	<p>Under the Companies Act 2006, "equity securities", being (i) shares in the company other than shares that, with respect to dividends and capital, carry a right to participate only up to a specified amount in a distribution ("ordinary shares") or (ii) rights to subscribe for, or to convert securities into, ordinary shares, proposed to be allotted for cash must be offered first to the existing equity shareholders in the company in proportion to the respective nominal value of their holdings, unless an exception applies or a special resolution to the contrary has been passed by shareholders in a general meeting or the articles of association provide otherwise in each case in accordance with the provisions of the Companies Act 2006.</p>	<p>Under Delaware law, shareholders have no preemptive rights to subscribe to additional issues of stock or to any security convertible into such stock unless, and except to the extent that, such rights are expressly provided for in the certificate of incorporation.</p>
Authority to Allot	<p>Under the Companies Act 2006, the directors of a company must not allot shares or grant of rights to subscribe for or to convert any security into shares unless an exception applies or an ordinary resolution to the contrary has been passed by shareholders in a general meeting or the articles of association provide otherwise in each case in accordance with the provisions of the Companies Act 2006.</p>	<p>Under Delaware law, if the corporation's charter or certificate of incorporation so provides, the board of directors has the power to authorize the issuance of stock. It may authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the corporation or any combination thereof. It may determine the amount of such consideration by approving a formula. In the absence of actual fraud in the transaction, the judgment of the directors as to the value of such consideration is conclusive.</p>
Liability of Directors and Officers	<p>Under the Companies Act 2006, any provision, whether contained in a company's articles of association or any contract or otherwise, that purports to exempt a director of a company, to any extent, from any liability that would otherwise attach to him in connection with any negligence, default, breach of duty or breach of trust in relation to the company is void.</p> <p>Any provision by which a company directly or indirectly provides an indemnity, to any extent, for a director of the company or of an associated company against any liability attaching to him in connection with any negligence, default, breach of duty or breach of trust in relation to the company of which he is a director is also void except as permitted by the Companies Act 2006, which provides exceptions for the company to (a) purchase and maintain insurance against such liability; (b) provide a "qualifying third party indemnity" (being an indemnity against liability incurred by the</p>	<p>Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for:</p> <ul style="list-style-type: none"><li>any breach of the director's duty of loyalty to the corporation or its stockholders;</li><li>acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;</li><li>intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or</li><li>any transaction from which the director derives an improper personal benefit.</li></ul>

director to a person other than the company or an associated company or criminal proceedings in which he is convicted); and (c) provide a "qualifying pension scheme indemnity" (being an indemnity against liability incurred in connection with the company's activities as trustee of an occupational pension plan).

Voting Rights

Under English law, unless a poll is demanded by the shareholders of a company or is required by the chairman of the meeting or the company's articles of association, shareholders shall vote on all resolutions on a show of hands. Under the Companies Act 2006, a poll may be demanded by (a) not fewer than five shareholders having the right to vote on the resolution; (b) any shareholder(s) representing not less than 10% of the total voting rights of all the shareholders having the right to vote on the resolution (excluding any voting rights attaching to treasury shares); or (c) any shareholder(s) holding shares in the company conferring a right to vote on the resolution (excluding any voting rights attaching to treasury shares) being shares on which an aggregate sum has been paid up equal to not less than 10% of the total sum paid up on all the shares conferring that right. A company's articles of association may provide more extensive rights for shareholders to call a poll.

Under English law, an ordinary resolution is passed on a show of hands if it is approved by a simple majority (more than 50%) of the votes cast by shareholders present (in person or by proxy) and entitled to vote. If a poll is demanded, an ordinary resolution is passed if it is approved by holders representing a simple majority of the total voting rights of shareholders present, in person or by proxy, who, being entitled to vote, vote on the resolution. Special resolutions require the affirmative vote of not less than 75% of the votes cast by shareholders present, in person or by proxy, at the meeting.

Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder.

Shareholder Vote on Certain Transactions

The Companies Act 2006 provides for schemes of arrangement, which are arrangements or compromises between a company and any class of shareholders or creditors and used in certain types of reconstructions, amalgamations, capital reorganizations or takeovers. These arrangements require:

the approval at a shareholders' or creditors' meeting convened by order of the court, of a majority in number of

Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires:

the approval of the board of directors; and approval by the vote of the holders of a

shareholders or creditors representing 75% in value of the capital held by, or debt owed to, the class of shareholders or creditors, or class thereof present and voting, either in person or by proxy; and

majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.

the approval of the court.

Standard of Conduct for Directors

Under English law, a director owes various statutory and fiduciary duties to the company, including:

to act in the way he considers, in good faith, would be most likely to promote the success of the company for the benefit of its members as a whole;

to avoid a situation in which he has, or can have, a direct or indirect interest that conflicts, or possibly conflicts, with the interests of the company;

to act in accordance with the company's constitution and only exercise his powers for the purposes for which they are conferred;

to exercise independent judgment;

to exercise reasonable care, skill and diligence;

not to accept benefits from a third party conferred by reason of his being a director or doing, or not doing, anything as a director; and

a duty to declare any interest that he has, whether directly or indirectly, in a proposed or existing transaction or arrangement with the company.

Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well-informed basis and in a manner they reasonably believe to be in the best interest of the stockholders.

Directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its shareholders. The duty of care generally requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. In general, but subject to certain exceptions, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation.

In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the shareholders.

Stockholder Suits

Under English law, generally, the company, rather than its shareholders, is the proper claimant in an action in respect of a wrong done to the company or where there is an irregularity in the company's internal

Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must:

management. Notwithstanding this general position, the Companies Act 2006 provides that (i) a court may allow a shareholder to bring a derivative claim (that is, an action in respect of and on behalf of the company) in respect of a cause of action arising from a director's negligence, default, breach of duty or breach of trust and (ii) a shareholder may bring a claim for a court order where the company's affairs have been or are being conducted in a manner that is unfairly prejudicial to some of its shareholders.

state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiff's shares thereafter devolved on the plaintiff by operation of law; and

allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action; or

state the reasons for not making the effort.

Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.

## **DESCRIPTION OF AMERICAN DEPOSITARY SHARES**

### **American Depositary Shares**

We are providing you with a summary description of the material terms of our ADSs and of the material rights of owners of our ADSs. Please remember that summaries by their nature lack the precision of the information summarized and that the rights and obligations of an owner of ADSs will be determined by reference to the terms of the deposit agreement and not by this summary. We urge you to review the deposit agreement in its entirety. We have registered 100,000,000 of our ADSs with the SEC under a registration statement on Form F-6 (file no. 333-217353), or the F-6 Registration Statement.

Citibank, N.A., or Citibank, has agreed to act as the depository for our ADSs. Citibank's depository offices are located at 388 Greenwich Street, New York, New York 10013. ADSs represent ownership interests in securities that are on deposit with the depository. ADSs may be represented by certificates that are commonly known as American Depositary Receipts, or ADRs. The depository typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Citibank, N.A., London Branch, located at 25 Canada Square, Canary Wharf, London, E14 5LB, United Kingdom.

We have appointed Citibank as depository pursuant to a deposit agreement. A copy of the deposit agreement is on file with the SEC under cover of the F-6 Registration Statement. You may obtain a copy of the deposit agreement from the SEC's website ([www.sec.gov](http://www.sec.gov)). Please refer to registration number 333-217353 when retrieving such copy.

Each ADS represents the right to receive, and to exercise the beneficial ownership interests in, eight of our ordinary shares that are on deposit with the depository and/or custodian. An ADS also represents the right to receive, and to exercise the beneficial interests in, any other property received by the depository or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. We and the depository may agree to change the ADS-to-ordinary share ratio by amending the deposit agreement. This amendment may give rise to, or change, the depository fees payable by ADS owners. The custodian, the depository and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depository, the custodian or their nominees. Beneficial ownership in the deposited property will, under the terms of the deposit agreement, be vested in the beneficial owners of the ADSs. The depository, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of the ADSs, the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the depository, and the depository (on behalf of the owners of the corresponding ADSs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

If you become an owner of ADSs, you will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents your ADSs. The deposit agreement and the ADR specify our rights and obligations as well as your rights and obligations as owner of ADSs and those of the depository. As an ADS holder you appoint the depository to act on your behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of ordinary shares will

continue to be governed by the laws of England and Wales, which may be different from the laws in the United States.

In addition, applicable laws and regulations may require you to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. You are solely responsible for complying with such reporting requirements and obtaining such approvals. Neither the depositary, the custodian, us or any of their or our respective agents or affiliates shall be required to take any actions whatsoever on your behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

As an owner of ADSs, we will not treat you as one of our shareholders and you will not have direct shareholder rights. The depositary will hold on your behalf the shareholder rights attached to the ordinary shares underlying your ADSs. As an owner of ADSs you will be able to exercise the shareholders rights for the ordinary shares represented by your ADSs through the depositary only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement you will, as an ADS owner, need to arrange for the cancellation of your ADSs and become a direct shareholder.

As an owner of ADSs, you may hold your ADSs either by means of an ADR registered in your name, through a brokerage or safekeeping account, or through an account established by the depositary in your name reflecting the registration of uncertificated ADSs directly on the books of the depositary (commonly referred to as the direct registration system, or DRS). The DRS reflects the uncertificated (book-entry) registration of ownership of ADSs by the depositary. Under the DRS, ownership of ADSs is evidenced by periodic statements issued by the depositary to the holders of the ADSs. The DRS includes automated transfers between the depositary and The Depository Trust Company, or DTC, the central book-entry clearing and settlement system for equity securities in the United States. If you decide to hold your ADSs through your brokerage or safekeeping account, you must rely on the procedures of your broker or bank to assert your rights as an ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit your ability to exercise your rights as an owner of ADSs. Please consult with your broker or bank if you have any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC. This summary description assumes you have opted to own the ADSs directly by means of an ADS registered in your name and, as such, we will refer to you as the "holder." When we refer to "you," we assume the reader owns ADSs and will own ADSs at the relevant time.

The registration of the ordinary shares in the name of the depositary or the custodian shall, to the maximum extent permitted by applicable law, vest in the depositary or the custodian the record ownership in the applicable ordinary shares with the beneficial ownership rights and interests in such ordinary shares being at all times vested with the beneficial owners of the ADSs representing the ordinary shares. The depositary or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of the ADSs representing the deposited property.

#### **Dividends and Other Distributions**

As a holder of ADSs, you generally have the right to receive the distributions we make on the ordinary shares deposited with the custodian. Your receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deducting the

applicable fees, taxes and expenses.

### ***Distributions of Cash***

Whenever we make a cash distribution for the ordinary shares on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary will arrange for the funds to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to the laws and regulations of England and Wales.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depositary will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of ordinary shares on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The depositary will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

### ***Distributions of Shares***

Whenever we make a free distribution of ordinary shares for the ordinary shares on deposit with the custodian, we will deposit the applicable number of ordinary shares with the custodian. Upon receipt of confirmation of such deposit, the depositary will either distribute to holders new ADSs representing the ordinary shares deposited or modify the ADS-to-ordinary shares ratio, in which case each ADS you hold will represent rights and interests in the additional ordinary shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADSs or the modification of the ADS-to-ordinary shares ratio upon a distribution of ordinary shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depositary may sell all or a portion of the new ordinary shares so distributed.

No such distribution of new ADSs will be made if it would violate a law (*e.g.*, the U.S. securities laws) or if it is not operationally practicable. If the depositary does not distribute new ADSs as described above, it may sell the ordinary shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

### ***Distributions of Rights***

Whenever we intend to distribute rights to purchase additional ordinary shares, we will give prior notice to the depositary and we will assist the depositary in determining whether it is lawful and reasonably practicable to distribute rights to purchase additional ADSs to holders.

The depositary will establish procedures to distribute rights to purchase additional ADSs to holders and to enable such holders to exercise such rights if it is lawful and reasonably practicable to make the rights available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). You may have to pay fees, expenses, taxes and other

governmental charges to subscribe for the new ADSs upon the exercise of your rights. The depositary is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to purchase new ordinary shares other than in the form of ADSs.

The depositary will *not* distribute the rights to you if:

- we do not timely request that the rights be distributed to you or we request that the rights not be distributed to you; or
- we fail to deliver satisfactory documents to the depositary; or
- it is not reasonably practicable to distribute the rights.

The depositary will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary is unable to sell the rights, it will allow the rights to lapse.

#### ***Elective Distributions***

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to you. In such case, we will assist the depositary in determining whether such distribution is lawful and reasonably practicable.

The depositary will make the election available to you only if it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary will establish procedures to enable you to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement.

If the election is not made available to you, you will receive either cash or additional ADSs, depending on what a shareholder in England and Wales would receive upon failing to make an election, as more fully described in the deposit agreement.

#### ***Other Distributions***

Whenever we intend to distribute property other than cash, ordinary shares or rights to purchase additional ordinary shares, we will notify the depositary in advance and will indicate whether we wish such distribution to be made to you. If so, we will assist the depositary in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to you and if we provide all of the documentation contemplated in the deposit agreement, the depositary will distribute the property to the holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depositary may

sell all or a portion of the property received.

The depositary will *not* distribute the property to you and will sell the property if:

- we do not request that the property be distributed to you or if we ask that the property not be distributed to you; or
- we do not deliver satisfactory documents to the depositary; or
- the depositary determines that all or a portion of the distribution to you is not reasonably practicable.

The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

### ***Redemption***

Whenever we decide to redeem any of the ordinary shares on deposit with the custodian, we will notify the depositary in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depositary will provide notice of the redemption to the holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depositary will convert the redemption funds received into U.S. dollars upon the terms of the deposit agreement and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the depositary. You may have to pay fees, expenses, taxes and other governmental charges upon the redemption of your ADSs. If less than all ADSs are being redeemed, the ADSs to be retired will be selected by lot or on a *pro rata* basis, as the depositary may determine.

### **Changes Affecting Ordinary Shares**

The ordinary shares held on deposit for your ADSs may change from time to time. For example, there may be a change in nominal or par value, split-up, cancellation, consolidation or any other reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation or sale of assets of Verona.

If any such change were to occur, your ADSs would, to the extent permitted by law, represent the right to receive the property received or exchanged in respect of the ordinary shares held on deposit. The depositary may in such circumstances deliver new ADSs to you, amend the deposit agreement, the ADRs and the applicable registration statement(s) on Form F-6, call for the exchange of your existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to the ADSs the change affecting the Shares. If the depositary may not lawfully distribute such property to you, the depositary may sell such property and distribute the net proceeds to you as in the case of a cash distribution.

### **Issuance of ADSs upon Deposit of Ordinary Shares**

The depositary may create ADSs on your behalf if you or your broker deposit ordinary shares with the custodian. The depositary will deliver these ADSs to the person you indicate only after you pay any applicable issuance fees and any charges and taxes payable for the transfer of the ordinary shares to the custodian. Your ability to deposit

ordinary shares and receive ADSs may be limited by U.S. and England and Wales legal considerations applicable at the time of deposit.

The issuance of ADSs may be delayed until the depository or the custodian receives confirmation that all required approvals have been given and that the ordinary shares have been duly transferred to the custodian. The depository will only issue ADSs in whole numbers.

When you make a deposit of ordinary shares, you will be responsible for transferring good and valid title to the depository. As such, you will be deemed to represent and warrant that:

- the ordinary shares are duly authorized, validly issued, fully paid, non-assessable and legally obtained;
- all preemptive (and similar) rights, if any, with respect to such ordinary shares have been validly waived or exercised;
- you are duly authorized to deposit the ordinary shares;
- the ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and are not, and the ADSs issuable upon such deposit will not be, "restricted securities" (as defined in the deposit agreement); and
- the ordinary shares presented for deposit have not been stripped of any rights or entitlements.

