

As filed with the Securities and Exchange Commission on August 25, 2020

Registration No. 333-247928

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

**Amendment No. 1
to
Form F-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

VERONA PHARMA PLC

(Exact Name of Registrant as Specified in its Charter)

Not Applicable

(Translation of Registrant's Name into English)

United Kingdom
(State or other Jurisdiction of
Incorporation or Organization)

2834
(Primary Standard Industrial
Classification Code Number)

Not Applicable
(I.R.S. Employer
Identification Number)

**3 More London Riverside
London SE1 2RE
United Kingdom**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Cogency Global Inc.
10 E. 40th Street, 10th floor
New York, New York 10016
+1 800 221 0102**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

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Nathan Ajashvili
Latham & Watkins LLP
200 Clarendon Street
Boston, Massachusetts 02116
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Approximate date of commencement of proposed sale to the public :

From time to time after the effective date of this Registration Statement

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

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 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of each Class of Securities to be Registered	Amount to Be Registered ⁽¹⁾	Proposed Maximum Offering Price per Ordinary Share ⁽²⁾	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Ordinary Shares, nominal value £0.05 per share	355,831,184	\$0.99	\$352,272,872.16	\$45,725.02

- (1) Consists of (a) 307,742,288 Ordinary Shares of which 307,520,072 are in the form of American Depository Shares and (b) 48,088,896 Ordinary Shares that may be re-designated from the Issuer's Non-Voting Ordinary Shares. American Depository Shares issuable on deposit of the ordinary shares registered hereby have been registered under a separate registration statement on Form F-6 (File No. 333-217353). Each American Depository Share represents the right to receive eight ordinary shares. Pursuant to Rule 416(a) of the Securities Act of 1933, as amended, this registration statement also covers such additional shares as may hereafter be offered or issued to prevent dilution resulting from share splits, share dividends, recapitalizations or certain other capital adjustments.
- (2) Estimated in accordance with Rule 457(c) solely for purposes of calculating the registration fee. The maximum price per Ordinary Share and the maximum aggregate offering price are based on the average of the \$1.05 (high) and \$0.93 (low) sale price of the Registrant's ordinary shares as reported on the AIM, a market of the London Stock Exchange, on August 24, 2020, which date is within five business days prior to filing this Registration Statement and converted to \$0.99 at the noon buying rate of the Federal Reserve Bank of New York of £1.00 to \$1.3098 on August 21, 2020. The Registrant previously paid \$45,234.88 of the registration fee.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. The selling shareholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED AUGUST 25, 2020

PROSPECTUS



Verona Pharma

355,831,184 Shares

VERONA PHARMA PLC

**Ordinary Shares
(including Ordinary Shares in the form of American Depository Shares)**

This prospectus relates to the resale from time to time in one or more offerings by the selling shareholders named herein of up to an aggregate of 355,831,184 of our ordinary shares, nominal value £0.05 per share, of which 307,520,072 are in the form of American Depository Shares, or ADSs, and 48,088,896 are ordinary shares that may be re-designated from our non-voting ordinary shares, nominal value £0.05 per share.

The ordinary shares registered hereby may be offered and sold by the selling shareholders through one or more underwriters, broker-dealers, agents or directly to purchasers, or through a combination of these methods. If the ordinary shares are sold through underwriters or broker-dealers, the selling shareholders will be responsible for underwriting discounts or commissions or agent's commissions. The ordinary shares may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of sale, at varying prices determined at the time of sale, or at negotiated prices. See "Plan of Distribution."

We are not selling any ordinary shares under this prospectus, and we will not receive any of the proceeds from the offer and sale of ordinary shares by the selling shareholders.

Our ADSs are listed on The Nasdaq Global Market under the symbol "VRNA." On August 24, 2020, the last reported sale price of our ADSs on The Nasdaq Global Market was \$7.67 per ADS. Our ordinary shares are listed on AIM of the London Stock Exchange, or AIM, under the symbol "VRP." On August 24, 2020, the last reported sale price of our ordinary shares on AIM was £0.74 per share.

Investing in our securities involves risks. See "Risk Factors" beginning on page [7](#) of this prospectus and THE DOCUMENTS INCORPORATED BY REFERENCE INTO THIS PROSPECTUS concerning factors you should consider before investing in our securities.

We are an "emerging growth company" under applicable Securities and Exchange Commission rules and are eligible for reduced public company disclosure requirements. See "Summary — Implications of Being an Emerging Growth Company and a Foreign Private Issuer."

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is **, 2020**

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You should rely only on the information contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We have not and the selling shareholders have not authorized anyone to provide you with different information. The selling shareholders are offering to sell, and seeking offers to buy, our ordinary shares (including in the form of ADSs) only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of ordinary shares (including in the form of ADSs).

For investors outside the United States: Neither we nor the selling shareholders have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction, other than the United States, where action for that purpose is required. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of our ordinary shares (including in the form of ADSs) and the distribution of this prospectus outside the United States.

This prospectus is a part of a registration statement on Form F-1 that we filed with the Securities and Exchange Commission, or the SEC, using a “shelf” registration or continuous offering process. Under this shelf process, the selling shareholders may from time to time sell the ordinary shares (including in the form of ADSs) covered by this prospectus. Additionally, under the shelf process, in certain circumstances, we or the selling shareholder may provide a prospectus supplement that will contain certain specific information about the terms of a particular offering by one or more of the selling shareholders or to add information to, or update or change information contained in this prospectus. You should read this prospectus or any prospectus supplement before deciding to invest in our ordinary shares (including in the form of ADSs). You may obtain this information without charge by following the instructions under “Where You Can Find More Information; Incorporation by Reference” appearing elsewhere in this prospectus.

Under the rules of the SEC, we are currently eligible for treatment as a “foreign private issuer.” As a foreign private issuer, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as domestic registrants whose securities are registered under the Securities Exchange Act of 1934, as amended. However, we determined that, beginning January 1, 2021, we will be subject to the rules and regulations of the SEC applicable to U.S. domestic issuers.

PRESENTATION OF FINANCIAL INFORMATION

We report under International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or the IASB. None of the financial statements incorporated by reference in this prospectus 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 as issued by the IASB. We have made rounding adjustments to some of the figures included in this prospectus. 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 prospectus to “\$,” “US\$,” “U.S.\$,” “U.S. dollars,” “dollars” and “USD” mean U.S. dollars and all references to “£” and “GBP” mean pounds sterling, unless otherwise noted.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains statements that constitute forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, prospective products, 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 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.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. These forward-looking statements are subject to numerous risks, including, without limitation, the following:

- the impact of the novel coronavirus disease 2019, or COVID-19, pandemic on our business, including our clinical trials and operations;
- 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;
- 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; and
- the other risks described in the section titled “Risk Factors” in this prospectus and described in the documents incorporated by reference into this prospectus.

SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary may not contain all the information that may be important to you, and we urge you to read this entire prospectus carefully, including the “Risk Factors,” “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections and our audited financial statements, including the notes thereto, incorporated by reference into this prospectus, before deciding to invest in our ordinary shares (including in the form of ADSs).

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, ensifentribe 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 ensifentribe has the potential to be the first novel class of bronchodilator in over 40 years. A nebulized formulation of ensifentribe has completed Phase 2 clinical development for the treatment of chronic obstructive pulmonary disease, or COPD, and we expect to commence Phase 3 clinical trials later in 2020. We are investigating the potential impact of the COVID-19 pandemic on the Phase 3 program, including the planned design, cost and timelines and we are evaluating potential mitigations including pre-enrollment COVID-19 screening among others.

Successful Phase 1 and 2 studies have been completed with nebulized ensifentribe 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 ensifentribe formulated in a dry powder inhaler, or DPI, has been completed, with positive clinical results reported in August 2019. We commenced a Phase 2 study in COPD with ensifentribe formulated in a pressurized metered dose inhaler, or pMDI, and completed the single-dose portion (Part A) of the study in March 2020. We postponed the multiple-dose portion of this study (Part B) due to concerns regarding the safety of trial subjects, caregivers and medical staff during the COVID-19 pandemic, but following an assessment of the safety plans and procedures put in place by the UK clinical trial site, we are planning to initiate Part B of this study in the third quarter of 2020. In addition, in July 2020, we received a notice to proceed from the FDA to evaluate pMDI ensifentribe in a randomized, double-blind, placebo-controlled pilot clinical study for the treatment of patients hospitalized with COVID-19. We plan to start this study in the third quarter of 2020.

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 ensifentribe 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.

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.

Private Placements

On July 17, 2020, we entered into a Securities Purchase Agreement, or the Purchase Agreement, with the selling shareholders. Pursuant to the Purchase Agreement, we agreed to sell an aggregate of 38,440,009 ADSs, each representing eight ordinary shares, and 48,088,896 non-voting ordinary shares, at a purchase price equal to \$4.50 per ADS and \$0.5625 per non-voting ordinary share, which we refer to as the 2020 Private Placement in this prospectus. The Purchase Agreement contained customary representations and warranties from us and the selling shareholders and customary closing conditions. The closing of the 2020 Private Placement occurred on July 22, 2020. We received aggregate gross proceeds from the 2020 Private Placement of approximately \$200 million.

In connection with the 2020 Private Placement, we entered into a Registration Rights Agreement with the selling shareholders. Pursuant to the Registration Rights Agreement, we agreed to prepare and file a registration statement with the SEC no later than 30 days following the closing date for purposes of registering

the resale of the ordinary shares underlying the ADSs and the ordinary shares into which the non-voting ordinary shares may be re-designated. We also agreed to use our commercially reasonable efforts to cause the registration statement to be declared effective by the SEC.

Additionally, on July 14, 2020, we entered into a subscription agreement with David Ebsworth, a director, pursuant to which Dr. Ebsworth purchased 222,216 ordinary shares at a purchase price per share of £0.45 concurrently with, and contingent upon, the 2020 Private Placement, which we refer to as the Concurrent Placement in this prospectus.

Corporate Information

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. 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. 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. .

Implications of Being an Emerging Growth Company and a Foreign Private Issuer

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or JOBS Act. As such, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other publicly traded entities that are not emerging growth companies. These exemptions include:

- We are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- we are not required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board, regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);
- we are not required to submit certain executive compensation matters to shareholder advisory votes, such as “say-on-pay,” “say-on-frequency” and “say-on-golden parachutes”; and
- we are not required to disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer’s compensation to median employee compensation.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the closing of the initial public offering of our ADSs or such earlier time that we no longer qualify as an emerging growth company. As a result, the information we provide to our shareholders may be different than you might receive from other public reporting companies in which you hold equity interests.

Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 13(a) of the Exchange Act, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have chosen to irrevocably opt out of this extended transition period and as a result, we comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Under federal securities laws, our decision to opt out of the extended transition period is irrevocable.

We will remain an emerging growth company until the earliest of: (i) the last day of the first fiscal year in which our total annual gross revenues are \$1.07 billion; (ii) the last day of the fiscal year following the

fifth anniversary of the date of the closing of the initial public offering of our ADSs; (iii) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the aggregate market value of our common shares that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter; or (iv) the date on which we have issued more than \$1 billion in non-convertible debt securities during the previous three-year period.

We currently report under the Exchange Act as a non-U.S. company with “foreign private issuer” status. Foreign private issuers under the Exchange Act, are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- 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.

Beginning January 1, 2021, we will be subject to the rules and regulations of the SEC applicable to U.S. domestic public companies, including, among other things, the requirement to file an annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, as required, rules governing solicitation of proxies, the provisions of Regulation Fair Disclosure, which regulate the selective disclosure of material information, and the requirement for insiders to file public reports of their ownership and trading activities. In addition, we will be subject to the Nasdaq Global Market listing requirements applicable to U.S. domestic companies, including, among other things, requirements with respect to the composition of our board of directors and committees, certain corporate governance matters and shareholder approval of certain actions. We will also be required to report our financial statements in accordance with U.S. generally accepted accounting principles.

We have elected to take advantage of certain of the reduced disclosure obligations in this prospectus and in our filings with the SEC that are incorporated by reference herein. As a result, the information that we provide to our shareholders may be different than you might receive from other public reporting companies in which you hold equity interests.

THE OFFERING	
Ordinary shares offered by the selling shareholders	307,742,288 ordinary shares of which 307,520,072 are in the form of ADSs and 48,088,896 ordinary shares upon re-designation of non-voting ordinary shares
Ordinary shares issued and outstanding	414,278,294 ordinary shares (including ordinary shares in the form of ADSs)
Non-Voting ordinary shares issued and outstanding	48,088,896
Use of proceeds	The selling shareholders will receive the proceeds from the sale of the ordinary shares (including in the form of ADSs) in this offering. We will not receive any proceeds from the sale of the ordinary shares but will pay the expenses (other than any underwriting discounts and broker's commissions and similar expense) of this offering.
Dividend Policy	We have never paid or declared any cash dividends on our ordinary shares or ADSs, and we do not anticipate paying any cash dividends on our ordinary shares or ADSs in the foreseeable future.
Risk Factors	See "Risk Factors" and the other information included in this prospectus for a discussion of factors you should consider before deciding to invest in our ordinary shares (including in the form of ADSs).
Listing	Our ADSs are listed on The Nasdaq Global Market under the symbol "VRNA." Our ordinary shares are listed on the AIM under the symbol "VRP."
The number of our ordinary shares and non-voting ordinary shares issued and outstanding is provided as of July 31, 2020 and excludes the following:	
<ul style="list-style-type: none"> • 12,902,320 ordinary shares issuable upon the exercise of share options outstanding as of July 31, 2020 at a weighted average exercise price of £0.99 per share; • 8,750,760 ordinary shares issuable upon the vesting of restricted share units outstanding as of July 31, 2020; • 63,236,453 ordinary shares reserved for future issuance under our 2017 Incentive Award Plan, or the 2017 Plan, as of July 31, 2020, and ordinary shares that may become available pursuant to provisions in the 2017 Plan that automatically increase the share reserve under the 2017 Plan; and • 12,401,262 ordinary shares issuable upon the exercise of warrants outstanding as of July 31, 2020 at a weighted average exercise price of £1.7238 per share. 	
Unless otherwise indicated, all information contained in this prospectus assumes no exercise of the outstanding options and warrants and no vesting of the restricted share units described above after July 31, 2020 and excludes 54,356,608 ordinary shares issuable upon the vesting of restricted share units granted after July 31, 2020.	

