

Theravance Biopharma, Inc.
Form 10-K
February 28, 2019
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

OR

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

For the transition period from _____ to _____

Commission File No. 001-36033

THERAVANCE BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Cayman Islands

98-1226628

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(State or Other Jurisdiction of
Incorporation or Organization)

(I.R.S. Employer
Identification No.)

P.O. Box 309

Ugland House, South Church Street

George Town, Grand Cayman, Cayman Islands

(Address of Principal Executive Offices)

KY1-1104

(Zip Code)

Registrant's telephone number, including area code: 650-808-6000

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of Each Class	Name of Each Exchange On Which Registered
Ordinary Share \$0.00001 Par Value	NASDAQ Global Market

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: NONE

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price on the NASDAQ Global Market on June 30, 2018 was \$1,209,092,732.

On February 15, 2019, there were 55,579,495 of the registrant's ordinary shares outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's definitive Proxy Statement to be issued in conjunction with the registrant's 2019 Annual Meeting of Shareholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2018, are incorporated by reference into Part III of this Annual Report. Except as expressly incorporated by reference, the registrant's Proxy Statement shall not be deemed to be a part of this Annual Report on Form 10-K.

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THERAVANCE BIOPHARMA, INC.

2018 Form 10 K Annual Report

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Special Note regarding Forward Looking Statements

This Annual Report on Form 10 K contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Such forward looking statements involve substantial risks, uncertainties and assumptions. All statements in this Annual Report on Form 10 K, other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions, designs, expectations and objectives could be forward looking statements. The words “aim,” “anticipate,” “believe,” “contemplate,” “continue,” “could,” “designed,” “developed,” “drive,” “estimate,” “expect,” “goal,” “i,” “mission,” “opportunities,” “plan,” “potential,” “predict,” “project,” “pursue,” “represent,” “seek,” “suggest,” “should,” “target” similar expressions (including the negatives thereof) are intended to identify forward looking statements, although not all forward looking statements contain these identifying words. These statements reflect our current views with respect to future events or our future financial performance, are based on assumptions, and involve known and unknown risks, uncertainties and other factors which 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. We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward looking statements and the assumptions underlying our forward looking statements may prove incorrect. Therefore, you should not place undue reliance on our forward looking statements. Actual results or events could differ materially from the plans, intentions, expectations and objectives disclosed in the forward looking statements that we make. Factors that we believe could cause actual results or events to differ materially from our forward looking statements include, but are not limited to, those discussed below in “Risk Factors” in Item 1A, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Item 7 and elsewhere in this Annual Report on Form 10 K. Our forward looking statements in this Annual Report on Form 10 K are based on current expectations and we do not assume any obligation to update any forward looking statements for any reason, even if new information becomes available in the future. When used in this report, all references to “Theravance Biopharma”, the “Company”, or “we” and other similar pronouns refer to Theravance Biopharma, Inc. collectively with its subsidiaries.

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PART I

ITEM 1. BUSINESS

Overview

Theravance Biopharma, Inc. ("Theravance Biopharma") is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines. Our purpose is to create transformational medicines to improve the lives of patients suffering from serious illnesses. Our research is focused in the areas of inflammation and immunology.

In pursuit of our purpose, we apply insights and innovation at each stage of our business and utilize our internal capabilities and those of partners around the world. We apply organ-selective expertise to biologically compelling targets to discover and develop medicines designed to treat underserved localized diseases and to limit systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing lung-selective medicines to treat respiratory disease, including US Food and Drug Administration-approved YUPELRITM (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease ("COPD"). Our pipeline of internally discovered programs is targeted to address significant patient needs.

We have an economic interest in potential future payments from Glaxo Group or one of its affiliates ("GSK") pursuant to its agreements with Innoviva, Inc. ("Innoviva") relating to certain programs, including TRELEGY ELLIPTA.

2018 Highlights

In 2018, we accomplished a number of key corporate goals. As our programs advanced through various stages of development, clinical results further informed our focus on strategic priorities and our plans towards creating transformational medicines to help improve the lives of patients.

FDA Approval of YUPELRI

We announced US Food and Drug Administration ("FDA") approval of YUPELRITM (revefenacin) inhalation solution for the maintenance treatment of patients with COPD. YUPELRI, a long-acting muscarinic antagonist, is the first and only once-daily, nebulized bronchodilator approved for the treatment of COPD in the US. Additionally, we completed a Phase 3b study of YUPELRI in patients with suboptimal peak inspiratory flow rate, which showed encouraging findings in the pre-specified subgroup of severe and very severe COPD patients. Commercial launch is underway with our partner Mylan.

TD-1473 Co-Development and Commercialization Agreement

We announced a global co-development and commercialization agreement with Janssen Biotech, Inc., for our gut-selective JAK inhibitor TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease. We subsequently completed the remaining two cohorts of the Phase 1b study of TD-1473 in ulcerative colitis. Results from this study provided the basis to advance TD-1473 into a larger Phase 2b/3 adaptive design induction and maintenance study in ulcerative colitis patients and a Phase 2 induction study in Crohn's disease. Following completion of the Phase 1b study, we completed discussions with US and European Union ("EU") regulators and gained agreement on the Phase 2b/3 study design in ulcerative colitis.

Positive Phase 2 Data for Ampreloxetine

We reported positive top-line four-week data from the Phase 2 study of ampreloxetine (TD-9855), our norepinephrine reuptake inhibitor ("NRI") in development for the treatment of patients with symptomatic neurogenic orthostatic hypotension ("nOH"). Data collected in the study provided the basis to advance ampreloxetine into a registrational Phase 3 program in symptomatic nOH, for which we also gained FDA agreement on program design in 2018.

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Sale of VIBATIV

In order to sharpen our focus on our most important programs outside of the anti-infectives market, we announced and closed the sale of VIBATIV® to Cumberland Pharmaceuticals Inc., a specialty pharmaceutical company.

Economic Interest in GSK-Partnered Respiratory Programs and Issuance of \$250.0 million in Aggregate Principal Amount of 9.0% Non-Recourse Notes

Multiple milestones were achieved in 2018 with TRELEGY ELLIPTA, a respiratory program managed by GSK and Innoviva in which we have an economic interest that effectively entitles us to receive an upward tiering royalty of approximately 5.5% to 8.5% of worldwide net sales of TRELEGY ELLIPTA. Over the course of the year, GSK announced expanded COPD indications for TRELEGY ELLIPTA in both the US and EU, based on submissions to regulatory authorities supported by data from its IMPACT study. Results from the IMPACT study were also published in the New England Journal of Medicine. Outside the US and EU, GSK announced TRELEGY ELLIPTA regulatory applications submitted in additional markets including China and Japan.

We announced the closing of a private placement of \$250.0 million in aggregate principal amount of 9.0% non-recourse notes, secured by a portion of the future payments we receive related to royalties due on net sales of TRELEGY ELLIPTA. In order to comply with Regulation RR – Credit Risk Retention (17 C.F.R. Part 246), 5% of the principal amount of these notes were retained by Theravance Biopharma R&D, Inc., a wholly-owned subsidiary of Theravance Biopharma. Excluding the \$12.5 million of retained notes and other fees related to the transaction, net proceeds of the offering were approximately \$229.4 million.

Hosted an Investor Event to Highlight Our Research Projects (“R&D Day”)

We also described at our R&D Day event our innovative research and development strategy of organ-selective medicines designed to expand the therapeutic index compared to conventional systemic therapies. We introduced several new research programs, each specifically tailored for the organ of interest. We progressed TD-8236, our novel, lung-selective inhaled JAK inhibitor, into a Phase 1 clinical trial in healthy volunteers and asthma patients.

Our Programs

The table below summarizes the status of our approved product and our other product candidates in development. The table also includes the status of the respiratory programs in which we have an economic interest and for which GSK is responsible pursuant to agreements between Innoviva and GSK (“GSK Partnered Respiratory Programs”). These programs consist of the Trelegy Ellipta program, the inhaled Bifunctional Muscarinic Antagonist Beta2 Agonist (“MABA”) program and any other future products that may be combined with Trelegy Ellipta or MABA. We have an economic interest in these programs through our interest in Theravance Respiratory Company, LLC, a limited liability company managed by Innoviva. The status of all GSK-Partnered Respiratory Programs referenced in this Annual Report on Form 10 K are based solely upon publicly available information and may not reflect the most recent developments under the programs.

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PORTFOLIO	STATUS
Program	Phase 1Phase 2Phase 3Filed Approved Collaborators
RESPIRATORY	
YUPELRITM (revefenacin) inhalation solution:	
COPD	
TD-8236:	Mylan
Asthma	
GASTROINTESTINAL	
TD-1473:	Janssen Biotech
Ulcerative colitis	
TD-1473:	Janssen Biotech
Crohn's disease	
NEUROLOGICAL	
Amprexetine (TD-9855):	
Symptomatic nOH	
ECONOMIC INTEREST IN GSK-PARTNERED RESPIRATORY PROGRAMS *	
TRELEGY ELLIPTA (FF/UMEC/VI): COPD	GSK & Innoviva
TRELEGY ELLIPTA:	GSK & Innoviva
Asthma	
MABA, MABA/ICS (batefenterol, batefenterol/FF):	GSK & Innoviva
COPD	
OTHER ECONOMIC INTERESTS	
VIBATIV® (telavancin): cSSSI, HABP/VABP, concurrent bacteremia	Cumberland Pharmaceuticals
Velusetrag:	Alfasigma
Gastroparesis	
TD-8954 (TAK-954):	Takeda
POGD IV	

*The information regarding Trelegy Ellipta and MABA programs are based solely upon publicly available information and may not reflect the most recent developments under the programs.

Glossary of Defined Terms used in Table Above:

COPD: Chronic Obstructive Pulmonary Disease;

cSSSI: Complicated Skin and Skin Structure Infections;

FF: Fluticasone Furoate;

HABP/VABP: Hospital Acquired and Ventilator Associated Bacterial Pneumonia;

ICS: Inhaled Corticosteroid;

IV: Intravenous

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MABA: Bifunctional Muscarinic Antagonist Beta2 Agonist;

nOH: Neurogenic Orthostatic Hypotension;

POGD: Post-operative Gastrointestinal Dysfunction

UMEC: Umeclidinium;

VI: Vilanterol;

Status: The most advanced stage of clinical development that has been completed or is in process;

Phase 1: Initial clinical safety testing into patients or healthy human volunteers, or studies directed toward understanding the mechanisms of action of the drug;

Phase 2: Further clinical safety testing and preliminary efficacy testing in a limited patient population;

Phase 3: Evaluation of clinical efficacy and safety within an expanded patient population;

Filed: A marketing application has been submitted to a regulatory authority; and

Approved: Approved for marketing

Program Highlights

Gut-selective Pan-Janus Kinase (JAK) Inhibitor Program (TD-1473)

JAK inhibitors function by inhibiting the activity of one or more of the Janus kinase family of enzymes (JAK1, JAK2, JAK3, TYK2) that play a key role in cytokine signaling. Inhibiting these JAK enzymes interferes with the JAK/STAT signaling pathway and, in turn, modulates the activity of a wide range of pro-inflammatory cytokines. JAK inhibitors are currently approved for the treatment of rheumatoid arthritis, myelofibrosis, and ulcerative colitis and have demonstrated therapeutic benefit for patients with Crohn's disease. However, these products are known to have side effects based on their systemic exposure. Our goal is to develop an orally administered, gut-selective pan-JAK inhibitor specifically designed to distribute adequately and predominantly to the tissues of the intestinal tract, treating inflammation in those tissues while minimizing systemic exposure. TD-1473 is our lead gut-selective pan-JAK inhibitor in development as a potential treatment for a range of inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease. TD-1473 is progressing into multiple clinical studies, as further described below.

Phase 1 Single Ascending Dose and Multiple Ascending Dose Studies

In June 2016, we completed a Phase 1 clinical study of TD-1473, an internally-discovered JAK inhibitor that has demonstrated a high affinity for each of the JAK family of enzymes. The primary objective of the study was to evaluate the safety and tolerability of single ascending and multiple ascending doses of TD-1473 in healthy volunteers. A key secondary objective of the trial was to characterize the pharmacokinetics of TD-1473, including the determination of the amount of TD-1473 that entered systemic circulation following oral administration. Data from

the study demonstrated TD-1473 to be generally well tolerated. Study results also demonstrated that systemic exposures of TD-1473 were low relative to that reported for tofacitinib, a JAK inhibitor approved for the treatment ulcerative colitis. At steady state, the plasma exposures of TD-1473 were significantly lower than the plasma exposure of tofacitinib.

Furthermore, subjects exhibited high stool concentrations of TD-1473, which were comparable to concentrations associated with efficacy in preclinical colitis models. Preclinical studies also demonstrated penetration of TD-1473 into the intestinal wall and membrane. Data generated from the study met our target pharmacokinetic profile and supported clinical progression of the compound.

Previously announced findings from a preclinical model of colitis evaluating TD-1473 and tofacitinib demonstrated that both compounds significantly reduced disease activity scores. However, at doses providing similar preclinical efficacy, the systemic exposure of TD-1473 was much lower than that of tofacitinib and, in contrast to tofacitinib, TD-1473 did not reduce systemic immune cell counts. Also, we completed six and nine month toxicology studies of TD-1473 and demonstrated favorable safety margins in these studies, in support of the dose ranges planned in the Phase 3 registrational program. Based on these preclinical findings, we believe that TD-1473 represents a potential breakthrough approach to treating inflammatory intestinal diseases without the risk generally associated with systemically active therapies.

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Phase 1b Study

In late 2016, we announced dosing of the first patient in a Phase 1b clinical study of TD-1473 in patients with moderate to severe ulcerative colitis. The Phase 1b exploratory study in 40 patients was designed to evaluate the safety, tolerability, and pharmacokinetics (“PK”) of TD-1473 over a 28-day treatment period. In addition, the study incorporated biomarker analysis and clinical, endoscopic, and histologic assessments to evaluate biological effect.

In August 2017, we announced encouraging data from the first cohort of patients in the Phase 1b study. Data from the first cohort demonstrated evidence of localized biological activity for TD-1473 after four weeks of treatment, based on a compilation of clinical, endoscopic, and biomarker assessments. Pharmacokinetic data demonstrated minimal systemic exposure, and there was no evidence of systemic immunosuppression.

In August 2018, we announced top-line results from all cohorts in the Phase 1b study of TD-1473 in ulcerative colitis. Full results were shared as an oral late-breaker presentation at the United European Gastroenterology Week (“UEGW”) in October 2018. Data from the Phase 1b study demonstrated that four weeks of TD-1473 treatment led to signals of biological activity and localized target engagement with low systemic exposures and no evidence of systemic immunosuppression or opportunistic infections in patients with moderately to severely active ulcerative colitis. More specifically, rates of clinical response were higher on all active doses (20, 80, 270 mg) compared with placebo using both partial and total Mayo endpoints, with greatest effect seen at the 270 mg dose. Rectal bleeding scores improved above placebo at the 80 and 270 mg doses. Endoscopic improvements and mucosal healing were reported in all active arms, and none was reported in the placebo arm. Additionally, plasma levels were low and consistent with data from healthy volunteers, and TD-1473 was generally well tolerated at all doses.

Based on positive results from the Phase 1b study and following dialogues with the FDA and European Medicines Agency (“EMA”) regarding study design, we began to initiate sites for the registrational Phase 2b/3 (RHEA) induction and maintenance study in ulcerative colitis. In addition, we announced first patient dosed in a Phase 2 (DIONE) induction study of TD-1473 in Crohn’s disease in late 2018.

Janssen Biotech Collaboration

In February 2018, we announced a global co-development and commercialization agreement with Janssen Biotech, Inc. (“Janssen”) for TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn’s disease. Under the terms of the agreement, we received an upfront payment of \$100.0 million and will be eligible to receive up to an additional \$900.0 million in potential payments, inclusive of a potential opt-in payment following completion of the Phase 2 Crohn’s study and the Phase 2b induction portion of the ulcerative colitis study. At that time, Janssen can elect to obtain an exclusive license to develop and commercialize TD-1473 and certain related compounds by paying us a fee of \$200.0 million. Upon such election, we and Janssen will jointly develop and commercialize TD-1473 in inflammatory intestinal diseases, and we and Janssen will share profits and losses in the US and expenses related to a potential Phase 3 program (67% to Janssen; 33% to Theravance Biopharma). In addition, we would receive royalties on ex-US sales at double-digit tiered percentage royalty rates.