If any of the representations or warranties are incorrect in any way, we and the depository may, at your cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

#### **Transfer, Combination and Split Up of ADRs**

As an ADR holder, you will be entitled to transfer, combine or split up your ADRs and the ADSs evidenced thereby. For transfers of ADRs, you will have to surrender the ADRs to be transferred to the depository and also must:

- ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;

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provide such proof of identity and genuineness of signatures as the depository deems appropriate;

- provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have your ADRs either combined or split up, you must surrender the ADRs in question to the depository with

your request to have them combined or split up, and you must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

#### **Withdrawal of Ordinary Shares Upon Cancellation of ADSs**

As a holder, you will be entitled to present your ADSs to the depository for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian's offices. Your ability to withdraw the ordinary shares held in respect of the ADSs may be limited by U.S. and England and Wales considerations applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by your ADSs, you will be required to pay to the depository the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the ordinary shares. You assume the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADSs will not have any rights under the deposit agreement.

If you hold ADSs registered in your name, the depository may ask you to provide proof of identity and genuineness of any signature and such other documents as the depository may deem appropriate before it will cancel your ADSs. The withdrawal of the ordinary shares represented by your ADSs may be delayed until the depository receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depository will only accept ADSs for cancellation that represent a whole number of securities on deposit.

You will have the right to withdraw the securities represented by your ADSs at any time except as a result of:

- temporary delays that may arise because (i) the transfer books for the ordinary shares or ADSs are closed, or (ii) ordinary shares are immobilized on account of a shareholders' meeting or a payment of dividends;
- obligations to pay fees, taxes and similar charges; and/or
- restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit.

The deposit agreement may not be modified to impair your right to withdraw the securities represented by your ADSs except to comply with mandatory provisions of law.

#### **Voting Rights**

As a holder, you generally have the right under the deposit agreement to instruct the depository to exercise the voting rights for the ordinary shares represented by your ADSs. The voting rights of holders of ordinary shares are described in "Description of Share Capital and Articles of Association - Articles of Association" above.

At our request, the depository will distribute to you any notice of shareholders' meeting received from us together with information explaining how to instruct the depository to exercise the voting rights of the securities represented by ADSs.

If the depository timely receives voting instructions from a holder of ADSs, it will endeavor to vote the securities (in person or by proxy) represented by the holder's ADSs as follows:

- *In the event of voting by show of hands*, the depositary will vote (or cause the custodian to vote) all ordinary held on deposit at that time in accordance with the voting instructions received from a majority of holders of ADSs who provide timely voting instructions.
- *In the event of voting by poll*, the depositary will vote (or cause the custodian to vote) the ordinary shares held on deposit in accordance with the voting instructions received from the holders of ADSs.

Securities for which no voting instructions have been received will not be voted (except as otherwise contemplated herein). Please note that the ability of the depositary to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure you that you will receive voting materials in time to enable you to return voting instructions to the depositary in a timely manner.

### **Fees and Charges**

As an ADS holder, you will be 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

As an ADS holder you will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;

- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depository 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 depository in the conversion of foreign currency;
- the fees and expenses incurred by the depository in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and ADRs; and
- the fees and expenses incurred by the depository, 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 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. Certain of the depository fees and charges (such as the ADS services fee) may become payable shortly after the closing of any applicable ADS offering. Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depository. You will receive prior notice of such changes. The depository may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depository agree from time to time.

#### **Amendments and Termination**

We may agree with the depository to modify the deposit agreement at any time without your consent. We undertake to give holders 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to your substantial rights any modifications or supplements that are reasonably necessary for the ADSs to be registered under the

Securities Act of 1933, as amended, or the Securities Act, or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges you are required to pay. In addition, we may not be able to provide you with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

You will be bound by the modifications to the deposit agreement if you continue to hold your ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent you from withdrawing the ordinary shares represented by your ADSs (except as permitted by law).

We have the right to direct the depository to terminate the deposit agreement. Similarly, the depository may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depository must give notice to the holders at least 30 days before termination. Until termination, your rights under the deposit agreement will be unaffected.

### **Termination**

After termination, the depository will continue to collect distributions received (but will not distribute any such property until you request the cancellation of your ADSs) and may sell the securities held on deposit. After the sale, the depository will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the depository will have no further obligations to holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses).

In connection with the termination of the deposit agreement, the depository may, independently and without the need for any action by us, make available to holders a means to withdraw the ordinary shares and other deposited securities represented by their ADSs and to direct the deposit of such ordinary shares and other deposited securities into an unsponsored American depository shares program established by the depository, upon such terms and conditions as the depository may deem reasonably appropriate, subject however, in each case, to satisfaction of the applicable registration requirements by the unsponsored American depository shares program under the Securities Act, and to receipt by the depository of payment of the applicable fees and charges of, and reimbursement of the applicable expenses incurred by, the depository.

### **Books of Depository**

The depository will maintain ADS holder records at its depository office. You may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADSs and the deposit agreement.

The depository will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

### **Transmission of Notices, Reports and Proxy Soliciting Material**

The depository will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. Subject to the terms of the deposit agreement, the depository will send you copies of those communications or otherwise make

those communications available to you if we ask it to.

#### **Limitations on Obligations and Liabilities**

The deposit agreement limits our obligations and the depositary's obligations to you. Please note the following:

- We and the depositary are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- The depositary disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and in accordance with the terms of the deposit agreement.
- The depositary disclaims any liability for any failure to determine the lawfulness or practicality of any action, for the content of any document forwarded to you on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADSs, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice.
- We and the depositary will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.
- We and the depositary disclaim any liability if we or the depositary are prevented or forbidden from or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, or by reason of present or future provision of any provision of our Articles of Association, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.
- We and the depositary disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our Articles of Association or in any provisions of or governing the securities on deposit.
- We and the depositary further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting Shares for deposit, any holder of ADSs or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.
- We and the depositary also disclaim liability for the inability by a holder to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to you.

- We and the depository may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.
- We and the depository also disclaim liability for any consequential or punitive damages for any breach of the terms of the deposit agreement.
- No disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.

### **Pre-Release Transactions**

Subject to the terms and conditions of the deposit agreement, the depository may issue to broker/dealers ADSs before receiving a deposit of ordinary shares or release ordinary shares to broker/dealers before receiving ADSs for cancellation. These transactions are commonly referred to as "pre-release transactions," and are entered into between the depository and the applicable broker/dealer. The deposit agreement limits the aggregate size of pre-release transactions (not to exceed 30% of the ordinary shares on deposit in the aggregate) and imposes a number of conditions on such transactions (e.g., the need to receive collateral, the type of collateral required, the representations required from brokers, etc.). The depository may retain the compensation received from the pre-release transactions.

### **Taxes**

You will be responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs. We, the depository and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. You will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depository may refuse to issue ADSs, to deliver, transfer, split and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depository and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on your behalf. However, you may be required to provide to the depository and to the custodian proof of taxpayer status and residence and such other information as the depository and the custodian may require to fulfill legal obligations. You are required to indemnify us, the depository and the custodian for any claims with respect to taxes based on any tax benefit obtained for you.

### **Foreign Currency Conversion**

The depository will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. You may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practical or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the depository may take the following actions in its discretion:

- Convert the foreign currency to the extent practical and lawful and distribute the U.S. dollars to the holders for whom the conversion and distribution is lawful and practical.
- Distribute the foreign currency to holders for whom the distribution is lawful and practical.
- Hold the foreign currency (without liability for interest) for the applicable holders.

**Governing Law/Waiver of Jury Trial**

The deposit agreement and the ADRs will be interpreted in accordance with the laws of the State of New York. The rights of holders of ordinary shares (including ordinary shares represented by ADSs) is governed by the laws of England and Wales.

AS A PARTY TO THE DEPOSIT AGREEMENT, YOU WAIVE YOUR RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF THE DEPOSIT AGREEMENT OR THE ADRs AGAINST US AND/OR THE DEPOSITARY.





**Verona Pharma**

January 28, 2020

David S. Zaccardelli  
100 Ogden Street  
Sarasota, FL 34242

**Re: Offer of Employment**

Dear David:

On behalf of Verona Pharma Inc. (the “Company” or “Verona Pharma”), I am pleased to offer you the position of President and Chief Executive Officer. This offer letter agreement, together with Exhibit A hereto (together, 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, 2020 (“Commencement Date”). The term of this Agreement (the “Term”) shall commence on the Commencement Date and end on the date this Agreement is terminated under Section 5.

- DUTIES.** As President and Chief Executive Officer, you will have such responsibilities, duties and authority normally associated with such position and as may from time to time be lawfully assigned to you by the board of directors (the “Board”) of Verona Pharma plc (“Parent”). You will report to the Board. During the Term, you will also serve as a member of the Board, subject to any required approval of the equityholders of Parent, and as Chief Executive Officer of Parent. During the Term, you will also serve on the Board of Directors of the Company. You shall devote your full time and attention to the business affairs of the Company and Parent (which shall include service to their respective affiliates, if applicable) and shall not engage in outside business activities (including serving on outside boards or committees) without the consent of the Board, provided that you shall be permitted to (i) manage your personal, financial and legal affairs, (ii) participate in trade associations, and (iii) serve on the Board of Directors of Melinta Therapeutics, Inc., CoreRx, Inc. and Evecxia Therapeutics, Inc., subject, in each case, to compliance with this Agreement and provided that such activities do not materially interfere with your performance of your duties and responsibilities hereunder. You will be based out of your home office in Florida but will be required to undertake reasonable business travel and will be expected to be available in the Company's offices in North Carolina as necessary to achieve the objectives established by the Board. The Company will reimburse you for the cost of your airline tickets to Raleigh in accordance with general expense reimbursement policies. You agree to observe and comply with the written rules and policies of the Company as adopted by the Company from time to time, in each case as amended from time to time, as set forth in writing, and as delivered or made available to you. The Company agrees that it will locate its main U.S. offices to the Research Triangle Park region of North Carolina.

Verona Pharma, Inc.

E-mail: [info@veronapharma.com](mailto:info@veronapharma.com) · Website: [www.veronapharma.com](http://www.veronapharma.com)

2. **REMUNERATION.** During the Term, you will be entitled to receive the payments and benefits set forth on Exhibit A hereto.
3. **SEVERANCE BENEFITS.**

(a) **Termination By The Company Without Cause or Termination by You for Good Reason.** If this Agreement is terminated by the Company without Cause (as defined below) or by you for Good Reason (as defined below), and if you sign an agreement reasonably acceptable to the Company that (i) waives any rights you may otherwise have against the Company, Parent and their respective affiliates, except for vested rights under any employee benefits plan or program or rights that cannot lawfully be waived, (ii) releases the Company, Parent and their respective affiliates 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:

- i. an amount in cash equal to the product obtained by multiplying (x) 1.5 (or 1.0 if such termination occurs after the second anniversary of the Commencement Date) times (y) the Annual Base Salary (as defined in Exhibit A hereto), which amount shall be paid ratably over the 18 month period (or 12 month period if such termination occurs after the second anniversary of the Commencement Date) following the termination date in accordance with the Company's regular payroll practices. For the avoidance of doubt, the severance amounts that could become payable under this paragraph upon a qualifying termination of employment that occurs on or prior the second anniversary of the Commencement Date are a deviation from Parent's remuneration policy (the "Remuneration Policy") and are being offered as an incentive for you to join the Company.
- ii. if you elect to receive continued medical, dental or vision coverage under one or more of the Company's group healthcare plans pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), continued payment, or reimbursement, as the case may be, of your COBRA premiums at the rate in effect upon termination for a period commencing on your termination of employment and ending on the earliest of (x) the date that is 18 months (or 12 months if such termination occurs after the second anniversary of the Commencement Date) following the termination of your employment, (y) the date that you and/or your covered dependents become no longer eligible for COBRA, and (z) the date that you become eligible to receive substantially similar coverage from a subsequent employer (and you agree to promptly notify the Company of such eligibility or provide proof that such coverage is not substantially similar), provided that, notwithstanding the foregoing, if the Company determines in its sole discretion that it cannot provide the foregoing benefit without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act) or incurring an excise tax, the Company shall in lieu thereof provide to you a taxable monthly payment in an amount equal to the monthly COBRA premium that you would be required

to pay to continue your and your covered dependents' group health coverage in effect on the date of termination (which amount shall be based on the premium for the first month of COBRA coverage), less the amount you would have had to pay to receive group health coverage for you and your covered dependents based on the cost sharing levels in effect on the date of termination, which payments shall be made regardless of whether you elect COBRA continuation coverage and shall commence in the month following the month in which the date of termination occurs and shall end on the earlier of (X) the date that is 18 months (or 12 months if such termination occurs after the second anniversary of the Commencement Date) following the termination of your employment, (Y) the date that you and/or your covered dependents become no longer eligible for COBRA or (Z) the date you become eligible to receive healthcare coverage from a subsequent employer (and you agree to promptly notify the Company of such eligibility or provide proof that such coverage is not substantially similar). For the avoidance of doubt, the severance benefits that could become payable under this paragraph upon a qualifying termination of employment that occurs on or prior the second anniversary of the Commencement Date are a deviation from the Remuneration Policy and are being offered as an incentive for you to join the Company;

- iii. (A) if such termination occurs after the first anniversary of the Commencement Date, immediate full vesting of all of the unvested equity or equity-based awards held by you under the 2017 Incentive Award Plan of Parent (the "Plan") or otherwise (collectively, the "Equity Awards"), provided that such Equity Awards that vest in whole or in part based on the attainment of performance-vesting conditions shall vest based on the attainment of target level performance (unless otherwise provided by the terms of the applicable award agreement) or (B) if such termination occurs on or before the first anniversary of the Commencement Date, each unvested Equity Award shall become immediately vested as to the portion of the applicable Equity Award that would have otherwise vested on or prior to the first anniversary of the date of such termination had you remained employed with the Company during such period (and any remaining unvested portion of the Equity Awards will be immediately forfeited upon termination);
- iv. the Company shall pay you upon such termination a cash bonus equal to (a) 150% (or 100% if such termination occurs after the second anniversary of the Commencement Date) of the amount of your full annual discretionary bonus calculated as though all objectives had been achieved for the year of your termination; and (b) any discretionary bonus that was earned in the previous fiscal year and not yet paid, which cash payment shall be made within 60 days following the date of termination; and
- v. the Company shall pay you for all accrued and unused paid time off within 60 days following the date of termination.

**(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 without Good Reason, you shall not be entitled to any severance pay, severance benefits, accelerated vesting or any compensation or benefits from the Company whatsoever but you shall be entitled to receive (i) the Cash Base Salary (as defined in Exhibit A hereto) earned but not yet paid as of the date of termination; (ii) reimbursement of all outstanding expenses owed to you under Section 5 of Exhibit A hereto; (iii) payment of any discretionary bonus that was earned but not yet paid for the year prior to the year in which the date of termination occurs; and (iv) all accrued and unused paid time off.

(c) **Determinations.** All decisions and determinations made by the Company under this Section 3 shall be made by the Board.

(d) **Definitions:**

- i. **Cause.** "Cause" for purposes of this Agreement shall mean if you: (1) shall have been convicted of 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, Parent or their respective affiliates or cause material damage to the property, goodwill, or business of Company, Parent or their respective affiliates; (3) shall have refused to, or willfully failed to, perform your duties hereunder or carry out, in any material respect, the lawful and reasonable directive of the Board; (4) shall have materially violated any written policies or procedures of the Company or any of its affiliates; (5) shall have breached a material provision of this Agreement; or (6) shall have unlawfully used (including being under the influence) or possessed illegal drugs on the Company's (or any of its affiliates') premises or while performing your duties and responsibilities hereunder.
- ii. **Good Reason.** "Good Reason" for purposes of this Agreement shall mean if (i) the Company requires you to relocate more than 50 miles from your primary residence in Florida ; (ii) a material decrease in your authority, reporting or areas of responsibility; (iii) any change in your title or following a Change in Control (as defined in the 2017 Incentive Award Plan of Parent), your ceasing to serve as the most senior executive of Parent or the Company, except if such change or cessation occurs as a result of action taken by you; (iv) the Company decreases by 10% or more the Annual Base Salary or target bonus under this Agreement; or (v) a material breach of this Agreement by the Company. In order for you to terminate your Employment for "Good Reason" under this paragraph, within thirty (30) days after becoming aware of the breach or other event giving rise to your right to terminate, you must have provided the Company with written notice of your right to terminate pursuant to this paragraph, the Company must have failed to cure the breach or other event so specified, if curable, within thirty days after receiving such notice and you must resign your employment within thirty days thereafter.