RISK FACTORS

You should carefully consider the risks and uncertainties described below and the other information in this prospectus before making an investment in our ordinary shares (including in the form of ADSs). Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occur, and as a result, the market price of our ordinary shares or ADSs could decline and you could lose all or part of your investment. This prospectus also contains forward-looking statements that involve risks and uncertainties. See “Cautionary Statement Regarding Forward-Looking Statements.” Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors.

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 and £19.9 million for the years ended December 31, 2019, and 2018, respectively, and £16.9 million for the six months ended June 30, 2020. As of June 30, 2020, we had an accumulated loss of £117.6 million. Our losses have resulted principally from expenses incurred in research and development of ensifentri ne, 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 ensifentri ne, and seek to obtain regulatory approval for and commercialize ensifentri ne. We anticipate that our expenses will increase substantially as we:

- initiate and conduct Phase 3 clinical trials of nebulized ensifentri ne for the treatment of chronic obstructive pulmonary disease, or COPD;
- conduct our ongoing Phase 2 clinical trial with ensifentri ne formulated in a pMDI, or initiate and conduct other future clinical trials in other formulations, for the treatment of COPD;
- initiate and conduct clinical trials of ensifentri ne for the treatment of cystic fibrosis, or CF, asthma, COVID-19 or other indications;
- seek to discover and develop or in-license additional respiratory product candidates;
- conduct pre-clinical studies to support ensifentri ne and potentially other future product candidates;
- develop the manufacturing processes and produce clinical and commercial supplies of the ensifentri ne active pharmaceutical ingredient and formulated drug products derived from it;
- seek regulatory approvals of ensifentri ne;
- potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize ensifentri ne, 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 ensifentri ne. We are continuing development of ensifentri ne, 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 ensifentri ne, discovering and developing additional product candidates, obtaining regulatory approval for ensifentri ne 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 ensifentri ne 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 ensifentri ne 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 Phase 2 and our planned Phase 3 clinical trials of ensifentri ne, and develop ensifentri ne for other indications. In addition, if we obtain regulatory approval for ensifentri ne 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.

If we obtain regulatory approval for ensifentri ne, we estimate that our existing cash resources and short-term investments will not be sufficient to commercialize ensifentri ne. We will require additional funds to conduct any post-marketing studies to support the commercial positioning of ensifentri ne 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;
- the costs, timing and outcome of the regulatory review of ensifentri ne, 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 ensifentri ne for the treatment of COPD, if regulatory approval is received;

- the cost, progress and results of any clinical trials for the treatment of CF, COVID-19 or other indications;
- the cost of manufacturing clinical and commercial supplies of the ensifentribe active ingredient and derived formulated drug products;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for ensifentribe in other indications and of the development of DPI and MDI formulations of ensifentribe 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 ensifentribe;
- 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 ensifentribe;
- the sales price and availability of adequate third-party coverage and reimbursement for ensifentribe;
- 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 ensifentribe, 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 ensifentribe. 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 ensifentribe 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 ensifentribe, our only product candidate under development. We cannot give any assurance that ensifentribe 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 ensifentribe, are unable to commercialize ensifentribe, 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 ensifentribe, 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 ensifentribe, if approved, which may never occur. Ensifentribe 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 ensifentribe 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 ensifentribe 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 ensifentribe will depend on many factors, including the following:

- we may not be able to demonstrate that ensifentribe 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 ensifentribe 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 ensifentribe 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 ensifentribe to others, the efforts of those parties in completing clinical trials of, receiving regulatory approval for, and commercializing ensifentribe;
- through our clinical trials, we may discover factors that limit the commercial viability of ensifentribe or make the commercialization of ensifentribe unfeasible;
- if we retain rights under a collaboration agreement for ensifentribe, our efforts in completing pre-clinical studies and clinical trials of, receiving marketing approvals for, establishing commercial manufacturing capabilities for, and commercializing ensifentribe; and
- if approved, acceptance of ensifentribe 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 ensifentribe.

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.

The COVID-19 coronavirus has and may continue to adversely impact our business, including our preclinical studies and clinical trials.

In December 2019, a novel strain of coronavirus, which causes COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread to multiple countries, including the United Kingdom and the United States, where we have planned or ongoing preclinical studies and clinical trials. On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic. Since then, governments from many countries have established stay at home measures including, among other things, the prohibition of public gatherings of more than two people and restrictions on domestic and international travel. The pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we have closed our principal office in the UK and our office in the US with all employees continuing their work outside of our offices. . In addition, whilst we have previously reported that we anticipate initiating our Phase 3 program in the third quarter of 2020, we are investigating the potential impact of the COVID-19 pandemic on the program, including the planned design, cost and timelines.

If the COVID-19 coronavirus continues to spread in the United Kingdom, United States and elsewhere, or if the outbreak continues for a significant length of time, we may experience additional disruptions that could severely impact our business, preclinical studies and clinical trials, including in particular initiation of our Phase 3 program and:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- disruption to manufacturers that could affect the supply of drug product for our clinical trials or difficulty sourcing key components necessary for the manufacture of ensifentrine drug product;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 coronavirus pandemic which may require us to undertake additional testing or change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;

- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruptions or delays in preclinical studies due to restricted or limited operations at our third party research and development services;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- diversion of or limitations on employee resources that would otherwise be focused on the operations of our business and the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- higher clinical trial insurance costs and/or delays in operations at insurance agencies, which may impact timelines for the issuance of insurance coverage policies and local coverage determinations delays; and
- refusal of the FDA, the EMA or comparable foreign regulatory authorities to accept data from clinical trials in affected geographies.

Health regulatory agencies globally may also experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA, EMA and comparable foreign regulatory agencies may have slower response times or be under-resourced to review or meet to discuss our regulatory submissions, or to continue to monitor our clinical trials and, as a result, review, inspection and other timelines may be materially delayed. For example, as a result of the COVID-19 pandemic, the FDA has advised that it will provide a written response to our End-of-Phase 2 package, rather than hold a meeting. This may impact our timelines and our ability to obtain clear guidance from the FDA on the design of our Phase 3 program for nebulized ensifentribe. Furthermore, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. It is unknown how long such delays or disruptions could last. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United Kingdom and other countries, business closures or business disruptions and the effectiveness of actions taken in the United Kingdom and other countries to contain and treat the disease.

While the potential economic impact brought by and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, the recession or market correction resulting from the spread of COVID-19 could materially affect our business.

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 ensifentribe, 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 ensifentri falling below acceptable standards for either safety or efficacy; and
- discoveries that may reduce the commercial viability of ensifentri.

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 ensifentri.

If we experience delays in the completion of any clinical trial of ensifentri or any clinical trial of ensifentri is terminated, the commercial prospects of ensifentri may be harmed, and our ability to generate product revenues from ensifentri, 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 ensifentri 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 ensifentri and could impair our ability to commercialize ensifentri. 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 ensifentri.

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 ensifentri 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 16 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 ensifentri ne will increase our costs, slow down our development and approval of ensifentri ne 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 ensifentri ne.

We may become exposed to costly and damaging liability claims, either when testing ensifentri ne 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 ensifentri ne by us and any collaborators in clinical trials, and the sale of ensifentri ne, 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 ensifentri ne. Any claims against us, regardless of their merit, could be difficult and costly to defend and could adversely affect the market for ensifentri ne or any prospects for commercialization of ensifentri ne. In addition, regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for ensifentri ne;
- 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 ensifentri ne.

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 ensifentri ne 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 ensifentri ne.

Although we maintain product liability insurance for ensifentri ne, 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 ensifentri ne. 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;
- 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 ensifentribe 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 ensifentribe 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 ensifentribe. 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 ensifentribe may also be subject to limitations on the approved indicated uses for which ensifentribe 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 ensifentribe.

If problems are discovered with the drug product or manufacture of ensifentribe, 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 ensifentribe or its manufacture and requiring us to recall or remove ensifentribe 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 ensifentribe 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 ensifentribe for multiple indications, including asthma, CF, COVID-19 or other respiratory diseases.

Part of our strategy is to continue to develop ensifentribe in indications other than COPD, such as CF. Although our research and development efforts to date have suggested that ensifentribe has the potential to treat CF, we may not be able to develop ensifentribe in CF or any other disease, or development may not be successful. In addition, the potential use of ensifentribe 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 ensifentribe 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 ensifentribe for any indication in a major pharmaceutical market such as the United States or EU, we may never obtain approval or commercialize ensifentribe 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 ensifentribe 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 inseverable 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 ensifentribe 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 ensifentribe.

Given the number of products already on the market to treat COPD and CF, we expect to face intense competition if ensifentribe 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 ensifentribe, 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 ensifentribe 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 supplies, or we are unable to purchase these supplies after

regulatory approval has been obtained for ensifentri ne, the commercial launch of ensifentri ne would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of ensifentri ne. In addition, growth in the costs and expenses of these supplies may impair our ability to cost-effectively manufacture ensifentri ne.

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 ensifentri ne 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 ensifentri ne, 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 ensifentri ne, formulations of ensifentri ne, polymorphs, salts and analogs of ensifentri ne, methods used to manufacture ensifentri ne, 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 ensifentri ne alone or in combination with other available products, or on in-licensing such rights. Our ensifentri ne 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 ensifentri ne.

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 ensifentri ne, 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 ensifentri ne 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 ensifentri ne 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 ensifentri ne 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 ensifentri ne, 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 ensifentri ne 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 vice president of commercial, Christopher Martin, 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 be able to exercise significant control over us.

As of July 31, 2020, our senior management, board of directors and greater than 5% shareholders and their respective affiliates, in the aggregate, owned approximately 64.5% of our ordinary shares (including ordinary shares represented by ADSs) assuming no exercise of outstanding options or warrants, and

approximately 65.4% 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 have determined that we no longer meet the requirements for being a foreign private issuer and, as of January 1, 2021, we will be required to comply with the provisions of the Exchange Act, and the rules of Nasdaq, applicable to U.S. domestic issuers, which will require us to incur significant expenses and expend time and resources.

As we announced in our Report 6-K filed with the SEC on July 22, 2020 (File No. 001-38067), we did not meet the requirements for being a foreign private issuer. As a result, as of January 1, 2021, we will be required to comply with all of the provisions applicable to a U.S. domestic issuer under the Exchange Act, including filing an annual report on Form 10-K, quarterly periodic reports and current reports for certain events, complying with the sections of the Exchange Act regulating the solicitation of proxies, requiring insiders to file public reports of their share ownership and trading activities and insiders being liable for profit from trades made in a short period of time. We will also be required to comply with the rules of Nasdaq applicable to U.S. domestic issuers, including that our articles of association specify a quorum of no less than one-third of our outstanding voting common shares for meetings of our common shareholders, the solicitation of proxies and the approval by our shareholders in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control and certain private placements. In addition, we will be required to report our financial results under U.S. generally accepted accounting principles, including our historical financial results, which have previously been prepared in accordance with IFRS. We expect to incur significant legal, accounting, insurance and other expenses and to expend greater time and resources, as we prepare for compliance, and comply, with these requirements.

We currently 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 currently report under the Exchange Act as a non-U.S. company with foreign private issuer status. However, we have determined that we will no longer qualify as a foreign private issuer as of January 1, 2021. Foreign private issuers 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 currently qualify as 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. However, we have determined that we will no longer qualify as a foreign private issuer as of January 1, 2021.

We are currently 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 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.

Changes in our tax rates, unavailability of certain tax credits or reliefs or exposure to additional tax liabilities or assessments could affect our profitability, and audits by tax authorities could result in additional tax payments for prior periods.

We carry out research and development activities including, but not limited to, developing ensifentrine for various indications and delivery methods, and as a result we benefit in the U.K. from the HM Revenue and Customs, or HMRC, small and medium sized enterprises research and development relief, or SME R&D Relief, which provides relief against U.K. Corporation Tax.

Broadly, SME R&D Relief comprises two elements, (a) allowing qualifying SMEs to deduct a total of 230% (an additional 130% deduction plus the usual 100% deduction) of their “qualifying expenditure” from their yearly profit for U.K. Corporation Tax purposes, or the SME R&D Additional Deduction and, (b) where there are not sufficient profits for U.K. Corporation Tax purposes to fully utilise the SME R&D Additional Deduction, the excess (“surrenderable losses”) can be carried forward to offset against future taxable profits, or a tax credit currently equal to 14.5% of such surrenderable loss can be claimed in cash, or the SME R&D Tax Credit.

Based on criteria established by HMRC a portion of expenditure incurred in relation to our research and development activities including, but not limited to, operating clinical trials, manufacturing, consultant and salary and related costs, is eligible for the SME R&D Additional Deduction. Our consequential surrendered losses are currently eligible for the SME R&D Tax Credit, in accordance with HMRC criteria.