The closing of the opt-in portion of the transaction is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act (“HSR Act”). After Phase 2, Janssen would lead subsequent development of TD-1473 in Crohn’s disease if it makes such an election. We will lead development of TD-1473 in ulcerative colitis through completion of the Phase 2b/3 study. If TD-1473 is commercialized, we have the option to co-commercialize in the US, and Janssen would have sole commercialization responsibilities outside the US.

Amprexetine (TD 9855)

Amprexetine is an investigational, once-daily norepinephrine reuptake inhibitor (“NRI”) being developed for the treatment of patients with symptomatic neurogenic orthostatic hypotension (“nOH”). nOH is caused by primary autonomic failure conditions, including multiple system atrophy, Parkinson’s disease and pure autonomic failure. The compound has high affinity for binding to norepinephrine transporters. By blocking the action of these transporters, amprexetine causes an increase in extracellular concentrations of norepinephrine.

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In May 2016, we initiated a Phase 2 study of amprelosetine in nOH. The initial study design of the Phase 2 trial consisted of two parts. Part A, a single ascending dose study, with doses ranging from 1 mg up to 20 mg based on patient response, was designed to evaluate impact on blood pressure and standing time for amprelosetine as compared to placebo. Part B, a double-blind, single dose study was designed to evaluate impact on blood pressure and standing time for amprelosetine as compared to placebo. Based on encouraging treatment responses in the first part of the study, we amended the study design to allow responders to continue dosing for up to 20 weeks to assess the durability of their response (Part C). Part C, an open label extension to Part A, was designed to evaluate improvement in patients' symptoms and impact on blood pressure. Responders in Part A were eligible to enroll in Part C at up to their highest tolerated Part A dose, which included 5 mg, 10 mg and 20 mg. The primary endpoint of the study was measured after four weeks, although patients can continue to receive medication for up to five months. We believe the ability to demonstrate a durable effect in nOH with amprelosetine could lead to significant benefits for patients over existing therapy.

In August 2018, we announced positive top-line four-week data from the Phase 2 trial of amprelosetine for the treatment of nOH. Top-line results from the study included durable improvements in patients' disease symptom severity after four weeks of treatment with amprelosetine, as measured by Orthostatic Hypotension Symptom Assessment Question #1 ("OHSA #1"). OHSA #1 is a measure of dizziness, lightheadedness, or the sensation of being about to black out. Patients treated in the extension phase of the study showed a mean symptom improvement of 2.4 points at four weeks. Importantly, mean symptom improvement was greatest (3.8 points) in nOH patients who reported dizziness symptoms (OHSA #1 > 4) at baseline. Additionally, amprelosetine consistently increased systolic blood pressure ("SBP"), including clinically meaningful increases in standing SBP at the three-minute assessment on all weekly clinic visits. Amprelosetine was generally well tolerated, with no new safety findings attributable to drug observed in the study. Based on positive top-line four-week results from the Phase 2 study and discussions with the FDA, we advanced amprelosetine into a Phase 3 program. The Phase 3 program includes two studies. The first study is a four-week, randomized double-blind, placebo-controlled study designed to evaluate the efficacy, safety, and tolerability of amprelosetine in patients with symptomatic nOH. The second study is a randomized withdrawal study designed to evaluate the durability of patient response of amprelosetine. We announced that we initiated patient dosing in each Phase 3 study in January and February 2019, respectively.

In late February 2019, we announced emerging five-month data from the Phase 2 study further support previously-announced clinical observations after four weeks of treatment. Detailed study data will be submitted for presentation at a mid-2019 scientific meeting.

YUPELRITM (revefenacin) Inhalation Solution

YUPELRI (revefenacin) inhalation solution is a once-daily, nebulized long-acting muscarinic antagonist ("LAMA") approved for the maintenance treatment of COPD in the US. Our market research indicates there is an enduring population of COPD patients in the US that either need or prefer nebulized delivery for maintenance therapy. LAMAs are recognized by international COPD treatment guidelines as a cornerstone of maintenance therapy for COPD, regardless of severity of disease. YUPELRI is the first and only once-daily, long-acting single-agent product for COPD patients who require, or prefer, nebulized therapy. YUPELRI's stability in both metered dose inhaler and dry powder inhaler ("MDI/DPI") formulations suggest that this LAMA could also serve as a foundation for novel handheld combination products.

Mylan Collaboration

In January 2015, Mylan Ireland Limited (“Mylan”) and we established a strategic collaboration for the development and commercialization of revefenacin. Partnering with a world leader in nebulized respiratory therapies enables us to expand the breadth of our revefenacin development program and extend our commercial reach beyond the acute care setting. Mylan funded the Phase 3 development program of YUPELRI, enabling us to advance other high value pipeline assets alongside YUPELRI.

Under the terms of the Mylan Development and Commercialization Agreement (the “Mylan Agreement”), Mylan and we co-develop revefenacin for COPD and other respiratory diseases. We have led the US Phase 3 development program for YUPELRI in COPD, and Mylan was responsible for reimbursement of our costs related to the registrational program up until the approval of the first new drug application (“NDA”), after which costs are shared. With YUPELRI

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approved in the US, Mylan is leading commercialization, and we co-promote the product in the US under a profit and loss sharing arrangement (65% to Mylan; 35% to Theravance Biopharma). Following shipments into commercial channel in late 2018, we and Mylan formally launched our sales and marketing efforts in early 2019. Outside the US (excluding China), Mylan will be responsible for development and commercialization and will pay us a tiered royalty on net sales at percentage royalty rates ranging from low double-digits to mid-teens.

Under the Mylan Agreement, Mylan paid us an initial payment of \$15.0 million in cash in the second quarter of 2015. Also, pursuant to an agreement to purchase ordinary shares entered into on January 30, 2015, Mylan Inc., the indirect parent corporation of Mylan, made a \$30.0 million equity investment in us, buying 1,585,790 ordinary shares from us in February 2015 in a private placement transaction at a price of approximately \$18.918 per share, which represented a 10% premium over the volume weighted average price per share of our ordinary shares for the five trading days ending on January 30, 2015. In February 2016, we earned a \$15.0 million development milestone payment for achieving 50% enrollment in the Phase 3 twelve-month safety study. As of December 31, 2018, we are eligible to receive from Mylan additional potential development, regulatory and sales milestone payments totaling up to \$205.0 million in the aggregate, with \$160.0 million associated with YUPELRI monotherapy, and \$45.0 million associated with future potential combination products. Of the \$160.0 million associated with monotherapy, \$150.0 million relates to sales milestones based on achieving certain levels of net sales and \$10.0 million relates to regulatory actions in the EU. We do not expect to earn any milestone payments from Mylan in 2019.

We retain worldwide rights to revefenacin delivered through other dosage forms, such as a MDI/DPI, while Mylan has certain rights of first negotiation with respect to our development and commercialization of revefenacin delivered other than via a nebulized inhalation product. In China, we retain all rights to revefenacin in any dosage form.

Phase 3 Clinical Program in COPD and FDA Approval

In September 2015, we announced with our partner Mylan the initiation of the Phase 3 development program for YUPELRI for the treatment of COPD. The Phase 3 development program included two replicate three-month efficacy studies and a single twelve-month safety study. The two efficacy studies examined two doses (88 mcg and 175 mcg) of YUPELRI inhalation solution administered once-daily via nebulizer in patients with moderate to severe COPD. The Phase 3 efficacy studies were replicate, randomized, double-blind, placebo-controlled, parallel-group trials designed to provide pivotal efficacy and safety data for once-daily YUPELRI over a dosing period of 12 weeks, with a primary endpoint of trough forced expiratory volume in one second (FEV1) on day 85. The Phase 3 safety study was an open-label, active comparator study of 12 months duration.

In October 2016, we announced positive top-line results from the two replicate Phase 3 efficacy studies of YUPELRI in more than 1,200 moderate to very severe COPD patients, and in May and November 2017 we reported additional data from these studies. Both Phase 3 efficacy studies met their primary endpoints, demonstrating statistically significant improvements over placebo in trough FEV1 after 12 weeks of dosing for each of the YUPELRI doses studied (88 mcg once daily and 175 mcg once daily). The studies also demonstrated that the 88 mcg and 175 mcg doses of YUPELRI were generally well tolerated, with comparable rates of adverse events and serious adverse events across all treatment groups (active and placebo). In July 2017, we announced positive top-line results from the

twelve-month safety study in more than 1,000 COPD patients. Data demonstrated that both the 88 mcg and 175 mcg doses of YUPELRI were generally well tolerated, with low rates of adverse events and serious adverse events, comparable to those seen with the active comparator. Together, the three studies enrolled approximately 2,280 patients.

In November 2017, we submitted to the FDA for filing an NDA for YUPELRI supported by data from the two replicate Phase 3 efficacy studies and twelve-month safety study. In November 2018, YUPELRI was approved by the FDA for the maintenance treatment of patients with COPD.

Phase 3b PIFR Study

In March 2017, we initiated a Phase 3b study of YUPELRI in patients with suboptimal peak inspiratory flow rate (“PIFR”). This study was not required for NDA approval and was designed to support commercialization of YUPELRI. The purpose of the study was to assess whether nebulized YUPELRI was superior to handheld tiotropium (dosed via the Handihaler® device) in a broad population of COPD patients with suboptimal PIFR. The primary endpoint was

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improvement in lung function, as measured by trough forced expiratory volume in one second (FEV1) after 4 weeks of treatment.

The PIFR study was completed in the first quarter of 2018. In the overall population of approximately 200 moderate to very severe (GOLD Stage 2/3/4) COPD patients, we saw numerical improvements for YUPELRI over tiotropium, but these improvements were not statistically significant, and as a result the study failed to meet the primary endpoint. In the pre-specified subgroup of severe and very severe (GOLD 3/4) COPD patients, which represented approximately 80% of the patients in the study, YUPELRI demonstrated nominally statistically significant and clinically relevant improvements in trough FEV1 versus tiotropium. Data generated in the study provide important insights to inform future potential studies of YUPELRI in COPD patients with suboptimal PIFR. YUPELRI was well tolerated in this study, with no new safety issues identified. We plan to publish additional analyses of these results from this study in a future medical meeting or publication.

TD-8236

TD-8236 is an investigational, lung-selective inhaled JAK inhibitor that has demonstrated a high affinity and selectivity for each of the JAK family enzymes (JAK1, JAK2, JAK3 and TYK2). Through the inhibition of these kinases, TD-8236 interferes with the JAK/STAT signaling pathway and, in turn, modulates the activity of a wide range of pro-inflammatory cytokines. TD-8236 is specifically designed to be an inhaled treatment delivered exclusively to the lungs with a dry-powder inhaler with minimal systemic exposure. With multiple JAK-dependent pathways clinically validated in asthma and COPD, we believe it offers potentially broad activity across a range of serious respiratory diseases. In severe asthma, patient heterogeneity includes both Th2-high (eosinophilic) and Th2-low (neutrophilic, paucigranulocytic, and mixed granulocytic) phenotypes, but current approved novel biologics address only Th2-high asthma. We recognize a treatment need for the prevention of exacerbations and symptom control for patients regardless of Th2 phenotype. In pre-clinical assessments, TD-8236 has shown to potently inhibit targeted mediators of Th2-high and Th2-low asthma in human cells. In November 2018, we announced first subject dosed in a Phase 1 study of TD-8236, designed to evaluate safety and provide biomarker data in both healthy volunteers and asthma patients.

Velusetrag (TD 5108)

Velusetrag is an oral, investigational medicine developed for gastrointestinal motility disorders. It is a highly selective agonist with high intrinsic activity at the human 5-HT4 receptor. In 2012, we partnered with Alfasigma S.p.A. (“Alfasigma”) (formerly Alfa Wassermann S.p.A.) in the development of velusetrag and its commercialization in certain countries. In April 2014, we announced top-line results from the initial Phase 2 proof-of-concept study under this partnership, which evaluated gastric emptying, safety and tolerability of multiple doses of velusetrag.

In August 2017, we announced positive top-line results from a 12-week, Phase 2b study of velusetrag characterizing the impact on symptoms and gastric emptying of three oral doses of velusetrag (5, 15 and 30 mg) compared to placebo administered once daily over 12 weeks of therapy. Results from the study demonstrated statistically significant improvements in gastroparesis symptoms and gastric emptying for patients receiving 5 mg of velusetrag as compared

to placebo. Patients in the 15 and 30 mg velusetrag study arms demonstrated statistically significant improvements in gastric emptying, but they did not experience statistically significant improvements in gastroparesis symptoms. Velusetrag was shown to be generally well tolerated, with 5 mg and placebo having comparable rates of adverse events and serious adverse events. Completion of the Phase 2b study was followed by dialogue with regulatory authorities in the US and EU regarding further development of velusetrag.

In late April 2018, Alfasigma exercised its option to develop and commercialize velusetrag. As a result, Alfasigma paid us a total of \$11.0 million, comprised of a \$10.0 million option exercise fee and a \$1.0 million non-refundable reimbursement. Additionally, we elected not to pursue further development of velusetrag, based on our planned pipeline investments and in light of an FDA requirement that a chronically administered gastroparesis product in this class complete a large Phase 3 safety study. Global rights to develop, manufacture and commercialize velusetrag transferred to Alfasigma under the terms of the existing collaboration agreement. Also under the terms of the collaboration with Alfasigma, we are entitled to receive future potential development, regulatory and commercial milestone payments of up to \$26.8 million, and tiered royalties on global net sales ranging from high single digits to the mid-teens.

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VIBATIV® (telavancin)

VIBATIV is a bactericidal, once-daily injectable antibiotic to treat patients with serious, life-threatening infections due to *Staphylococcus aureus* and other Gram-positive bacteria, including methicillin-resistant (“MRSA”) strains, discovered and developed by Theravance Biopharma. VIBATIV is approved in the US for the treatment of adult patients with complicated skin and skin structure infections (“cSSSI”) caused by susceptible Gram-positive bacteria and for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (“HABP”/“VABP”) caused by susceptible isolates of *Staphylococcus aureus* when alternative treatments are not suitable. In addition, in 2016, the FDA authorized new clinical data into the VIBATIV label concerning concurrent bacteremia in cases of HABP/VABP and cSSSI. VIBATIV is also indicated in Canada and Russia for cSSSI and HABP and VABP caused by Gram-positive bacteria, including MRSA.

In November 2018, we sold VIBATIV to Cumberland Pharmaceuticals Inc. (“Cumberland”) pursuant an Asset Purchase Agreement (the “Agreement”). Cumberland paid us \$20.0 million at the closing of the transaction and will pay (i) \$5.0 million on or before April 1, 2019 and (ii) tiered royalties of up to 20% of US net sales of VIBATIV until such time as royalties cumulatively total \$100.0 million.

In connection with the sale of VIBATIV, Cumberland acquired, among other things, (i) intellectual property rights relating to VIBATIV, (ii) active pharmaceutical ingredient for VIBATIV, work-in-process and finished drug product, (iii) the US marketing authorization for VIBATIV, (iv) certain assigned contracts relating to the manufacture and commercialization of VIBATIV, and (v) books and records related to VIBATIV. Cumberland also assumed certain clinical study obligations related to VIBATIV and post-closing liabilities and obligations relating to VIBATIV as described in the Agreement. The Company agreed to provide transition services to Cumberland for limited periods of time following the consummation of the transaction.

Our acute care sales force, supported by our independent marketing and medical affairs teams, marketed VIBATIV in the US until shortly after the sale to Cumberland in late 2018. As of early 2019, the commercial organization is focused on supporting YUPELRI in the US in partnership with Mylan.

Selective 5-HT₄ Agonist (TD-8954)

Takeda Collaborative Arrangement

In June 2016, we entered into a License and Collaboration Agreement with Millennium Pharmaceuticals, Inc., a Delaware corporation (“Millennium”) (the “Takeda Agreement”), in order to establish a collaboration for the development and commercialization of TD-8954 (TAK-954), a selective 5-HT₄ receptor agonist. Millennium is an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (TSE: 4502), a publicly-traded Japanese corporation listed on the Tokyo Stock Exchange (collectively with Millennium, “Takeda”). TD-8954 is being developed for potential use in the treatment of gastrointestinal motility disorders. Under the terms of the Takeda Agreement,

Takeda will be responsible for worldwide development and commercialization of TD-8954. We received an upfront cash payment of \$15.0 million and will be eligible to receive success-based development, regulatory and sales milestone payments from Takeda. We will also be eligible to receive a tiered royalty on worldwide net sales by Takeda at percentage royalty rates ranging from low double-digits to mid-teens.