- iii. **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.
4. **COMPANY POLICIES AND CONFIDENTIALITY AGREEMENT.** As an executive of the Company, you will be expected to abide by all of the applicable written policies and procedures of the Company and its affiliates. As a condition of your employment, you agree to sign and to abide by the terms of a Confidential Information and Inventions Assignment Agreement with the Company, which is attached hereto as Exhibit B.
5. **AT-WILL EMPLOYMENT.** As an executive 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. Your at-will employment relationship with the Company as modified by the terms of this Agreement cannot be changed except in writing signed by the Company's Chairman. Upon termination of your employment for any reason, you shall be deemed to have resigned from all offices and directorships, if any, then held with the Company, Parent or any of their respective affiliates.
6. **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 Company's Chairman.
7. **GOVERNING LAW.** This Agreement will be governed by and construed in accordance with the laws of the State of North Carolina.
8. **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 the State of

Florida, 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 North Carolina. 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 Confidential Information and Inventions Assignment 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 (½) of the costs of the arbitrator.

9. **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 9. 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 3 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 3 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 9 shall only apply to in-kind benefits and reimbursements that would result in taxable compensation income to you.

**10. EXCISE TAX.**

(a) **280G Parachute Payments.** If any payment or benefit that you would receive following a Change of Control or otherwise (“**Payment**”) would (i) constitute a “parachute payment” within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then such Payment shall be reduced to the Reduced Amount. The “Reduced Amount” shall be either (A) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (B) the largest portion, up to and including the total amount, of the Payment, whichever of the amounts determined under (A) and (B), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in your receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting “parachute payments” is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the following order: reduction of cash payments; cancellation of accelerated vesting of outstanding awards under the Plan; and reduction of employee benefits. In the event that acceleration of vesting of outstanding awards under the Plan is to be reduced, such acceleration of vesting shall be undertaken in the reverse order of the date of grant of your outstanding equity awards.

(b) **Calculations.** All calculations required to be performed under this Section 10 shall be made by a public accounting or employee benefits consulting firm with a national practice selected by the Company (the “Accounting Firm”). The Accounting Firm shall provide detailed supporting calculations on the applicable matter to both to the Company and you. All fees and expenses of the Accounting Firm shall be borne solely by the Company. Any determination by the Accounting Firm shall be binding upon the Company and you.

**11. 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 executive. 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.

**12. KEY PERSON INSURANCE.** At any time during the Term, the Company, Parent and their respective affiliates shall have the right (but not the obligation) to insure your life for the benefit of the Company, Parent and their respective affiliates. The Company, Parent or one of their respective affiliates shall have the right to determine the amount of insurance and the type of policy. You shall reasonably cooperate with the Company, Parent and their respective affiliates in obtaining such insurance by submitting to physical examinations, by supplying all information reasonably required by any insurance carrier, and by executing all necessary documents reasonably required by any insurance carrier,

provided that any information provided to an insurance company or broker shall not be provided to the Company, Parent or their respective affiliates without your prior written authorization. You shall incur no financial obligation by executing any required document and shall have no interest in any such policy.

- 13. INDEMNIFICATION.** The Company will indemnify you to the fullest extent permitted by law and the Company's Bylaws as further described in the Indemnification Agreement between you and the Company attached hereto as Exhibit C and incorporated herein by reference.

If you choose to accept this Agreement under the terms described above, please sign below and return this letter to me no later than January 31, 2020.

[Signature Page Follows]

We look forward to a productive and enjoyable work relationship.

Yours sincerely,

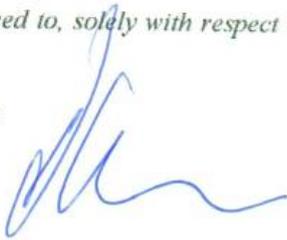
Verona Pharma Inc.



Name: Dr. David Ebsworth  
Position: Authorized Representative

*Accepted and Agreed to, solely with respect to the matters set forth herein related to Verona Pharma plc, by:*

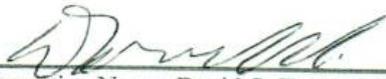
Verona Pharma plc



1. Feb 2020

Name: Dr. David Ebsworth  
Position: Chairman

*Accepted and Agreed to by:*



Executive Name: David S. Zaccardelli

Date:

30 Jan 2020

## Exhibit A

### **Remuneration**

Capitalized terms used but not defined in this Exhibit A shall have the meanings ascribed to such terms in the offer letter agreement to which this Exhibit A is attached.

#### **1. BASE SALARY.**

- (a) During the Term, you will be entitled to receive an annual aggregate base salary at a rate of \$750,000, which will be payable in two components each year, cash and restricted stock units. For the first year of the Term, your Annual Base Salary (as defined below) will consist of \$250,000 payable in cash and the issuance of restricted stock units under the Plan worth \$500,000 on the date of issue based on the Fair Market Value (as defined in the Plan) on the date of issue. For subsequent years, you and the Company will agree upon the percentages of your Annual Base Salary to be allocated to cash or restricted stock units, provided that the cash component of your Annual Base Salary shall always be a minimum of \$250,000. The cash salary will be 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 and which shall be pro-rated for partial years of employment in accordance with the Company's policy (as may be adjusted from time to time, the "Cash Base Salary").
- (b) During the Term, subject to the approval of the Board, and as soon as reasonably practicable after January 1 of each calendar year during the Term, having regard to the Parent's Share Dealing Policy, you will be granted, pursuant to, and subject to, the Plan an award of restricted stock units having a grant date value of the amount of the Annual Base Salary agreed upon to be allocated to restricted stock units for the applicable year (the "RSU Value"), which amount shall be pro-rated for any partial years of employment (each, an "Annual RSU Award"). The definitive terms of each Annual RSU Award will be governed by the Plan, which requires, as a condition of the grant, that you enter into a written restricted stock unit agreement, which will contain the definitive terms of the Annual RSU Award. Each Annual RSU Award shall vest quarterly during the calendar year in which the date of grant occurs, subject to your continued employment through each such quarter and subject to Section 3 of the Agreement. The payment of a portion of your Annual Base Salary in the form of an Annual RSU Award as described hereunder is intended to satisfy any obligations for you to maintain an investment or reinvest your annual base salary under the Remuneration Policy. Any award agreement issued to you will clearly state that Section 9.6 of the Plan shall apply to the Equity Award to which such award agreement relates.
- (c) The amounts payable under this Section 1 shall be annually reviewed from time to time by the Board beginning in January 2021 and may be increased by the Board. For purposes of the Agreement, the term "Annual Base Salary" shall mean the sum

of (i) the Cash Base Salary and (ii) the RSU Value, in each case, as may be allocated from time to time.

2. **BONUS.** During the Term, you will be eligible to participate in the Company's annual bonus plan, with a target discretionary bonus of 50% of your Annual 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, except as otherwise provided in Section 3 of the Agreement. The bonus will be pro-rated for any partial year of employment.
3. **ADDITIONAL EQUITY.**
  - (a) In addition to the Annual RSU Award, and subject to approval at the Annual General Meeting of Parent in April 2020, you will be granted during or prior to the first open trading window of Parent following the date of such Annual General Meeting, pursuant to, and subject to, the Plan an award of restricted stock units in an amount equal to 4% of the outstanding ordinary shares of the Parent (the "Equity RSU Award"), as determined as of the date of such Annual General Meeting. The definitive terms of the Equity RSU Award will be governed by the Plan, which requires, as a condition of the grant, that you enter into a written restricted stock unit agreement, which will contain the definitive terms of the Equity RSU Award. The Equity RSU Award shall vest over four years, with 25% vesting on the first anniversary of the Commencement Date and the remainder vesting quarterly over the three remaining years following the first anniversary of the Commencement Date, subject to your continued employment through the applicable vesting date and subject to Section 3 of this Agreement.
  - (b) You and the Company acknowledge and agree that, if the Company raises additional equity capital during fiscal year 2020, such financing will likely result in the dilution of the Equity RSU Award. Therefore, the Company agrees that, upon the closing of any round of financing during fiscal year 2020 (excluding any Change in Control or any financing that occurs following your termination of employment from the Company), the Company will issue to you additional awards of restricted stock units ("Additional Equity RSU Award," and, together with the Equity RSU Award, the "Combined Equity RSU Awards") during or prior to the first open trading window of Parent following such closing, so that after each such issuance, all of the Combined Equity RSU Awards, plus any other equity awards granted to you from the Plan (specifically excluding any and all Annual RSU Awards), will equal 4% of the outstanding ordinary shares of the Parent on the applicable date of issuance. All Additional Equity RSU Awards will have the same vesting schedule as the Equity RSU Award including the commencement date of the vesting.
  - (c) Notwithstanding the foregoing, the Board may settle a portion of any Combined Equity RSU Award and any Annual RSU Award in cash as necessary to satisfy tax withholding requirements. Any award agreement issued to you will clearly state

that Section 9.6 of the Plan shall apply to the Equity Award to which such award agreement relates. Furthermore, in the event that the Administrator (as defined in the Plan) takes any action with respect to any Equity Award pursuant to Section 8.2 of the Plan, other than pursuant to Section 8.2(c) of the Plan, the unvested portion of the Equity Award will become immediately vested upon the applicable Corporate Event (as defined in the Plan).

4. **STOCK OPTIONS.** You shall be entitled to participate in the Plan with such awards as the Board of Directors recommends.
5. **BENEFITS.** During the Term, you will be entitled to participate in the 401(k) plan and healthcare plan generally available from time to time to executives of the Company, subject to the terms of such plans. 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 you may carry over only five days of accrued but unused time into the first quarter of the subsequent year. Such time off shall be taken at the reasonable and mutual convenience of you and the Company. You will be paid for all accrued and unused paid time off upon termination of employment.
6. **EXPENSES.** During the Term, 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, Parent and their respective affiliates, provided that you produce to the Company such evidence of actual payment as the Company may require.

Exhibit B

**Confidential Information and Inventions Assignment Agreement**

(attached)

**EXECUTIVE CONFIDENTIAL INFORMATION AND INVENTIONS  
ASSIGNMENT AGREEMENT**

THIS EXECUTIVE CONFIDENTIAL INFORMATION AND INVENTIONS ASSIGNMENT AGREEMENT is made and entered into as of the 1 day of Feb., 2020, by and between David S. Zaccardelli and Verona Pharma plc and each of its subsidiaries, affiliates, successors or assigns (collectively, Verona Pharma plc and each of its subsidiaries, affiliates, successors and assigns shall be referred to herein as the "**Company**").

1. I acknowledge and agree that solely by virtue of my employment with Verona Pharma Inc., a wholly-owned subsidiary of the Company, I will acquire "**Confidential Information**," as well as special knowledge of the Company's relationships with its customers, prospective customers and suppliers, and that, but for my association with the Company, I will not have had access to the Confidential Information or knowledge of the relationships. As a condition precedent to the Company employing me, and as consideration for my employment, I represent and warrant as follows:
  - A. I have voluntarily signed this Agreement after determining that the provisions contained in this Agreement are of a material benefit to me, and that the duties and obligations imposed on me are fair and reasonable and will not prevent me from earning a comparable livelihood following the termination of my employment with the Company.
  - B. I have read and fully understand the terms of this Agreement and have considered its benefits and consequences. I also have informed the Company of, and provided the Company with copies of, any non-competition, confidentiality, work-for-hire or similar agreements to which I am subject or may be bound.
  - C. I agree that, during the time of my employment with the Company and for a period of one (1) year after the termination of my employment, whether voluntary or involuntary, I will not, directly or indirectly, except on behalf of the Company:
    - (1) contact, solicit or accept if offered to me, or direct any person or entity to contact, solicit or accept if offered to it, any of the Company's customers or prospective customers for the purpose of providing any products and/or services that are the same as or similar to the products and services provided by the Company to its customers during the term of my employment or for the purpose of otherwise interfering with the business relationships between the Company and its customers or prospective customers;

- (2) solicit, divert or take away any customers, clients, or business acquisition or other business opportunity of the Company;
- (3) induce any distributor, supplier, representative or agent of the Company to terminate or modify its relationship with the Company; or
- (4) solicit or accept if offered to me, with or without solicitation, on my own behalf or on behalf of any other person or entity, the services of any person who is a current employee or independent contractor of the Company (or was an employee or independent contractor of the Company during the year preceding such solicitation), nor solicit any of the Company's current employees or independent contractors (or any individual who was an employee or independent contractor of the Company during the year preceding such solicitation) to terminate employment or an engagement with the Company, nor agree to hire any current employee or independent contractor (or any individual who was an employee or independent contractor of the Company during the year preceding such hire) of the Company into employment or an engagement with me or any other person or entity; or
- (5) become, directly or indirectly, associated or engaged with any business, whether as an investor (excluding passive investments representing less than one percent (1%) of the common stock of a public company), lender, owner, stockholder, member, manager, officer, director, employee, consultant, agent or in any other capacity, involved in the development and/or marketing of medicines to treat respiratory diseases or any other business that may be carried on by the Company from time to time (as such business may be expanded from time to time), including any business that the Company has taken substantial steps to enter into as of applicable date.

D. I acknowledge and agree that the scope described above is necessary and reasonable in order to protect the Company in the conduct of its business and that, if I become employed by another employer, I will be required to disclose the existence of this Paragraph 1 to such employer and I consent to and the Company is given permission to disclose the existence of this Paragraph 1 to such employer. I further acknowledge and agree that, if I breach any of the requirements of subparagraph C, the one (1) year restricted period set forth therein shall be tolled during the time of such breach.

- E. For purposes of this Paragraph 1: (i) "**customer**" is defined as any person or entity that purchased any type of product and/or service from the Company (including as a licensee) or is or was doing business with the Company or me within the twelve (12) month period immediately preceding the solicitation or other activity prohibited by subparagraph C; (ii) "**prospective customer**" is defined as any person or entity contacted or solicited by the Company or me (whether directly or indirectly) or who contacted the Company or me (whether directly or indirectly) within the twelve (12) month period immediately preceding the solicitation or other activity prohibited by subparagraph C for the purpose of having such persons or entities become a customer of the Company (including as a licensee); and (iii) "**supplier**" is defined as any person or entity who is or was supplying products or services to the Company (including as a licensor) within the twelve (12) month period immediately preceding the activity prohibited by subparagraph C.
- F. I agree that both during my employment and thereafter I will not use for myself or disclose to any person not employed by the Company any "Confidential Information" of the Company acquired by me during my relationship with the Company, except where such disclosure is consented to, or approved by, the Company. I agree that "**Confidential Information**" includes but is not limited to:
- (1) the Company's corporate, business development and marketing strategy and plans;
  - (2) budgets, management accounts, bank account details and other confidential financial data of the Company;
  - (3) know-how and products being developed by the Company, including inventions and discoveries, biological and chemical formulations, research and development methods and processes, scientific techniques and formulas and results of experimentation and testing including, without limitation, clinical, biological, pharmaceutical, toxicological and pre-clinical and clinical test data;
  - (4) reports, confidential aspects of the Company's computer technology and systems, confidential algorithms developed or used by the Company, confidential information relating to proprietary computer hardware or software (including updates) not generally known to the public;
  - (5) confidential methods and processes, information relating to the running of the Company's business which is not in the

public domain, including details of salaries, bonuses, commissions and other employment terms applicable within the Company;

- (6) the names, addresses and contact details of any existing or prospective customers, suppliers or business partners of the Company and their requirements for any of the Company's products or services. Without prejudice to the foregoing, this includes personal information provided to the Company by visitors to and users of any of its websites;
- (7) the terms on which the Company does business with any existing or prospective customers, suppliers or business partners of the Company and the terms of any partnership, joint venture or other form of commercial co-operation or agreement the Company enters into with any third party;
- (8) software and technical information necessary for the development, maintenance or operation of any of the Company's websites and the source code of each website;
- (9) any other information which the Company is bound by an obligation of confidence owed to a third party, in particular the content of discussions or communications with any prospective customers, suppliers or business partners; and
- (10) any other information, written, oral or electronic, whether existing now or at some time in the future, which pertains to the Company's affairs or interests or with whom the Company does business.