In our latest accounts for the year ended December 31, 2019, we recorded an SME R&D Tax Credit of £7.3 million (\$9.7 million) which was subsequently received in cash in the six months ended June 30, 2020. We estimate that in the financial years 2021-2023 we could be eligible to receive £20 million – £28 million (\$25 million – \$35 million) in cash from HMRC in SME R&D Tax Credits.

If, however, there are unexpected adverse changes to the SME R&D Relief, or for any reason we are unable to qualify for such advantageous tax legislation, then our business, results of operations and financial condition may be adversely affected.

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

Because we do not earn revenue from our business operations, 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 current taxable year. 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 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 “Certain Material Tax Considerations for U.S. Holders”.

If a U.S. Holder 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. Because 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.

MARKET AND INDUSTRY DATA

Certain industry data and market data included in this prospectus were obtained from independent third-party surveys, market research, publicly available information, reports of governmental agencies and industry publications and surveys. All of the market data used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We believe that the information from these industry publications and surveys included in this prospectus is reliable. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors". These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

TRADEMARKS, SERVICE MARKS AND TRADENAMES

Solely for convenience, the trademarks, service marks, logos and trade names referred to in this prospectus are without the ® and ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names. This prospectus contains additional trademarks, service marks and trade names of others, which are the property of their respective owners. All trademarks, service marks and trade names appearing in this prospectus are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies' trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of our ordinary shares (including in the form of ADSs) in this offering. The selling shareholders will receive all of the proceeds from this offering.

The selling shareholders will pay any underwriting discounts, selling commissions and share transfer taxes or any other expenses incurred by the selling shareholders in connection with the sale of the ordinary shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, fees and expenses of our counsel and our independent registered public accountants.

DIVIDEND POLICY

We have never paid or declared any cash dividends on our ordinary shares or ADSs, and we do not anticipate paying any cash dividends on our ordinary shares or ADSs 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.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2020:

- on an actual basis; and
- on a pro forma basis to give effect to the 2020 Private Placement and the Concurrent Placement.

Investors should read this table in conjunction with our audited annual financial statements and unaudited interim financial statements incorporated by reference in this prospectus, as well as “Use of Proceeds,” “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	As of June 30, 2020,			
	Actual		Pro Forma	
	(in thousands)			
Cash and cash equivalents	£ 18,081	\$ 22,364	£ 164,398	\$ 207,009
Derivative financial instrument	711	879	711	879
Equity:				
Share capital	5,324	6,585	23,116	29,037
Share premium	118,862	147,020	249,459	311,827
Share-based payments reserve	12,572	15,550	12,572	15,550
Accumulated loss	(117,565)	(145,416)	(119,637)	(148,030)
Total equity	19,193	23,739	165,510	208,384
Total capitalization	<u>19,904</u>	<u>24,618</u>	<u>£ 166,221</u>	<u>\$ 209,263</u>

The information presented above excludes the following:

- 12,902,320 ordinary shares issuable upon the exercise of options outstanding as of June 30, 2020 at a weighted average exercise price of £0.99 per share;
- 8,750,760 ordinary shares issuable upon the vesting of restricted share units outstanding as of June 30, 2020;
- 5,133,949 ordinary shares reserved for future issuance under our 2017 Plan as of June 30, 2020 and ordinary shares that may become available pursuant to provisions in the 2017 Plan that automatically increase the share reserve under the 2017 Plan; and
- 12,401,262 ordinary shares issuable upon the exercise of warrants outstanding as of June 30, 2020 at a weighted average exercise price of £1.7328 per share.

Unless otherwise indicated, all information contained in this prospectus assumes no exercise of the outstanding options and warrants and no vesting of the restricted share units described above after June 30, 2020.

SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of this prospectus. We have derived the consolidated statement of comprehensive income data and the consolidated statement of financial position data as of December 31, 2019 and 2018 from our audited financial statements incorporated by reference in this prospectus. We have derived the consolidated statement of comprehensive income data and the consolidated statement of financial position data as of December 31, 2017, 2016 and 2015 from our audited financial statements that are not incorporated by reference in this prospectus. Our historical results are not necessarily indicative of the results that should be expected in the future. We have derived the consolidated statement of comprehensive income data and the consolidated statement of financial position data as of June 30, 2020 and 2019 from our unaudited financial statements incorporated by reference in this prospectus. 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 our audited financial statements incorporated by reference in this prospectus).

	Six Months Ended June 30,		Year Ended December 31,				
	2020	2019	2019	2018	2017	Restated 2016	Restated 2015
		(£'000s)		(£'000s)			
Consolidated statement of comprehensive income data:							
Research and development costs	(12,075)	(15,844)	(33,476)	(19,294)	(23,717)	(4,522)	(7,270)
General and administrative costs	(7,616)	(3,961)	(7,607)	(6,297)	(6,039)	(2,498)	(1,706)
Operating loss	(19,691)	(19,805)	(41,083)	(25,591)	(29,756)	(7,020)	(8,976)
Finance income	532	2,202	2,351	2,783	7,018	1,841	45
Finance expense	(447)	(187)	(474)	(1,325)	(2,465)	(670)	(64)
Loss before taxation	(19,606)	(17,790)	(39,206)	(24,133)	(25,203)	(5,849)	(8,995)
Taxation – credit	2,683	3,412	7,265	4,232	4,706	954	1,509
Loss for the period	(16,923)	(14,378)	(31,941)	(19,901)	(20,497)	(4,895)	(7,486)
Other comprehensive income / (loss):							
Exchange differences on translating foreign operations	3	43	(33)	38	(29)	43	4
Total comprehensive loss attributable to owners of the company	(16,880)	(14,377)	(31,974)	(19,863)	(20,526)	(4,852)	(7,482)
Loss per ordinary share – basic and diluted (pence)*	(16.0)	(13.7)	(30.3)	(18.9)	(23.4)	(14.6)	(37.1)

* Each ADS represents 8 ordinary shares of the Company, so the loss per ADS in any period is equal to 8 times the loss per ordinary share.

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

	As of June 30, 2020 (£'000s)	Year Ended December 31,				
		2019	Restated 2018 (£'000s)	Restated 2017 (£'000s)	Restated 2016 (£'000s)	Restated 2015 (£'000s)
Consolidated statement of financial position data:						
Cash and cash equivalents	18,081	22,934	19,784	31,443	39,785	3,524
Short term investments	—	7,823	44,919	48,819	—	—
Total assets	52,275	45,135	74,745	89,988	46,627	7,840
Share premium	118,862	118,862	118,862	118,862	58,526	26,650
Total liabilities	33,082	11,270	11,327	9,623	11,674	2,407
Accumulated loss	(117,565)	(100,627)	(68,633)	(48,770)	(28,244)	(23,392)
Total equity	19,1932	33,865	63,418	80,365	34,953	5,434

MANAGEMENT

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 prospectus:

Name	Age	Position
Executive Officers		
David Zaccardelli, Pharm.D.	55	President, Chief Executive Officer and Director
Mark W. Hahn	57	Chief Financial Officer
Claire Poll	53	General Counsel
Kathleen Rickard, M.D.	61	Chief Medical Officer
Other Key Management		
Christopher Martin	44	Vice President, Commercial
Desiree Luthman	61	Vice President, Regulatory Affairs
Tara Rheault	45	Vice President, R&D Operations and Global Project Management
Peter Spargo	58	Senior Vice President, Chemistry Manufacturing and Controls
Non-Executive Directors		
Ken Cunningham, M.D. ⁽²⁾	67	Non-executive Director
David Ebsworth, Ph.D. ⁽¹⁾⁽²⁾⁽³⁾	66	Chairman of the Board
Rishi Gupta ⁽²⁾	43	Non-executive Director
Mahendra Shah, Ph.D. ⁽³⁾	75	Non-executive Director
Andrew Sinclair, Ph.D. ⁽¹⁾	48	Non-executive Director
Vikas Sinha ⁽¹⁾	57	Non-executive Director
Anders Ullman, Ph.D. ⁽³⁾	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 U.S. 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.

Mark Hahn. Mr. Hahn has served as our Chief Financial Officer since February 2020. From January 2018 until its acquisition by Swedish Orphan Biovitrum for up to \$915 million in November 2019, Mr. Hahn served as CFO of Dova Pharmaceuticals, a company developing therapeutics for rare diseases. Previously, from 2010 until its acquisition by Melinta Therapeutics in November 2017, Mr. Hahn was CFO of Cempra, Inc. Mr. Hahn received a B.B.A. degree in Accounting and Finance from the University of Wisconsin-Milwaukee and is a Certified Public Accountant in Maryland and North Carolina.

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 employed 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, an investment firm, where he is currently a Partner. Prior to OrbiMed Advisors LLC, Mr. Gupta 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, Rosen & Katz. Mr. Gupta currently serves on the boards of directors of several private companies. 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, a healthcare investment firm, pursuant to a relationship agreement that we entered into with such funds in June 2016. Although such agreement automatically terminated on the closing of the 2020 Private Placement, Dr. Shah continues to serve as a Non-Executive Director. Dr. Shah is a successful pharmaceutical entrepreneur and executive and, since March 2010, has served as a Managing Director of Vivo Capital. Dr. Shah serves as a member of the board of directors of Scilex Pharmaceuticals, Inc. and several other 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 a relationship agreement that we entered into with Abingworth in June 2016. Although such agreement automatically terminated on the closing of the 2020 Private Placement, Dr. Sinclair continues to serve as a Non-Executive Director. 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.

Christopher Martin. Mr. Martin has served as our Vice President, Commercial since June 2020. From March 2018 to June 2020 he served as Executive Director of Marketing at SK Life Science, a subsidiary of SK Biopharmaceutical, where he was instrumental in launching the company's first commercial product, an anti-epileptic medication. From January 2016 to November 2017 Mr. Martin was the Director of Marketing at Cempra, Inc. Mr. Martin received a bachelor's degree in Financial Management from Clemson University.

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.

PRINCIPAL AND SELLING SHAREHOLDERS

The following table sets forth information relating to the beneficial ownership of our ordinary shares as of July 31, 2020, by:

- each person, or group of affiliated persons, who 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
- each selling shareholder.

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 July 31, 2020, through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all ordinary shares held by that person.

The percentage of ordinary shares beneficially owned is computed on the basis of 414,278,294 of our ordinary shares outstanding (including ordinary shares in the form of ADSs) as of July 31, 2020. Ordinary shares that a person has the right to acquire within 60 days of July 31, 2020 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person. The shares beneficially owned after the offering assumes that each selling shareholder sells all of the ordinary shares acquired by such holder in the 2020 Private Placement or Concurrent Placement, including ordinary shares acquired upon the re-designation of non-voting ordinary shares acquired in the 2020 Private Placement. As of July 31, 2020, 387,037,904 ordinary shares, representing 84.7% of our issued and outstanding ordinary shares were held in the form of our ADSs. 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	Shares Beneficially Owned Prior to Offering			Shares Beneficially Owned After Offering		
	Number of Ordinary Shares	Number of Non-Voting Ordinary Shares	Percentage	Number of Shares Being Offered	Number of Ordinary Shares	Number of Non-Voting Ordinary Shares
3% or Greater Shareholders and selling shareholders:						
Novo A/S ⁽¹⁾	23,048,499	—	5.54%	8,888,888	14,159,611	—
Vivo Capital affiliates ⁽²⁾	26,256,032	—	6.31%	12,444,448	13,811,584	—
OrbiMed affiliates ⁽³⁾	47,426,666	—	11.40%	35,555,560	11,871,106	—
New Enterprise Associates affiliates ⁽⁴⁾	42,638,131	—	10.25%	31,111,112	11,527,019	—
Abingworth Bioventures VI, LP ⁽⁵⁾	21,064,222	—	5.07%	12,444,448	8,619,774	—
Tekla Capital affiliates ⁽⁶⁾	6,900,061	—	1.66%	1,777,784	5,122,277	—
Polar Capital Holdings plc ⁽⁷⁾	11,679,931	—	2.82%	7,111,112	4,568,819	—
Aisling Capital IV, LP ⁽⁸⁾	11,249,755	—	2.71%	7,111,112	4,138,643	—
Inshan Sinha 2019 Trust ⁽⁹⁾	355,552	—	*	266,664	88,888	—
Natasha Sinha 2019 Trust ⁽¹⁰⁾	355,552	—	*	266,664	88,888	—
Foresite Capital Fund III, L.P. ⁽¹¹⁾	8,888,896	—	2.15%	8,888,896	—	—
RA Capital Management affiliates ⁽¹²⁾	46,025,807	48,088,896	9.99%	88,888,896	—	—
AI Biotechnology LLC ⁽¹³⁾	44,444,448	—	10.73%	44,444,448	—	—
Perceptive Life Sciences Master Fund, Ltd. ⁽¹⁴⁾	23,111,112	—	5.58%	23,111,112	—	—