Research Projects

Our research goal is to design organ-selective medicines that target diseased tissues, without systemic exposure, in order to maximize patient benefit and minimize risk. The intention is to expand the therapeutic index of our potential medicines compared to conventional systemic therapies. Our efforts leverage years of experience in developing lung-selective medicines, such as YUPELRI, to treat respiratory diseases, and have led to the discovery of the gut-selective pan-JAK inhibitor TD-1473 in inflammatory intestinal diseases and the lung-selective inhaled JAK inhibitor TD-8236 in serious respiratory disease. We plan to advance towards the clinic other research projects with various mechanisms of action, each specifically tailored for the organ of interest, as we identify and validate potentially appropriate compounds. Our research is focused in the areas of inflammation and immunology, and our pipeline of internally discovered programs is targeted to address significant patient needs.

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Other Programs

Neprilysin (“NEP”) Inhibitor Program (TD-0714 and TD-1439)

Neprilysin (“NEP”) is an enzyme that degrades natriuretic peptides. These peptides play a protective role in controlling blood pressure and preventing cardiovascular tissue remodeling. Inhibiting NEP may result in clinical benefit for patients, including diuresis, control of blood pressure, and reversing maladaptive changes in the heart and vascular tissue in patients with congestive heart failure. We recognize significant potential for a NEP inhibitor that can be used across a broad population of patients with cardiovascular and renal diseases, including acute and chronic heart failure and chronic kidney disease, including diabetic nephropathy. Our NEP inhibitor program consists of two compounds (TD-0714 and TD-1439), each of which demonstrated characteristics in line with our target product profile in Phase 1 studies in healthy volunteers.

TD-0714

TD-0714 is our most advanced NEP inhibitor compound. In 2016, a Phase 1 single ascending dose (“SAD”) study in healthy volunteers demonstrated that the compound achieved maximal and sustained levels of target engagement for 24 hours after a single-dose, supporting the drug’s potential for once-daily dosing. Target engagement was measured by dose-related increases in the levels of cyclic GMP (cGMP, a well-precedented biomarker of NEP engagement). TD-0714 also demonstrated very low levels of renal elimination, as evidenced by intravenous microtracer testing technology, and a favorable tolerability profile. Findings from a Phase 1 multiple ascending dose (“MAD”) study in healthy volunteers were consistent with the SAD study in healthy volunteers, demonstrating sustained target engagement, low levels of renal elimination, and a favorable tolerability profile.

TD-1439

TD-1439 is a second NEP inhibitor compound, which is structurally distinct from TD-0714. In 2017, Phase 1 SAD and MAD studies of TD-1439 demonstrated characteristics which met our target product profile, including sustained 24-hour target engagement, low levels of renal elimination and a favorable tolerability profile.

The results from the Phase 1 programs demonstrate potential in a broad range of cardiovascular and renal diseases, including in patients with compromised renal function. We are evaluating next steps for both compounds in our NEP inhibitor program clinical program.

Economic Interest in GSK Partnered Respiratory Programs

We are entitled to receive an 85% economic interest in any future payments that may be made by GSK to Theravance Respiratory Company, LLC (“TRC”) pursuant to its agreements with Innoviva (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal

quarters) relating to the GSK-Partnered Respiratory Programs, which Innoviva partnered with GSK and assigned to TRC in connection with Innoviva's separation of its biopharmaceutical operations into its then wholly-owned subsidiary Theravance Biopharma in June 2014. The GSK-Partnered Respiratory Programs consist primarily of the TRELEGY ELLIPTA program and the inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist ("MABA") program, each of which are described in more detail below. We are entitled to this economic interest through our equity ownership in TRC. Our economic interest does not include any payments associated with RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® or vilanterol monotherapy. The following information regarding the TRELEGY ELLIPTA and MABA programs is based solely upon publicly available information and may not reflect the most recent developments under the programs.

TRELEGY ELLIPTA (the combination of fluticasone furoate/umeclidinium bromide/vilanterol)

TRELEGY ELLIPTA is the first treatment to provide the activity of an inhaled corticosteroid (FF) plus two bronchodilators (UMEC, a LAMA, and VI, a long-acting beta2 agonist, or LABA) in a single delivery device administered once-daily. TRELEGY ELLIPTA is approved for use in the US and EU for the long-term, once-daily, maintenance treatment of patients with COPD. We are entitled to receive an 85% economic interest in the royalties payable by GSK to TRC on worldwide net sales (net of TRC expenses paid and the amount of cash, if any, expected to be

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used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). Those royalties are upward-tiering from 6.5% to 10%, resulting in cash flows to Theravance Biopharma of approximately 5.5% to 8.5% of worldwide net sales of TRELEGY ELLIPTA. Theravance Biopharma is not responsible for any of GSK's costs related to the development or commercialization of TRELEGY ELLIPTA.

Innoviva and GSK conducted two global pivotal Phase 3 studies of TRELEGY ELLIPTA in COPD, the IMPACT study and the FULFIL study.

The IMPACT study, which enrolled 10,355 COPD patients, was initiated in July 2014. In September 2017, GSK and Innoviva disclosed positive headline results from the IMPACT study, in which data demonstrated statistically significant reductions in the annual rate of on-treatment moderate/severe exacerbations for TRELEGY ELLIPTA (100/62.5/25mcg) when compared with two, once-daily dual COPD therapies RELVAR® ELLIPTA®/BREO® ELLIPTA® (FF/VI), an ICS/LABA combination, and ANORO® ELLIPTA® (UMEC/VI), a LAMA/LABA combination. In addition, statistically significant improvements were observed across all pre-specified key secondary endpoints and associated treatment comparisons.

The FULFIL study, which enrolled 1,810 COPD patients, was initiated in February 2015. In June 2016, GSK and Innoviva disclosed positive top line results from the FULFIL study, in which data demonstrated superiority of TRELEGY ELLIPTA as compared to twice daily SYMBICORT® TURBOHALER® (budesonide/formoterol) in improving lung function and health related quality of life, as well as reducing exacerbations in COPD patients.

In September 2017, GSK and Innoviva announced that the FDA approved TRELEGY ELLIPTA for the long-term, once-daily, maintenance treatment of appropriate patients with COPD. In April 2018, GSK and Innoviva announced the FDA approved a supplemental new drug application ("sNDA") containing data from the IMPACT study, resulting in an expanded indication for the product. The updated indication is for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. In addition, the FDA removed a boxed warning from TRELEGY ELLIPTA prescribing information.

In December 2017, GSK and Innoviva announced that the European Commission granted marketing authorization for TRELEGY ELLIPTA as a maintenance treatment for appropriate patients with COPD.

In February 2018, GSK and Innoviva announced the submission of the IMPACT data to the EMA as part of a type II variation to support an expanded label for TRELEGY ELLIPTA in Europe for the maintenance treatment of moderate to severe COPD, and in November 2018, GSK and Innoviva announced the European Commission authorized an expanded label for once-daily TRELEGY ELLIPTA. The updated indication for TRELEGY ELLIPTA is as a maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an ICS and a LABA or a combination of a LABA and a LAMA.

Additionally, in December 2016, GSK and Innoviva announced the initiation of the Phase 3 (CAPTAIN) study of TRELEGY ELLIPTA in patients with asthma. GSK and Innoviva have indicated that the CAPTAIN study is expected to be completed in the first half of 2019, and if positive, an expected sNDA submission in the second half of 2019.

Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA)

GSK961081 ('081), also known as batefenterol, is an investigational, single-molecule bifunctional bronchodilator with both muscarinic antagonist and beta2 receptor agonist activity that was discovered by us when we were part of Innoviva.

If a single-agent MABA medicine containing '081 is successfully developed and commercialized, we are entitled to receive an 85% economic interest in the royalties payable by GSK to TRC on worldwide net sales (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters), which royalties range between 10% and 20% of annual global net sales up to \$3.5 billion, and 7.5% for all annual global net sales above \$3.5 billion. If a MABA medicine containing '081 is commercialized only as a combination product, such as '081/FF, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA

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medicine. If a MABA medicine containing ‘081 is successfully developed and commercialized in multiple regions of the world, TRC is eligible to receive contingent milestone payments from GSK. The agreements allow for total milestones of up to \$125.0 million for a single-agent medicine and an incremental \$125.0 million for a combination medicine. Of these amounts, \$112.0 million in potential milestones remain for a single-agent medicine, and \$122.0 million remain for a combination medicine. In each case, we would be entitled to receive an 85% economic interest in any such payments (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters).

Theravance Respiratory Company, LLC

Our equity interest in TRC is the mechanism by which we are entitled to the 85% economic interest in any future payments made by GSK under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC by Innoviva (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). The royalty payments from GSK to TRC arising from the net sales of Trelegy Ellipta are presented on our consolidated statements of operations under “income from investment in TRC, LLC” and is classified as non-operating income. 75% of the “income from investment in TRC, LLC,” as evidenced by the Issuer Class C Units, is available only for payment of the 9.0% fixed-rate non-recourse term notes due 2033 (the “Non-Recourse 2033 Notes”) and is not available to pay our other obligations or the claims of our other creditors. The drug programs assigned to TRC include all Trelegy Ellipta products and the MABA program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid (“ICS”), as well as any other product or combination of products that may be discovered and developed in the future under these GSK agreements.

Our special purpose subsidiary Triple Royalty Sub LLC (the “Issuer”) issued the Non-Recourse 2033 Notes in November 2018, which are secured by all of the Issuer’s right, title and interest as a holder of certain membership interests (the “Issuer Class C Units”) in TRC. The Issuer Class C Units entitle the Issuer to receive 63.75% of the economic interest that TRC receives in any future payments made by GSK under the agreements described above, or 75% of the income from our ownership interest in TRC. The primary source of funds to make payments on the Non-Recourse 2033 Notes will be 75% of the income from our ownership interest in TRC, as evidenced by the Issuer Class C Units. Since the principal and interest payments on the Non-Recourse 2033 Notes are ultimately based on royalties from TRELEGY ELLIPTA product sales, which will vary from quarter to quarter, the Non-Recourse 2033 Notes may be repaid prior to the final maturity date in 2033.

Our Strategy

Our core purpose is to create transformational medicines to improve the lives of patients suffering from serious illnesses. We strive to apply insight and innovation at each stage of our business, including research, development and commercialization. Our principle strategic objective is to transform the treatment of serious diseases with novel, organ-selective medicines, designed to expand the therapeutic index compared to conventional systemic therapies, in order to deliver value to patients, as well as payers and healthcare providers.

We follow these core guiding principles in our mission to drive value creation:

- Focus on insight and innovation;
- Outsource non core activities;
- Create and foster an integrated environment; and
- Aggressively manage uncertainty.

We manage our pipeline with the goal of optimizing program value and allocation of resources. We employ multiple strategies for commercialization of our products. Our approach may involve retaining product rights and marketing a product independently in the US or we may partner a product to extend our commercial reach to expand our geographic reach, and/or to manage the financial risk associated with the program. Alternatively, we may monetize or

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divest an asset that we designate as outside our core business, where we believe the program is optimized by leveraging partner capabilities and removing or limiting our research and development costs.

Manufacturing

We rely primarily on a network of third party manufacturers, including contract manufacturing organizations, to produce our active pharmaceutical ingredient (“API”) and our drug product. We believe that we have in house expertise to manage this network of third party manufacturers, and we believe that we will be able to continue to negotiate third party manufacturing arrangements on commercially reasonable terms and that it will not be necessary for us to obtain internal manufacturing capacity in order to develop or, potentially, commercialize our products. However, if we are unable to obtain contract manufacturing or obtain such manufacturing on commercially reasonable terms, or if manufacturing is interrupted at one of our suppliers, whether due to regulatory or other reasons, we may not be able to develop our products as planned.

Any inability to acquire sufficient quantities of API or drug product in a timely manner from current or future sources could disrupt our research and development programs and the conduct of future clinical trials. For more information, see the risk factors under the heading “We rely on a single source of supply for a number of our product candidates, and our business will be harmed if any of these single-source manufacturers are not able to satisfy demand and alternative sources are not available” of this Annual Report on Form 10 K.

Government Regulation

The development and commercialization of pharmaceutical products and our product candidates by us, our collaboration partners and licensees and Cumberland, GSK and Innoviva and our ongoing research are subject to extensive regulation by governmental authorities in the US and other countries. Before marketing in the US, any medicine must undergo rigorous preclinical studies and clinical studies and an extensive regulatory approval process implemented by the FDA under the Federal Food, Drug, and Cosmetic Act. Outside the US, the ability to market a product depends upon receiving a marketing authorization from the appropriate regulatory authorities which are subject to equally rigorous regulatory obligations. The requirements governing the conduct of clinical studies, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, however, the commercialization of pharmaceutical products is permitted only if the appropriate regulatory authority is satisfied that we have presented adequate evidence of the safety, quality and efficacy of the product.

Before commencing clinical studies in humans in the US, we must submit to the FDA an investigational new drug application (“IND”) that includes, among other things, the general investigational plan and protocols for specific human studies, and the results of preclinical studies. An IND will go into effect 30 days following its receipt by the FDA unless the FDA issues a clinical hold. Once clinical studies have begun under the IND, they are usually conducted in three phases and under FDA oversight. These phases generally include the following:

Phase 1. The product candidate is introduced into patients or healthy human volunteers and is tested for safety, dose tolerance and pharmacokinetics.

Phase 2. The product candidate is introduced into a limited patient population to assess the efficacy of the drug in specific, targeted indications, assess dosage tolerance and optimal dosage, and identify possible adverse effects and safety risks.

Phase 3. If a compound is found to be potentially effective and to have an acceptable safety profile in Phase 2 evaluations, the clinical study will be expanded to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population.

The results of product development, preclinical studies and clinical studies must be submitted to the FDA as part of an NDA. The NDA also must contain extensive manufacturing information. The Prescription Drug User Fee Act (“PDUFA”) establishes timeframes for FDA review of NDAs, with a performance goal of reviewing and acting on 90 percent of priority new molecular entity (“NME”) NDA submissions within 6 months of the 60 day filing date, and to

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review and act on 90 percent of standard NME NDA submissions within 10 months of the 60 day filing date. The 2007 Food and Drug Administration Amendments Act gave the FDA authority to require implementation of a formal Risk Evaluation and Management Strategy to ensure that the benefits of a product outweigh its risks. At the end of the review period, the FDA communicates either approval of the NDA or a complete response listing the application's deficiencies.

Once approved, the FDA may withdraw the product approval if compliance with post marketing regulatory standards is not maintained or if safety or quality issues are identified after the product reaches the marketplace. In addition, the FDA may require post marketing studies, sometimes referred to as Phase 4 studies, to monitor the safety and effectiveness of approved products, and may limit further marketing of the product based on the results of these post marketing studies. The FDA has broad post market regulatory and enforcement powers, including the ability to suspend or delay issuance of approvals, seize products, withdraw approvals, enjoin violations, and initiate criminal prosecution.

If regulatory approval for a medicine is obtained, the clearance to market the product will be limited to those diseases and conditions approved by FDA and for which the medicine was shown to be effective, as demonstrated through clinical studies and specified in the medicine's labeling. Even if this regulatory approval is obtained, a marketed medicine, its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections by the FDA. The FDA ensures the quality of approved medicines by carefully monitoring manufacturers' compliance with its current Good Manufacturing Practice ("cGMP") regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packaging of a medicine. The regulations are intended to make sure that a medicine is safe for use, and that it has the ingredients and strength it claims to have. Discovery of previously unknown problems with a medicine, manufacturer or facility may result in restrictions on the medicine or manufacturer, including costly recalls or withdrawal of the medicine from the market.

We, our collaboration partners and licensees are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA and other regulatory authorities have broad regulatory and enforcement powers, including the ability to suspend or delay issuance of approvals, seize products, withdraw approvals, enjoin violations, and initiate criminal prosecution, any one or more of which could have a material adverse effect upon our business, financial condition and results of operations.