The Company acknowledges and agrees that Confidential Information does not include (a) information properly in the public domain, or (b) information in my possession prior to the date of my original employment with the Company, except to the extent that such information is or has become a trade secret of the Company or is or otherwise has become the property of the Company.

- G. I shall not, except in the proper performance of my duties, or with the Company's permission, remove any property belonging or relating to the Company from the Company's premises, or make any copies of documents or records relating to the Company's affairs. Upon the Company's request at any time, and in any event on the termination of my employment, I shall immediately deliver up to the Company or its authorized representative any plans, keys, mobile telephone, security passes, credit cards, equipment, documents, records, papers, computer disks, tapes or other computer hardware or software (together with all copies of the same), and all property

of whatever nature in my possession or control which belongs to the Company or relates to its affairs. I shall, at the Company's request, provide the Company with a written statement that I have complied with this obligation. If I have any information relating to the Company or work I have carried out for the Company which is stored on a computer or laptop computer, whether or not the computer is owned by the Company, the Company shall be entitled to download the information and/or supervise its deletion from the computer or laptop concerned.

- H. I recognize and agree that all ideas, know how, confidential information, inventions, discoveries, biological and chemical formulations, research and development methods and processes, scientific techniques and formulas and results of experimentation and testing including, without limitation, clinical, biological, pharmaceutical, toxicological and pre-clinical and clinical test data, products, patents, designs, trademarks, database right or copyright work or any right to prevent reproduction whether or not any of these is registered and including applications for any such right, matter or thing or registration thereof and all rights or forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world, and all trade secrets, business applications, plans, writings and other developments or improvements and all other intellectual property and proprietary rights and any derivative works based thereon (the "**Inventions**") made, conceived, or completed by me, alone or with others, during the time of my employment, whether or not during working hours, that are within the scope of the Company's business operations, or that relate to any of the Company's work or projects, are the sole and exclusive property of the Company. I further agree that (1) I will promptly disclose all Inventions to the Company and hereby assign to the Company all present and future rights I have or may have in those Inventions; and (2) all of the Inventions eligible under the copyright laws are "work made for hire." At the request of and without charge to the Company, I will do all things deemed by the Company to be reasonably necessary to perfect title to the Inventions in the Company and to assist in obtaining for the Company such patents, copyrights or other protection as may be provided under law and desired by the Company, including but not limited to executing and signing any and all relevant applications, assignments, or other instruments. I hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as my agents and attorneys in fact to act for and in my behalf and instead of me, to execute and file any documents and to do all other lawfully permitted acts to further the above purposes with the same legal force and effect as if executed by me, and I acknowledge that this designation and appointment constitutes an irrevocable power

of attorney and is coupled with an interest. I agree and acknowledge that all original works of authorship (“**Works**”) that have been or are, during the term of my employment, made by me within the scope of my employment or made previously in association with the Company or in connection with the creation or development of any of the Company’s products, marketing materials, designs, logos or other content shall be deemed to be “works made for hire” pursuant to the United States Copyright Act and all right, title and interest in and to such works are and shall be owned by the Company. In the event any such Works are not deemed to be works made for hire, I hereby irrevocably assign to the Company all my right, title and interest in and to such Works. I also waive any “moral rights” I may have in such Works, including any right to object to or prevent the modification of the Work or to withdraw from circulation or control the publication or distribution of the Work. Notwithstanding the foregoing, I acknowledge that, the Company has informed me that the provisions of this Paragraph H will not apply to any Inventions for which no equipment, supplies, facility or trade secret information of the Company was used and which were developed entirely on my own time, unless (1) the Invention relates (i) to the business of the Company, or (ii) to actual or demonstrably anticipated research or development of the Company, or (2) the Invention results from any work performed by me for the Company.

- I. I acknowledge and agree that I have no expectation of privacy with respect to the Company’s telecommunications, networking or information processing systems (including, without limitation, stored computer files (whether on a Company computer or a home personal computer), email messages and voice messages) and that my activity and any files or messages on or using any of those systems may be monitored at any time without notice.
- J. It is agreed that any breach of any of the covenants contained in this Paragraph I will result in irreparable harm and continuing damages to the Company and its business and that the Company’s remedy at law for any such breach will be inadequate and, accordingly, in addition to any and all other remedies that may be available to the Company, any court of competent jurisdiction may issue a decree of specific performance or issue a temporary and permanent injunction, without the necessity of the Company posting bond or furnishing other security and without proving special damages or irreparable injury, enjoining and restricting the breach of any such covenant. I agree to pay all of the Company’s costs and expenses, including reasonable attorneys’ and accountants’ fees, incurred in enforcing such covenants.

- K. I agree, during the term of my employment and following the termination of employment, to refrain from Disparaging (as defined below) the Company and its affiliates, including any of its services, technologies or practices, or any of its directors, officers, agents, representatives or equityholders, either orally or in writing. Nothing in this paragraph shall preclude me from making truthful statements that are reasonably necessary to comply with applicable law, regulation or legal process, or to defend or enforce my rights under this Agreement. For purposes of this Agreement, "Disparaging" means making remarks, comments or statements, whether written or oral, that impugn the character, integrity, reputation or abilities of the Person being disparaged.
2. Nothing contained in this Agreement creates any right of employment or limits or restricts the Company's or my right to terminate my employment at any time with or without cause.
  3. I hereby authorize the Company, at any time during my employment or following my termination, to withhold from any monies it otherwise owes me (including without limitation salary, bonus, commissions and expense reimbursements) any and all monies due from me to the Company (including without limitation cash and travel advances, overpayments made to me by the Company, and any debt I owe the Company for any reason, including without limitation misuse or misappropriation of Company assets). At the termination of my employment with the Company or at any other time upon reasonable notice, I agree to execute whatever documentation may be necessary to authorize the Company to make the withholdings described in this paragraph.
  4. I may respond to a lawful and valid subpoena or other legal process but shall give the Company the earliest possible notice thereof, and shall, as much in advance of the return date as possible, make available to the Company and its counsel the documents and other information sought and shall assist such counsel at Company's expense in resisting or otherwise responding to such process, in each case to the extent permitted by applicable laws or rules. Nothing in this Agreement shall prohibit me from (i) disclosing information and documents when required by law, subpoena or court order (subject to the requirements of this Section), (ii) disclosing information and documents to my attorney or financial or tax adviser for the purpose of securing legal, financial or tax advice, (iii) reporting possible violations of federal law or regulation to any United States governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation (including the right to receive an award for information provided to any such government agencies), (iv) disclosing my post-employment restrictions in this Agreement in confidence to any potential

new employer, or (v) retaining, at any time, my personal correspondence, my personal contacts and documents related to my own personal benefits, entitlements and obligations. Furthermore, in accordance with 18 U.S.C. § 1833, the Company hereby notifies me that, notwithstanding anything to the contrary herein: (a) I shall not be in breach of this Agreement, and shall not be held criminally or civilly liable under any federal or state trade secret law (i) for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (ii) for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal and (b) if I file a lawsuit for retaliation by the Company for reporting a suspected violation of law, I may disclose the trade secret to my attorney, and may use the trade secret information in the court proceeding, if I file any document containing the trade secret under seal, and does not disclose the trade secret, except pursuant to court order.

5. It is our intention that all provisions of this Agreement be enforced to the fullest extent permitted by law. If any provision of this Agreement shall be found invalid or unenforceable for any reason, in whole or in part, then such provision shall be deemed modified, restricted, or reformulated to the extent and in the manner necessary to render the same valid and enforceable, or shall be deemed excised from this Agreement, as the case may require, and this Agreement shall be construed and enforced to the maximum extent permitted by law, as if such provision had been originally incorporated herein as so modified, restricted, or reformulated or as if such provision had not been originally incorporated herein, as the case may be. The Company and I further agree to seek a lawful substitute for any provision found to be unlawful; provided, that, if we are unable to agree upon a lawful substitute, the Company and I desire and request that a court or other authority called upon to decide the enforceability of this Agreement modify those restrictions in this Agreement that, once modified, will result in an agreement that is enforceable to the maximum extent permitted by the law in existence at the time of the requested enforcement. This Agreement contains the entire understanding and agreement between us with respect to this subject matter, and supersedes all prior oral and written agreements, if any, between us with respect to that subject matter. I understand and acknowledge that the Company's rights under this Agreement shall inure to the benefit of any of its successors and/or assigns, and I shall continue to be bound by the terms hereof with any of the Company's successors and/or assigns.
6. I understand that the Company does not wish to incorporate any unlicensed or unauthorized material into its products or services or those of its subsidiaries. Therefore, I agree that I will not knowingly disclose to the Company, use in the Company's business, or cause the Company to use, any information or material which is confidential or proprietary to any third

party including, but not limited to, any former employer, competitor or client, unless the Company has a right to receive and use such information. I will not incorporate into my work any material that is subject to the copyrights of any third party unless the Company has a written agreement with that third party or otherwise has the right to receive and use such information.

7. This Agreement will be governed and construed in accordance with the laws of the State of North Carolina, including the internal conflicts of law. I agree and consent to submit to personal jurisdiction in the State of North Carolina in any state or federal court of competent subject matter jurisdiction situated in the State of North Carolina. **I further agree to waive any right I otherwise may have to a trial by jury in any action to enforce the terms of this Agreement.**

We have executed this Agreement on the day and year first above written.

Verona Pharma plc

By:   
Name: Dr. David Ebsworth  
Title: Chairman

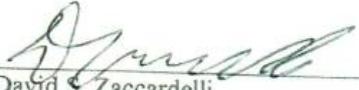
  
David S. Zaccardelli

Exhibit C

**Indemnification Agreement**

(attached)

## DIRECTOR DEED OF INDEMNITY

THIS DEED OF INDEMNITY is made the 1 day of February 2020.

### BETWEEN:

- (1) Verona Pharma plc, a public limited company registered in England and Wales with company number 05375156 whose registered office is at One Central Square, Cardiff, United Kingdom, CF10 1FS (the “**Company**”); and
- (2) David S. Zaccardelli of 100 Ogden Street, Sarasota, FL 34242 (the “**Indemnified Person**”).

### WHEREAS

- (A) The Indemnified Person is a director of the Company.
- (B) The Company has agreed to indemnify the Indemnified Person on the terms and conditions set out in this Deed.
- (C) The Company has further agreed to maintain appropriate directors’ and officers’ liability insurance for the benefit of the Indemnified Person.

**NOW THIS DEED WITNESSETH** as follows:

### 1. INDEMNITY

- 1.1. Subject to Clauses 1.2 and 6.1 of this Deed, the Company shall, to the fullest extent permitted by law and without prejudice to any other indemnity to which the Indemnified Person may otherwise be entitled, indemnify and hold the Indemnified Person harmless in respect of all claims, actions and proceedings, whether civil, criminal or regulatory (“**Claims**”), and any losses, damages, penalties, liabilities, compensation or other awards arising in connection with any such Claims (“**Losses**”), whether instigated, imposed or incurred under the laws of England and Wales or the law of any other jurisdiction and arising out of, or in connection with, the actual or purported exercise of, or failure to exercise, any of the Indemnified Person’s powers, duties or responsibilities as a director or officer of the Company or any of its subsidiaries (as defined in section 1159 of the Companies Act 2006, as amended (the “**Companies Act**”)) and including any modification or re-enactment of it for the time being in force) for the time being, subject to the remaining provisions of this Deed.
- 1.2. The indemnity in Clause 1.1 above shall be deemed not to provide for, or entitle the Indemnified Person to, any indemnification that would cause this Deed, or any part of it, to be treated as void under the Companies Act and, in particular, except as provided in Clause 1.3 of this Deed, shall not provide directly or indirectly (to any extent) any indemnity against:

- (a) any liability incurred by the Indemnified Person to the Company or any associated company (as defined in section 256 of the Companies Act) (“**Associated Company**”); or
- (b) any liability incurred by the Indemnified Person to pay a fine imposed in criminal proceedings or a sum payable to a regulatory authority by way of a penalty in respect of non-compliance by the Indemnified Person with any requirement of a regulatory nature (however arising); or
- (c) any liability incurred by the Indemnified Person:
  - (i) in defending any criminal proceedings in which such Indemnified Person is convicted;
  - (ii) in defending any civil proceedings brought by the Company, or an Associated Company, in which judgment is given against such Indemnified Person; or
  - (iii) in connection with any application under section 661(3) or (4) or section 1157 of the Companies Act in which the court refuses to grant him relief,

where, in any such case, any such conviction, judgment or refusal of relief has become final. Reference in this Clause 1.2 to a conviction, judgment or refusal of relief being “final” shall be construed in accordance with sections 234(4) and (5) of the Companies Act.

**1.3.** Without prejudice to the generality of the indemnity set out in Clause 1.1 above, the Company shall, to the fullest extent permitted by law, indemnify and hold the Indemnified Person harmless on an “as incurred” basis against all legal and other costs, charges and expenses reasonably incurred or to be incurred:

- (a) in defending Claims including, without limitation, Claims brought by, or at the request of, the Company or any Associated Company and any investigation into the affairs of the Company or any Associated Company by any judicial, governmental, regulatory or other body; or
- (b) in connection with any application under section 661(3) or (4) or section 1157 of the Companies Act,

provided that, in accordance with section 205 of the Companies Act, the Indemnified Person agrees that any such legal and other costs, charges and expenses paid by the Company shall fall to be repaid, or any liability of the Company under any transaction connected thereto shall fall to be discharged, not later than:

- (c) in the event of the Indemnified Person being convicted in the proceedings, the date when the conviction becomes final;
- (d) in the event of judgment being given against the Indemnified Person in the proceedings, the date when the judgment becomes final; or

- (e) in the event of the court refusing to grant the Indemnified Person relief on the application, the date when the refusal of relief becomes final.

References in this Clause 1.3 to a conviction, judgment or refusal of relief being 'final' shall be construed in accordance with sections 205(3) and (4) of the Companies Act.

## **2. CLAIMING UNDER THE INDEMNITY**

**2.1.** The Indemnified Person shall give written notice to the Company as soon as reasonably practical after receipt of any demand relating to any Claims (or becoming aware of circumstances which are reasonably be expected to give rise to a demand relating to Claims) giving full details and providing copies of all relevant correspondence and the Indemnified Person shall keep the Company fully informed of the progress of any Claims, including providing all such information in relation to any Claims or Losses or any other costs, charges or expenses incurred as the Company may reasonably request, and shall take all such action as the Company may reasonably request to avoid, dispute, resist, appeal, compromise or defend any Claims.

**2.2.** For the avoidance of doubt:

- (a) if a company ceases to be a subsidiary of the Company after the date of this Deed, the Company shall only be liable to indemnify the Indemnified Person in respect of liabilities in relation to that company which arose before the date on which that company ceased to be a subsidiary of the Company; and
- (b) the Indemnified Person, as director or manager of any company which becomes a subsidiary of the Company after the date of this Deed, shall be indemnified only in respect of liabilities arising after the date on which that company became a subsidiary of the Company.