Name and address of beneficial owner	Shares Beneficially Owned Prior to Offering			Number of Shares Being Offered	Shares Beneficially Owned After Offering		
	Number of Ordinary Shares	Number of Non-Voting Ordinary Shares	Percentage		Number of Ordinary Shares	Number of Non-Voting Ordinary Shares	Percentage
Acorn Bioventures VI L.P. ⁽¹⁵⁾	12,444,448	—	3.00%	12,444,448	—	—	—
Entities affiliated with Paul B. Manning ⁽¹⁶⁾	12,444,448	—	3.00%	12,444,448	—	—	—
Samsara BioCapital, L.P. ⁽¹⁷⁾	8,888,896	—	2.15%	8,888,896	—	—	—
Sphera affiliates ⁽¹⁸⁾	8,000,000	—	1.93%	8,000,000	—	—	—
Soleus Capital Master Fund, L.P. ⁽¹⁹⁾	7,111,112	—	1.72%	7,111,112	—	—	—
Fairmount affiliates ⁽²⁰⁾	7,111,112	—	1.72%	7,111,112	—	—	—
Ghost Tree Master Fund, LP ⁽²¹⁾	4,444,448	—	1.07%	4,444,448	—	—	—
CVI Investments, Inc. ⁽²²⁾	3,555,560	—	*	3,555,560	—	—	—
Logos Global Master Fund, L.P. ⁽²³⁾	2,666,672	—	*	2,666,672	—	—	—
Altium Growth Fund, L.P. ⁽²⁴⁾	1,777,784	—	*	1,777,784	—	—	—
DAFNA affiliates ⁽²⁵⁾	1,777,776	—	*	1,777,776	—	—	—
John A. Stalfort III ⁽²⁶⁾	888,896	—	*	888,896	—	—	—
Revach Fund LP ⁽²⁷⁾	444,448	—	*	444,448	—	—	—
Steven M. Goldman ⁽²⁸⁾	444,448	—	*	444,448	—	—	—
Parallax Biomedical Fund, LP ⁽²⁹⁾	355,560	—	*	355,560	—	—	—
Executive Officers and Directors:							
David Zaccardelli, Pharm.D. ⁽³⁰⁾	757,440	—	*	444,440	313,000	—	*
Mark W. Hahn ⁽³¹⁾	329,248	—	*	177,784	151,464	—	*
Kathleen Rickard, M.D. ⁽³²⁾	198,328	—	*	—	198,328	—	*
Claire Poll ⁽³³⁾	1,144,803	—	*	—	1,144,803	—	*
Ken Cunningham, M.D.	—	—	—	—	—	—	—
Martin Edwards ⁽³⁴⁾	53,328	—	*	53,328	—	—	—
David Ebsworth, Ph.D. ⁽³⁵⁾	622,519	—	*	222,216	400,303	—	*
Rishi Gupta	—	—	—	—	—	—	—
Mahendra Shah, Ph.D.	—	—	—	—	—	—	—
Andrew Sinclair, Ph.D.	—	—	—	—	—	—	—
Vikas Sinha ⁽³⁶⁾	120,384	—	*	—	120,384	—	*
Anders Ullman, Ph.D. ⁽³⁷⁾	266,664	—	*	266,664	—	—	—

* Less than 1%.

- (1) After offering consists of (a) 21,278,873 ordinary shares held directly by Novo A/S, or Novo, of which 14,814,808 are held in the form of ADSs, 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/A filed with the SEC on July 24, 2020. 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) 11,990,717 ordinary shares held directly by Vivo Ventures Fund VII L.P., or Vivo VII, of which 6,942,840 are held in the form of ADSs, (e) 53,088 ordinary shares held directly by Vivo Ventures VII Affiliates Fund, L.P., or Vivo Affiliates VII, all of which are

held in the form of ADSs, (f) 9,955,560 ordinary shares held directly by Vivo Ventures Fund Cayman VII, L.P., or Vivo Ventures Cayman VII, all of which are held in the form of ADSs, (g) warrants to purchase 1,462,477 ordinary shares held directly by Vivo VII, (h) warrants to purchase 31,874 ordinary shares held directly by 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, Vivo Affiliates VII and Vivo Ventures Cayman VII. Vivo Ventures VI and Vivo Ventures VII disclaim beneficial ownership of all shares held by Vivo VI, Vivo Affiliates VI, Vivo VII, Vivo Affiliates VII and Vivo Ventures Cayman 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, 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. Beneficial ownership information is based on information known to us and a Schedule 13G/A filed with the SEC on July 24, 2020. Vivo Ventures VI's and Vivo Ventures VII's mailing address is 192 Lytton Avenue, Palo Alto, CA, 94301.

- (3) Consists of (a) 40,225,392 ordinary shares held directly by OrbiMed Private Investments VI, LP, or OPI VI, all of which are held in the form of ADSs, (b) warrants to purchase 1,867,938 ordinary shares are held directly by OPI VI, and (c) 5,333,336 ordinary shares held by The Biotech Growth Trust PLC, or BIOG, all of which are held in the form of ADSs. OrbiMed Capital GP VI LLC, or OrbiMed GP VI, is the general partner of OPI VI. OrbiMed Advisors LLC, or OrbiMed Advisors, is the managing member of OrbiMed GP VI. By virtue of such relationships, OrbiMed GP VI and OrbiMed Advisors may be deemed to have voting and investment power over the securities held by OPI VI and as a result, may be deemed to have beneficial ownership over such securities. OrbiMed Capital LLC, or OrbiMed Capital, is the portfolio manager of BIOG. OrbiMed Advisors and OrbiMed Capital exercise 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 and BIOG. Beneficial ownership information is based on information known to us and a Schedule 13 D/A filed with the SEC on January 26, 2018. The mailing address of OPI VI, BIOG, OrbiMed GP VI, and OrbiMed Advisors is c/o OrbiMed Advisors LLC, 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, (b) warrants to purchase 1,769,626 ordinary shares held directly by GEO, and (c) 31,111,112 ordinary shares held directly by Growth Equity Opportunities 17, LP, or GEO 17, all of which are held in the form of ADSs. 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. Forest Baskett, Anthony Florence, Jr., Mohamad Makhzoumi, Scott D. Sandell, and Peter Sonsini 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. New Enterprise Associates 17, L.P., or NEA 17, is the sole member of GEO 17. NEA Partners 17, L.P., or NEA Partners 17, is the sole general partner of NEA 17. NEA 17 GP, LLC, or NEA 17 LLC, is the sole general partner of NEA Partners 17. Forest Baskett, Ali Behbahani, Carmen Chang, Anthony Florence, Jr., Mohamad Makhzoumi, Joshua Makower, Edward Mathers, Scott D. Sandell, Paul Walker, Rick Yang, Liza Landsman, and Peter Sonsini, are the managers of NEA 17 LLC. NEA 17, NEA Partners 17, NEA 17 LLC and the managers of NEA 17 LLC share voting and dispositive power with regard to the securities held by GEO 17. Each of NEA 17, NEA Partners 17 and NEA 17 LLC as well as each of the managers of NEA 17 LLC disclaims beneficial ownership of all shares held by GEO 17 except to the extent of their actual pecuniary interest therein. Beneficial ownership information is based on information known to us and a Schedule 13D/A filed with the SEC on August 3, 2020. GEO's and GEO 17's mailing address is 1954 Greenspring Drive, Suite 600, Timonium, MD 21093-4135.

- (5) Consists of (a) 1 ordinary share held directly by Abingworth Bioventures VI, LP, or Abingworth VI, and 19,660,000 ordinary shares 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 Timothy Haines, Kurt von Emster, Genghis Lloyd-Harris, Shelley Chu, Brian Gallagher and Bali Muralidhar 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 Timothy Haines, Kurt von Emster, Genghis Lloyd-Harris, Shelley Chu, Brian Gallagher and Bali Muralidhar 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. Abingworth VI's mailing address is 38 Jermyn Street, London SW1Y 6DN, United Kingdom.
- (6) Consists of (a) 5,268,575 ordinary shares held directly by Tekla World Healthcare Fund, or Tekla World, of which 3,231,112 are held in the form of ADSs, (b) warrants to purchase 513,192 ordinary shares held directly by Tekla World, (c) 746,672 ordinary shares held directly by Tekla Life Sciences Investors, or Tekla Life, all of which are held in the form of ADSs, (d) 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, 2020. Tekla Capital's mailing address is 100 Federal Street, 19th Floor, Boston, MA 02110.
- (7) Consists of (a) 11,611,112 ordinary shares of which 4,500,000 ordinary shares are held directly by Polar Capital Funds plc, or PCF, and 7,111,112 ordinary shares are held by Polar Capital Partners LLP — Biotechnology Fund, or Polar Capital, in the form of ADSs and (b) warrants to purchase 68,819 ordinary shares held directly by PCF. PCF and Polar Capital are managed by Polar Capital Holdings plc, or PCH. Beneficial ownership information is based on information known to us. The mailing address for Polar Capital Biotechnology Fund is c/o Polar Capital PLC, 16 Palace Street, London, SW1E 5JD.
- (8) Consists of (a) 10,659,880 ordinary shares held directly by Aisling Capital IV, L.P., or Aisling, all of which are held in the form of ADSs, and (b) warrants to purchase 589,875 ordinary shares held directly by Aisling. These shares are owned directly by Aisling and held indirectly by Aisling Capital Partners IV, LP, or Aisling GP, as general partner of Aisling, Aisling Capital Partners IV LLC, or Aisling Partners, as general partner of Aisling GP, and each of the individual managing members of Aisling Partners. The individual managing members, or Managers, of Aisling Partners are Dr. Andrew Schiff and Steve Elms. Aisling GP, Aisling Partners and the Managers share voting and dispositive power over the shares directly held by Aisling. Each of Aisling GP, Aisling Partners and the Managers may be deemed to be the beneficial owner of the securities listed above only to the extent of its pecuniary interest therein. The above information shall not be deemed an admission that any of Aisling GP, Aisling Partners or any of the Managers is the beneficial owner of any securities reported herein in excess of such amount. Beneficial ownership information is based on information known to us and a TR-1 provided to us on June 6, 2017. The address of the principal business offices of each of these entities and individuals is 888 Seventh Avenue, 12th Floor, New York, New York 10106.
- (9) Consists of 355,552 ordinary shares held directly by Inshan Sinha 2019 Trust, all of which are held in the form of ADSs. Beneficial ownership information is based on information known to us.

- (10) Consists of 355,552 ordinary shares held directly by Natasha Sinha 2019 Trust, all of which are held in the form of ADSs. Beneficial ownership information is based on information known to us.
- (11) Consists of 8,888,896 ordinary shares held directly by Foresite Capital Fund III, L.P., or FCF III, all of which are held in the form of ADSs. Foresite Capital Management III, LLC, or FCM III, is the general partner of FCF III, and Mr. James Tananbaum is the managing member of FCM III. Each of FCM III and Mr. Tananbaum disclaims beneficial ownership of all shares held by FCF III except to the extent of their actual pecuniary interest therein. Beneficial ownership information is based on information known to us. FCF III's mailing address is 600 Montgomery Street, Suite 4500, San Francisco, CA 94111.
- (12) Consists of (a) 36,770,504 ordinary shares held directly by RA Capital Healthcare Fund, L.P., or RA Capital, all of which are held in the form of ADSs, (b) 43,339,542 non-voting ordinary shares to be re-designated as ordinary shares, held directly by RA Capital, (c) 4,029,496 ordinary shares held directly by Blackwell Partners LLC — Series A, or Blackwell, all of which are held in the form of ADSs, and (d) 4,749,354 non-voting ordinary shares to be re-designated as ordinary shares, held directly by Blackwell. RA Capital and Blackwell may elect to have any portion of their non-voting ordinary shares re-designated as voting ordinary shares at any time, unless, immediately following such conversion, they would beneficially own more than 9.99% of the outstanding ordinary shares. If RA Capital or Blackwell would beneficially own more than 9.99% of the outstanding ordinary shares following such re-designation, then the re-designation would occur no earlier than 61 days following the election for such re-designation. RA Capital Management, L.P., or Adviser, is the investment manager for RA Capital and Blackwell. The general partner of the Adviser is RA Capital Management GP, LLC, or Adviser GP, of which Dr. Peter Kolchinsky and Mr. Rajeev Shah are the managing members. The Adviser, the Adviser GP, Dr. Kolchinsky, and Mr. Shah disclaim beneficial ownership of securities held by RA Capital and Blackwell except to the extent of their pecuniary interest therein. Beneficial ownership information is based on information known to us. RA Capital Management's mailing address is 200 Berkeley Street, 18th Floor, Boston, MA 02116.
- (13) Consists of 44,444,448 ordinary shares held directly by AI Biotechnology LLC, or AI, all of which are held in the form of ADSs. AI is a subsidiary in a multi-tier corporate structure of which Access Industries Holdings LLC, or Access Holdings, is the parent holding company and is ultimately managed by Access Industries Management, LLC, or Access Industries, and controlled by Mr. Len Blavatnik. Each of Access Holdings, Access Industries and Mr. Blavatnik disclaims beneficial ownership of all shares held by AI except to the extent of their actual pecuniary interest therein. Beneficial ownership information is based on information known to us and a Schedule 13G filed with the SEC on July 24, 2020. The mailing address of AI, Access Holdings, Access Industries and Mr. Blavatnik is 40 West 57th Street, 28th Floor, New York, NY 10019.
- (14) Consists of 23,111,112 ordinary shares held directly by Perceptive Life Sciences Master Fund, Ltd., all of which are held in the form of ADSs. Beneficial ownership information is based on information known to us. The mailing address of Perceptive Life Sciences Master Fund, Ltd. is 51 Astor Place, 10th Floor, New York, NY 10003.
- (15) Consists of 12,444,448 ordinary shares held directly by Acorn Bioventures, L.P., all of which are held in the form of ADSs. Beneficial ownership information is based on information known to us.
- (16) Consists of 6,222,224 ordinary shares held directly by BKB Growth Investments, LLC, or BKB Growth, all of which are held in the form of ADSs and (b) 6,222,224 ordinary shares held directly by PD Joint Holdings, LLC Series 2016-A, or PD Joint, all of which are held in the form of ADSs. Paul B. Manning and Bradford Manning are each managers of Tiger Lily Capital, LLC, the manager of BKB Growth and PD Joint. Beneficial ownership information is based on information known to us. The address for each of BKB Growth and PD Joint is c/o Tiger Lily Capital, LLC, 200 Garrett Street, Suite O, Charlottesville, VA 22902.
- (17) Consists of 8,888,896 ordinary shares held directly by Samsara BioCapital, L.P., all of which are held in the form of ADSs. Beneficial ownership information is based on information known to us. The mailing address of Samsara BioCapital, L.P. is 628 Middlefield Road, Palo Alto, CA 94301.
- (18) Consists of 6,000,000 ordinary shares held directly by Sphera Global Healthcare Master Fund, or Sphera Healthcare, all of which are held in the form of ADSs and (b) 2,000,000 ordinary shares held

directly by Sphera Biotech Master Fund, or Sphera Biotech, all of which are held in the form of ADSs. Beneficial ownership information is based on information known to us. The mailing address for Sphera Healthcare is 21 Ha'arbaa Street, 4th Floor, Tel Aviv, Israel.