Outside the US our, our collaboration partners', licensees', GSK's and Cumberland's ability to market products will also depend on receiving marketing authorizations from the appropriate regulatory authorities. Risks similar to those associated with FDA approval described above exist with the regulatory approval processes in other countries.

United States Healthcare Reform

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together the “Healthcare Reform Act”), substantially changed the way healthcare is financed by both governmental and private insurers, and impacts pricing and reimbursement of YUPELRI and the marketed drugs with respect to which we are entitled to royalty or similar payments, and related commercial operations. Moreover, certain legislative changes to and regulatory changes under the Healthcare Reform Act have occurred in the 115th US Congress and under the Trump Administration and additional changes remain possible. We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on the ability of us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved. For more information, see the risk factor under the heading “Changes in healthcare law and implementing regulations, including government restrictions on pricing and reimbursement, as well as healthcare policy and other healthcare payor cost containment initiatives, may negatively impact us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties” of this Annual Report on Form 10 K.

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Pharmaceutical Pricing and Reimbursement

We participated in and had certain price reporting obligations under the Medicaid Drug Rebate program for VIBATIV for which we remain responsible, as described in greater detail under the risk factor “If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects” of this Annual Report on Form 10 K.

Our ability, and the ability of our collaboration partners, licensees, GSK and Cumberland to commercialize our products successfully, and our ability to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the US, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. The reimbursement environment is described in greater detail under the risk factor “Changes in healthcare law and implementing regulations, including government restrictions on pricing and reimbursement, as well as healthcare policy and other healthcare payor cost containment initiatives, may negatively impact us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties” of this Annual Report on Form 10 K.

Fraud and Abuse Laws

Our interactions and arrangements with customers and third party payors are subject to applicable US federal and state fraud and abuse laws. These laws and the related risks are described in greater detail under the risk factor “Our relationships with customers and third party payors are subject to applicable anti kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion, contractual damages, reputational harm and diminished profits and future earnings” of this Annual Report on Form 10 K.

Data Privacy and Protection

We are subject to laws and regulations that address privacy and data security. In the US, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act), govern the collection, use, disclosure, and protection of health related and other personal information. Similar obligations apply in foreign countries. For example, the General Data Protection Regulation (“GDPR”) which entered into force on May 25, 2018 amplified existing data protection obligations in the EU. These laws and related risks are described in greater detail under the risk factor “If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business” of this Annual Report on Form 10 K.

Patents and Proprietary Rights

We will be able to protect our technology from unauthorized use by third parties only to the extent that our technology is covered by valid and enforceable patents or is effectively maintained as trade secrets. Our success in the future will depend in part on obtaining patent protection for our product candidates. Accordingly, patents and other proprietary rights are essential elements of our business. Our policy is to seek in the US and selected foreign countries patent protection for novel technologies and compositions of matter that are commercially important to the development of our business. For proprietary know how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery process that involve proprietary know how and technology that is not covered by patent applications, we rely on trade secret protection and confidentiality agreements to protect our interests. We require all of our employees, consultants and advisors to enter into confidentiality agreements. Where it is necessary to share our proprietary information or data with outside parties, our policy is to make available only that information and data required to accomplish the desired purpose and only pursuant to a duty of confidentiality on the part of those parties.

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As of December 31, 2018, we owned 438 issued US patents and 1,672 granted foreign patents, as well as additional pending US patent applications and foreign patent applications. The claims in these various patents and patent applications are typically directed to compositions of matter, including claims covering product candidates, crystalline forms, lead compounds and key intermediates, pharmaceutical compositions, methods of use and/or processes for making our compounds. In particular, our wholly owned subsidiary Theravance Biopharma R&D IP, LLC owns the following US patents which are listed in the FDA Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) for YUPELRI (revefenacin) inhalation solution: US Patent No. 7,288,657, expiring on December 23, 2025; US Patent No. 7,491,736, expiring March 10, 2025; US Patent No. 7,521,041, expiring March 10, 2025; US Patent No. 7,550,595, expiring March 10, 2025; US Patent No. 7,585,879, expiring March 10, 2025; US Patent No. 7,910,608, expiring March 10, 2025; US Patent No. 8,034,946, expiring March 10, 2025; US Patent No. 8,053,448, expiring March 10, 2025; US Patent No. 8,273,894, expiring March 10, 2025; and US Patent No. 10,106,503, expiring March 10, 2025 (each of the aforementioned expiration dates not including any patent term extensions that may be available under the Drug Price Competition and Patent Term Restoration Act of 1984). Thus, the last to expire patent currently listed in the Orange Book for YUPELRI (revefenacin) inhalation solution expires on December 23, 2025. On December 19, 2018, we filed patent term extension (“PTE”) applications in the US Patent and Trademark Office (“USPTO”) for US Patent Nos. 7,288,657 and 7,585,879. These PTE applications are currently pending and if granted, we will be permitted to extend the term of one of these patents for the period determined by the USPTO.

US issued patents and foreign patents generally expire 20 years after filing with the USPTO. The patent rights relating to YUPELRI (revefenacin) inhalation solution currently consist of US patents that expire in 2025, additional pending US patent applications and counterpart patents and patent applications in a number of jurisdictions, including Europe. Additionally, our patent rights relating to velusetrag, amprelosetine and TD-1473 currently include issued US composition of matter patents that expire in 2025, 2030 and 2036, respectively (not including any patent term extensions that may be available under the Drug Price Competition and Patent Term Restoration Act of 1984), as well as additional issued US patents, pending US patent applications and/or counterpart patents and patent applications in a number of jurisdictions. Nevertheless, issued patents can be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products and threaten our ability to commercialize our product candidates. Our patent position, similar to other companies in our industry, is generally uncertain and involves complex legal and factual questions. To maintain our proprietary position we will need to obtain effective claims and enforce these claims once granted. It is possible that, before any of our products can be commercialized, any related patent may expire or remain in force only for a short period following commercialization, thereby reducing any advantage of the patent. Also, we do not know whether any of our patent applications will result in any issued patents or, if issued, whether the scope of the issued claims will be sufficient to protect our proprietary position.

Competition

The marketed products to which we are entitled to profit share revenue, royalty or similar payments, and our development programs target four therapeutic areas—infectious disease, respiratory, gastrointestinal, and neurological. In research, we apply organ-selective expertise to biologically compelling targets to discover and develop medicines designed to treat underserved localized diseases and to limit systemic exposure, in order to maximize patient benefit and minimize risk. Our commercial infrastructure is focused primarily on the acute care setting. We expect that any medicines that we commercialize with our collaborative partners or on our own will compete with existing and future market leading medicines.

Many of our competitors have substantially greater financial, technical and personnel resources than we have. In addition, many of these competitors have significantly greater commercial infrastructures than we have. Our ability to compete successfully will depend largely on our ability to leverage our experience in drug discovery, development and commercialization to:

- discover and develop medicines that are superior to other products in the market;
- attract and retain qualified scientific, clinical development and commercial personnel;
- obtain patent and/or other proprietary protection for our medicines and technologies;

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- obtain required regulatory approvals;
- commercialize approved products; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

YUPELRI (revefenacin) inhalation solution, a long acting muscarinic antagonist (LAMA). YUPELRI competes predominantly with short acting nebulized bronchodilators used three to four times per day and the nebulized LAMA Lonhala™ Magnair™ (SUN-101/eFlow®) used two times per day. YUPELRI has the potential to be a primary maintenance therapy or to be used with nebulized long acting beta agonist (LABA) products used two times per day.

Trelegy Ellipta or FF/UMEC/VI (fluticasone furoate/umeclidinium bromide/vilanterol). Trelegy Ellipta competes in Europe with Trimbaw (beclometasone dipropionate/formoterol fumarate/glycopyrronium bromide, dosed twice per day) from Chiesi Farmaceutici and, in the future, may compete with other closed triple products that are currently under development. AstraZeneca and Novartis both have closed triple products dosed twice per day in late stage development for COPD and/or asthma.

VIBATIV (telavancin). VIBATIV competes with vancomycin, linezolid and daptomycin, generic drugs that are manufactured by a variety of companies, as well as other drugs marketed to treat complicated skin and skin structure infections and hospital acquired and ventilator associated bacterial pneumonia caused by Gram positive bacteria. Currently marketed branded competitive products include but are not limited to Sivextro® (tedizolid) marketed by Merck & Co., Inc.; Teflaro® (ceftaroline) and Dalvance™ (dalbavancin) marketed by Allergan; and Orbactiv™ (oritavancin) marketed by Melinta Therapeutics.

Employees

As of December 31, 2018, we had 363 employees, of which 217 were engaged in research and development activities. Of our 363 employees, 345 were located in the US, and 18 were located in Ireland. We consider our employee relations to be good.

In January 2019, we announced a reduction in workforce to align with our focus on continued execution of key strategic programs, and advancement of selected late-stage research programs toward clinical development. Our overall headcount was reduced by approximately 50 individuals with the affected employees primarily focused on early research or the infrastructure in support of VIBATIV which we recently sold to Cumberland in November 2018. The workforce reduction is expected to be substantially completed in the first quarter of 2019.

Financial Information About Geographic Areas

Information on our total revenues attributed to geographic areas and customers who represented at least 10% of our total revenues is included in Note 4, "Segment Information," to our consolidated financial statements in this Annual Report on Form 10-K.

Corporation Information

Theravance Biopharma was incorporated in the Cayman Islands in July 2013 under the name Theravance Biopharma, Inc. Theravance Biopharma began operating as an independent, publicly traded company on June 2, 2014 following a spin off from Innoviva, Inc. Our corporate address in the Cayman Islands and principal executive office is P.O. Box 309, Ugland House, Grand Cayman, KY1 1104, Cayman Islands and the address of our wholly owned US operating subsidiary Theravance Biopharma US, Inc. is 901 Gateway Boulevard, South San Francisco, California 94080. While Theravance Biopharma is incorporated under Cayman Island law, the Company became an Irish tax resident effective July 1, 2015. The address of our wholly owned Irish operating subsidiary, Theravance Biopharma Ireland Limited, is Connaught House, Burlington Road, Dublin 4, Ireland.

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Available Information

Our Internet address is www.theravance.com. Our investor relations website is located at <http://investor.theravance.com>. We make available free of charge on our investor relations website under “SEC Filings” our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, our directors’ and officers’ Section 16 Reports and any amendments to those reports as soon as reasonably practicable after filing or furnishing such materials to the US Securities and Exchange Commission (“SEC”). Our current Code of Business Conduct, Corporate Governance Guidelines, Articles of Association, Board of Director Committee charters, and other materials, including amendments thereto, may also be found on our investor relations website under “Corporate Governance.” The information found on our website is not part of this or any other report that we file with or furnish to the SEC. Theravance Biopharma and the Theravance Biopharma logo are registered trademarks of the Theravance Biopharma group of companies. Trademarks, tradenames or service marks of other companies appearing in this report are the property of their respective owners.

ITEM 1A. RISK FACTORS

RISKS RELATING TO OUR COMPANY

The risks described below and elsewhere in this Annual Report on Form 10-K and in our other public filings with the SEC are not the only risks facing the Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

We anticipate that we will incur losses for the foreseeable future. We may never achieve or sustain profitability.

First as part of Innoviva, and since June 2, 2014 as Theravance Biopharma, we have been engaged in discovery and development of compounds and product candidates since mid-1997. We may never generate sufficient revenue from the sale of medicines, royalties on sales by our partners or from our interest in Theravance Respiratory Company, LLC (“TRC”) to achieve profitability. During the years ended December 31, 2018, 2017 and 2016, we recognized net losses of \$215.5 million, \$285.4 million and \$190.7 million, respectively, which are reflected in the shareholders’ (deficit) equity on our consolidated balance sheets. We reflect cumulative net loss incurred after June 2, 2014, the effective date of our spin-off from Innoviva, Inc. (the “Spin-Off”), as accumulated deficit on our consolidated balance sheets, which was \$1.0 billion as of December 31, 2018. We expect to continue to incur net losses at least over the next several years as we continue our drug discovery and development efforts and incur significant preclinical and clinical development costs related to our current product candidates and commercialization and development costs relating to YUPELRI. In particular, to the extent we continue to advance our product candidates into and through additional clinical studies, we will incur substantial expenses. For example: in August 2018 we announced that we intend to progress ampreloxetine (TD-9855) into a Phase 3 registrational program; in late 2018 we initiated a Phase 2 induction study of TD-1473 in Crohn’s disease; and we have initiated sites in a Phase 2b/3 induction and maintenance study of TD-1473 in ulcerative colitis. The expenses associated with these clinical studies are very significant. We will incur costs and expenses associated with our co-promotion agreement with Mylan for commercialization of YUPELRI in the US, including the maintenance of an independent sales and marketing organization with appropriate technical expertise, a medical affairs presence and consultant support, and post-marketing studies. We recently sold our VIBATIV product, and therefore will not recognize revenue from future product sales, other than through royalties from sales by Cumberland, the purchaser of the product. Our commitment

of resources to the continued development of our existing product candidates, our discovery programs, and YUPELRI will require significant additional funding. Our operating expenses also will increase if, among other things:

- our earlier stage potential products move into later-stage clinical development, which is generally more expensive than early stage development;
- additional preclinical product candidates are selected for clinical development;
- we pursue clinical development of our potential or current products in new indications;

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- we increase the number of patents we are prosecuting or otherwise expend additional resources on patent prosecution or defense; or
- we acquire or in-license additional technologies, product candidates, products or businesses.

Other than (i) potential revenues from sales of YUPELRI, (ii) our economic interest in royalties from net sales of Trelegy Ellipta paid to TRC (63.75% of which amounts are used to make payments on the Non-Recourse 2033 Notes), (iii) potential payments under collaboration agreements, and (iv) minor royalties from the net sales of VIBATIV, we do not expect to generate revenues in the immediate future. Since we or our collaborators or licensees may not successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost or with appropriate quality, or successfully market and sell such products with desired margins, our expenses will continue to exceed any revenues we may receive for the foreseeable future.

In the absence of substantial licensing payments, contingent payments or other revenues from third-party collaborators, royalties on sales of products licensed under our intellectual property rights, future revenues from those product candidates in development that receive regulatory approval or other sources of revenues, we will continue to incur operating losses and will require additional capital to execute our business strategy. The likelihood of reaching, and the time required to reach, and then to sustain, profitability are highly uncertain. As a result, we expect to continue to incur substantial losses for the foreseeable future. We are uncertain when or if we will ever be able to achieve or sustain profitability. Failure to become and remain profitable would adversely affect the price of our securities and our ability to raise capital and continue operations.

Any delay in commencing or completing clinical studies for product candidates and any adverse results from clinical or non-clinical studies or regulatory obstacles product candidates may face, would harm our business and the price of our securities could fall.

Each of our product candidates must undergo extensive non-clinical and clinical studies as a condition to regulatory approval. Non-clinical and clinical studies are expensive, take many years to complete and study results may lead to delays in further studies, new requirements for conducting future studies or decisions to terminate programs. The commencement and completion of clinical studies for our product candidates may be delayed and programs may be terminated due to many factors, including, but not limited to:

- lack of effectiveness of product candidates during clinical studies;
- adverse events, safety issues or side effects relating to the product candidates or their formulation into medicines;
- inability to raise additional capital in sufficient amounts to continue our development programs, which are very expensive;
- inability to enter into partnering arrangements relating to the development and commercialization of our programs and product candidates;
- delays in patient enrollment and variability in the number and types of patients available for clinical studies;
- the need to sequence clinical studies as opposed to conducting them concomitantly in order to conserve resources;
- our inability or the inability of our collaborators or licensees to manufacture or obtain from third parties materials sufficient for use in non-clinical and clinical studies;
- governmental or regulatory delays or suspensions of the conduct of the clinical trials and changes in regulatory requirements, policy and guidelines;

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- failure of our partners to advance our product candidates through clinical development;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- varying regulatory requirements or interpretations of data among the FDA and foreign regulatory authorities; and
- a regional disturbance where we or our collaborative partners are enrolling patients in clinical trials, such as a pandemic, terrorist activities or war, political unrest or a natural disaster.

Any adverse developments or results or perceived adverse developments or results with respect to our clinical programs including, without limitation, any delays in development in our programs, any halting of development in our programs, any difficulties or delays encountered with regard to the FDA or other regulatory authorities with respect to our programs, or any indication from clinical or non-clinical studies that the compounds in our programs are not safe or efficacious, could have a material adverse effect on our business and cause the price of our securities to fall.