## **3. TERM**

This Deed shall remain in force until such time as any relevant limitation periods for bringing Claims against the Indemnified Person have expired, or for so long as the Indemnified Person remains liable for any Losses, notwithstanding that such Indemnified Person may have ceased to be a director or officer of the Company or any of its subsidiaries.

## **4. DIRECTORS' AND OFFICERS' INSURANCE**

The Company shall provide and maintain appropriate "directors and officers" liability insurance (including ensuring that premiums are properly paid) for the benefit of the Indemnified Person for so long as any Claims may lawfully be brought against the Indemnified Person.

## **5. GOVERNING LAW AND JURISDICTION**

This Deed and any non-contractual rights or obligations arising out of or in connection with it shall be governed by, and interpreted in accordance with, the laws of England and Wales. Each of the Company and the Indemnified Person irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any Disputes (as defined below) and waive any objection to proceedings before such courts on the grounds of venue

or on the grounds that such proceedings have been brought in an inappropriate forum. For the purposes of this Clause 5, "Dispute" means any dispute, controversy, claim or difference of whatever nature arising out of, relating to, or having any connection with this Deed, including a dispute regarding the existence, formation, validity, interpretation, performance or termination of this Deed or the consequences of its nullity and also including any dispute relating to any non-contractual rights or obligations arising out of, relating to, or having any connection with this Deed.

**6. GENERAL**

- 6.1. If this Deed is finally judicially determined in a relevant jurisdiction to provide for, or entitle the Indemnified Person to, indemnification against any Claims or Losses that would cause this Deed, or any part of it, to be treated as void under the laws of that jurisdiction, this Deed shall, in so far as it relates to such jurisdiction, be deemed not to provide for, or entitle the Indemnified Person to, any such indemnification, and the Company shall instead indemnify the Indemnified Person against any Claims or Losses to the fullest extent permitted by law in that jurisdiction.
- 6.2. A person who is not a party to this Deed shall have no right under the Contracts (Rights of Third Parties) Act 1999 to enforce any of its terms.

IN WITNESS whereof this Deed has been executed the day and year first above written.

EXECUTED and delivered )  
as a DEED by )  
VERONA PHARMA PLC )  
acting by )  
a director, in the presence of: ) Director *Dr. David Gibson*

*SG* ..... Signature of Witness  
*SHELLEY GEORGE* ..... Name of Witness  
*3 MORE LONDON* ..... Address of Witness  
*RIVERSIDE, LONDON SE1 2RE*  
*EXECUTIVE ASSISTANT* Occupation of Witness

**SIGNED as a DEED by**  
David S. Zaccardelli  
in the presence of:

)  
)  
)



Maire Weaver

Signature of Witness

Diane Weaver

Name of Witness

100 Ogden Street

Address of Witness

Sarasota, FL 34242

Account Manager

Occupation of Witness





THIS AGREEMENT HAS BEEN UPDATED PLEASE CLICK THE LINK BELOW TO VIEW THE MOST RECENT VERSION.

[> View Agreement](#)

Agreement Date : 16 September 2019      Confirmation No : R-802100

Business Centre Details		Client Details	
LONDON, London Bridge - More London		Company Name	VERONA PHARMA PLC
Sales Manager	Ronnie Portsmouth	Phone	+44 20 3283 4000
		Email	Piers.morgan@veronapharma.com

Office Payment Details (exc.VAT and exc. services)		
Office Number	Number of people	Price per Office
143	4	£ 6,350.00
139	4	£ 2,505.00

Service Provision :	Start Date	End Date
	1 February 2020	28 February 2022

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](#)

These General Terms and Conditions apply to Office/Co-Working, Virtual Office and Membership agreements for services We supply to You.

## 1. General Agreement

- 1.1. Nature of an agreement: At all times, each Centre remains in Our possession and control. YOU ACCEPT THAT AN AGREEMENT CREATES NO TENANCY INTEREST, LEASEHOLD ESTATE OR OTHER REAL PROPERTY INTEREST IN YOUR FAVOUR WITH RESPECT TO THE ACCOMMODATION. Occupation by You is the commercial equivalent of an agreement for accommodation in a hotel. We are giving You the right to share the use of the Centre with Us and other clients.
- 1.2. House Rules: The House Rules, which are incorporated into these terms and conditions, are primarily in place and enforced to ensure that all clients have a professional environment to work in.
- 1.3. Availability at the start of an agreement: If for any unfortunate reason We cannot provide the services or accommodation in the Centre stated in an agreement by the start date, We will have no liability to You for any loss or damage but You may either move to one of Our other Centres (subject to availability), delay the start of the agreement or cancel it.
- 1.4. AUTOMATIC RENEWAL: SO THAT WE CAN MANAGE YOUR SERVICES EFFECTIVELY AND TO ENSURE SEAMLESS CONTINUITY OF THOSE SERVICES, ALL AGREEMENTS WILL RENEW AUTOMATICALLY FOR SUCCESSIVE PERIODS EQUAL TO THE CURRENT TERM UNTIL BROUGHT TO AN END BY YOU OR US. 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. IF YOU DO NOT WISH FOR AN AGREEMENT TO RENEW THEN YOU CAN CANCEL IT EASILY WITH EFFECT FROM THE END DATE STATED IN THE AGREEMENT, OR AT THE END OF ANY EXTENSION OR RENEWAL PERIOD, BY GIVING US PRIOR NOTICE. NOTICE MUST BE GIVEN THROUGH YOUR ONLINE ACCOUNT OR THROUGH THE APP. THE NOTICE PERIODS REQUIRED ARE AS FOLLOWS

<u>Term</u>	<u>Notice Period</u>
Month-to-Month	no less than 1 month's notice from the 1 <sup>st</sup> day of any calendar month
3 months	no less than 2 months' notice prior to the end of the term
More than 3 months	no less than 3 months' notice prior to the end of the term

- 1.5. We may elect not to renew an agreement. If so, We will inform You by email, through the App or Your online account, following the same notice periods specified above.
  - 1.6. If the Centre is no longer available: In the event that We are permanently unable to provide the services and accommodation at the Centre stated in an agreement, We will offer You accommodation in one of Our other centres. In the unlikely event we unable to find an alternative accommodation that is acceptable to You, Your agreement will end and You will only have to pay monthly fees up to that date and for any additional services You have used.
  - 1.7. Ending an agreement immediately: We may put an end to an agreement immediately by giving You notice if (a) You become insolvent or bankrupt; or (b) You breach one of your obligations which cannot be put right, or which We have given You notice to put right and which You have failed to put right within 14 days of that notice; or (c) Your conduct, or that of someone at the Centre with Your permission or invitation, is incompatible with ordinary office use and, (i) that conduct continues despite You having been given notice, or (ii) that conduct is material enough (in Our reasonable opinion) to warrant immediate termination; or (d) You are in breach of the "Compliance With Law" clause below. If We put an end to an agreement for any of the reasons referred to in this clause it does not put an end to any of Your financial obligations, including, without limitation, for the remainder of the period for which Your agreement would have lasted if We had not terminated it.
  - 1.8. When an Office agreement ends: When an agreement ends You must vacate Your accommodation immediately, leaving it in the same state and condition as it was when You took it. Upon Your departure or if You choose to relocate to a different room within a Centre, We will charge a fixed office restoration service fee to cover normal cleaning and any costs incurred to return the accommodation to its original condition and state. This fee will differ by country and is listed in the House Rules. We reserve the right to charge additional reasonable fees for any repairs needed above and beyond normal wear and tear. If You leave any property in the Centre We may dispose of it at Your cost in any way, We choose without owing You any responsibility for it or any proceeds of sale. If You continue to use the accommodation when an agreement has ended, You are responsible for any loss, claim or liability We may incur as a result of Your failure to vacate on time.
-

## 2. Use of the Centres:

- 2.1. **Business Operations:** You may not carry on a business that competes with Our business of providing serviced offices and flexible working. You may not use Our name (or that of Our affiliates) in any way in connection with Your business. You are only permitted to use the address of a Centre as Your registered office address if it is permitted by both law and if We have given You prior written consent (given the additional administration there is an additional fee chargeable for this service). You must only use the accommodation for office business purposes. If We decide that a request for any particular service is excessive, We reserve the right to charge an additional fee. In order to ensure that the Centre provides a great working environment for all, We kindly ask you to limit any excessive visits by members of the public.
  - 2.2. **Accommodation**
    - 2.2.1. **Alterations or Damage:** You are liable for any damage caused by You or those in the Centre with Your permission, whether express or implied, including but not limited to all employees, contractors and/or agents.
    - 2.2.2. **IT Installations:** We take great pride in Our IT infrastructure and its upkeep and therefore You must not install any cabling, IT or telecom connections without Our consent, which We may refuse in our absolute discretion. As a condition to Our consent, You must permit Us 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 by other clients or Us or any landlord of the building. Fees for installation and de-installation will be at Your cost.
    - 2.2.3. **Use of the Accommodation:** An agreement will list the accommodation We initially allocate for Your use. You will have a non-exclusive right to the rooms allocated to You. Occasionally to ensure the efficient running of the Centre, We may need to allocate different accommodation to You, but it will be of reasonably equivalent size and We will notify You with respect to such different accommodation in advance.
    - 2.2.4. **Access to the Accommodation:** In order to maintain a high level of service, We may need to enter Your accommodation and may do so at any time, including without limitation, in an emergency, for cleaning and inspection or in order to re-sell the space if You have given notice to terminate. We will always endeavour to respect any of Your reasonable security procedures to protect the confidentiality of Your business.
  - 2.3. **Membership:**
    - 2.3.1. If You have subscribed to a Membership Agreement You will have access to all participating centres worldwide during standard business working hours and subject to availability.
    - 2.3.2. **Membership Usage:** Usage is measured in whole days and unused days cannot be carried over to the following month. A membership is not intended to be a replacement for a full-time workspace and all workspaces must be cleared at the end of each day. You are solely responsible for Your belongings at the centre at all times. We are not responsible for any property that is left unattended. Should You use more than Your membership entitlement, We will charge You an additional usage fee. You may bring in 1 guest free of charge (subject to fair usage). Any further guests will be required to purchase a day pass.
    - 2.3.3. As a Member, You may not use any Centre as Your business address without an accompanying office or virtual office agreement in place. Any use of the Centre address in such a way will result in an automatic enrolment in the Virtual Office product for the same term as Your membership and You will be invoiced accordingly.
  - 2.4. **Compliance with Law:** You must comply with all relevant laws and regulations in the conduct of Your business. You must not do anything that may interfere with the use of the Centre by Us or by others (including but not limited to political campaigning or immoral activity), cause any nuisance or annoyance, or cause loss or damage to Us (including damage to reputation) or to the owner of any interest in the building. If We have been advised by any government authority or other legislative body that it has reasonable suspicion that You are conducting criminal activities from the Centre, or You are or become subject to any government sanctions, then We shall be entitled to terminate any and all of Your agreements with immediate effect. You acknowledge that any breach by You of this clause shall constitute a material default, entitling Us to terminate Your agreement without further notice.
  - 2.5. **Ethical Trading:** Both We and You shall comply at all times with all relevant anti-slavery, anti-bribery and anti-corruption laws.
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- 2.6. Data protection: You acknowledge that We may collect and process personal data from You and Your employees as strictly necessary to ensure compliance with applicable laws and regulations and to enable Us effectively to provide services to You. You acknowledge and accept that such personal data may be transferred or made accessible to other entities in our group, wherever located, for the purposes of providing the services, in each case in accordance with all applicable data protection legislation.
  - 2.7. Employees: We will both have invested a great deal in training Our staff, therefore, neither of us may knowingly solicit or offer employment to the other's staff employed in the Centre (or for 3 months after they have left their employment). To recompense the other for staff training and investment costs, if either of us breaches this clause the breaching party will pay upon demand the other the equivalent of 6 months' salary of any employee concerned.
  - 2.8. Confidentiality: The terms of an agreement are confidential. Neither of us may 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 an agreement ends.
  - 2.9. Assignment: An agreement is personal to You and cannot be transferred to anyone else without prior consent from Us unless such transfer is required by law. However, We will not unreasonably withhold our consent to assignment to an affiliate provided that You execute our standard form of assignment. We may transfer any agreement and any and all amounts payable by You under an agreement to any other member of Our group.
  - 2.10. Applicable law: An agreement is interpreted and enforced in accordance with the law of the place where the Centre is located other than in a few specific jurisdictions which are detailed in the House Rules. We and You both accept the exclusive jurisdiction of the courts of that jurisdiction. If any provision of these terms and conditions is held void or unenforceable under the applicable law, the other provisions shall remain in force.
3. Our liability to You and Insurance
- 3.1. The extent of Our liability: To the maximum extent permitted by applicable law, We are not liable to You in respect of any loss or damage You suffer in connection with an agreement, including without limitation any loss or damage arising as a result of our failure to provide a service as a result of mechanical breakdown, strike or other event outside of Our reasonable control otherwise unless We have acted deliberately or have been negligent. In no event shall We be liable for any loss or damage until You provide written notice and give Us a reasonable time to put it right. If We are liable for failing to provide You with any service under an agreement then, subject to the exclusions and limits set out immediately below, We will pay any actual and the reasonable additional expense You have incurred in obtaining the same or similar service from elsewhere.
  - 3.2. Your Insurance: It is Your responsibility to arrange insurance for property which You bring in to the Centre, for any post You send or receive and for Your own liability to your employees and to third parties. We strongly recommend that You put such insurance in place.
  - 3.3. IT Services and Obligations: Whilst We have security internet protocols in place and strive to provide seamless internet connectivity, WE DO NOT MAKE ANY REPRESENTATION AND CANNOT GUARANTEE ANY MAINTAINED LEVEL OF CONNECTIVITY TO OUR NETWORK OR TO THE INTERNET, NOR THE LEVEL OF SECURITY OF IT INFORMATION AND DATA THAT YOU PLACE ON IT. You should adopt whatever security measures (such as encryption) You believe are appropriate to Your business. Your sole and exclusive remedy in relation to issues of reduced connectivity which are within Our reasonable control shall be for Us to rectify the issue within a reasonable time following notice from You to Us.
  - 3.4. EXCLUSION OF CONSEQUENTIAL LOSSES: WE WILL NOT IN ANY CIRCUMSTANCES HAVE ANY LIABILITY TO YOU FOR LOSS OF BUSINESS, LOSS OF PROFITS, LOSS OF ANTICIPATED SAVINGS, LOSS OF OR DAMAGE TO DATA, THIRD PARTY CLAIMS OR ANY CONSEQUENTIAL LOSS. WE STRONGLY RECOMMEND THAT YOU INSURE AGAINST ALL SUCH POTENTIAL LOSS, DAMAGE, EXPENSE OR LIABILITY.
  - 3.5. Financial limits to our liability: In all cases, our liability to You is subject to the following limits:
    - 3.5.1. without limit for personal injury or death;
    - 3.5.2. up to a maximum of GBP 1 million (or USD 1.5 million or EUR 1 million or other local equivalent) for any one event or series of connected events for damage to Your personal property; and
    - 3.5.3. in respect of any other loss or damage, up to a maximum equal to 125% of the total fees paid between the date services under an agreement commenced and the date on which the claim in question arises; or if higher, for office agreements only, GBP 50,000 / USD 100,000 / EUR 66,000 (or local equivalent).
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#### 4. Fees

- 4.1. **Service Retainer/Deposit:** Your service retainer / deposit will be held by Us without generating interest as security for performance of all Your obligations under an agreement. All requests for the return must be made through Your online account or App after which the service retainer/deposit or any balance will be returned within 30 days to You once your agreement has ended and when You have settled Your account. We will deduct any outstanding fees and other costs due to Us before returning the balance to You. We may require You to pay an increased retainer if the monthly office or virtual office fee increases upon renewal, outstanding fees exceed the service retainer/deposit held and/or You frequently fail to pay invoices when due.
- 4.2. **Taxes and duty charges:** You agree to pay promptly (i) all sales, use, excise, consumption and any other taxes and license fees which You are required to pay to any governmental authority (and, at Our request, You will provide to Us evidence of such payment) and (ii) any taxes paid by Us to any governmental authority that are attributable to Your accommodation, where applicable, including, without limitation, any gross receipts, rent and occupancy taxes, tangible personal property taxes, stamp tax/duty or other documentary taxes and fees.
- 4.3. **Payment:** We are continually striving to reduce our environmental impact and support You in doing the same. Therefore, We will send all invoices electronically and You will make payments via an automated method such as Direct Debit or Credit Card, wherever local banking systems permit.
- 4.4. **Late payment:** If You do 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 You dispute any part of an invoice You must pay the amount not in dispute by the due date or be subject to late fees. We also reserve the right to withhold services (including for the avoidance of doubt, denying You access to the Centre where applicable) while there are any outstanding fees and/or interest, or You are in breach of an agreement.
- 4.5. **Insufficient Funds:** Due to the additional administration We incur You will pay a fee for any returned or declined payments due to insufficient funds. This fee will differ by country and is listed in the House Rules.
- 4.6. **Indexation:** If an agreement is for a term of more than 12 months, We will increase the monthly fee on each anniversary of the start date in line with the relevant inflation index detailed in the House Rules.
- 4.7. **Standard services:** Monthly fees, plus applicable taxes, and any recurring services requested by You are payable monthly in advance. 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.
- 4.8. **Pay-as-you-use and Additional Variable Services:** Fees for pay-as-you-use services, plus applicable taxes, are payable monthly in arrears at our standard rates which may change from time to time and are available on request.
- 4.9. **Discounts, Promotions and Offers:** If You benefited from a special discount, promotion or offer, We will discontinue that discount, promotion or offer without notice if You materially breach Your agreement.