- (19) Consists of 7,111,112 ordinary shares held directly by Soleus Capital Master Fund, L.P., all of which are held in the form of ADSs. Soleus Capital, LLC, or Soleus Capital, is the general partner of Soleus Master Fund. The managing member of Soleus Capital is Soleus Capital Group, LLC, or Soleus Capital Group, of which Mr. Guy Levy is the managing member. Soleus Capital, Soleus Capital Group and Mr. Levy disclaim beneficial ownership of securities held by Soleus Master Fund except to the extent of their pecuniary interest therein. Beneficial ownership information is based on information known to us. Soleus Master Fund's and Soleus Capital's mailing address is 104 Field Point Road, 2nd Floor, Greenwich, CT 06830.
- (20) Consists of 5,980,760 ordinary shares held directly by Fairmount Healthcare Fund II LP, or Fairmount II, all of which are held in the form of ADSs and (b) 1,130,352 ordinary shares held directly by Fairmount Healthcare Fund LP, or Fairmount, all of which are held in the form of ADSs. Beneficial ownership information is based on information known to us. The mailing address of Fairmount and Fairmount II is 2001 Market Street, Suite 2500, Philadelphia, PA 19103.
- (21) Consists of 4,444,448 ordinary shares held directly by Ghost Tree Master Fund, LP, all of which are held in the form of ADSs. The mailing address of Ghost Tree Master Fund, LP is 200 Dorado Beach Drive, 3732 West Beach, Dorado, Puerto Rico, 00646. Beneficial ownership information is based on information known to us.
- (22) Consists of 3,555,560 ordinary shares held directly by CVI Investments, Inc., or CVI, all of which are held in the form of ADSs. Heights Capital Management, Inc., the authorized agent of CVI, has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. Martin Kobinger, in his capacity as Investment Manager of Heights Capital Management, Inc., may also be deemed to have investment discretion and voting power over the shares held by CVI. Mr. Kobinger disclaims any such beneficial ownership of the shares. CVI is affiliated with one or more FINRA members, none of whom are currently expected to participate in the sale pursuant to the prospectus contained in the Registration Statement of ordinary shares (in the form of ADSs) purchased by CVI in this offering. CVI purchased the shares being registered hereunder in the ordinary course of business and at the time of purchase, had no agreements or understandings, directly or indirectly, with any other person to distribute such shares. Beneficial ownership information is based on information known to us. The principal business address of Heights Capital Management, Inc. is P.O. Box 309GT, Ugland House, South Church Street, George Town, Grand Cayman, Cayman Islands.
- (23) Consists of 2,666,672 ordinary shares held directly by Logos Global Master Fund L.P., all of which are held in the form of ADSs. Beneficial ownership information is based on information known to us.
- (24) Consists of 1,777,784 ordinary shares held directly by Altium Growth Fund, LP, all of which are held in the form of ADSs. Beneficial ownership information is based on information known to us.
- (25) Consists of 1,306,672 ordinary shares held directly by DAFNA LifeScience LP, all of which are held in the form of ADSs and (b) 471,104 ordinary shares held directly by DAFNA LifeScience Select LP, all of which are held in the form of ADSs. DAFNA Capital Management LLC is the sole general partner of DAFNA LifeScience LP and DAFNA LifeScience Select LP. The Chief Executive Officer and Chief Investment Officer of DAFNA Capital Management LLC are Dr. Nathan Fischel and Dr. Fariba Ghodsian, respectively. These individuals may be deemed to have shared voting and investment power of the shares held by DAFNA LifeScience LP and DAFNA LifeScience Select LP. Each of Dr. Fischel and Dr. Fariba disclaim beneficial ownership of such shares, except to the extent of his or her pecuniary interest therein. Beneficial ownership information is based on information known to us. DAFNA Capital's mailing address is 10990 Wilshire Blvd. #1400, Los Angeles, CA 90024.
- (26) Consists of 888,896 ordinary shares held directly by John A. Stalfort III, all of which are held in the form of ADSs. Beneficial ownership information is based on information known to us. The mailing address for Mr. Stalfort is 200 Garrett Street, Suite S, Charlottesville, VA 22902.
- (27) Consists of 444,448 ordinary shares held directly by Revach Fund LP, all of which are held in the form of ADSs. Beneficial ownership information is based on information known to us. The mailing address of Revach Fund LP is 80 Brainard Road, West Hartford, CT 06117.

- (28) Consists of 444,448 ordinary shares held directly by Steven M. Goldman, all of which are held in the form of ADSs. Beneficial ownership information is based on information known to us. The mailing address of Mr. Goldman is 390 West End Avenue, Apt. 6J, New York, NY 10024.
- (29) Consists of 355,560 ordinary shares held directly by Parallax Biomedical Fund, LP, all of which are held in the form of ADSs. Beneficial ownership information is based on information known to us. The mailing address of Parallax Biomedical Fund, LP is c/o Vista Point Capital, P.O. Box 357, Walnut Creek, CA 94597.
- (30) Consists of (a) 579,240 ordinary shares, all of which are held in the form of ADSs and (b) 178,200 restricted stock units that are, or will be within 60 days of July 31, 2020, immediately exercisable.
- (31) Consists of (a) 240,152 ordinary shares, all of which are held in the form of ADSs and (b) 89,096 restricted stock units that are, or will be within 60 days of July 31, 2020, immediately exercisable.
- (32) Consists of 198,328 options to purchase ordinary shares that are, or will be within 60 days of July 31, 2020.
- (33) Consists of (a) 130,575 ordinary shares, (b) 903,678 options to purchase ordinary shares that are, or will be within 60 days of July 31, 2020, immediately exercisable, and (c) 110,550 restricted stock units that are, or will be within 60 days of July 31, 2020, immediately exercisable.
- (34) Consists of 53,328 ordinary shares, all of which are held in the form of ADSs.
- (35) Consists of (a) 617,603 ordinary shares and (b) warrants to purchase 4,916 ordinary shares.
- (36) Consists of 120,384 options to purchase ordinary shares that are or will be immediately exercisable within 60 days of July 31, 2020.
- (37) Consists of 266,664 ordinary shares, all of which are held in the form of ADSs.

To our knowledge, other than as provided in the table above, our other filings with the SEC and this prospectus, there has been no significant change in the percentage ownership held by any major shareholder since July 31, 2020.

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.

RELATED PARTY TRANSACTIONS

The following is a description of related party transactions we have entered into since January 1, 2017 or currently in effect with any member of our board of directors and executive officers.

2020 Private Placement

On July 17, 2020, we entered into the Purchase Agreement, with the selling shareholders. Pursuant to the Purchase Agreement, we agreed to sell an aggregate of 38,440,009 ADSs, each representing eight ordinary shares, and 48,088,896 non-voting ordinary shares, at a purchase price equal to \$4.50 per ADS and \$0.5625 per non-voting ordinary share. The Purchase Agreement contained customary representations and warranties from us and the selling shareholders and customary closing conditions. The closing of the 2020 Private Placement occurred on July 22, 2020. We received aggregate gross proceeds from the 2020 Private Placement of approximately \$200 million.

In connection with the 2020 Private Placement, we entered into a Registration Rights Agreement with the selling shareholders. Pursuant to the Registration Rights Agreement, we agreed to prepare and file a registration statement with the SEC no later than 30 days following the closing date for purposes of registering the resale of the ordinary shares underlying the ADSs and the ordinary shares into which the non-voting ordinary shares may be re-designated. We also agreed to use our commercially reasonable efforts to cause the registration statement to be declared effective by the SEC. Under Registration Rights Agreement, we will pay all expenses relating to the registration, other than selling commission, discounts or brokerage fees and stock transfer taxes, subject to specified conditions and limitations.

The following table sets forth the aggregate number of ADSs and non-voting ordinary shares acquired by our directors, executive officers and our major shareholders in the 2020 Private Placement. Each ADS represents eight ordinary shares.

Participants ⁽¹⁾	ADSs	Non-Voting Ordinary Shares
RA Capital Healthcare Fund L.P.	4,596,313	43,339,542
Blackwell Partners LLC – Series A	503,687	4,749,354
AI Biotechnology LLC	5,555,556	—
Growth Equity Opportunities 17 LP	3,888,889	—
OrbiMed Private Investments VI, LP	3,777,778	—
Perceptive Life Sciences Masters Fund, Ltd.	2,888,889	—
Abingworth Bioventures VI, LP	1,555,556	—
Acorn Bioventures, L.P.	1,555,556	—
Vivo Venture Fund Cayman VII, L.P.	1,244,445	—
Vivo Ventures Fund VII, L.P.	304,475	—
Vivo Ventures VII Affiliates Fund, L.P.	6,636	—
Novo Holdings A/S	1,111,111	—
David Zaccardelli	55,555	—
Mark W. Hahn	22,223	—
Martin Edwards	6,666	—

(1) Additional details regarding these shareholders and their equity holdings are provided in this prospectus under the caption “Principal and Selling Shareholders.”

Some of our directors are associated with certain of the major shareholders that participated in the 2020 Private Placement, as indicated in the table below:

Director	Principal Shareholder
Rishi Gupta	OrbiMed Private Investments VI, LP
Mahendra Shah	Vivo Venture Fund Cayman VII, L.P.
	Vivo Ventures Fund VII, L.P.
	Vivo Ventures VII Affiliates Fund, L.P.
Andrew Sinclair	Abingworth Bioventures VI, LP

Concurrent Placement

On July 14, 2020, we entered into a subscription agreement with David Ebsworth, a director, pursuant to which Dr. Ebsworth purchased 222,216 ordinary shares at a purchase price per share of £0.45 concurrently with, and contingent upon, the 2020 Private Placement.

2016 Registration Rights Agreement

In July 2016, we entered into a registration rights agreement, or the 2016 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, 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

Under both the 2016 Registration Rights Agreement, 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 2016 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.

Material Contracts

In addition to the contracts described elsewhere in this prospectus, 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 prospectus.

Relationship Agreements

In June 2016, we entered into relationship agreements with each of Vivo Capital, OrbiMed Private Investments VI, LP, 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 Private Investments VI, LP, 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 Private Investments VI, LP, 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 Private Investments VI, LP, or Abingworth, as applicable, cease to have certain rights and obligations under the relationship agreements. Upon closing of the 2020 Private Placement, Vivo Capital and Abingworth ceased to beneficially hold 6.5% of our issued ordinary shares and, as a result, the appointment rights under the relationship agreements with such parties and the relationship agreements themselves automatically terminated as of July 22, 2020.

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, as well as separation agreements with certain of our former executive officers. See "Item 6. Directors, Senior Management and Employees — Compensation" and Note 8 of our Annual Consolidated Financial Statements in our Annual Report filed on Form 20-F.

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 "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).

Interests of Experts and Counsel

Not applicable.

DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

Set forth below is a summary of certain information concerning our share capital 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 this prospectus. 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 is incorporated by reference as an exhibit to the registration statement of which this prospectus is a part.

General

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.

Share Capital

As of July 31, 2020, our issued share capital was £23,118,359.50, comprised of 414,278,294 ordinary shares each carrying one voting right and 48,088,896 non-voting ordinary shares. As of June 30, 2020, our issued share capital was £5,324,050.30, comprised of 106,481,006 ordinary shares each carrying one voting right. The nominal value of our ordinary shares is £0.05 per share. Each issued ordinary share is fully paid.

History of Share Capital

On February 10, 2017, we effected a 1-for-50 reverse share split of our ordinary shares.

On May 2, 2017, we issued 5,768,000 ADSs at a price per ADS of \$13.50 and 1,255,001 ordinary shares at a price per share of £1.32 (\$1.69). On the same day, as part of a private placement, we issued 254,099 shares at a price per share of £1.32 (\$1.69). On May 18, 2017, and May 26, 2017, we issued 692,385 ADSs and 41,353 ADSs, respectively, upon the exercise in part of the underwriters' option to purchase additional ADSs. We received aggregate net proceeds of \$80.5 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

On July 22, 2020, we issued 38,440,009 ADSs at a price per ADS of \$4.50 and 48,088,896 non-voting ordinary shares at a price per share of \$0.5625 in the 2020 Private Placement. On the same day, we issued 222,216 ordinary shares to a director at a price per share of £0.45 in the Concurrent Placement. We received approximately \$200 million in gross proceeds from the 2020 Private Placement and the concurrent purchase of ordinary shares by the director.

Options

We have established equity incentive plans pursuant to which we have issued options to purchase ordinary shares or ADSs and restricted share units to employees and directors. As of July 31, 2020, there were options to purchase 12,920,320 ordinary shares and 8,750,760 unvested restricted share units outstanding. We granted an additional 54,356,608 restricted share units to our employees after July 31, 2020.

The tables below summarize our outstanding options to purchase ordinary shares or ADSs and unvested restricted share units as of July 31, 2020, that we have granted to our directors and our employees pursuant to our equity incentive plans. Options to purchase ordinary shares or ADSs granted under the Verona Pharma plc Unapproved Share Option Scheme, Verona Pharma plc EMI Option Scheme and Verona Pharma plc 2017 Incentive Award Plan have a term of ten years.