If our product candidates are not approved by regulatory authorities, including the FDA, we will be unable to commercialize them.

The FDA must approve any new medicine before it can be marketed and sold in the US. We will not obtain this approval for a product candidate unless and until the FDA approves an NDA. We, or our collaborative partners, must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that our product candidates comply with the regulatory requirements for the quality of medicinal products and are safe and effective for a defined indication before they can be approved for commercial distribution. FDA or foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. The processes by which regulatory approvals are obtained from the FDA and foreign regulatory authorities to market and sell a new product are complex, require a number of years, depend upon the type, complexity and novelty of the product candidate and involve the expenditure of substantial resources for research, development and testing. The FDA has substantial discretion in the drug approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. Further, the implementation of new laws and regulations, and revisions to FDA clinical trial design guidance may lead to increased uncertainty regarding the approvability of new drugs. In addition, the FDA has additional standards for approval of new drugs, including recommended advisory committee meetings for certain new molecular entities, and formal risk evaluation and mitigation requirements at the FDA's discretion. Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed or impose significant restrictions or limitations on the use and/or distribution of such product.

In addition, in order to market our medicines in foreign jurisdictions, we or our collaborative partners must obtain separate regulatory approvals in each country. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Conversely, failure to obtain approval in one or more jurisdictions may make approval in other jurisdictions more difficult. These laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's or other regulatory authorities' review and approval of our and our collaborative partner's product candidates, which would materially harm our business and financial condition and could cause the price of our securities to fall.

If additional capital is not available, we may have to curtail or cease operations or we could be forced to share our rights to commercialize our product candidates with third parties on terms that may not be favorable to us.

Based on our current operating plans and financial forecasts, we believe that our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next twelve months. However, our current operating plans or financial forecasts occasionally change. For example, in August 2017, we announced an increase in our anticipated operating loss for 2017, primarily driven by our decision to accelerate funding associated with the next phase of development of our JAK inhibitor program. If our current operating plans or financial

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forecasts change, we may require or seek additional funding sooner in the form of public or private equity or equity-linked offerings, debt financings or additional collaborations and licensing arrangements.

We may need to raise additional capital in the future to, among other things:

- fund our discovery efforts and research and development programs;
- fund our commercialization strategies for any approved products and to prepare for potential product approvals;
- support our independent sales and marketing organization and medical affairs team;
- support our additional investments in YUPELRI, including potential post-marketing clinical studies;
- progress any additional product candidates into later-stage development without funding from a collaboration partner;
- progress mid-to-late stage product candidates into later-stage development, if warranted;
- respond to competitive pressures; and
- acquire complementary businesses or technologies.

Our future capital needs depend on many factors, including:

- the scope, duration and expenditures associated with our discovery efforts and research and development programs;
- continued scientific progress in these programs;
- the extent to which we encounter technical obstacles in our research and development programs;
- the outcome of potential licensing or partnering transactions, if any;
- competing technological developments;
- the extent of our proprietary patent position in any approved products and our product candidates;
- our facilities expenses, which will vary depending on the time and terms of any facility lease or sublease we may enter into, and other operating expenses;
- the scope and extent of the expansion of our sales and marketing efforts;
- potential litigation and other contingencies; and
- the regulatory approval process for our product candidates.

We may seek to raise additional capital or obtain future funding through public or private equity offerings, debt financings or additional collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions may make it difficult for us to seek financing from the capital markets. We may be required to relinquish rights to our technologies, product candidates or territories, or grant licenses on terms that are not favorable to us, in order to raise additional funds through collaborations or licensing arrangements.

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We may sequence preclinical and clinical studies as opposed to conducting them concomitantly in order to conserve resources, or delay, reduce or eliminate one or more of our research or development programs and reduce overall overhead expenses. If we are unable to raise additional capital or obtain future funding in sufficient amounts or on terms acceptable to us, we may have to make reductions in our workforce and may be prevented from continuing our discovery, development and commercialization efforts and exploiting other corporate opportunities. This would likely harm our business, prospects and financial condition and cause the price of our securities to fall.

We may seek to obtain future financing through the issuance of debt or equity, which may have an adverse effect on our shareholders or may otherwise adversely affect our business.

If we raise funds through the issuance of additional debt, including convertible debt or debt secured by some or all of our assets, or equity, any debt securities or preferred shares issued will have rights, preferences and privileges senior to those of holders of our ordinary shares in the event of liquidation. Neither the terms of our \$230.0 million of 3.25% convertible senior notes, due 2023 (the "Convertible Senior 2023 Notes") nor the terms of the Issuer's Non-Recourse 2033 Notes restrict our ability to issue additional debt. If additional debt is issued, there is a possibility that once all senior claims are settled, there may be no assets remaining to pay out to the holders of ordinary shares. Moreover, 75% of the income from our investment in TRC, as evidenced by the Issuer Class C Units, is available only for payment of the Non-Recourse 2033 Notes and is not available to pay our other obligations or the claims of our other creditors. In addition, if we raise funds through the issuance of additional equity, whether through private placements or public offerings, such an issuance would dilute ownership of our current shareholders that do not participate in the issuance. Since our Spin-Off in June 2014, we have raised an aggregate of \$583.9 million in a combination of (i) the sale of approximately 17.5 million ordinary shares, and (ii) \$480.0 million aggregate principal amount of notes. If we are unable to obtain any needed additional funding, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned research, development and commercialization activities or to license to third parties the rights to develop and/or commercialize products or technologies that we would otherwise seek to develop and/or commercialize ourselves or on terms that are less attractive than they might otherwise be, any of which could materially harm our business.

Furthermore, the terms of any additional debt securities we may issue in the future may impose restrictions on our operations, which may include limiting our ability to incur additional indebtedness, pay dividends on or repurchase our share capital, or make certain acquisitions or investments. In addition, we may be subject to covenants requiring us to satisfy certain financial tests and ratios, and our ability to satisfy such covenants may be affected by events outside of our control.

If our partners do not satisfy their obligations under our agreements with them, or if they terminate our partnerships with them, we may not be able to develop or commercialize our partnered product candidates as planned.

We have an exclusive development and commercialization agreement with Alfasigma for velusetrag, our internally discovered 5-HT4 agonist for the treatment of gastromotility disorders, under which we are transferring to Alfasigma global rights for velusetrag. In January 2015, we entered into a collaboration agreement with Mylan for the development and commercialization of a nebulized formulation of our LAMA revefenacin, including YUPELRI. Under the terms of the agreement, we and Mylan will co-develop nebulized revefenacin, including YUPELRI, for COPD and other respiratory diseases. In June 2016, we entered into a License and Collaboration Agreement with

Millennium Pharmaceuticals, Inc., an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (collectively with Millennium, "Takeda") in order to establish a collaboration for the development and commercialization of TD-8954, a selective 5-HT₄ receptor agonist. Under the terms of the agreement, Takeda is responsible for worldwide development and commercialization of TD-8954. In February 2018, we announced a global co-development and commercialization agreement with Janssen for TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease. In connection with these agreements, these parties have certain rights regarding the use of patents and technology with respect to the compounds in our development programs, including development and marketing rights.

Our partners have in the past and may in the future not fulfill all of their obligations under these agreements, and, in certain circumstances, they or we may terminate our partnership with them as Astellas did in January 2012 with its VIBATIV agreement and as we and Clinigen did in August 2016 with the commercialization agreement for VIBATIV in the EU and certain other European countries. In either event, we may be unable to assume the development and

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commercialization responsibilities covered by the agreements or enter into alternative arrangements with a third-party to develop and commercialize such product candidates. If a partner elected to promote alternative products and product candidates such as its own products and product candidates in preference to those licensed from us, does not devote an adequate amount of time and resources to our product candidates or is otherwise unsuccessful in its efforts with respect to our products or product candidates, the development and commercialization of product candidates covered by the agreements could be delayed or terminated, and future payments to us could be delayed, reduced or eliminated and our business and financial condition could be materially and adversely affected. Accordingly, our ability to receive any revenue from the product candidates covered by these agreements is dependent on the efforts of our partners. If a partner terminates or breaches its agreements with us, otherwise fails to complete its obligations in a timely manner or alleges that we have breached our contractual obligations under these agreements, the chances of successfully developing or commercializing product candidates under the collaboration could be materially and adversely affected. In addition, effective collaboration with a partner requires coordination to achieve complex and detail-intensive goals between entities that potentially have different priorities, capabilities and processes and successful navigation of the challenges such coordination entails. We could also become involved in disputes with a partner, which could lead to delays in or termination of our development and commercialization programs and time-consuming and expensive litigation or arbitration. Furthermore, termination of an agreement by a partner could have an adverse effect on the price of our ordinary shares or other securities even if not material to our business.

We do not control TRC and, in particular, have no control over the GSK-Partnered Respiratory Programs or access to non-public information regarding the development of the GSK-Partnered Respiratory Programs.

Innoviva has assigned to TRC its strategic alliance agreement with GSK and all of its rights and obligations under its LABA collaboration agreement other than with respect to RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® and vilanterol monotherapy. Our equity interest in TRC entitles us to an 85% economic interest in any future payments made by GSK under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC (the “GSK Agreements”) (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters), which agreements govern Innoviva’s and GSK’s respective interests in the GSK-Partnered Respiratory Programs. Our equity interest covers various drug programs including all Trelegy Ellipta (the combination of fluticasone furoate, umeclidinium, and vilanterol in a single ELLIPTA® inhaler, previously referred to as the Closed Triple) products and the MABA program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid (“ICS”), and any other product or combination of products that may be discovered and developed in the future under the GSK Agreements. Our economic interest does not include any payments by GSK associated with RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® or vilanterol monotherapy. Innoviva controls TRC and, except for certain limited consent rights, we have no right to participate in the business and affairs of TRC. Innoviva has the exclusive right to appoint TRC’s manager who, among other things, is responsible for the day-to-day management of the GSK-Partnered Respiratory Programs and exercises the rights relating to the GSK-Partnered Respiratory Programs. As a result, we have no rights to participate in, or access to non-public information about, the development and commercialization work GSK and Innoviva are undertaking with respect to the GSK-Partnered Respiratory Programs and no right to enforce rights under the GSK Agreements assigned to TRC. Moreover, we have many of the same risks with respect to our and TRC’s dependence on GSK as we have with respect to our dependence on our own partners.

If there are any adverse developments or perceived adverse developments with respect to the GSK-Partnered Respiratory Programs in which we have a substantial economic interest, including Trelegy Ellipta and the MABA

program, our business will be harmed, and the price of our securities could fall.

We have no access to confidential information regarding the development progress of, or plans for, the GSK-Partnered Respiratory Programs, including Trelegy Ellipta and the MABA program, and we have little, if any, ability to influence the progress of those programs because our interest in these programs is only through our ownership interest in TRC, which is controlled by Innoviva. However, if any of the GSK-Partnered Respiratory Programs in which we have a substantial economic interest encounter delays, do not demonstrate required quality, safety and efficacy, are terminated, or if there are any adverse developments or perceived adverse developments with respect to such programs,

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our business will be harmed, and the price of our securities could fall. Examples of such adverse developments include, but are not limited to:

- disappointing or lower than expected sales of Trelegy Ellipta;
- disappointing results from GSK's Phase 3 clinical study of Trelegy Ellipta in asthma patients, which is scheduled to be completed in 2019;
- the emergence of new closed triple or other alternative therapies or any developments regarding these potentially competitive therapies, comparative price or efficacy of such potentially competitive therapies;
- GSK deciding to delay or halt any of the GSK-Partnered Respiratory Programs in which we have a substantial economic interest;
- the FDA and/or other national or foreign regulatory authorities determining that any of the studies under these programs do not demonstrate the required quality, safety or efficacy, or that additional non-clinical or clinical studies are required with respect to such programs;
- any safety, efficacy or other concerns regarding any of the GSK-Partnered Respiratory Programs in which we have a substantial economic interest;
- any particular FDA requirements or changes in FDA policy or guidance regarding these programs or any particular regulatory requirements in other jurisdictions or changes in the policies or guidance adopted by foreign regulatory authorities; or
- disputes between GSK and Innoviva or between us and Innoviva.

Because GSK is a strategic partner of Innoviva, a strategic partner of TRC and a significant shareholder of us, it may take actions that in certain cases are materially harmful to our business and to our other shareholders.

Based on our review of publicly available filings, as of December 31, 2018 GSK beneficially owned approximately 17.3% of our outstanding ordinary shares. GSK is also a strategic partner to Innoviva with rights and obligations under the GSK Agreements, which include the strategic alliance agreement and the collaboration agreement assigned to TRC, that may cause GSK's interests to differ from our interests and those of our other shareholders. For example, GSK's commercialization efforts are guided by a portfolio approach across products in which we have an indirect interest through TRC and products in which we have no interest. Accordingly, GSK's commercialization efforts may have the effect of reducing the value of our interest in TRC. Furthermore, GSK has a substantial respiratory product portfolio in addition to the products covered by the GSK Agreements. GSK may make respiratory product portfolio decisions or statements about its portfolio which may be, or may be perceived to be, harmful to the respiratory products partnered with Innoviva and TRC. For example, GSK could promote its own respiratory products and/or delay or terminate the development or commercialization of the respiratory programs covered by the GSK Agreements. Also, given the potential future royalty payments GSK may be obligated to pay under the GSK Agreements, GSK may seek to acquire us or acquire our interests in TRC in order to effectively reduce those payment obligations and the price at which GSK might seek to acquire us may not reflect our true value. Before 2018, the actions GSK could have taken to acquire us were limited under our governance agreement with GSK (the "Governance Agreement"), but this agreement expired on December 31, 2017. In May 2018, our shareholders approved a resolution authorizing our board of directors to adopt a shareholder rights plan in the future which may deter GSK from acquiring more than 19.9% of our outstanding ordinary shares. However, our board of directors might not adopt such shareholder rights plan, and we otherwise might not be able to respond successfully to a takeover attempt. The timing of when GSK may seek to acquire us could potentially be when it possesses information regarding the status of drug programs covered by the GSK Agreements that has not been publicly disclosed and is not otherwise known to us. As a result of these differing interests, GSK may take actions that it believes are in its best interest but which might not be in the best interests of either us or our other shareholders. In addition, GSK could also seek to challenge our or

Innoviva's post-Spin-Off operations as violating or allowing it to terminate the GSK Agreements, including by violating the confidentiality provisions of those agreements or the master agreement between

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GSK, Innoviva and us entered into in connection with the Spin-Off (the “Master Agreement”), or otherwise violating its legal rights. While we believe our operations fully comply with the GSK Agreements, the Master Agreement and applicable law, there can be no assurance that we or Innoviva will prevail against any such claims by GSK. Moreover, regardless of the merit of any claims by GSK, we may incur significant cost and diversion of resources in defending them. In addition, any other action or inaction by either GSK or Innoviva that results in a material dispute, allegation of breach, litigation, arbitration, or significant disagreement between those parties or between us and either of those parties may be interpreted negatively by the market or by our investors, could harm our business and cause the price of our securities to fall. Examples of these kinds of issues include but are not limited to non-performance of contractual obligations and allegations of non-performance, disagreements over the relative marketing and sales efforts for Innoviva’s partnered products and other GSK respiratory products, disputes over public statements, and similar matters. In general, any uncertainty about the respiratory programs partnered with GSK, the enforceability of the GSK Agreements or the relationship/partnership between Innoviva and GSK could result in significant reduction in the market price of our securities and other material harm to our business.

We do not control the commercialization of TRELEGY ELLIPTA and the amount of royalties we receive will depend on GSK’s ability to further commercialize TRELEGY ELLIPTA, among other factors.

We only receive revenues from TRELEGY ELLIPTA based on the amount of sales of this product by GSK in the form of our economic interest in the royalties paid by GSK to TRC, which is managed by Innoviva. There are no required minimum future payments associated with the product and any royalties we receive will depend on GSK’s ability to commercialize the product. This involves a number of risks and uncertainties, including:

- GSK’s ability to have an adequate supply of their respective product;
- Ongoing compliance by GSK or its suppliers with the FDA’s current Good Manufacturing Practice;
- Compliance with other applicable FDA and other regulatory requirements in the US or other foreign jurisdictions, including those described elsewhere in this report;
- Competition, whether from current competitors or new products developed by others in the future;
- Claims relating to intellectual property;
 - Any future disruptions in GSK’s business which would affect its ability to commercialize the product;
- The ability of TRELEGY ELLIPTA to achieve wider acceptance among physicians, patients, third-party payors, or the medical community in general;
- Global economic conditions; and
- Any of the other risks relating to commercialization of products described elsewhere in this section.