THIS AGREEMENT HAS BEEN UPDATED PLEASE CLICK THE LINK BELOW TO VIEW THE MOST RECENT VERSION.

[> View Agreement](#)

Agreement Date : 16 September 2019      Confirmation No : R-713325

Business Centre Details		Client Details	
LONDON, London Bridge - More London		Company Name	VERONA PHARMA PLC
Sales Manager	Ronnie Portsmouth	Phone	+44 20 3283 4000
		Email	Piers.morgan@veronapharma.com

Office Payment Details (exc.VAT and exc. services)		
Office Number	Number of people	Price per Office
142	2	£ 2,048.00
144	6	£ 6,208.51

Service Provision :	Start Date	End Date
	1 January 2020	28 February 2022

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](#)

These General Terms and Conditions apply to Office/Co-Working, Virtual Office and Membership agreements for services We supply to You.

## 1. General Agreement

- 1.1. Nature of an agreement: At all times, each Centre remains in Our possession and control. YOU ACCEPT THAT AN AGREEMENT CREATES NO TENANCY INTEREST, LEASEHOLD ESTATE OR OTHER REAL PROPERTY INTEREST IN YOUR FAVOUR WITH RESPECT TO THE ACCOMMODATION. Occupation by You is the commercial equivalent of an agreement for accommodation in a hotel. We are giving You the right to share the use of the Centre with Us and other clients.
- 1.2. House Rules: The House Rules, which are incorporated into these terms and conditions, are primarily in place and enforced to ensure that all clients have a professional environment to work in.
- 1.3. Availability at the start of an agreement: If for any unfortunate reason We cannot provide the services or accommodation in the Centre stated in an agreement by the start date, We will have no liability to You for any loss or damage but You may either move to one of Our other Centres (subject to availability), delay the start of the agreement or cancel it.
- 1.4. AUTOMATIC RENEWAL: SO THAT WE CAN MANAGE YOUR SERVICES EFFECTIVELY AND TO ENSURE SEAMLESS CONTINUITY OF THOSE SERVICES, ALL AGREEMENTS WILL RENEW AUTOMATICALLY FOR SUCCESSIVE PERIODS EQUAL TO THE CURRENT TERM UNTIL BROUGHT TO AN END BY YOU OR US. 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. IF YOU DO NOT WISH FOR AN AGREEMENT TO RENEW THEN YOU CAN CANCEL IT EASILY WITH EFFECT FROM THE END DATE STATED IN THE AGREEMENT, OR AT THE END OF ANY EXTENSION OR RENEWAL PERIOD, BY GIVING US PRIOR NOTICE. NOTICE MUST BE GIVEN THROUGH YOUR ONLINE ACCOUNT OR THROUGH THE APP. THE NOTICE PERIODS REQUIRED ARE AS FOLLOWS

<u>Term</u>	<u>Notice Period</u>
Month-to-Month	no less than 1 month's notice from the 1 <sup>st</sup> day of any calendar month
3 months	no less than 2 months' notice prior to the end of the term
More than 3 months	no less than 3 months' notice prior to the end of the term

- 1.5. We may elect not to renew an agreement. If so, We will inform You by email, through the App or Your online account, following the same notice periods specified above.
  - 1.6. If the Centre is no longer available: In the event that We are permanently unable to provide the services and accommodation at the Centre stated in an agreement, We will offer You accommodation in one of Our other centres. In the unlikely event we unable to find an alternative accommodation that is acceptable to You, Your agreement will end and You will only have to pay monthly fees up to that date and for any additional services You have used.
  - 1.7. Ending an agreement immediately: We may put an end to an agreement immediately by giving You notice if (a) You become insolvent or bankrupt; or (b) You breach one of your obligations which cannot be put right, or which We have given You notice to put right and which You have failed to put right within 14 days of that notice; or (c) Your conduct, or that of someone at the Centre with Your permission or invitation, is incompatible with ordinary office use and, (i) that conduct continues despite You having been given notice, or (ii) that conduct is material enough (in Our reasonable opinion) to warrant immediate termination; or (d) You are in breach of the "Compliance With Law" clause below. If We put an end to an agreement for any of the reasons referred to in this clause it does not put an end to any of Your financial obligations, including, without limitation, for the remainder of the period for which Your agreement would have lasted if We had not terminated it.
  - 1.8. When an Office agreement ends: When an agreement ends You must vacate Your accommodation immediately, leaving it in the same state and condition as it was when You took it. Upon Your departure or if You choose to relocate to a different room within a Centre, We will charge a fixed office restoration service fee to cover normal cleaning and any costs incurred to return the accommodation to its original condition and state. This fee will differ by country and is listed in the House Rules. We reserve the right to charge additional reasonable fees for any repairs needed above and beyond normal wear and tear. If You leave any property in the Centre We may dispose of it at Your cost in any way, We choose without owing You any responsibility for it or any proceeds of sale. If You continue to use the accommodation when an agreement has ended, You are responsible for any loss, claim or liability We may incur as a result of Your failure to vacate on time.
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## 2. Use of the Centres:

- 2.1. **Business Operations:** You may not carry on a business that competes with Our business of providing serviced offices and flexible working. You may not use Our name (or that of Our affiliates) in any way in connection with Your business. You are only permitted to use the address of a Centre as Your registered office address if it is permitted by both law and if We have given You prior written consent (given the additional administration there is an additional fee chargeable for this service). You must only use the accommodation for office business purposes. If We decide that a request for any particular service is excessive, We reserve the right to charge an additional fee. In order to ensure that the Centre provides a great working environment for all, We kindly ask you to limit any excessive visits by members of the public.
  - 2.2. **Accommodation**
    - 2.2.1. **Alterations or Damage:** You are liable for any damage caused by You or those in the Centre with Your permission, whether express or implied, including but not limited to all employees, contractors and/or agents.
    - 2.2.2. **IT Installations:** We take great pride in Our IT infrastructure and its upkeep and therefore You must not install any cabling, IT or telecom connections without Our consent, which We may refuse in our absolute discretion. As a condition to Our consent, You must permit Us 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 by other clients or Us or any landlord of the building. Fees for installation and de-installation will be at Your cost.
    - 2.2.3. **Use of the Accommodation:** An agreement will list the accommodation We initially allocate for Your use. You will have a non-exclusive right to the rooms allocated to You. Occasionally to ensure the efficient running of the Centre, We may need to allocate different accommodation to You, but it will be of reasonably equivalent size and We will notify You with respect to such different accommodation in advance.
    - 2.2.4. **Access to the Accommodation:** In order to maintain a high level of service, We may need to enter Your accommodation and may do so at any time, including without limitation, in an emergency, for cleaning and inspection or in order to re-sell the space if You have given notice to terminate. We will always endeavour to respect any of Your reasonable security procedures to protect the confidentiality of Your business.
  - 2.3. **Membership:**
    - 2.3.1. If You have subscribed to a Membership Agreement You will have access to all participating centres worldwide during standard business working hours and subject to availability.
    - 2.3.2. **Membership Usage:** Usage is measured in whole days and unused days cannot be carried over to the following month. A membership is not intended to be a replacement for a full-time workspace and all workspaces must be cleared at the end of each day. You are solely responsible for Your belongings at the centre at all times. We are not responsible for any property that is left unattended. Should You use more than Your membership entitlement, We will charge You an additional usage fee. You may bring in 1 guest free of charge (subject to fair usage). Any further guests will be required to purchase a day pass.
    - 2.3.3. As a Member, You may not use any Centre as Your business address without an accompanying office or virtual office agreement in place. Any use of the Centre address in such a way will result in an automatic enrolment in the Virtual Office product for the same term as Your membership and You will be invoiced accordingly.
  - 2.4. **Compliance with Law:** You must comply with all relevant laws and regulations in the conduct of Your business. You must not do anything that may interfere with the use of the Centre by Us or by others (including but not limited to political campaigning or immoral activity), cause any nuisance or annoyance, or cause loss or damage to Us (including damage to reputation) or to the owner of any interest in the building. If We have been advised by any government authority or other legislative body that it has reasonable suspicion that You are conducting criminal activities from the Centre, or You are or become subject to any government sanctions, then We shall be entitled to terminate any and all of Your agreements with immediate effect. You acknowledge that any breach by You of this clause shall constitute a material default, entitling Us to terminate Your agreement without further notice.
  - 2.5. **Ethical Trading:** Both We and You shall comply at all times with all relevant anti-slavery, anti-bribery and anti-corruption laws.
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- 2.6. Data protection: You acknowledge that We may collect and process personal data from You and Your employees as strictly necessary to ensure compliance with applicable laws and regulations and to enable Us effectively to provide services to You. You acknowledge and accept that such personal data may be transferred or made accessible to other entities in our group, wherever located, for the purposes of providing the services, in each case in accordance with all applicable data protection legislation.
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  - 2.8. Confidentiality: The terms of an agreement are confidential. Neither of us may 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 an agreement ends.
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  - 2.10. Applicable law: An agreement is interpreted and enforced in accordance with the law of the place where the Centre is located other than in a few specific jurisdictions which are detailed in the House Rules. We and You both accept the exclusive jurisdiction of the courts of that jurisdiction. If any provision of these terms and conditions is held void or unenforceable under the applicable law, the other provisions shall remain in force.
3. Our liability to You and Insurance
- 3.1. The extent of Our liability: To the maximum extent permitted by applicable law, We are not liable to You in respect of any loss or damage You suffer in connection with an agreement, including without limitation any loss or damage arising as a result of our failure to provide a service as a result of mechanical breakdown, strike or other event outside of Our reasonable control otherwise unless We have acted deliberately or have been negligent. In no event shall We be liable for any loss or damage until You provide written notice and give Us a reasonable time to put it right. If We are liable for failing to provide You with any service under an agreement then, subject to the exclusions and limits set out immediately below, We will pay any actual and the reasonable additional expense You have incurred in obtaining the same or similar service from elsewhere.
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  - 3.3. IT Services and Obligations: Whilst We have security internet protocols in place and strive to provide seamless internet connectivity, WE DO NOT MAKE ANY REPRESENTATION AND CANNOT GUARANTEE ANY MAINTAINED LEVEL OF CONNECTIVITY TO OUR NETWORK OR TO THE INTERNET, NOR THE LEVEL OF SECURITY OF IT INFORMATION AND DATA THAT YOU PLACE ON IT. You should adopt whatever security measures (such as encryption) You believe are appropriate to Your business. Your sole and exclusive remedy in relation to issues of reduced connectivity which are within Our reasonable control shall be for Us to rectify the issue within a reasonable time following notice from You to Us.
  - 3.4. EXCLUSION OF CONSEQUENTIAL LOSSES: WE WILL NOT IN ANY CIRCUMSTANCES HAVE ANY LIABILITY TO YOU FOR LOSS OF BUSINESS, LOSS OF PROFITS, LOSS OF ANTICIPATED SAVINGS, LOSS OF OR DAMAGE TO DATA, THIRD PARTY CLAIMS OR ANY CONSEQUENTIAL LOSS. WE STRONGLY RECOMMEND THAT YOU INSURE AGAINST ALL SUCH POTENTIAL LOSS, DAMAGE, EXPENSE OR LIABILITY.
  - 3.5. Financial limits to our liability: In all cases, our liability to You is subject to the following limits:
    - 3.5.1. without limit for personal injury or death;
    - 3.5.2. up to a maximum of GBP 1 million (or USD 1.5 million or EUR 1 million or other local equivalent) for any one event or series of connected events for damage to Your personal property; and
    - 3.5.3. in respect of any other loss or damage, up to a maximum equal to 125% of the total fees paid between the date services under an agreement commenced and the date on which the claim in question arises; or if higher, for office agreements only, GBP 50,000 / USD 100,000 / EUR 66,000 (or local equivalent).
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#### 4. Fees

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- 4.2. **Taxes and duty charges:** You agree to pay promptly (i) all sales, use, excise, consumption and any other taxes and license fees which You are required to pay to any governmental authority (and, at Our request, You will provide to Us evidence of such payment) and (ii) any taxes paid by Us to any governmental authority that are attributable to Your accommodation, where applicable, including, without limitation, any gross receipts, rent and occupancy taxes, tangible personal property taxes, stamp tax/duty or other documentary taxes and fees.
- 4.3. **Payment:** We are continually striving to reduce our environmental impact and support You in doing the same. Therefore, We will send all invoices electronically and You will make payments via an automated method such as Direct Debit or Credit Card, wherever local banking systems permit.
- 4.4. **Late payment:** If You do 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 You dispute any part of an invoice You must pay the amount not in dispute by the due date or be subject to late fees. We also reserve the right to withhold services (including for the avoidance of doubt, denying You access to the Centre where applicable) while there are any outstanding fees and/or interest, or You are in breach of an agreement.
- 4.5. **Insufficient Funds:** Due to the additional administration We incur You will pay a fee for any returned or declined payments due to insufficient funds. This fee will differ by country and is listed in the House Rules.
- 4.6. **Indexation:** If an agreement is for a term of more than 12 months, We will increase the monthly fee on each anniversary of the start date in line with the relevant inflation index detailed in the House Rules.
- 4.7. **Standard services:** Monthly fees, plus applicable taxes, and any recurring services requested by You are payable monthly in advance. 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.
- 4.8. **Pay-as-you-use and Additional Variable Services:** Fees for pay-as-you-use services, plus applicable taxes, are payable monthly in arrears at our standard rates which may change from time to time and are available on request.
- 4.9. **Discounts, Promotions and Offers:** If You benefited from a special discount, promotion or offer, We will discontinue that discount, promotion or offer without notice if You materially breach Your agreement.



THIS AGREEMENT HAS BEEN UPDATED PLEASE CLICK THE LINK BELOW TO VIEW THE MOST RECENT VERSION.