Options granted to employees and directors:

Share Options Granted Under the EMI Share Option Scheme		
No of options	Exercise Price (£)	Expiry Date
49,998	1.75	5/15/2024
41,997	1.25	1/29/2025
21,996	2	2/9/2026

Share Options Granted Under the Unapproved Share Option Scheme		
No of options	Exercise Price (£)	Expiry Date
300,000	2.04	9/26/2026
199,998	1.89	9/13/2026
109,998	1.8	8/3/2026
79,992	2.00	4/15/2023
60,000	2	7/29/2023
49,998	1.75	5/15/2024

Share Options Granted Under the 2017 Incentive Award Plan		
No of options	Exercise Price (£)	Expiry Date
2,075,684	0.57	3/29/2029
2,005,102	1.32	4/26/2027
1,505,000	0.55	3/3/2030
667,340	1.46	3/8/2028
346,000	0.60	6/11/2029
160,000	1.32	6/14/2027
100,000	0.46	8/22/2029
13,333	1.525	5/26/2027
6,667	1.525	5/25/2027

Restricted share units granted to employees:

Unvested Restricted Share Units Granted Under the 2017 Incentive Award Plan		
No of RSUs	Exercise Price (£)	Fully Vested Date
54,356,608	n/a	8/20/2024
7,372,864	n/a	2/1/2024
801,896	n/a	1/31/2021
332,266	n/a	3/29/2024
182,668	n/a	4/26/2022
61,066	n/a	3/8/2023

Options granted to third parties:

The table below summarizes our outstanding options to purchase ordinary shares as of July 31, 2020, that we have granted to third parties.

Share Options Granted Under the Unapproved Share Option Scheme		
No of options	Exercise Price (£)	Expiry Date
500,000	1.80	8/3/2026
300,000	1.25	1/29/2025
100,000	2.00	2/9/2026
99,999	2.00	7/29/2023
60,000	1.75	5/15/2024

Share Options Granted Under the 2017 Incentive Award Plan

No of options	Exercise Price (£)	Expiry Date
1,385,598	1.32	4/26/2027
1,026,944	0.57	3/29/2029
868,758	1.46	8/3/2028
500,000	0.45	11/26/2029
267,918	1.22	12/31/2020

Memorandum and Articles of Association

A copy of our Articles of Association is attached as Exhibit 1.1 to our Annual Report filed on Form 20-F. The information called for by this section is set forth in Exhibit 2.5 to our Annual Report and is incorporated by reference into this prospectus.

Listing

Our ADSs are listed on The Nasdaq Global Market under the symbol “VRNA.” Our ordinary shares are listed on AIM of the London Stock Exchange, or AIM, under the symbol “VRP.”

Transfer Agent and Registrar

Our ordinary share register is maintained by Computershare Investor Services plc.

Depository

The depository for our ADSs is Citibank N.A.

CERTAIN MATERIAL TAX CONSIDERATIONS FOR U.S. HOLDERS

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 do not expect to earn revenue from our business operations during the current taxable year 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 current taxable year. 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.

PLAN OF DISTRIBUTION

The selling shareholders and any of their pledgees, donees, transferees, assignees or other successors-in-interest may, from time to time, sell, transfer or otherwise dispose of any or all of their ordinary shares in the form of ADSs or interests in such ADSs on any stock exchange, market or trading facility on which the ADSs are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. The selling shareholders may use one or more of the following methods when disposing of the ADSs or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the ADSs as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- through brokers, dealers or underwriters that may act solely as agents;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- through the writing or settlement of options or other hedging transactions entered into after the effective date of the registration statement of which this prospectus is a part, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling shareholders to sell a specified number of such ADSs at a stipulated price per ADS;
- a combination of any such methods of disposition; and
- any other method permitted pursuant to applicable law.

The selling shareholders may also sell ADSs under Rule 144 or Rule 904 under the Securities Act of 1933, as amended, or Securities Act, if available, or Section 4(a)(1) under the Securities Act, rather than under this prospectus.

Broker-dealers engaged by the selling shareholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling shareholders (or, if any broker-dealer acts as agent for the purchaser of ADSs, from the purchaser) in amounts to be negotiated. The selling shareholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling shareholders may, from time to time, pledge or grant a security interest in some or all of the ADSs owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the ADSs from time to time under this prospectus, or under a supplement or amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling shareholders to include the pledgee, transferee or other successors in interest as selling shareholders under this prospectus.

Upon being notified in writing by a selling shareholder that any material arrangement has been entered into with a broker-dealer for the sale of ADSs through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, we will file a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling shareholder and of the participating broker-dealer(s), (ii) the number of ADSs involved, (iii) the price at which such ADSs were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction.

The selling shareholders also may transfer ADSs in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of the ADSs or interests in the ADSs, the selling shareholders may enter into hedging transactions after the effective date of the registration statement of which this prospectus is a part with broker-dealers or other financial institutions, which may in turn engage in short sales of the ADSs in the course of hedging the positions they assume. The selling shareholders may also sell ADSs short after the effective date of the registration statement of which this prospectus is a part and deliver these ADSs to close out their short positions, or loan or pledge the ADSs to broker-dealers that in turn may sell these ADSs. The selling shareholders may also enter into options or other transactions after the effective date of the registration statement of which this prospectus is a part with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of ADSs offered by this prospectus, which ADSs such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling shareholders and any broker-dealers or agents that are involved in selling the ADSs may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the ADSs purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The maximum commission or discount to be received by any member of the Financial Industry Regulatory Authority or independent broker-dealer will not be greater than 8% of the initial gross proceeds from the sale of any security being sold.

We have advised the selling shareholders that they are required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended, during such time as they may be engaged in a distribution of the ADSs. The foregoing may affect the marketability of the ADSs.

The aggregate proceeds to the selling shareholders from the sale of the ADSs offered by them will be the purchase price of the ADSs less discounts or commissions, if any. Each of the selling shareholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of ADSs to be made directly or through agents. We will not receive any of the proceeds from this offering.

We are required to pay all fees and expenses incident to the registration of the ADSs. We have agreed to indemnify the selling shareholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act or otherwise.

We have agreed with the selling shareholders to keep the registration statement of which this prospectus constitutes a part effective until the earlier of (a) such time as all of the ordinary shares (including in the form of ADSs) covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement, (b) such time as all of the ordinary shares (including in the form of ADSs) covered by this prospectus have been previously sold or transferred in accordance with Rule 144 of the Securities Act, (c) such time as the ordinary shares (including in the form of ADSs) becoming eligible for resale by the holder without volume or manner-of-sale restrictions and without current public information requirements pursuant to Rule 144 of the Securities Act, and (d) the fifth anniversary of the closing of the 2020 Private Placement, which is July 22, 2025.

EXPENSES

The following is an estimate of the expenses (all of which are to be paid by us) that we may incur in connection with the common shares being registered hereby, other than the SEC registration fee.

SEC registration fee	\$ 45,725.02
Legal fees and expenses	650,000
Accounting fees and expenses	106,000
ADS depositary fees	1,600,000
Printing and miscellaneous expenses	1,098,274.98
Total	<u>\$ 3,500,000</u>

LEGAL MATTERS

The validity of our ordinary shares held by the selling shareholders and certain other matters of English law will be passed upon for us by Latham & Watkins LLP.

EXPERTS

The financial statements incorporated in this prospectus by reference to the [Annual Report on Form 20-F for the year ended December 31, 2019](#), have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The registered business address of PricewaterhouseCoopers LLP is 1 Embankment Place, London, WC2N 6RH, United Kingdom.

ENFORCEMENT OF CIVIL LIABILITIES

We are incorporated and currently existing under the laws of England and Wales. In addition, certain of our directors and officers reside outside of the United States and most of the assets of our non-U.S. subsidiaries are located outside of the United States. As a result, it may be difficult for investors to effect service of process on us or those persons in the United States or to enforce in the United States judgments obtained in United States courts against us or those persons based on the civil liability or other provisions of the United States securities laws or other laws.

In addition, uncertainty exists as to whether the courts of England and Wales would:

- recognize or enforce judgments of U.S. courts obtained against us or our directors or officers predicated upon the civil liabilities provisions of the securities laws of the United States or any state in the United States; or
- entertain original actions brought in England and Wales against us or our directors or officers predicated upon the securities laws of the United States or any state in the United States.

We have been advised by Latham & Watkins LLP that there is currently no treaty between (i) the United States and (ii) England and Wales providing for reciprocal recognition and enforcement of judgments of U.S. courts in civil and commercial matters (although the United States and the United Kingdom are both parties to the New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards) and that a final judgment for the payment of money rendered by any general or state court in the United States based on civil liability, whether or not predicated solely upon the U.S. securities laws, would not be automatically enforceable in England and Wales. We have also been advised by Latham & Watkins LLP that any final and conclusive monetary judgment for a definite sum obtained against us in U.S. courts would be treated by the courts of England and Wales 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:

- the relevant U.S. court had jurisdiction over the original proceedings according to English conflicts of laws principles at the time when proceedings were initiated;
- England and Wales courts had jurisdiction over the matter on enforcement and we either submitted to such jurisdiction or were resident or carrying on business within such jurisdiction and were duly served with process;
- the U.S. judgment was final and conclusive on the merits in the sense of being final and unalterable in the court that pronounced it and being for a definite sum of money;
- the judgment given by the courts was not in respect of penalties, taxes, fines or similar fiscal or revenue obligations (or otherwise based on a U.S. law that an English court considers to relate to a penal, revenue or other public law);
- the judgment was not procured by fraud;
- recognition or enforcement of the judgment in England and Wales would not be contrary to public policy or the Human Rights Act 1998;
- the proceedings pursuant to which judgment was obtained were not contrary to natural justice;
- the U.S. judgment was not arrived at by doubling, trebling or otherwise multiplying a sum assessed as compensation for the loss or damages sustained and not being otherwise in breach of Section 5 of the UK Protection of Trading Interests Act 1980, or is a judgment based on measures designated by the Secretary of State under Section 1 of that Act;
- there is not a prior decision of an English court or the court of another jurisdiction on the issues in question between the same parties; and
- the English enforcement proceedings were commenced within the limitation period.

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.

Subject to the foregoing, investors in our securities may be able to enforce in England and Wales judgments in civil and commercial matters that have been obtained from U.S. federal or state courts. Nevertheless, we cannot assure you that those judgments will be recognized or enforceable in England and Wales.

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. In addition, it may not be possible to obtain an English judgment or to enforce that judgment if the judgment debtor is or becomes subject to any insolvency or similar proceedings, or if the judgment debtor has any set-off or counterclaim against the judgment creditor. Also note that, in any enforcement proceedings, the judgment debtor may raise any counterclaim that could have been brought if the action had been originally brought in England unless the subject of the counterclaim was in issue and denied in the U.S. proceedings.

WHERE YOU CAN FIND MORE INFORMATION; INCORPORATION BY REFERENCE

Available Information

We are subject to the periodic reporting and other informational requirements of the Exchange Act. Under the Exchange Act, we file annual reports and other information with the SEC. As a foreign private issuer, we are exempt from, among other things, the rules under the Exchange Act prescribing the furnishing and content of proxy statements and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

The SEC also maintains a web site that contains reports and information statements and other information about issuers, such as us, who file electronically with the SEC. The address of that website is www.sec.gov.

This prospectus is part of a registration statement that we filed with the SEC and does not contain all of the information in the registration statement. The full registration statement may be obtained from the SEC or us, as provided below. Forms of the documents establishing the terms of the offered securities are or may be filed as exhibits to the registration statement of which this prospectus forms a part. Statements in this prospectus or any prospectus supplement about these documents are summaries and each statement is qualified in all respects by reference to the document to which it refers. You should refer to the actual documents for a more complete description of the relevant matters. You may inspect a copy of the registration statement through the SEC's website, as provided above.

Incorporation by Reference

The SEC's rules allow us to "incorporate by reference" information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be part of this prospectus. Any statement contained in a previously filed document incorporated by reference will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus modifies or replaces that statement.

This prospectus incorporates by reference the documents set forth below that have previously been filed with the SEC:

- Our [Annual Report on Form 20-F for the year ended December 31, 2019, filed with the SEC on February 27, 2020](#) and the amendment to our [Annual Report on Form 20-F filed with the SEC on July 16, 2020](#).
- Exhibits 1, 101.INS, 101.SCH, 101.CAL, 101.LAB, 101.PRE, and 101.DEF to the amendment to our Report on [Form 6-K furnished to the SEC on August 25, 2020](#).
- The information contained under the heading "Financial Review" in Exhibit 99.1 to our Report on [Form 6-K furnished to the SEC on August 14, 2020](#).
- [Our Report on Form 6-K furnished to the SEC on July 22, 2020](#).
- The FDA Response Press Release filed in the Report on [Form 6-K furnished to the SEC on May 14, 2020](#).
- [The information contained under the headings "Impact of COVID-19 on Certain Ongoing and Planned Clinical Trials" and "Supplemental Risk Factor Disclosure" contained in our Report on Form 6-K furnished to the SEC on April 30, 2020](#).
- [Our Report on Form 6-K furnished to the SEC on April 16, 2020, excluding Exhibit 1.1 thereto](#).
- [Our Report on Form 6-K furnished to the SEC on April 6, 2020, excluding Exhibit 1.1 thereto](#)
- [The information in the first paragraph under "Information Contained in this Report on Form 6-K" in the Report on Form 6-K furnished to the SEC on February 4, 2020](#).
- [Our Report on Form 6-K furnished on January 17, 2020, excluding Exhibit 1.1 thereto](#).