If GSK is unable to address these risks and uncertainties, the amount of future royalties or other revenues we may receive from sales of TRELEGY ELLIPTA could be materially affected, which could have a material adverse effect on our future revenues, other financial results and our financial position.

Our ongoing drug discovery and development efforts might not generate additional successful product candidates or approvable drugs.

Our compounds in clinical trials and our future leads for potential drug compounds are subject to the risks and failures inherent in the development of pharmaceutical products. These risks include, but are not limited to, the inherent difficulty in selecting the right drug and drug target and avoiding unwanted side effects, as well as unanticipated problems relating to product development, testing, enrollment, obtaining regulatory approvals, maintaining regulatory compliance, manufacturing, competition and costs and expenses that may exceed current estimates.

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Clinical studies involving our product candidates may reveal that those candidates are ineffective, inferior to existing approved medicines, unacceptably toxic, or that they have other unacceptable side effects. In addition, the results of preclinical studies do not necessarily predict clinical success, and larger and later-stage clinical studies may not produce the same results as earlier-stage clinical studies.

Frequently, product candidates that have shown promising results in early preclinical or clinical studies have subsequently suffered significant setbacks or failed in later non-clinical or clinical studies. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, varying levels of adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Clinical and non-clinical studies of product candidates often reveal that it is not possible or practical to continue development efforts for these product candidates. In addition, the design of a clinical trial can determine whether its results will support regulatory approval and flaws in the design of a clinical trial may not become apparent until the clinical trial is well underway or completed. If our clinical studies for our current product candidates, such as the clinical studies for our JAK inhibitor program or ampreloxetine in patients with nOH, are substantially delayed or suggest that any of our product candidates may not be efficacious or well tolerated, we could choose to cease development of these product candidates. In addition, our product candidates may have undesirable side effects or other unexpected characteristics that could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities.

We face substantial competition from companies with more resources and experience than we have, which may result in others discovering, developing, receiving approval for or commercializing products before or more successfully than we do.

Our ability to succeed in the future depends on our ability to demonstrate and maintain a competitive advantage with respect to our approach to the discovery, development and commercialization of medicines. Our objective is to discover, develop and commercialize new small molecule medicines with superior efficacy, convenience, tolerability and/or safety using our proprietary insight in chemistry, biology and multivalency, where applicable. We expect that any medicines that we commercialize with or without our collaborative partners will compete with existing or future market-leading medicines.

Many of our current and potential competitors have substantially greater financial, technical and personnel resources than we have. In addition, many of these competitors have significantly greater commercial infrastructures than we have. Our ability to compete successfully will depend largely on our ability to leverage our experience in drug discovery and development, and, more recently, commercialization, to:

- discover and develop medicines that are superior to other products in the market;
- attract and retain qualified personnel;
- obtain and enforce patent and/or other proprietary protection for our medicines and technologies;

- conduct effective clinical trials and obtain required regulatory approvals;
- develop and effectively implement commercialization strategies, with or without collaborative partners; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

Pharmaceutical companies, including companies with which we collaborate, may invest heavily to quickly discover and develop or in-license novel compounds that could make our product candidates obsolete. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or equivalent regulatory approval outside the US

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or discovering, developing and commercializing medicines before we do. Other companies are engaged in the discovery of medicines that would compete with the product candidates that we are developing.

Any new medicine that competes with a generic or proprietary market leading medicine must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to overcome severe price competition and be commercially successful. For example, YUPELRI competes predominantly with short acting nebulized bronchodilators used three to four times per day and the nebulized LAMA Lonhala™ Magnair™ (SUN-101/eFlow®) used twice per day. If we are not able to compete effectively against our current and future competitors, our business will not grow, our financial condition and operations will suffer and the price of our securities could fall.

If we are unable to enter into future collaboration arrangements or if any such collaborations with third parties are unsuccessful, we will be unable to fully develop and commercialize all of our product candidates and our business will be adversely affected.

We have collaborations with a number of third parties including Janssen for TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease and Mylan for the development and commercialization of a nebulized formulation of revefenacin, our LAMA compound (including YUPELRI). Also, through our interest in TRC we may participate economically in Innoviva's collaborations with GSK with respect to the GSK-Partnered Respiratory Programs. Additional collaborations will likely be needed to fund later-stage development of certain programs that have not been licensed to a collaborator, such as our NEP inhibitor program, and to commercialize the product candidates in our programs if approved by the necessary regulatory authorities. We evaluate commercial strategy on a product by product basis either to engage pharmaceutical or other healthcare companies with an existing sales and marketing organization and distribution system to market, sell and distribute our products or to commercialize a product ourselves. However, we may not be able to establish these sales and distribution relationships on acceptable terms, or at all, or may encounter difficulties in commercializing a product ourselves. For any of our product candidates that receive regulatory approval in the future and are not covered by our current collaboration agreements, we will need a partner in order to commercialize such products unless we establish independent sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure.

Collaborations with third parties regarding our programs may require us to relinquish material rights, including revenue from commercialization of our medicines, or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We face significant competition in seeking third-party collaborators. We may be unable to find third parties to pursue product collaborations on a timely basis or on acceptable terms. Furthermore, for any collaboration, we may not be able to control the amount of time and resources that our partners devote to our product candidates and our partners may choose to prioritize alternative programs or otherwise be unsuccessful in their efforts with respect to our products or product candidates. In addition, effective collaboration with a partner requires coordination to achieve complex and detail-intensive goals between entities that potentially have different priorities, capabilities and processes and successful navigation of the challenges such coordination entails. For example, Mylan has a substantial existing product portfolio and other considerations that influence its

resource allocation, and other priorities and internal organizational processes that differ from our own. As a result of these differing interests and processes, Mylan may take actions that it believes are in its best interest but which might not be in the best interests of either us or our other shareholders. Our inability to successfully collaborate with third parties would increase our development costs and may cause us to choose not to continue development of certain product candidates, would limit the likelihood of successful commercialization of some of our product candidates, may cause us not to continue commercialization of our authorized products and could cause the price of our securities to fall.

We depend on third parties in the conduct of our clinical studies for our product candidates.

We depend on independent clinical investigators, contract research and manufacturing organizations and other third-party service providers in the conduct of our non-clinical and clinical studies for our product candidates. We rely heavily on these parties for execution of our non-clinical and clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that our clinical studies are conducted in accordance with good clinical, laboratory and manufacturing practices (“GxPs”) and other regulations as required by the FDA and foreign

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regulatory authorities, and the applicable protocol. Failure by these parties to comply with applicable regulations and practices in conducting studies of our product candidates can result in a delay in our development programs or non-approval of our product candidates by regulatory authorities.

The FDA, and equivalent authorities in other countries, enforces GXP's and other regulations through periodic inspections of trial sponsors, clinical research organizations ("CROs"), principal investigators and trial sites. If we or any of the third parties on which we have relied to conduct our clinical studies are determined to have failed to comply with GXP's (or other equivalent regulations outside the US), the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or equivalent authorities in other countries, or we, the FDA, or equivalent authorities in other countries may decide to conduct additional audits or require additional clinical studies, which would delay our development programs, could result in significant additional costs and cause the price of our securities to fall.

We rely on a single source of supply for a number of our product candidates, and our business will be harmed if any of these single-source manufacturers are not able to satisfy demand and alternative sources are not available.

We have limited in-house production capabilities for preclinical and clinical study purposes, and depend primarily on a number of third-party Active Pharmaceutical Ingredient ("API") and drug product manufacturers. We may not have long-term agreements with these third parties and our agreements with these parties may be terminable at will by either party at any time. If, for any reason, these third parties are unable or unwilling to perform, or if their performance does not meet regulatory requirements, we may not be able to locate alternative manufacturers or enter into acceptable agreements with them. Any inability to acquire sufficient quantities of API and drug product in a timely manner from these third parties could delay preclinical and clinical studies and prevent us from developing our product candidates in a cost-effective manner or on a timely basis. In addition, manufacturers of our API and drug product are subject to the FDA's current Good Manufacturing Practice ("cGMP") regulations and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers.

Our manufacturing strategy presents the following additional risks:

- because of the complex nature of many of our compounds, our manufacturers may not be able to successfully manufacture our APIs and/or drug products in a cost-effective and/or timely manner and changing manufacturers for our APIs or drug products could involve lengthy technology transfer, validation and regulatory qualification activities for the new manufacturer;
- the processes required to manufacture certain of our APIs and drug products are specialized and available only from a limited number of third-party manufacturers;
- some of the manufacturing processes for our APIs and drug products have not been scaled to quantities needed for continued clinical studies or commercial sales, and delays in scale-up to higher quantities could delay clinical studies, regulatory submissions and commercialization of our product candidates; and
- because some of the third-party manufacturers are located outside of the US, there may be difficulties in importing our APIs and drug products or their components into the US as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging.

We have a significant amount of debt, including our Non-Recourse 2033 Notes and Convertible Senior 2023 Notes, that are senior in capital structure and cash flow, respectively, to holders of our ordinary shares. Satisfying the

obligations relating to our debt could adversely affect the amount or timing of distributions to our shareholders.

As of December 31, 2018, we had approximately \$513.3 million in total long-term liabilities outstanding, comprised primarily of \$237.5 million in net principal that remains outstanding under the Issuer's Non-Recourse 2033 Notes and \$230.0 million in principal that remains outstanding under our Convertible Senior 2023 Notes (together with the Non-Recourse 2033 Notes, the "Notes").

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The Convertible Senior 2023 Notes are unsecured debt and are not redeemable by us prior to the maturity date except for certain changes in tax law. Holders of the Convertible Senior 2023 Notes may require us to purchase all or any portion of their notes at 100% of their principal amount, plus any unpaid interest, upon a fundamental change such as a change of control of us or the termination of trading of our ordinary shares in accordance with the indenture governing the Convertible Senior 2023 Notes.

Until the Non-Recourse 2033 Notes are paid in full, holders of the Non-Recourse 2033 Notes have a perfected security interest in the Issuer Class C Units that represent a 63.75% economic interest in any future payments that may be made by GSK to TRC under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC by Innoviva (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters) relating to the GSK-Partnered Respiratory Programs, including the Trelegy Ellipta program.

Satisfying the obligations of these Notes could adversely affect the amount or timing of any distributions to our shareholders. We may choose to satisfy, repurchase, or refinance these Notes through public or private equity or debt financings if we deem such financings are available on favorable terms. If any or all of the Convertible Senior 2023 Notes are not converted into our ordinary shares before the maturity date, we will have to pay the holders the full aggregate principal amount of the Convertible Senior 2023 Notes then outstanding. If the Non-Recourse 2033 Notes are not refinanced or paid in full, the holders of the Non-Recourse 2033 Notes will have the right to foreclose on the Issuer Class C Units that represent a 63.75% economic interest in future royalties due on net sales of Trelegy Ellipta and related assets. If the Issuer Class C Units are foreclosed upon, we will lose any right to receive 75% of the future royalty payments made by GSK in connection with the net sales of Trelegy Ellipta and related assets. Any of the above payments could have a material adverse effect on our cash position. Our failure to satisfy these obligations may result in a default under the applicable indenture governing these Notes, which could result in a default under certain of our other debt instruments, if any. Any such default would harm our business and the price of our securities could fall.

Servicing our Convertible Senior 2023 Notes requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt. Additionally, holders may require us to repurchase our Convertible Senior 2023 Notes under certain circumstances, and we may not have sufficient cash to do so.

Our ability to make interest or principal payments when due or to refinance the Convertible Senior 2023 Notes depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations sufficient to satisfy our obligations under the Convertible Senior 2023 Notes and any future indebtedness we may incur and to make necessary capital expenditures. In addition, the issuance of the Non-Recourse 2033 Notes reduced the cash available for us to make interest or principal payments on, or to refinance, the Convertible Senior 2023 Notes. We may be required to adopt one or more alternatives, such as reducing or delaying investments or capital expenditures, selling assets, refinancing or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance the Convertible Senior 2023 Notes or future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities on desirable terms or at all, which could result in a default on the Convertible Senior 2023 Notes or future indebtedness.

The holders of the Convertible Senior 2023 Notes may have the right to require us to repurchase the Convertible Senior 2023 Notes upon the occurrence of a “fundamental change” such as a change of control of our Company or the termination of trading of our ordinary shares, as defined in the indenture governing the Convertible Senior 2023 Notes. We may not have sufficient funds to repurchase the Convertible Senior 2023 Notes in cash or have the ability to arrange necessary financing on acceptable terms. Our failure to repurchase the Convertible Senior 2023 Notes when required would result in an event of default with respect to the Convertible Senior 2023 Notes. In addition, any acceleration of the repayment of the Convertible Senior 2023 Notes or future indebtedness after any applicable notice or grace periods could have a material adverse effect on our business, results of operations and financial condition.

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Our business and operations would suffer in the event of significant disruptions of information technology systems or security breaches.

We rely extensively on computer systems to maintain information and manage our finances and business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including but not limited to trade secrets or other intellectual property, proprietary business information and personal information) and it is critical that we maintain the confidentiality and integrity of such confidential information. Although we have security measures in place, our internal information technology systems and those of our CROs and other service providers, including cloud-based and hosted applications, data and services, are vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, service providers and/or business partners, from cyber-attacks by malicious third parties, and/or from, natural disasters, terrorism, war and telecommunication and electrical failures. Cyber-attacks are increasing in their frequency, sophistication, and intensity, and have become increasingly difficult to detect. Significant disruptions of information technology systems or security breaches could adversely affect our business operations and result in financial, legal, business and reputational harm to us, including significant liability and/or significant disruption to our business. If a disruption of information technology systems or security breach results in a loss of or damage to our data or regulatory applications, unauthorized access, use, or disclosure of, or the prevention of access to, confidential information, or other harm to our business, we could incur liability and reputational harm, we could be required to comply with federal and/or state breach notification laws and foreign law equivalents, we may incur legal expenses to protect our confidential information, the further development of our product candidates could be delayed and the price of our securities could fall. For example, the loss of clinical trial data from completed or ongoing clinical trials of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. As another example, we may incur penalties imposed by the competent authorities in the EU Member States in case of breach of the EU rules governing the collection and processing of personal data, including unauthorized access to or disclosure of personal data. Although we have security and fraud prevention measures in place, we have been subject to immaterial payment fraud activity. In 2017, we filed a lawsuit (which has since been resolved) against a former employee for misappropriation of our confidential, proprietary and trade secret information. Moreover, there can be no assurance that such security measures will prevent service interruptions or security breaches that could adversely affect our business.

If we lose key management or scientific personnel, or if we fail to attract and retain key employees, our ability to discover and develop our product candidates and commercialize our products, if any, will be impaired.

We are highly dependent on principal members of our management team and scientific staff, and in particular, our Chief Executive Officer, Rick E Winningham, to operate our business. Mr. Winningham has significant pharmaceutical industry experience. The loss of Mr. Winningham's services could impair our ability to discover, develop and commercialize new medicines.

If we fail to retain our qualified personnel or replace them when they leave, we may be unable to continue our discovery, development and commercialization activities, which may cause the price of our securities to fall. For instance, we have undertaken a search for a new Chief Financial Officer, a position that has been vacant since the beginning of 2019.

In addition, our US operating subsidiary's facility and most of its employees are located in northern California, headquarters to many other biotechnology and biopharmaceutical companies and many academic and research institutions. As a result, competition for certain skilled personnel in our market is intense. None of our employees have employment commitments for any fixed period of time and they all may leave our employment at will. If we fail to retain our qualified personnel or replace them when they leave, we may be unable to continue our development and commercialization activities and the price of our securities could fall.

Global health and economic, political and social conditions may harm our ability to do business, increase our costs and negatively affect our stock price.

Worldwide economic conditions remain uncertain due to the decision by the United Kingdom to initiate the formal procedure of withdrawal from the EU (often referred to as "Brexit"), current economic challenges in Asia and other disruptions to global and regional economies and markets.