[> View Agreement](#)

Agreement Date : 16 September 2019      Confirmation No : R-802098

Business Centre Details		Client Details	
LONDON, London Bridge - More London		Company Name	VERONA PHARMA PLC
Sales Manager	Ronnie Portsmouth	Phone	+44 20 3283 4000
		Email	Piers.morgan@veronapharma.com

**Office Payment Details (exc.VAT and exc. services)**

Office Number	Number of people	Price per Office
145A	6	£ 11,264.00
151	1	£ 3,104.00

<b>Service Provision :</b>	<b>Start Date</b>	1 February 2020	<b>End Date</b>	28 February 2022
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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](#)

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 [Print Agreement](#)

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## 1. General Agreement

- 1.1. Nature of an agreement: At all times, each Centre remains in Our possession and control. YOU ACCEPT THAT AN AGREEMENT CREATES NO TENANCY INTEREST, LEASEHOLD ESTATE OR OTHER REAL PROPERTY INTEREST IN YOUR FAVOUR WITH RESPECT TO THE ACCOMMODATION. Occupation by You is the commercial equivalent of an agreement for accommodation in a hotel. We are giving You the right to share the use of the Centre with Us and other clients.
- 1.2. House Rules: The House Rules, which are incorporated into these terms and conditions, are primarily in place and enforced to ensure that all clients have a professional environment to work in.
- 1.3. Availability at the start of an agreement: If for any unfortunate reason We cannot provide the services or accommodation in the Centre stated in an agreement by the start date, We will have no liability to You for any loss or damage but You may either move to one of Our other Centres (subject to availability), delay the start of the agreement or cancel it.
- 1.4. AUTOMATIC RENEWAL: SO THAT WE CAN MANAGE YOUR SERVICES EFFECTIVELY AND TO ENSURE SEAMLESS CONTINUITY OF THOSE SERVICES, ALL AGREEMENTS WILL RENEW AUTOMATICALLY FOR SUCCESSIVE PERIODS EQUAL TO THE CURRENT TERM UNTIL BROUGHT TO AN END BY YOU OR US. 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. IF YOU DO NOT WISH FOR AN AGREEMENT TO RENEW THEN YOU CAN CANCEL IT EASILY WITH EFFECT FROM THE END DATE STATED IN THE AGREEMENT, OR AT THE END OF ANY EXTENSION OR RENEWAL PERIOD, BY GIVING US PRIOR NOTICE. NOTICE MUST BE GIVEN THROUGH YOUR ONLINE ACCOUNT OR THROUGH THE APP. THE NOTICE PERIODS REQUIRED ARE AS FOLLOWS:

<u>Term</u>	<u>Notice Period</u>
Month-to-Month	no less than 1 month's notice from the 1 <sup>st</sup> day of any calendar month
3 months	no less than 2 months' notice prior to the end of the term
More than 3 months	no less than 3 months' notice prior to the end of the term

- 1.5. We may elect not to renew an agreement. If so, We will inform You by email, through the App or Your online account, following the same notice periods specified above.
  - 1.6. If the Centre is no longer available: In the event that We are permanently unable to provide the services and accommodation at the Centre stated in an agreement, We will offer You accommodation in one of Our other centres. In the unlikely event we unable to find an alternative accommodation that is acceptable to You, Your agreement will end and You will only have to pay monthly fees up to that date and for any additional services You have used.
  - 1.7. Ending an agreement immediately: We may put an end to an agreement immediately by giving You notice if (a) You become insolvent or bankrupt; or (b) You breach one of your obligations which cannot be put right, or which We have given You notice to put right and which You have failed to put right within 14 days of that notice; or (c) Your conduct, or that of someone at the Centre with Your permission or invitation, is incompatible with ordinary office use and, (i) that conduct continues despite You having been given notice, or (ii) that conduct is material enough (in Our reasonable opinion) to warrant immediate termination; or (d) You are in breach of the "Compliance With Law" clause below. If We put an end to an agreement for any of the reasons referred to in this clause it does not put an end to any of Your financial obligations, including, without limitation, for the remainder of the period for which Your agreement would have lasted if We had not terminated it.
  - 1.8. When an Office agreement ends: When an agreement ends You must vacate Your accommodation immediately, leaving it in the same state and condition as it was when You took it. Upon Your departure or if You choose to relocate to a different room within a Centre, We will charge a fixed office restoration service fee to cover normal cleaning and any costs incurred to return the accommodation to its original condition and state. This fee will differ by country and is listed in the House Rules. We reserve the right to charge additional reasonable fees for any repairs needed above and beyond normal wear and tear. If You leave any property in the Centre We may dispose of it at Your cost in any way, We choose without owing You any responsibility for it or any proceeds of sale. If You continue to use the accommodation when an agreement has ended, You are responsible for any loss, claim or liability We may incur as a result of Your failure to vacate on time.
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## 2. Use of the Centres:

- 2.1. **Business Operations:** You may not carry on a business that competes with Our business of providing serviced offices and flexible working. You may not use Our name (or that of Our affiliates) in any way in connection with Your business. You are only permitted to use the address of a Centre as Your registered office address if it is permitted by both law and if We have given You prior written consent (given the additional administration there is an additional fee chargeable for this service). You must only use the accommodation for office business purposes. If We decide that a request for any particular service is excessive, We reserve the right to charge an additional fee. In order to ensure that the Centre provides a great working environment for all, We kindly ask you to limit any excessive visits by members of the public.
  - 2.2. **Accommodation**
    - 2.2.1. **Alterations or Damage:** You are liable for any damage caused by You or those in the Centre with Your permission, whether express or implied, including but not limited to all employees, contractors and/or agents.
    - 2.2.2. **IT Installations:** We take great pride in Our IT infrastructure and its upkeep and therefore You must not install any cabling, IT or telecom connections without Our consent, which We may refuse in our absolute discretion. As a condition to Our consent, You must permit Us 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 by other clients or Us or any landlord of the building. Fees for installation and de-installation will be at Your cost.
    - 2.2.3. **Use of the Accommodation:** An agreement will list the accommodation We initially allocate for Your use. You will have a non-exclusive right to the rooms allocated to You. Occasionally to ensure the efficient running of the Centre, We may need to allocate different accommodation to You, but it will be of reasonably equivalent size and We will notify You with respect to such different accommodation in advance.
    - 2.2.4. **Access to the Accommodation:** In order to maintain a high level of service, We may need to enter Your accommodation and may do so at any time, including without limitation, in an emergency, for cleaning and inspection or in order to re-sell the space if You have given notice to terminate. We will always endeavour to respect any of Your reasonable security procedures to protect the confidentiality of Your business.
  - 2.3. **Membership:**
    - 2.3.1. If You have subscribed to a Membership Agreement You will have access to all participating centres worldwide during standard business working hours and subject to availability.
    - 2.3.2. **Membership Usage:** Usage is measured in whole days and unused days cannot be carried over to the following month. A membership is not intended to be a replacement for a full-time workspace and all workspaces must be cleared at the end of each day. You are solely responsible for Your belongings at the centre at all times. We are not responsible for any property that is left unattended. Should You use more than Your membership entitlement, We will charge You an additional usage fee. You may bring in 1 guest free of charge (subject to fair usage). Any further guests will be required to purchase a day pass.
    - 2.3.3. As a Member, You may not use any Centre as Your business address without an accompanying office or virtual office agreement in place. Any use of the Centre address in such a way will result in an automatic enrolment in the Virtual Office product for the same term as Your membership and You will be invoiced accordingly.
  - 2.4. **Compliance with Law:** You must comply with all relevant laws and regulations in the conduct of Your business. You must not do anything that may interfere with the use of the Centre by Us or by others (including but not limited to political campaigning or immoral activity), cause any nuisance or annoyance, or cause loss or damage to Us (including damage to reputation) or to the owner of any interest in the building. If We have been advised by any government authority or other legislative body that it has reasonable suspicion that You are conducting criminal activities from the Centre, or You are or become subject to any government sanctions, then We shall be entitled to terminate any and all of Your agreements with immediate effect. You acknowledge that any breach by You of this clause shall constitute a material default, entitling Us to terminate Your agreement without further notice.
  - 2.5. **Ethical Trading:** Both We and You shall comply at all times with all relevant anti-slavery, anti-bribery and anti-corruption laws.
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- 2.6. Data protection: You acknowledge that We may collect and process personal data from You and Your employees as strictly necessary to ensure compliance with applicable laws and regulations and to enable Us effectively to provide services to You. You acknowledge and accept that such personal data may be transferred or made accessible to other entities in our group, wherever located, for the purposes of providing the services, in each case in accordance with all applicable data protection legislation.
  - 2.7. Employees: We will both have invested a great deal in training Our staff, therefore, neither of us may knowingly solicit or offer employment to the other's staff employed in the Centre (or for 3 months after they have left their employment). To recompense the other for staff training and investment costs, if either of us breaches this clause the breaching party will pay upon demand the other the equivalent of 6 months' salary of any employee concerned.
  - 2.8. Confidentiality: The terms of an agreement are confidential. Neither of us may 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 an agreement ends.
  - 2.9. Assignment: An agreement is personal to You and cannot be transferred to anyone else without prior consent from Us unless such transfer is required by law. However, We will not unreasonably withhold our consent to assignment to an affiliate provided that You execute our standard form of assignment. We may transfer any agreement and any and all amounts payable by You under an agreement to any other member of Our group.
  - 2.10. Applicable law: An agreement is interpreted and enforced in accordance with the law of the place where the Centre is located other than in a few specific jurisdictions which are detailed in the House Rules. We and You both accept the exclusive jurisdiction of the courts of that jurisdiction. If any provision of these terms and conditions is held void or unenforceable under the applicable law, the other provisions shall remain in force.
3. Our liability to You and Insurance
- 3.1. The extent of Our liability: To the maximum extent permitted by applicable law, We are not liable to You in respect of any loss or damage You suffer in connection with an agreement, including without limitation any loss or damage arising as a result of our failure to provide a service as a result of mechanical breakdown, strike or other event outside of Our reasonable control otherwise unless We have acted deliberately or have been negligent. In no event shall We be liable for any loss or damage until You provide written notice and give Us a reasonable time to put it right. If We are liable for failing to provide You with any service under an agreement then, subject to the exclusions and limits set out immediately below, We will pay any actual and the reasonable additional expense You have incurred in obtaining the same or similar service from elsewhere.
  - 3.2. Your Insurance: It is Your responsibility to arrange insurance for property which You bring in to the Centre, for any post You send or receive and for Your own liability to your employees and to third parties. We strongly recommend that You put such insurance in place.
  - 3.3. IT Services and Obligations: Whilst We have security internet protocols in place and strive to provide seamless internet connectivity, WE DO NOT MAKE ANY REPRESENTATION AND CANNOT GUARANTEE ANY MAINTAINED LEVEL OF CONNECTIVITY TO OUR NETWORK OR TO THE INTERNET, NOR THE LEVEL OF SECURITY OF IT INFORMATION AND DATA THAT YOU PLACE ON IT. You should adopt whatever security measures (such as encryption) You believe are appropriate to Your business. Your sole and exclusive remedy in relation to issues of reduced connectivity which are within Our reasonable control shall be for Us to rectify the issue within a reasonable time following notice from You to Us.
  - 3.4. EXCLUSION OF CONSEQUENTIAL LOSSES: WE WILL NOT IN ANY CIRCUMSTANCES HAVE ANY LIABILITY TO YOU FOR LOSS OF BUSINESS, LOSS OF PROFITS, LOSS OF ANTICIPATED SAVINGS, LOSS OF OR DAMAGE TO DATA, THIRD PARTY CLAIMS OR ANY CONSEQUENTIAL LOSS. WE STRONGLY RECOMMEND THAT YOU INSURE AGAINST ALL SUCH POTENTIAL LOSS, DAMAGE, EXPENSE OR LIABILITY.
  - 3.5. Financial limits to our liability: In all cases, our liability to You is subject to the following limits:
    - 3.5.1. without limit for personal injury or death;
    - 3.5.2. up to a maximum of GBP 1 million (or USD 1.5 million or EUR 1 million or other local equivalent) for any one event or series of connected events for damage to Your personal property; and
    - 3.5.3. in respect of any other loss or damage, up to a maximum equal to 125% of the total fees paid between the date services under an agreement commenced and the date on which the claim in question arises; or if higher, for office agreements only, GBP 50,000 / USD 100,000 / EUR 66,000 (or local equivalent).
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#### 4. Fees

- 4.1. **Service Retainer/Deposit:** Your service retainer / deposit will be held by Us without generating interest as security for performance of all Your obligations under an agreement. All requests for the return must be made through Your online account or App after which the service retainer/deposit or any balance will be returned within 30 days to You once your agreement has ended and when You have settled Your account. We will deduct any outstanding fees and other costs due to Us before returning the balance to You. We may require You to pay an increased retainer if the monthly office or virtual office fee increases upon renewal, outstanding fees exceed the service retainer/deposit held and/or You frequently fail to pay invoices when due.
- 4.2. **Taxes and duty charges:** You agree to pay promptly (i) all sales, use, excise, consumption and any other taxes and license fees which You are required to pay to any governmental authority (and, at Our request, You will provide to Us evidence of such payment) and (ii) any taxes paid by Us to any governmental authority that are attributable to Your accommodation, where applicable, including, without limitation, any gross receipts, rent and occupancy taxes, tangible personal property taxes, stamp tax/duty or other documentary taxes and fees.
- 4.3. **Payment:** We are continually striving to reduce our environmental impact and support You in doing the same. Therefore, We will send all invoices electronically and You will make payments via an automated method such as Direct Debit or Credit Card, wherever local banking systems permit.
- 4.4. **Late payment:** If You do 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 You dispute any part of an invoice You must pay the amount not in dispute by the due date or be subject to late fees. We also reserve the right to withhold services (including for the avoidance of doubt, denying You access to the Centre where applicable) while there are any outstanding fees and/or interest, or You are in breach of an agreement.
- 4.5. **Insufficient Funds:** Due to the additional administration We incur You will pay a fee for any returned or declined payments due to insufficient funds. This fee will differ by country and is listed in the House Rules.
- 4.6. **Indexation:** If an agreement is for a term of more than 12 months, We will increase the monthly fee on each anniversary of the start date in line with the relevant inflation index detailed in the House Rules.
- 4.7. **Standard services:** Monthly fees, plus applicable taxes, and any recurring services requested by You are payable monthly in advance. 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.
- 4.8. **Pay-as-you-use and Additional Variable Services:** Fees for pay-as-you-use services, plus applicable taxes, are payable monthly in arrears at our standard rates which may change from time to time and are available on request.
- 4.9. **Discounts, Promotions and Offers:** If You benefited from a special discount, promotion or offer, We will discontinue that discount, promotion or offer without notice if You materially breach Your agreement.



THIS AGREEMENT HAS BEEN UPDATED PLEASE CLICK THE LINK BELOW TO VIEW THE MOST RECENT VERSION.

[> View Agreement](#)

Agreement Date : July 16, 2019      Confirmation No : R-757796

Business Center Details	Client Details
<b>NY, New York - Spaces Hudson Yards</b> Sales Manager      Sharon Bajwa	Company Name      VERONA PHARMA Phone                      +44 20 3283 4200 Email                        Piers.morgan@veronapharma.com

**Office Payment Details (exc. tax and exc. services)**

Office Number	Number of people	Price per Office
1212	1	\$ 3,500.00
1210	1	\$ 4,840.00
1215	2	\$ 2,424.00
1216	2	\$ 2,424.00
1218	2	\$ 2,424.00

<b>Service Provision :</b>	<b>Start Date</b>	November 1, 2019	<b>End Date</b>	October 31, 2021
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All agreements end on the last calendar day of the month.

**Terms and Conditions**

We are Regus Management Group, LLC [the Provider], please click the link below for terms and conditions.