- The description of our ordinary shares contained in our registration statement on Form 8-A filed with the SEC on April 19, 2017, including any amendments or reports filed for the purpose of updating such description.

Unless expressly incorporated by reference, nothing in this prospectus shall be deemed to incorporate by reference information furnished to, but not filed with, the SEC. Copies of all documents incorporated by reference in this prospectus, other than exhibits to those documents unless such exhibits are specifically incorporated by reference in this prospectus, will be provided at no cost to each person, including any beneficial owner, who receives a copy of this prospectus on the written or oral request of that person made to:

Verona Pharma plc
3 More London Riverside
London SE1 2RE
United Kingdom
+44 203 283 4200

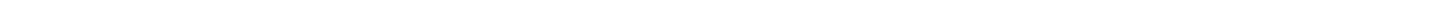
355,831,184 Shares

VERONA PHARMA PLC

**Ordinary Shares
(including Ordinary Shares in the form of American Depository Shares)**



PRELIMINARY PROSPECTUS
, 2020



PART II**INFORMATION NOT REQUIRED IN PROSPECTUS****Item 6. Indemnification of Directors and Officers.**

Members of the registrant's board of directors and its officers have the benefit of the following indemnification provisions in the registrant's articles of association:

- Current and former members of the registrant's board of directors or officers shall be reimbursed for:
- a) all costs, charges, losses, expenses and liabilities sustained or incurred in relation to his or her actual or purported execution of his or her duties in relation to the registrant, including any liability incurred in defending any criminal or civil proceedings; and
 - b) expenses incurred or to be incurred in defending any criminal or civil proceedings, in an investigation by a regulatory authority or against a proposed action to be taken by a regulatory authority, or in connection with any application for relief under the statutes of the United Kingdom and any other statutes that concern and affect the registrant as a company, or collectively the Statutes, arising in relation to the registrant or an associated company, by virtue of the actual or purported execution of the duties of his or her office or the exercise of his or her powers.

In the case of current or former members of the registrant's board of directors, there shall be no entitlement to reimbursement as referred to above for (i) any liability incurred to the registrant or any associated company, (ii) the payment of a fine imposed in any criminal proceeding or a penalty imposed by a regulatory authority for non-compliance with any requirement of a regulatory nature, (iii) the defense of any criminal proceeding if the member of the registrant's board of directors is convicted, (iv) the defense of any civil proceeding brought by the registrant or an associated company in which judgment is given against the director, and (v) any application for relief under the statutes of the United Kingdom and any other statutes that concern and affect the registrant as a company in which the court refuses to grant relief to the director.

In addition, members of the registrant's board of directors and its officers who have received payment from the registrant under these indemnification provisions must repay the amount they received in accordance with the Statutes or in any other circumstances that the registrant may prescribe or where the registrant has reserved the right to require repayment.

The registrant has also entered into indemnification agreements with each member of its board of directors and its executive officers. These indemnification agreements require the registrant, among other things, to indemnify its directors and executive officers with respect to any claims, actions and proceedings, whether civil, criminal or regulatory, or, collectively the Claims, and any losses, damages, penalties, liabilities, compensation or other awards arising in connection with such Claims, arising out of, or in connection with, his or her service as a director or executive officer, subject to certain limitations. The registrant also maintains liability insurance for its directors and executive officers.

Item 7. Recent Sales of Unregistered Securities*ADS and Share Issuances*

On July 17, 2020, the registrant issued (i) 38,440,009 of its American Depository Shares, each representing eight ordinary shares of the registrant at a price per American Depository Share of \$4.50, (ii) 48,088,896 non-voting ordinary shares at a price per share of \$0.5625, and (iii) 222,216 ordinary shares at price per share of £0.45. These securities were issued pursuant to Section 4(a)(2) and Regulation D of the Securities Act of 1933, as amended.

Item 8. Exhibits

Exhibit Number	Exhibit Description	Form	File No.	Exhibit No.	Filing date	Filed / Furnished
<u>3.1</u>	<u>Articles of Association, as amended and as currently in effect</u>	<u>F-1</u>	<u>333-217124</u>	<u>3.1</u>	<u>4/3/2017</u>	
<u>4.1</u>	<u>Deposit Agreement</u>	<u>20-F</u>	<u>001-38067</u>	<u>2.1</u>	<u>2/27/2018</u>	
<u>4.2</u>	<u>Form of American Depository Receipt (included in Exhibit 2.1)</u>	<u>20-F</u>	<u>001-38067</u>	<u>2.2</u>	<u>2/27/2018</u>	
<u>4.3</u>	<u>Form of Warrant issued to each of the investors named in Schedule A thereto</u>	<u>F-1</u>	<u>333-217124</u>	<u>4.3</u>	<u>4/3/2017</u>	
<u>4.4</u>	<u>Warrant Instrument issued to NPlus1 Singer LLP</u>	<u>F-1</u>	<u>333-217124</u>	<u>4.4</u>	<u>4/3/2017</u>	
<u>4.5</u>	<u>Description of Securities</u>	<u>20-F</u>	<u>001-38067</u>	<u>2.5</u>	<u>2/27/2020</u>	
<u>5.1</u>	<u>Opinion of Latham & Watkins LLP, counsel to Registrant</u>					*
<u>10.1</u>	<u>Registration Rights Agreement, dated July 29, 2016, by and among Verona Pharma plc and the investors set forth therein</u>	<u>F-1</u>	<u>333-217124</u>	<u>10.1</u>	<u>4/3/2017</u>	
<u>10.2</u>	<u>Registration Rights Agreement, dated July 16, 2020, by and among Verona Pharma plc and the investors set forth therein</u>	<u>6-K</u>	<u>001-38067</u>	<u>2</u>	<u>7/22/2020</u>	
<u>10.3†</u>	<u>Intellectual Property Assignment and Licence Agreement between Vernalis Development Limited and Rhinopharma Limited, as predecessor to Verona Pharma plc, dated February 7, 2005</u>	<u>F-1</u>	<u>333-217124</u>	<u>10.2</u>	<u>4/3/2017</u>	
<u>10.4</u>	<u>Renewal Agreement to Lease by and between the Verona Pharma plc and Regus Management (UK) Limited dated October 19, 2017</u>	<u>20-F</u>	<u>001-38067</u>	<u>4.3</u>	<u>3/19/2019</u>	
<u>10.4.1</u>	<u>Renewal Agreement to Lease by and between the Verona Pharma plc and Regus Management (UK) Limited dated November 8, 2017</u>	<u>20-F</u>	<u>001-38067</u>	<u>4.3.1</u>	<u>3/19/2019</u>	
<u>10.4.2</u>	<u>Renewal Agreement to Lease by and between the Verona Pharma plc and Regus Management (UK) Limited dated April 3, 2018</u>	<u>20-F</u>	<u>001-38067</u>	<u>4.3.2</u>	<u>3/19/2019</u>	
<u>10.4.3</u>	<u>Renewal Agreement to Lease by and between the Verona Pharma plc and Regus Management (UK) Limited dated September 16, 2017#1</u>	<u>20-F</u>	<u>001-38067</u>	<u>4.3.3</u>	<u>2/27/2020</u>	
<u>10.4.4</u>	<u>Renewal Agreement to Lease by and between the Verona Pharma plc and Regus Management (UK) Limited dated September 16, 2017#2</u>	<u>20-F</u>	<u>001-38067</u>	<u>4.3.4</u>	<u>2/27/2020</u>	

Exhibit Number	Exhibit Description	Form	File No.	Exhibit No.	Filing date	Filed / Furnished
<u>10.4.5</u>	<u>Renewal Agreement to Lease by and between the Verona Pharma plc and Regus Management (UK) Limited dated September 16, 2017#3</u>	<u>20-F</u>	<u>001-38067</u>	<u>4.3.5</u>	<u>2/27/2020</u>	
<u>10.4.6</u>	<u>Renewal Agreement to Lease by and between the Verona Pharma Inc. and Regus Management Group LLC dated July 16, 2019</u>	<u>20-F</u>	<u>001-38067</u>	<u>4.3.6</u>	<u>2/20/2020</u>	
<u>10.5#</u>	<u>EMI Option Scheme</u>	<u>F-1</u>	<u>333-217124</u>	<u>10.4</u>	<u>4/3/2017</u>	
<u>10.6#</u>	<u>Unapproved Share Option Scheme, as amended</u>	<u>F-1</u>	<u>333-217124</u>	<u>10.5</u>	<u>4/3/2017</u>	
<u>10.7#</u>	<u>2017 Incentive Award Plan and forms of award agreements thereunder</u>	<u>20-F</u>	<u>001-38067</u>	<u>4.6</u>	<u>2/27/2018</u>	
<u>10.8#</u>	<u>Employment Agreement, dated January 28, 2020, between Verona Pharma Inc. and David Zaccardelli, Pharm. D.</u>	<u>20-F</u>	<u>001-38067</u>	<u>4.7</u>	<u>2/27/2020</u>	
<u>10.9#</u>	<u>Employment Agreement, dated December 21, 2019, between Verona Pharma plc and Kathleen Rickard</u>	<u>20-F</u>	<u>001-38067</u>	<u>4.3.2</u>	<u>3/19/2019</u>	
<u>10.11#</u>	<u>Employment Agreement, dated October 1, 2016, between Verona Pharma plc and Claire Poll</u>	<u>F-1</u>	<u>333-217124</u>	<u>10.9</u>	<u>4/3/2017</u>	
<u>10.12#</u>	<u>Employment Agreement, dated February 1, 2020, between Verona Pharma plc and Mark Hahn</u>	<u>F-1</u>	<u>333-247928</u>	<u>10.12</u>	<u>8/17/2020</u>	
<u>10.13</u>	<u>Form of Indemnification Agreement for board members</u>	<u>F-1/A</u>	<u>333-217124</u>	<u>10.11.1</u>	<u>4/18/2017</u>	
<u>10.14</u>	<u>Form of Indemnification Agreement for executive officers</u>	<u>F-1/A</u>	<u>333-217124</u>	<u>10.11.2</u>	<u>4/18/2017</u>	
<u>10.15</u>	<u>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</u>	<u>F-1</u>	<u>333-217124</u>	<u>10.12</u>	<u>4/3/2017</u>	
<u>10.16</u>	<u>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</u>	<u>F-1</u>	<u>333-217124</u>	<u>10.13</u>	<u>4/3/2017</u>	

Exhibit Number	Exhibit Description	Form	File No.	Exhibit No.	Filing date	Filed / Furnished
<u>10.17</u>	<u>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</u>	F-1	<u>333-217124</u>	<u>10.14</u>	<u>4/3/2017</u>	
<u>10.18</u>	<u>Securities Purchase Agreement, dated as of July 17, 2020, by and among Verona Pharma plc and the investors set forth therein</u>	6-K	<u>01-38067</u>	1	<u>7/22/2020</u>	
<u>21.1</u>	<u>List of Subsidiaries</u>	F-1	<u>333-217124</u>	<u>21.1</u>	<u>4/3/2017</u>	*
<u>23.1</u>	<u>Consent of PricewaterhouseCoopers LLP</u>					—
<u>23.2</u>	<u>Consent of Latham & Watkins, counsel to registrant (included in Exhibit 5.1)</u>					*
<u>24.1</u>	<u>Powers of attorney (included on signature page to the registration statement)</u>	F-1	<u>333-247928</u>		<u>8/17/2020</u>	

* Filed 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.

Item 9. Undertakings

(a) The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement; and
 - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (a)(1)(i), (a)(1)(ii), and (a)(1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports

filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is a part of the registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) To file a post-effective amendment to the registration statement to include any financial statements required by Item 8.A. of Form 20-F at the start of any delayed offering or throughout a continuous offering. Financial statements and information otherwise required by Section 10(a)(3) of the Securities Act of 1933 need not be furnished, provided, that the registrant includes in the prospectus, by means of a post-effective amendment, financial statements required pursuant to this paragraph (a)(4) and other information necessary to ensure that all other information in the prospectus is at least as current as the date of those financial statements. Notwithstanding the foregoing, with respect to registration statements on Form F-3, a post-effective amendment need not be filed to include financial statements and information required by Section 10(a)(3) of the Securities Act of 1933, or 3-19 of Regulation S-X if such financial statements and information are contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the Form F-3.
- (5) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
 - (A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
 - (B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1) (i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.
- (6) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

 - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

- (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communications that is an offer in the offering made by the undersigned registrant to the purchaser.
- (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of London, the United Kingdom on August 25, 2020.

VERONA PHARMA PLC

By: /s/ David Zaccardelli, Pharm. D

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

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons on August 25, 2020 in the capacities indicated:

Name	Title
<u>/s/ David Zaccardelli</u> David Zaccardelli	Chief Executive Officer and Executive Director (Principal Executive Officer)
<u>/s/ Mark W. Hahn</u> Mark W. Hahn	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
<u>*</u> David Ebsworth, Ph.D.	Chairman of the Board of Directors
<u>*</u> Ken Cunningham, M.D.	Non-Executive Director
<u>*</u> Rishi Gupta	Non-Executive Director
<u>*</u> Mahendra Shah, Ph.D.	Non-Executive Director
<u>*</u> Andrew Sinclair, Ph.D.	Non-Executive Director
<u>*</u> Vikas Sinha	Non-Executive Director

Name	Title
*	Non-Executive Director
Anders Ullman, M.D., Ph.D.	
*	Non-Executive Director
Martin Edwards, M.D.	
<hr/> * /s/ Mark Hahn	
Mark Hahn Attorney-in-fact	

SIGNATURE OF AUTHORIZED UNITED STATES REPRESENTATIVE

Pursuant to the Securities Act, the undersigned, the duly authorized representative in the United States of Verona Pharma plc has signed this registration statement in the City of New York, New York on August 25, 2020.