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Brexit has created significant uncertainty about the future relationship between the United Kingdom and the EU, including with respect to the laws and regulations that will apply as the United Kingdom determines which EU laws to replace or replicate in the event of a withdrawal. From a regulatory perspective, the United Kingdom's withdrawal could bear significant complexity and risks. In addition, the exact terms of the United Kingdom's withdrawal and the laws and regulations that will apply after the United Kingdom withdraws from the EU would affect manufacturing sites that hold an EU manufacturing authorization issued by the United Kingdom competent authorities. The referendum has also given rise to calls for the governments of other EU Member States to consider withdrawal from the EU.

Further, development of our product candidates and/or regulatory approval may be delayed for other political events beyond our control. For example, a US federal government shutdown or budget sequestration, such as ones that occurred during 2013, 2018, and 2019, may result in significant reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our operations also depend upon favorable trade relations between the US and those foreign countries in which our materials suppliers have operations. A protectionist trade environment in either the US or those foreign countries in which we do business, such as a change in the current tariff structures, export compliance or other trade policies, may materially and adversely affect our operations. External factors, such as potential terrorist attacks, acts of war, geopolitical and social turmoil or epidemics and other similar outbreaks in many parts of the world, could also prevent or hinder our ability to do business, increase our costs and negatively affect our stock price. These geopolitical, social and economic conditions could harm our business.

Our US operating subsidiary's facility is located near known earthquake fault zones, and the occurrence of an earthquake, extremist attack or other catastrophic disaster could cause damage to our facilities and equipment, which could require us to cease or curtail operations.

Our US operating subsidiary's facility is located in the San Francisco Bay Area near known earthquake fault zones and therefore will be vulnerable to damage from earthquakes. In October 1989, a major earthquake struck this area and caused significant property damage and a number of fatalities. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods, communications failures and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. In addition, the unique nature of our research activities and of much of our equipment could make it difficult and costly for us to recover from this type of disaster. We may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition, which could cause the price of our securities to fall.

If YUPELRI is not broadly accepted by physicians, patients, third-party payors, or the medical community in general, we may never receive significant revenues from sales of this product.

The commercial success of YUPELRI depends upon its acceptance by physicians, patients, third-party payors and the medical community in general. YUPELRI may not be sufficiently accepted by these parties. YUPELRI competes with predominantly with short acting nebulized bronchodilators used three to four times per day and the nebulized LAMA Lonhala™ Magnair™ (SUN-101/eFlow®) used twice per day. If YUPELRI is not widely accepted, our business and financial results could be materially harmed.

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In collaboration with Mylan, we are responsible for marketing and sales of YUPELRI in the US, which subjects us to certain risks.

We currently maintain a sales force in the US and plan to continue to augment our sales and marketing personnel to support our co-promotion obligations for YUPELRI under our agreement with Mylan. The risks of fulfilling our US co-promotion obligations to Mylan include:

- costs and expenses associated with creating and maintaining an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure, including third-party vendor logistics and consultant support, which costs and expenses could, depending on the scope and method of the marketing effort, exceed any product revenue for several years;
- our ability to retain effective sales and marketing personnel and medical science liaisons in the US;
 - the ability of our sales and marketing personnel to obtain access to and educate adequate numbers of physicians about prescribing YUPELRI, in appropriate clinical situations; and
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines.

If we are not successful in maintaining an internal sales and marketing organization with appropriate experience, technical expertise, supporting infrastructure and the ability to obtain access to and educate adequate numbers of physicians about prescribing YUPELRI in appropriate clinical situations, we will have difficulty commercializing YUPELRI, which would adversely affect our business and financial condition and the price of our securities could fall.

We are subject to extensive and ongoing regulation, oversight and other requirements by the FDA and failure to comply with these regulations and requirements may subject us to penalties that may adversely affect our financial condition or our ability to commercialize any approved products.

Prescription drug advertising and promotion are closely scrutinized by the FDA, including substantiation of promotional claims, disclosure of risks and safety information, and the use of themes and imagery in advertising and promotional materials. As with all companies selling and marketing products regulated by the FDA in the US, we are prohibited from promoting any uses of an approved product, such as YUPELRI, that are outside the scope of those uses that have been expressly approved by the FDA as safe and effective on the product's label.

The manufacturing, labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for an approved product remain subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with an approved product in the US or overseas or at a contract manufacturer's facilities, a regulatory authority may impose restrictions on the product, the contract manufacturers or on us, including requiring us to reformulate the product, conduct additional clinical studies, change the labeling of the product, withdraw the product from the market or require the contract manufacturer to implement changes to its facilities.

We are also subject to regulation by regional, national, state and local agencies, including the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the US Department of Health and Human Services

(“OIG”) and other regulatory bodies with respect to any approved product, such as YUPELRI, as well as governmental authorities in those foreign countries in which any product is approved for commercialization. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including non-clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. If we or any third parties that provide these services for us are unable to comply, we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business.

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Regulatory approval for our product candidates, if any, may include similar or other limitations on the indicated uses for which we can market our medicines or the patient population that may utilize our medicines, which may limit the market for our medicines or put us at a competitive disadvantage relative to alternative therapies.

Failure to satisfy required post-approval requirements and/or commitments may have implications for a product's approval and may carry civil monetary penalties. Any failure to maintain regulatory approval will materially limit the ability to commercialize a product or any future product candidates and if we fail to comply with FDA regulations and requirements, the FDA could potentially take a number of enforcement actions against us, including the issuance of untitled letters, warning letters, preventing the introduction or delivery of the product into interstate commerce in the US, misbranding charges, product seizures, injunctions, and civil monetary penalties, which would materially and adversely affect our business and financial condition and may cause the price of our securities to fall.

The risks identified in this risk factor relating to regulatory actions and oversight by agencies in the US and throughout the world also apply to the commercialization of any partnered products by our collaboration partners and those commercializing products with respect to which we have an economic interest or right to receive royalties, including GSK and Cumberland, and such regulatory actions and oversight may limit those parties' ability to commercialize such products, which could materially and adversely affect our business and financial condition, and which may cause the price of our securities to fall.

We and/or our collaboration partners and those commercializing products with respect to which we have an economic interest or right to receive royalties may face competition from companies seeking to market generic versions of any approved products in which we have an interest, such as TRELEGY ELLIPTA or YUPELRI.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, a company may submit an abbreviated new drug application ("ANDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act to market a generic version of an approved drug. Because a generic applicant does not conduct its own clinical studies, but instead relies on the FDA's finding of safety and effectiveness for the approved drug, it is able to introduce a competing product into the market at a cost significantly below that of the original drug. Although we have multiple patents protecting YUPELRI until at least 2025 that are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, and those commercializing products with respect to which we have an economic interest or right to receive royalties similarly have patents protecting their products, such as TRELEGY ELLIPTA and VIBATIV, generic applicants could potentially submit "paragraph IV certifications" to FDA stating that such patents are invalid or will not be infringed by the applicant's product. We have not received any such paragraph IV notifications nor are we aware of any with respect to products in which we have an economic interest or right to receive royalties, but if any competitors successfully challenge the patents related to these products, we and/or our collaboration partners and those commercializing products with respect to which we have an economic interest or right to receive royalties would face substantial competition. If we are not able to compete effectively against such future competition, our business will not grow, our financial condition and operations will suffer and the price of our securities could fall.

For additional discussion of the risk of generic competition to YUPELRI, please see the following risk factor below “If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our current or future markets.”

We may be treated as a US corporation for US federal income tax purposes.

For US federal income tax purposes, a corporation generally is considered tax resident in the place of its incorporation. Theravance Biopharma is incorporated under Cayman Islands law and established tax residency in Ireland effective July 1, 2015. Therefore, it should be a non-US corporation under this general rule. However, Section 7874 of the Internal Revenue Code of 1986, as amended (the “Code”), contains rules that may result in a foreign corporation being treated as a US corporation for US federal income tax purposes. The application of these rules is complex and there is little guidance regarding certain aspects of their application.

Under Section 7874 of the Code, a corporation created or organized outside the US will be treated as a US corporation for US federal tax purposes if (i) the foreign corporation directly or indirectly acquires substantially all of the properties held directly or indirectly by a US corporation, (ii) the former shareholders of the acquired US corporation hold

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at least 80% of the vote or value of the shares of the foreign acquiring corporation by reason of holding stock in the US acquired corporation, and (iii) the foreign corporation's "expanded affiliated group" does not have "substantial business activities" in the foreign corporation's country of incorporation relative to its expanded affiliated group's worldwide activities. For this purpose, "expanded affiliated group" generally means the foreign corporation and all subsidiaries in which the foreign corporation, directly or indirectly, owns more than 50% of the stock by vote and value, and "substantial business activities" generally means at least 25% of employees (by number and compensation), assets and gross income of our expanded affiliated group are based, located and derived, respectively, in the country of incorporation.

We do not expect to be treated as a US corporation under Section 7874 of the Code, because we do not believe that the assets contributed to us by Innoviva constituted "substantially all" of the properties of Innoviva (as determined on both a gross and net fair market value basis). However, the Internal Revenue Service may disagree with our conclusion on this point and assert that, in its view, the assets contributed to us by Innoviva did constitute "substantially all" of the properties of Innoviva. In addition, there could be legislative proposals to expand the scope of US corporate tax residence and there could be changes to Section 7874 of the Code or the Treasury Regulations promulgated thereunder that could apply retroactively and could result in Theravance Biopharma being treated as a US corporation.

If it were determined that we should be treated as a US corporation for US federal income tax purposes, we could be liable for substantial additional US federal income tax on our post-Spin-Off taxable income. In addition, though we have no current plans to pay any dividends, payments of any dividends to non-US holders may be subject to US withholding tax.

Taxing authorities may challenge our structure and transfer pricing arrangements.

We are incorporated in the Cayman Islands, maintain subsidiaries in the Cayman Islands, the US, the United Kingdom and Ireland, and effective July 1, 2015, we migrated our tax residency from the Cayman Islands to Ireland. Due to economic and political conditions, various countries are actively considering changes to existing tax laws. We cannot predict the form or timing of potential legislative changes that could have a material adverse impact on our results of operations. We are aware that Ireland is expected to implement certain tax law changes to comply with the European Union Anti-Tax Avoidance Directives. These changes will include the first ever Irish controlled foreign company ("CFC") rules which were effective as of January 1, 2019. It is also expected that Ireland will implement certain transfer pricing rule changes, most likely with effect from 2020. We are continuing to evaluate and monitor the applicability of the CFC rules published in Finance Bill 2018, but our current assessment, based on the rules and guidance published to date, is that the rules are unlikely to have a material impact on our operations. Proposed statutory language has not yet been provided for transfer pricing rule changes and, as a result, we have not yet been able to determine the impact, if any, of such future legislation on our operations.

In addition, significant judgment is required in determining our worldwide provision for income taxes. Various factors may have favorable or unfavorable effects on our income tax rate including, but not limited to the performance of certain functions and ownership of certain assets in tax-efficient jurisdictions such as the Cayman Islands and Ireland, together with intra-group transfer pricing agreements. Taxing authorities may challenge our structure and transfer

pricing arrangements through an audit or lawsuit. Responding to or defending such a challenge could be expensive and consume time and other resources, and divert management's time and focus from operating our business. We cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging this structure, the cost involved in responding to any such audit or lawsuit, or the outcome. We may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future which could result in reduced cash flows and have a material adverse effect on our business, financial condition and growth prospects.

We were a passive foreign investment company, or "PFIC," for 2014, but we were not a PFIC from 2015 through 2018, and we do not expect to be a PFIC for the foreseeable future.

For US federal income tax purposes, we generally would be classified as a PFIC for any taxable year if either (i) 75% or more of our gross income (including gross income of certain 25% or more owned corporate subsidiaries) is "passive income" (as defined for such purposes) or (ii) the average percentage of our assets (including the assets of certain 25% or more owned corporate subsidiaries) that produce passive income or that are held for the production of passive income is at least 50%. In addition, whether our Company will be a PFIC for any taxable year depends on our assets and

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income over the course of each such taxable year and, as a result, cannot be predicted with certainty until after the end of the year.

Based upon our assets and income during the course of 2014, we believe that our Company and one of our Company's wholly-owned subsidiaries, Theravance Biopharma R&D, Inc. was a PFIC for 2014. Based upon our assets and income from 2015 through 2018, we do not believe that our company is a PFIC during these four years. We do not expect to be a PFIC for the foreseeable future based on our current business plans and current business model. For any taxable year (or portion thereof) in which our Company is a PFIC that is included in the holding period of a US holder, the US holder is generally subject to additional US federal income taxes plus an interest charge with respect to certain distributions from Theravance Biopharma or gain recognized on a sale of Theravance Biopharma shares. Similar rules would apply with respect to distributions from or gain recognized on an indirect sale of Theravance Biopharma Ireland Limited. US holders of our ordinary shares may have filed an election with respect to Company shares held at any time during 2014 to be treated as owning an interest in a "qualified electing fund" ("QEF") or to "mark to market" their ordinary shares to avoid the otherwise applicable interest charge consequences of PFIC treatment with respect to our ordinary shares. A foreign corporation will not be treated as a QEF for any taxable year in which such foreign corporation is not treated as a PFIC. QEF and mark to market elections generally apply to the taxable year for which the election is made and all subsequent taxable years unless the election is revoked with consent of the Secretary of Treasury. US holders of our ordinary shares should consult their tax advisers regarding the tax reporting implications with respect to any QEF and mark to market elections made with respect to our company and with respect to their indirect interests in Theravance Biopharma R&D, Inc.

If we are unable to maintain effective internal controls, our business, financial position and results of operations could be adversely affected.

If we are unable to maintain effective internal controls, our business, financial position and results of operations could be adversely affected. We are subject to the reporting and other obligations under the Exchange Act, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which require annual management assessments of the effectiveness of our internal control over financial reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the US. Any failure to achieve and maintain effective internal controls could have an adverse effect on our business, financial position and results of operations. In addition, our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting annually. If our independent registered public accounting firm is unable to attest to the effectiveness of our internal control over financial reporting, investor confidence in our reported results will be harmed and the price of our securities may fall. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

Agreements entered into with or for the benefit of GSK in connection with the Spin-Off may significantly restrict our business and affairs.

On March 3, 2014, in connection with the Spin-Off, we, Innoviva and GSK entered into a number of agreements that may significantly restrict our business and affairs. In particular, we, Innoviva and GSK entered into the Master Agreement which, among other things, requires GSK's consent to make any changes to (A) a Separation and Distribution Agreement and ancillary agreements that would, individually or in the aggregate, reasonably be expected to adversely affect GSK in any material respect or (B) the TRC Limited Liability Company Agreement, which consent is not to be unreasonably withheld, conditioned or delayed, provided that GSK may withhold, condition or delay such consent in its sole discretion with respect to certain sections of the TRC Limited Liability Company Agreement and any changes to the governance structure of TRC, the confidentiality restrictions, the consent rights, and the transfer restrictions in the TRC Limited Liability Company Agreement. We and GSK also entered into (i) the Governance Agreement that expired on December 31, 2017, (ii) a registration rights agreement that gives GSK certain registration rights with respect to our ordinary shares held by GSK and (iii) an extension agreement that extends to us certain restrictive covenants similar to those applicable to Innoviva under the GSK Agreements. There can be no assurance that these restrictions will not

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materially harm our business, particularly given that GSK's interests may not be aligned with the interests of our business or our other shareholders.

Certain of our directors and officers may have actual or potential conflicts of interest because of their equity ownership in Innoviva, which actual or potential conflicts may harm our business, prospects and financial condition and result in the diversion of corporate opportunities to Innoviva.

Certain of our directors and executive officers hold shares of Innoviva's common stock or rights to acquire such shares, and these holdings may be significant for some of these individuals compared to their total assets. This ownership of Innoviva common stock by most of our officers and directors may create, or may create the appearance of, conflicts of interest when these directors and officers are faced with decisions that could have different implications for Innoviva and for us. For example, potential or actual conflicts could arise relating to: our relationship with Innoviva, including Innoviva's and our respective rights and obligations under agreements entered into in connection with the Spin-Off; Innoviva's management of TRC, particularly given that we and Innoviva have different economic interests in TRC; and corporate opportunities that may be available to both companies in the future. Although we and Innoviva have implemented policies and procedures to identify and properly address such potential and actual conflicts of interest, there can be no assurance that, when such conflicts are resolved in accordance with applicable laws, such conflicts of interest will not harm our business, prospects and financial condition and result in the diversion of corporate opportunities to Innoviva.