AGREEMENT TO ARBITRATE: CLASS ACTION WAIVER: Any dispute or claim relating in any way to this agreement shall be resolved by binding arbitration administered by the American Arbitration Association in accord with its Commercial Arbitration Rules (available at www.adr.org), except that you or the Provider may assert claims in small claims court and the Client and the Provider may pursue court actions to remove you, or prevent your removal, from the Center if you do not leave when this agreement terminates. The arbitrator shall have exclusive authority to resolve any dispute relating to the interpretation, applicability, enforceability, or formation of this agreement. The arbitrator shall not conduct arbitration as a class or representative action. The Client and the Provider acknowledge that this agreement is a transaction in interstate commerce governed by the Federal Arbitration Act. The Client and the Provider agree to waive any right to pursue any dispute relating to this agreement in any class, private attorney general, or other representative action.

 [Download the terms and conditions](#)

 [Download the house rules](#)

 This website is secure. Your personal details are protected at all times.

 [Print Agreement](#)

These General Terms and Conditions apply to Office/Co-Working, Virtual Office and Membership agreements for services We supply to You.

## 1. General Agreement

- 1.1. Nature of an agreement: At all times, each Centre remains in Our possession and control. YOU ACCEPT THAT AN AGREEMENT CREATES NO TENANCY INTEREST, LEASEHOLD ESTATE OR OTHER REAL PROPERTY INTEREST IN YOUR FAVOUR WITH RESPECT TO THE ACCOMMODATION. Occupation by You is the commercial equivalent of an agreement for accommodation in a hotel. We are giving You the right to share the use of the Centre with Us and other clients.
- 1.2. House Rules: The House Rules, which are incorporated into these terms and conditions, are primarily in place and enforced to ensure that all clients have a professional environment to work in.
- 1.3. Availability at the start of an agreement: If for any unfortunate reason We cannot provide the services or accommodation in the Centre stated in an agreement by the start date, We will have no liability to You for any loss or damage but You may either move to one of Our other Centres (subject to availability), delay the start of the agreement or cancel it.
- 1.4. AUTOMATIC RENEWAL: SO THAT WE CAN MANAGE YOUR SERVICES EFFECTIVELY AND TO ENSURE SEAMLESS CONTINUITY OF THOSE SERVICES, ALL AGREEMENTS WILL RENEW AUTOMATICALLY FOR SUCCESSIVE PERIODS EQUAL TO THE CURRENT TERM UNTIL BROUGHT TO AN END BY YOU OR US. 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. IF YOU DO NOT WISH FOR AN AGREEMENT TO RENEW THEN YOU CAN CANCEL IT EASILY WITH EFFECT FROM THE END DATE STATED IN THE AGREEMENT, OR AT THE END OF ANY EXTENSION OR RENEWAL PERIOD, BY GIVING US PRIOR NOTICE. NOTICE MUST BE GIVEN THROUGH YOUR ONLINE ACCOUNT OR THROUGH THE APP. THE NOTICE PERIODS REQUIRED ARE AS FOLLOWS

<u>Term</u>	<u>Notice Period</u>
Month-to-Month	no less than 1 month's notice from the 1 <sup>st</sup> day of any calendar month
3 months	no less than 2 months' notice prior to the end of the term
More than 3 months	no less than 3 months' notice prior to the end of the term

- 1.5. We may elect not to renew an agreement. If so, We will inform You by email, through the App or Your online account, following the same notice periods specified above.
  - 1.6. If the Centre is no longer available: In the event that We are permanently unable to provide the services and accommodation at the Centre stated in an agreement, We will offer You accommodation in one of Our other centres. In the unlikely event we unable to find an alternative accommodation that is acceptable to You, Your agreement will end and You will only have to pay monthly fees up to that date and for any additional services You have used.
  - 1.7. Ending an agreement immediately: We may put an end to an agreement immediately by giving You notice if (a) You become insolvent or bankrupt; or (b) You breach one of your obligations which cannot be put right, or which We have given You notice to put right and which You have failed to put right within 14 days of that notice; or (c) Your conduct, or that of someone at the Centre with Your permission or invitation, is incompatible with ordinary office use and, (i) that conduct continues despite You having been given notice, or (ii) that conduct is material enough (in Our reasonable opinion) to warrant immediate termination; or (d) You are in breach of the "Compliance With Law" clause below. If We put an end to an agreement for any of the reasons referred to in this clause it does not put an end to any of Your financial obligations, including, without limitation, for the remainder of the period for which Your agreement would have lasted if We had not terminated it.
  - 1.8. When an Office agreement ends: When an agreement ends You must vacate Your accommodation immediately, leaving it in the same state and condition as it was when You took it. Upon Your departure or if You choose to relocate to a different room within a Centre, We will charge a fixed office restoration service fee to cover normal cleaning and any costs incurred to return the accommodation to its original condition and state. This fee will differ by country and is listed in the House Rules. We reserve the right to charge additional reasonable fees for any repairs needed above and beyond normal wear and tear. If You leave any property in the Centre We may dispose of it at Your cost in any way, We choose without owing You any responsibility for it or any proceeds of sale. If You continue to use the accommodation when an agreement has ended, You are responsible for any loss, claim or liability We may incur as a result of Your failure to vacate on time.
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## 2. Use of the Centres:

- 2.1. **Business Operations:** You may not carry on a business that competes with Our business of providing serviced offices and flexible working. You may not use Our name (or that of Our affiliates) in any way in connection with Your business. You are only permitted to use the address of a Centre as Your registered office address if it is permitted by both law and if We have given You prior written consent (given the additional administration there is an additional fee chargeable for this service). You must only use the accommodation for office business purposes. If We decide that a request for any particular service is excessive, We reserve the right to charge an additional fee. In order to ensure that the Centre provides a great working environment for all, We kindly ask you to limit any excessive visits by members of the public.
  - 2.2. **Accommodation**
    - 2.2.1. **Alterations or Damage:** You are liable for any damage caused by You or those in the Centre with Your permission, whether express or implied, including but not limited to all employees, contractors and/or agents.
    - 2.2.2. **IT Installations:** We take great pride in Our IT infrastructure and its upkeep and therefore You must not install any cabling, IT or telecom connections without Our consent, which We may refuse in our absolute discretion. As a condition to Our consent, You must permit Us 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 by other clients or Us or any landlord of the building. Fees for installation and de-installation will be at Your cost.
    - 2.2.3. **Use of the Accommodation:** An agreement will list the accommodation We initially allocate for Your use. You will have a non-exclusive right to the rooms allocated to You. Occasionally to ensure the efficient running of the Centre, We may need to allocate different accommodation to You, but it will be of reasonably equivalent size and We will notify You with respect to such different accommodation in advance.
    - 2.2.4. **Access to the Accommodation:** In order to maintain a high level of service, We may need to enter Your accommodation and may do so at any time, including without limitation, in an emergency, for cleaning and inspection or in order to re-sell the space if You have given notice to terminate. We will always endeavour to respect any of Your reasonable security procedures to protect the confidentiality of Your business.
  - 2.3. **Membership:**
    - 2.3.1. If You have subscribed to a Membership Agreement You will have access to all participating centres worldwide during standard business working hours and subject to availability.
    - 2.3.2. **Membership Usage:** Usage is measured in whole days and unused days cannot be carried over to the following month. A membership is not intended to be a replacement for a full-time workspace and all workspaces must be cleared at the end of each day. You are solely responsible for Your belongings at the centre at all times. We are not responsible for any property that is left unattended. Should You use more than Your membership entitlement, We will charge You an additional usage fee. You may bring in 1 guest free of charge (subject to fair usage). Any further guests will be required to purchase a day pass.
    - 2.3.3. As a Member, You may not use any Centre as Your business address without an accompanying office or virtual office agreement in place. Any use of the Centre address in such a way will result in an automatic enrolment in the Virtual Office product for the same term as Your membership and You will be invoiced accordingly.
  - 2.4. **Compliance with Law:** You must comply with all relevant laws and regulations in the conduct of Your business. You must not do anything that may interfere with the use of the Centre by Us or by others (including but not limited to political campaigning or immoral activity), cause any nuisance or annoyance, or cause loss or damage to Us (including damage to reputation) or to the owner of any interest in the building. If We have been advised by any government authority or other legislative body that it has reasonable suspicion that You are conducting criminal activities from the Centre, or You are or become subject to any government sanctions, then We shall be entitled to terminate any and all of Your agreements with immediate effect. You acknowledge that any breach by You of this clause shall constitute a material default, entitling Us to terminate Your agreement without further notice.
  - 2.5. **Ethical Trading:** Both We and You shall comply at all times with all relevant anti-slavery, anti-bribery and anti-corruption laws.
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- 2.6. Data protection: You acknowledge that We may collect and process personal data from You and Your employees as strictly necessary to ensure compliance with applicable laws and regulations and to enable Us effectively to provide services to You. You acknowledge and accept that such personal data may be transferred or made accessible to other entities in our group, wherever located, for the purposes of providing the services, in each case in accordance with all applicable data protection legislation.
  - 2.7. Employees: We will both have invested a great deal in training Our staff, therefore, neither of us may knowingly solicit or offer employment to the other's staff employed in the Centre (or for 3 months after they have left their employment). To recompense the other for staff training and investment costs, if either of us breaches this clause the breaching party will pay upon demand the other the equivalent of 6 months' salary of any employee concerned.
  - 2.8. Confidentiality: The terms of an agreement are confidential. Neither of us may 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 an agreement ends.
  - 2.9. Assignment: An agreement is personal to You and cannot be transferred to anyone else without prior consent from Us unless such transfer is required by law. However, We will not unreasonably withhold our consent to assignment to an affiliate provided that You execute our standard form of assignment. We may transfer any agreement and any and all amounts payable by You under an agreement to any other member of Our group.
  - 2.10. Applicable law: An agreement is interpreted and enforced in accordance with the law of the place where the Centre is located other than in a few specific jurisdictions which are detailed in the House Rules. We and You both accept the exclusive jurisdiction of the courts of that jurisdiction. If any provision of these terms and conditions is held void or unenforceable under the applicable law, the other provisions shall remain in force.
3. Our liability to You and Insurance
- 3.1. The extent of Our liability: To the maximum extent permitted by applicable law, We are not liable to You in respect of any loss or damage You suffer in connection with an agreement, including without limitation any loss or damage arising as a result of our failure to provide a service as a result of mechanical breakdown, strike or other event outside of Our reasonable control otherwise unless We have acted deliberately or have been negligent. In no event shall We be liable for any loss or damage until You provide written notice and give Us a reasonable time to put it right. If We are liable for failing to provide You with any service under an agreement then, subject to the exclusions and limits set out immediately below, We will pay any actual and the reasonable additional expense You have incurred in obtaining the same or similar service from elsewhere.
  - 3.2. Your Insurance: It is Your responsibility to arrange insurance for property which You bring in to the Centre, for any post You send or receive and for Your own liability to your employees and to third parties. We strongly recommend that You put such insurance in place.
  - 3.3. IT Services and Obligations: Whilst We have security internet protocols in place and strive to provide seamless internet connectivity, WE DO NOT MAKE ANY REPRESENTATION AND CANNOT GUARANTEE ANY MAINTAINED LEVEL OF CONNECTIVITY TO OUR NETWORK OR TO THE INTERNET, NOR THE LEVEL OF SECURITY OF IT INFORMATION AND DATA THAT YOU PLACE ON IT. You should adopt whatever security measures (such as encryption) You believe are appropriate to Your business. Your sole and exclusive remedy in relation to issues of reduced connectivity which are within Our reasonable control shall be for Us to rectify the issue within a reasonable time following notice from You to Us.
  - 3.4. EXCLUSION OF CONSEQUENTIAL LOSSES: WE WILL NOT IN ANY CIRCUMSTANCES HAVE ANY LIABILITY TO YOU FOR LOSS OF BUSINESS, LOSS OF PROFITS, LOSS OF ANTICIPATED SAVINGS, LOSS OF OR DAMAGE TO DATA, THIRD PARTY CLAIMS OR ANY CONSEQUENTIAL LOSS. WE STRONGLY RECOMMEND THAT YOU INSURE AGAINST ALL SUCH POTENTIAL LOSS, DAMAGE, EXPENSE OR LIABILITY.
  - 3.5. Financial limits to our liability: In all cases, our liability to You is subject to the following limits:
    - 3.5.1. without limit for personal injury or death;
    - 3.5.2. up to a maximum of GBP 1 million (or USD 1.5 million or EUR 1 million or other local equivalent) for any one event or series of connected events for damage to Your personal property; and
    - 3.5.3. in respect of any other loss or damage, up to a maximum equal to 125% of the total fees paid between the date services under an agreement commenced and the date on which the claim in question arises; or if higher, for office agreements only, GBP 50,000 / USD 100,000 / EUR 66,000 (or local equivalent).
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#### 4. Fees

- 4.1. **Service Retainer/Deposit:** Your service retainer / deposit will be held by Us without generating interest as security for performance of all Your obligations under an agreement. All requests for the return must be made through Your online account or App after which the service retainer/deposit or any balance will be returned within 30 days to You once your agreement has ended and when You have settled Your account. We will deduct any outstanding fees and other costs due to Us before returning the balance to You. We may require You to pay an increased retainer if the monthly office or virtual office fee increases upon renewal, outstanding fees exceed the service retainer/deposit held and/or You frequently fail to pay invoices when due.
- 4.2. **Taxes and duty charges:** You agree to pay promptly (i) all sales, use, excise, consumption and any other taxes and license fees which You are required to pay to any governmental authority (and, at Our request, You will provide to Us evidence of such payment) and (ii) any taxes paid by Us to any governmental authority that are attributable to Your accommodation, where applicable, including, without limitation, any gross receipts, rent and occupancy taxes, tangible personal property taxes, stamp tax/duty or other documentary taxes and fees.
- 4.3. **Payment:** We are continually striving to reduce our environmental impact and support You in doing the same. Therefore, We will send all invoices electronically and You will make payments via an automated method such as Direct Debit or Credit Card, wherever local banking systems permit.
- 4.4. **Late payment:** If You do 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 You dispute any part of an invoice You must pay the amount not in dispute by the due date or be subject to late fees. We also reserve the right to withhold services (including for the avoidance of doubt, denying You access to the Centre where applicable) while there are any outstanding fees and/or interest, or You are in breach of an agreement.
- 4.5. **Insufficient Funds:** Due to the additional administration We incur You will pay a fee for any returned or declined payments due to insufficient funds. This fee will differ by country and is listed in the House Rules.
- 4.6. **Indexation:** If an agreement is for a term of more than 12 months, We will increase the monthly fee on each anniversary of the start date in line with the relevant inflation index detailed in the House Rules.
- 4.7. **Standard services:** Monthly fees, plus applicable taxes, and any recurring services requested by You are payable monthly in advance. 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.
- 4.8. **Pay-as-you-use and Additional Variable Services:** Fees for pay-as-you-use services, plus applicable taxes, are payable monthly in arrears at our standard rates which may change from time to time and are available on request.
- 4.9. **Discounts, Promotions and Offers:** If You benefited from a special discount, promotion or offer, We will discontinue that discount, promotion or offer without notice if You materially breach Your agreement.



## CERTIFICATIONS

I, David Zaccardelli, Pharm.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
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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: February 27, 2020

By: /s/ David Zaccardelli, Pharm.D.  
David Zaccardelli, Pharm.D.  
Chief Executive Officer  
(Principal Executive Officer)

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## CERTIFICATIONS

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
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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: February 27, 2020

By: /s/ Piers Morgan  
Piers Morgan  
Chief Financial Officer  
(Principal Financial Officer)

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CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, David Zaccardelli, Pharm.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, 2019 (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: February 27, 2020

/s/ David Zaccardelli, Pharm.D.  
David Zaccardelli, Pharm.D.  
Chief Executive Officer  
(Principal Executive Officer)

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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, 2019 (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: February 27, 2020

/s/ Piers Morgan  
Piers Morgan  
Chief Financial Officer  
(Principal Financial Officer)

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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 (No. 333-217521) of Verona Pharma plc of our report dated February 27, 2020 relating to the financial statements, which appears in this Form 20-F.

/s/ PricewaterhouseCoopers LLP  
Reading, United Kingdom  
February 27, 2020