Authorized U.S. Representative

Cogency Global Inc.

By: /s/ Colleen A. De Vries

Name: Colleen A. De Vries

Title: Senior Vice President on behalf of Cogency Global Inc.

LATHAM & WATKINS

25 August 2020

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Milan	

Verona Pharma plc
One Central Square
Cardiff
CF10 1FS
United Kingdom

Re: Verona Pharma plc – Registration Statement on Form F-1 Exhibit 5.1

Ladies and Gentlemen:

We have acted as English legal advisers to Verona Pharma plc, a public limited company incorporated in England and Wales (the “**Company**”) in connection with the private placement of 38,440,009 American Depository Shares (the “**ADSs**”) each representing eight ordinary shares of £0.05 each in the capital of the Company (the “**Ordinary Shares**”) and 48,088,896 non-voting ordinary shares of £0.05 each that may be re-designated as ordinary shares, nominal value £0.05 per share (the “**Non-Voting Ordinary Shares**”) and the subscription of 222,216 ordinary shares of £0.05 each (the “**Subscription Ordinary Shares**”, together, with the Non-Voting Ordinary Shares and the Ordinary Shares allotted and issued in connection with the private placement therewith, the “**Shares**”) (the “**Offering**”).

1. INTRODUCTION

1.1 Purpose

In connection with the preparation and filing of the registration statement on Form F-1 to which this letter is attached as an exhibit (such registration statement, as amended, including the documents incorporated by reference therein, the “**Registration Statement**”) with the United States Securities and Exchange Commission (the “**SEC**”) pursuant to the United States Securities Act of 1933, as amended (the “**Securities Act**”), we have been asked to provide an opinion on certain matters, as set out below. We have taken instruction in this regard solely from the Company.

1.2 Defined terms and headings

In this letter:

- (a) capitalised terms used without definition in this letter or the schedules hereto have the meanings assigned to them in the Registration Statement unless a contrary indication appears; and

Latham & Watkins is the business name of Latham & Watkins (London) LLP, a registered limited liability partnership organised under the laws of New York and authorised and regulated by the Solicitors Regulation Authority (SRA No. 203820). A list of the names of the partners of Latham & Watkins (London) LLP is open to inspection at its principal place of business, 99 Bishopsgate, London EC2M 3XF, and such persons are either solicitors, registered foreign lawyers, European lawyers or managers authorised by the SRA. We are affiliated with the firm Latham & Watkins LLP, a limited liability partnership organised under the laws of Delaware.

- (b) headings are for ease of reference only and shall not affect interpretation.

1.3 **Legal review**

For the purpose of issuing this letter we have reviewed only the following documents and conducted only the following enquiries and searches:

- (a) a search at Companies House in respect of the Company conducted on 14 August 2020;
- (b) an enquiry at the Central Registry of Winding Up Petitions, London on 14 August 2020 at 11:11 a.m. (London time) with respect to the Company ((a) and (b) together, the “**Searches**”);
- (c) a PDF copy of the minutes of the annual general meeting of the Company held on 16 April 2020 (the “**Annual General Meeting**”);
- (d) a PDF copy of the minutes of the meeting of the board of directors of the Company (the “**Board**”) held on 15 July 2020,
- (e) a PDF copy of a written resolution of the Board dated 21 July 2020;
- (f) a copy of the terms of issue of the Non-Voting Ordinary Shares;
- (g) a copy of the certificate of incorporation of the Company dated 24 February 2005;
- (h) a copy of the certificate of incorporation on change of name of the Company dated 18 September 2006;
- (i) a PDF copy of the current articles of association of the Company adopted pursuant to a special resolution of shareholders passed at the general meeting held on 8 February 2017; and
- (j) a draft copy of the Registration Statement as at 24 August 2020 and to be filed with the SEC on 25 August 2020.

1.4 **Applicable law**

This letter, the opinions given in it, and any non-contractual obligations arising out of or in connection with this letter and/or the opinions given in it, are governed by, and shall be construed in accordance with English law (including European Union law to the extent directly applicable) and relate only to English law (including European Union law to the extent directly applicable) as applied by the English courts as at today’s date. In particular:

- (a) we have not investigated the laws of any country other than England and we assume that no foreign law affects any of the opinions stated below; and
- (b) we express no opinion in this letter on the laws of any jurisdiction other than England.

The United Kingdom exited the European Union on 31 January 2020. By virtue of sections 1A and 1B of the European Union (Withdrawal) Act 2018 (as amended by the European Union (Withdrawal Agreement) Act 2020) (“EUWA”), European Union law will continue to be applicable to the United Kingdom for the duration of the implementation period set out in section 1A(6) of the EUWA. We express no opinion on the effect of European Union law in the United Kingdom after the end of such implementation period.

LATHAM & WATKINS

1.5 Assumptions and reservations

The opinions given in this letter are given on the basis of each of the assumptions set out in Schedule 1 (*Assumptions*) and are subject to each of the reservations set out in Schedule 2 (*Reservations*) to this letter. The opinions given in this letter are strictly limited to the matters stated in paragraph 2 (*Opinions*) below and do not extend, and should not be read as extending, by implication or otherwise, to any other matters.

2. OPINION

Subject to paragraph 1 (*Introduction*) and the other matters set out in this letter and its Schedules, and subject further to the following:

- (a) the Registration Statement, as finally amended, having become effective under the Securities Act;
- (b) valid entries having been made in relation to the allotment and issue of the Shares in the name of the recipient in the books and registers of the Company; and
- (c) the Shares having been delivered in accordance with the terms and conditions of the Offering and the Registration Statement,

it is our opinion that the Shares were duly and validly authorised and issued, fully paid or credited as fully paid (subject to the receipt of valid consideration by the Company for the issue thereof) and are not subject to any call for payment of further capital.

3. EXTENT OF OPINIONS

We express no opinion as to any agreement, instrument or other document other than as specified in this letter or as to any liability to tax which may arise or be suffered as a result of or in connection with the Offering.

This letter only applies to those facts and circumstances which exist as at today's date and we assume no obligation or responsibility to update or supplement this letter to reflect any facts or circumstances which may subsequently come to our attention, any changes in laws which may occur after today, or to inform the addressee of any change in circumstances happening after the date of this letter which would alter our opinion.

4. RELIANCE AND DISCLOSURE

This letter is addressed to you solely for your benefit in connection with the Registration Statement. We consent to the filing of this letter as an exhibit to the Registration Statement. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations thereunder.

This letter may not be relied upon by you for any other purpose, and, other than as set out above, may not be furnished to, or assigned to or relied upon by any other person, firm or entity for any purpose, without our prior written consent, which may be granted or withheld in our discretion.

Yours faithfully

/s/

LATHAM & WATKINS

SCHEDULE 1

ASSUMPTIONS

The opinion in this letter has been given on the basis of the following assumptions:

- (a) The genuineness of all signatures, stamps and seals on all documents, the authenticity and completeness of all documents submitted to us as originals, and the conformity to authentic original documents of all documents submitted to us as copies;
- (b) that in the case of a document signed electronically, the person signing it intended to sign and be bound by the document;
- (c) that, where a document has been examined by us in draft or specimen form, it will be or has been duly executed in the form of that draft or specimen;
- (d) that the articles of association of the Company referred to in paragraph 1.3(i) of this letter remain in full force and effect, and no alteration had been made to such articles of association, in each case, prior to the date on which the Shares were allotted, issued or rights are granted to subscribe for Shares (each such date being an "**Allotment Date**");
- (e) that all documents, forms and notices which should have been delivered to the UK Companies House in respect of the Company have been so delivered, that the results of the Searches are complete and accurate, that the position has not changed since the times at which the Searches were made and that the results of the Searches remained complete and accurate as at each Allotment Date;
- (f) that (i) the resolutions described in the written resolutions of the board of directors of the Company provided to us in connection with the giving of this opinion or otherwise contemplated in connection with the matters referred to herein were duly passed as written resolutions of the board of directors of the Company, all constitutional, statutory and other formalities were and such resolutions have not been revoked or varied and remained in full force and effect at each Allotment Date; and (ii) the proceedings and resolutions described in the minutes of the meetings of the board of directors of the Company provided to us in connection with the giving of this opinion or otherwise contemplated in connection with the matters referred to herein were duly conducted as so described, and that each of the meetings referred to therein was duly constituted, convened and conducted and all constitutional, statutory and other formalities were duly observed (including, if applicable, those relating to the declaration of directors' interests or the power of interested directors to vote), a quorum was present throughout, the requisite majority of directors voted in favour of approving the resolutions and the resolutions passed thereat were duly adopted, were not revoked or varied and remained in full force and effect as at each Allotment Date;
- (g) that the resolutions of the shareholders of the Company provided to us in connection with the giving of this opinion or otherwise contemplated in connection with the matters referred to herein were duly passed at a general meeting of the Company, all constitutional, statutory and other formalities were observed in relation to such general meeting and such resolutions were not revoked or varied prior to each Allotment Date and remained in full force and effect as at each Allotment Date;
- (h) that at the time of each allotment and issue of any Shares the Company received in full "cash consideration" (as such term is defined in section 583(3) of the Companies Act) equal to the subscription price payable for such Shares and shall have entered the holder or holders thereof in the register of members of the Company showing that all such Shares shall have been fully paid up as to their nominal value and any premium thereon as at each Allotment Date;

- (i) that immediately prior to each Allotment Date, the directors of the Company had sufficient authority and powers conferred upon them to allot and issue such Shares and grant such rights (as applicable) under section 551 of the Companies Act and under section 570 of the Companies Act as if section 561 of the Companies Act did not apply to such allotment and issue or grant, and the directors of the Company did not allot or issue (or purport to allot or issue) Shares and did not grant rights (or purport to grant rights) to acquire Shares in excess of such powers or in breach of any other limitation on their power to allot and issue Shares or grant rights to acquire Shares;
- (j) that no Shares were allotted or issued, or are or were committed to be allotted or issued, at a discount to their nominal value (whether in dollars or equivalent in any other currency);
- (k) that no Shares or rights to subscribe for Shares have been offered to the public in the United Kingdom in breach of the Financial Services and Markets Act 2000 (“FSMA”) or of any other United Kingdom laws or regulations concerning offers of securities to the public, and no communication has been made in relation to the Shares in breach of section 21 of the FSMA or any other United Kingdom laws or regulations relating to offers or invitations to subscribe for, or to acquire rights to subscribe for or otherwise acquire, shares or other securities;
- (l) that in issuing and allotting and granting rights to acquire Shares, the Company is not carrying on a regulated activity for the purposes of section 19 of FSMA;
- (m) that the Company has complied and will comply with all applicable anti-terrorism, anti-money laundering, sanctions and human rights laws and regulations and that each allotment and issue of Shares will be consistent with all such laws and regulations;
- (n) the Shares will be allotted and issued in good faith and on bona fide commercial terms and on arms' length terms and for the purpose of carrying on the business of the Company and that there are reasonable grounds for believing that the allotment and issue of the Shares will promote the success of the Company for the benefit of its members as a whole; and
- (o) that the Company has not taken any corporate or other action nor have any steps been taken or legal proceedings been started against the Company for:
 - (i) the liquidation, administration, winding up, dissolution, reorganisation or bankruptcy or similar procedures in other relevant jurisdictions, of; or
 - (ii) the commencement of a moratorium in respect of; or
 - (iii) the appointment of a liquidator, receiver, trustee, administrator, administrative receiver, monitor or similar officer of, the Company or all or any of its assets (or any analogous proceedings in any jurisdiction) and the Company is not unable to pay its debts as they fall due within the meaning of section 123 of the Insolvency Act 1986 and will not become unable to pay its debts within the meaning of that section as a result of any of the transactions contemplated herein, is not insolvent and has not been dissolved or declared bankrupt (although the Searches gave no indication that any: winding-up, dissolution, moratorium or administration order, application or filing; or appointment of a liquidator, receiver, monitor, administrator, administrative receiver or similar officer has been made with respect to the Company), and such actions and steps were not taken as at any Allotment Date.

SCHEDULE 2
RESERVATIONS

The opinion in this letter is subject to the following reservations:

- (a) the Searches are not capable of revealing conclusively whether or not a winding-up or administration petition, filing or order has been presented or made, a monitor or receiver appointed, a company voluntary arrangement proposed or approved or a moratorium or any other insolvency proceeding commenced. We have not made enquiries of any District Registry or County Court;
- (b)
 - (i) any limitations arising from applicable laws relating to insolvency, bankruptcy, administration, reorganisation, liquidation, moratoria, schemes or analogous circumstances; and
 - (ii) an English court exercising its discretion under section 426 of the Insolvency Act 1986 (*co-operation between courts exercising jurisdiction in relation to insolvency*) to assist the courts having the corresponding jurisdiction in any part of the United Kingdom or any relevant country or territory;
- (c) we express no opinion as to matters of fact;
- (d) it should be understood that we have not been responsible for investigating or verifying the accuracy of the facts, including statements of foreign law, or the reasonableness of any statements of opinion, contained in the Registration Statement, or that no material facts have been omitted from it.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in this Amendment No. 1 to the Registration Statement on Form F-1 of Verona Pharma Plc of our report dated February 27, 2020 relating to the financial statements, which appears in Verona Pharma Plc's Annual Report on Form 20-F for the year ended December 31, 2019. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ PricewaterhouseCoopers LLP
Reading, United Kingdom
August 25, 2020