If we are required to indemnify Innoviva or Cumberland, or if we are not able to enforce our indemnification rights against Innoviva or Cumberland, our business prospects and financial condition may be harmed.

We agreed to indemnify Innoviva from and after the Spin-Off with respect to (i) all debts, liabilities and obligations transferred to us in connection with the Spin-Off (including our failure to pay, perform or otherwise promptly discharge any such debts, liabilities or obligations after the Spin-Off), (ii) any misstatement or omission of a material fact resulting in a misleading statement in our Information Statement distributed to Innoviva stockholders in connection with the Spin-Off and (iii) any breach by us of certain agreements entered into with Innoviva in connection with the Spin-Off (namely, the Separation and Distribution Agreement, a Transition Services Agreement, an Employee Matters Agreement, a Tax Matters Agreement, and a Facility Sublease Agreement). We are not aware of any existing indemnification obligations at this time, but any such indemnification obligations that may arise could be significant. Under the terms of the Separation and Distribution Agreement, Innoviva agreed to indemnify us from and after the Spin-Off with respect to (i) all debts, liabilities and obligations retained by Innoviva after the Spin-Off (including its failure to pay, perform or otherwise promptly discharge any such debts, liabilities or obligations after the Spin-Off) and (ii) any breach by Innoviva of the Separation and Distribution Agreement, the Transition Services Agreement, the Employee Matters Agreement, the Tax Matters Agreement, and the Facility Sublease Agreement. Our and Innoviva's ability to satisfy these indemnities, if called upon to do so, will depend upon our and Innoviva's future financial strength. If we are required to indemnify Innoviva, or if we are not able to enforce our indemnification rights against Innoviva, our business prospects and financial condition may be harmed.

In addition, the agreement relating to the sale of VIBATIV to Cumberland contains indemnification obligations of both us and Cumberland. If we are required to indemnify Cumberland or if we are unable to enforce our indemnification rights against Cumberland for any reason, our business and financial condition may be harmed.

We commenced a workforce restructuring during the first quarter of 2019 to focus our efforts on our key programs. Even after giving effect to this restructuring, we will not have sufficient cash to fully execute on our key programs, and the restructuring may impact our ability to execute our business plan.

During the first quarter of 2019, we commenced a workforce restructuring involving the reduction of our overall headcount by approximately 50 individuals, with affected employees primarily focused on early research or the infrastructure in support of VIBATIV. Our objective with the restructuring was to align with our focus on continued execution of key strategic programs, and advancement of selected late-stage research programs toward clinical development. There can be no assurance that we will be able to reduce spending as planned or that unanticipated costs will not occur. Our restructuring efforts to focus on key programs may not prove successful due to a variety of factors, including, without limitation, risks that a smaller workforce may have difficulty achieving our goals. In addition, we may

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in the future decide to restructure operations and reduce expenses further by taking such measures as additional reductions in our workforce and program spending. Any restructuring places a substantial strain on remaining management and employees and on operational resources and there is a risk that our business will be adversely affected by the diversion of management time to the restructuring efforts. There can be no assurance that following this restructuring, we will have sufficient cash resources to allow us to fund our operations as planned.

RISKS RELATED TO LEGAL AND REGULATORY UNCERTAINTY

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our current or future markets.

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of December 31, 2018, we owned 438 issued US patents and 1,672 granted foreign patents, as well as additional pending US and foreign patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be invalidated or be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by our patents with respect to a product candidate is threatened, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize products. Further, if we encounter delays in our clinical trials or in obtaining regulatory approval of our product candidates, the patent lives of the related product candidates would be reduced.

In addition, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our drug discovery and development processes that involve proprietary know-how, information and technology that is not covered by patent applications. Although we require our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be misappropriated, disclosed or used for unauthorized purposes or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the US. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the US and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or, if established, maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition and results of operations, which could cause the price of our securities to fall.

Litigation to protect or defend our intellectual property or third-party claims of intellectual property infringement would require us to divert resources and may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on us and our partners not infringing the patents and proprietary rights of third parties. Third parties may assert that we or our partners are using their proprietary rights without authorization.

There are third-party patents that may cover materials or methods for treatment related to our product candidates. At present, we are not aware of any patent infringement claims with merit that would adversely and materially affect our ability to develop our product candidates, but nevertheless the possibility of third-party allegations cannot be ruled out. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Furthermore, parties making claims against us or our partners may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense against these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we

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have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

In addition, in the future we could be required to initiate litigation to enforce our proprietary rights against infringement by third parties, prevent the unauthorized use or disclosure of our trade secrets and confidential information, or defend the validity of our patents. For example, in 2017, we filed a lawsuit against a former employee for misappropriation of certain of our confidential, proprietary and trade secret information. While this litigation has since been resolved, prosecution of claims to enforce or defend our rights against others involve substantial litigation expenses and divert substantial employee resources from our business but may not result in adequate remedy to us or sufficiently mitigate the harm to our business caused by any intellectual property infringement, unauthorized access, use or disclosure of trade secrets. If we fail to effectively enforce our proprietary rights against others, our business will be harmed and the price of our securities could fall.

If the efforts of our partners or future partners to protect the proprietary nature of the intellectual property related to collaboration assets are not adequate, the future commercialization of any medicines resulting from collaborations could be delayed or prevented, which would materially harm our business and could cause the price of our securities to fall.

The risks identified in the two preceding risk factors may also apply to the intellectual property protection efforts of our partners or future partners and to GSK with respect to the GSK-Partnered Respiratory Programs in which we hold an economic interest. To the extent the intellectual property protection of any partnered assets are successfully challenged or encounter problems with the US Patent and Trademark Office or other comparable agencies throughout the world, the future commercialization of these potential medicines could be delayed or prevented. Any challenge to the intellectual property protection of a late-stage development asset, particularly those of the GSK-Partnered Respiratory Programs in which we hold an economic interest, could harm our business and cause the price of our securities to fall.

Product liability and other lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our medicines.

The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical products. Side effects of, or manufacturing defects in, products that we or our partners develop or commercialize could result in the deterioration of a patient's condition, injury or even death. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits tends to increase. Claims may be brought by individuals seeking relief for themselves or by individuals or groups seeking to represent a class, asserting injuries based both on potential adverse effects described in the label as well as adverse events not yet observed. We also face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials. In addition, changes in laws outside the US are expanding our potential liability for injuries that occur during clinical trials. Product liability claims could harm our reputation, regardless of the merit or ultimate success of the claim, which may adversely affect our and our partners' ability to commercialize our products and cause the price of our securities to fall. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may

be forced to limit or forgo further commercialization of the applicable products.

Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities and we cannot be sure that our insurer will not disclaim coverage as to a future claim. In addition, inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercial production and sale of our products, which could adversely affect our business.

We may also be required to prosecute or defend general commercial, intellectual property, securities and other lawsuits. Litigation typically involves substantial expenses and diverts substantial employee resources from our business. The cost of defending any product liability litigation or engaging in any other legal proceeding, even if resolved in our favor, could be substantial and uncertainties resulting from the initiation and continuation of the litigation or other

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proceedings could have a material adverse effect on our ability to compete in the marketplace and achieve our business goals.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.

We are subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the US, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (“HIPAA”). Although we are not directly subject to HIPAA—other than with respect to providing certain employee benefits—we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. HIPAA generally requires that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health information of the patient (unless an exception to the authorization requirement applies). If authorization is required and the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we may not be allowed access to and use of the patient’s information and our research efforts could be impaired or delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (e.g., for use in research and in submissions to regulatory authorities for product approvals). In addition, HIPAA does not replace federal, state, international or other laws that may grant individuals even greater privacy protections.

EU Member States and other jurisdictions where we operate have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the General Data Protection Regulation (“GDPR”) which become applicable on May 25, 2018, replacing the EU Data Protection Directive, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting.

Switzerland has adopted similar restrictions. These obligations and restrictions concern, in particular, the consent of the individuals to whom the personal data relate, the information provided to the individuals, the transfer of personal data out of the European Economic Area (“EEA”) or Switzerland, security breach notifications, security and confidentiality of the personal data, as well as substantial potential fines for breaches of the data protection obligations. Data protection authorities from the different EU Member States may interpret the GDPR and applicable related national laws differently and impose requirements additional to those provided in the GDPR. In addition, guidance on implementation and compliance practices may be updated or otherwise revised, which adds to the complexity of processing personal data in the EU. When processing personal data of subjects in the EU, we have to comply with the applicable data protection laws. In particular, as we rely on services providers processing personal

data of subjects in the EU, we have to enter into suitable contract terms with such providers and receive sufficient guarantees that such providers meet the requirements of the applicable data protection laws, particularly the GDPR which imposes specific and relevant obligations.

Although there are legal mechanisms to allow for the transfer of personal data from the EEA to the US, a decision of the European Court of Justice in the Schrems case (Case C-362/14 Maximilian Schrems v. Data Protection Commissioner) that invalidated the safe harbor framework has increased uncertainty around compliance with EU privacy law requirements. As a result of the decision, it was no longer possible to rely on the safe harbor certification as a legal basis for the transfer of personal data from the EU to entities in the US. On February 29, 2016, however, the European Commission announced an agreement with the US Department of Commerce (“DOC”) to replace the invalidated Safe Harbor framework with a new EU-US “Privacy Shield.” On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the

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requirements set out by the European Court of Justice in its ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and Federal Trade Commission, and making commitments on the part of public authorities regarding access to information. US companies have been able to certify to the US Department of Commerce their compliance with the privacy principles of the Privacy Shield since August 1, 2016.

On September 16, 2016, an Irish privacy advocacy group brought an action for annulment of the EC decision on the adequacy of the Privacy Shield before the European Court of Justice (Case T-670/16). In October 2016, a further action for annulment was brought by three French digital rights advocacy groups (Case T-738/16). Case T-670/16 was declared inadmissible and Case T-738/16 is still pending before the European Court of Justice. The US was admitted as an intervener in the action on September 4, 2018. If the European Court of Justice invalidates the Privacy Shield, it will no longer be possible to rely on the Privacy Shield certification to support transfer of personal data from the EU to entities in the US. Adherence to the Privacy Shield is not, however, mandatory. US-based companies are permitted to rely either on their adherence to the Privacy Shield or on the other authorized means and procedures to transfer personal data provided by the GDPR. If we or our vendors fail to comply with applicable data privacy laws, or if the legal mechanisms we or our vendors rely upon to allow for the transfer of personal data from the EEA or Switzerland to the US (or other countries not considered by the European Commission to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted if our ability to transfer personal data outside of the EEA or Switzerland is restricted, which could adversely impact our operating results.

Changes in healthcare law and implementing regulations, including government restrictions on pricing and reimbursement, as well as healthcare policy and other healthcare payor cost-containment initiatives, may negatively impact us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties in regard to one or more of the following:

- the ability to set and collect a price believed to be reasonable for products;
- the ability to generate revenues and achieve profitability; and
- the availability of capital.

The pricing and reimbursement environment for products may change in the future and become more challenging due to, among other reasons, policies advanced by the current or new presidential administrations, federal agencies, new healthcare legislation passed by Congress or fiscal challenges faced by all levels of government health administration authorities. Among policy makers and payors in the US and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare. In the US, the pharmaceutical industry has been a particular focus of these efforts and has been and may in the future be significantly affected by major legislative initiatives. For instance, in the fourth quarter of 2018, the Centers for Medicare & Medicaid Services (“CMS”), the federal agency that administers the Medicare and Medicaid programs, released an advance notice of proposed rule-making to solicit feedback on a potential change in

the way Medicare Part B pays for certain physician-administered drugs. Under Part B's current reimbursement policy, Medicare pays providers the average sales price of the drug plus 6 percent (reduced to 4.3 percent as a result of sequestration). CMS is considering a proposal that would more closely align payment for these drugs with prices in certain countries (such as Canada, the United Kingdom, Japan, and Germany), allow private-sector vendors to negotiate prices, and pay providers a flat add-on payment not tied to the price of the drug. We expect we, our collaboration partners or those commercializing products with respect to which we have an economic interest or right to receive royalties may experience pricing pressures in connection with the sale of drug products, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative enactments.

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The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together the “Healthcare Reform Act”), is a sweeping measure intended to expand healthcare coverage within the US, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. This law has substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that impact our business and operations, including those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the “donut hole”), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicare Drug Rebate program, expansion of the Public Health Service’s 340B drug pricing program, fraud and abuse and enforcement. These changes have impacted previously existing government healthcare programs and have resulted in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

In particular, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act. These regulations became effective on April 1, 2016. Congress could enact additional legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase the costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on results of operations for us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties.

Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level, as is permitted under the Healthcare Reform Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact the sales, business and financial condition of us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties. Where Medicaid patients receive insurance coverage under any of the new options made available through the Healthcare Reform Act, manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, which could impact manufacturer revenues. In addition, there have been delays in the implementation of key provisions of the Healthcare Reform Act.

Moreover, certain legislative changes to and regulatory changes under the Healthcare Reform Act have occurred in the 115th US Congress and under the Trump Administration. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, effective January 1, 2019. Additional legislative changes to and regulatory changes under the Healthcare Reform Act remain possible, but the nature and extent of such potential additional changes are uncertain at this time. We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on the ability of us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties to maintain or increase sales of existing products or to successfully commercialize product candidates, if approved.

In addition, there have been proposals to impose federal rebates on Medicare Part D drugs, requiring federally-mandated rebates on all drugs dispensed to Medicare Part D enrollees or on only those drugs dispensed to certain groups of lower income beneficiaries. If any of these proposals are adopted and result in additional rebates, this could have a negative impact on revenues for our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties, which could impact our revenues.

Beginning on April 1, 2013, Medicare payments for all items and services under Part A and B, including drugs and biologicals, were reduced by 2% under the sequestration (i.e., automatic spending reductions) as required by federal law, which requires sequestration for most federal programs, excluding Medicaid, Social Security, and certain other programs. The law caps the cuts to Medicare payments for items and services at 2% and this will continue to 2027. As long as these cuts remain in effect, they could adversely impact payment for any products that are reimbursed under

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Medicare. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for product or additional pricing pressures for our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties, which could impact our revenues.

If we failed to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Prior to the sale of VIBATIV to Cumberland, we had certain price reporting obligations to the Medicaid Drug Rebate program and other governmental pricing programs, and we had obligations to report average sales price under the Medicare program. Following the consummation of the transaction with Cumberland, our price reporting obligations related to VIBATIV have been transitioned to Cumberland, and price reporting obligations for YUPELRI reside with Mylan. However, we retain liability related to price reporting for VIBATIV for historic periods.

Under the Medicaid Drug Rebate program, a manufacturer is required to pay a rebate to each state Medicaid program for its covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by the manufacturer on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the US in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs to a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. A final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities became effective on January 1, 2019.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report average sales price information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate the average sales price based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by the manufacturer, governmental or regulatory agencies and the courts. A manufacturer that becomes aware that its Medicaid reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, is obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase the costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the 340B ceiling price.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted any false price information to the government, we may be liable for significant civil monetary penalties per item of false information. If we are found to have made a misrepresentation in the reporting of our average sales price, the Medicare statute provides for significant civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit the required price data on a timely basis could result in a significant civil monetary penalty per day for each day

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the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

In order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by the Department of Veterans Affairs (“VA”), Department of Defense (“DoD”), Public Health Service, and Coast Guard (the “Big Four agencies”) and certain federal grantees, a manufacturer is required to participate in the VA Federal Supply Schedule (“FSS”) pricing program, established under Section 603 of the Veterans Health Care Act of 1992. Under this program, the manufacturer is obligated to make its covered drugs available for procurement on an FSS contract and charge a price to the Big Four agencies that is no higher than the Federal Ceiling Price (“FCP”), which is a price calculated pursuant to a statutory formula. The FCP is derived from a calculated price point called the “non-federal average manufacturer price” (“Non-FAMP”), which the manufacturer calculates and reports to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant penalties for each item of false information. The FSS contract also contains extensive disclosure and certification requirements.

Under Section 703 of the National Defense Authorization Act for FY 2008, the manufacturer is required to pay quarterly rebates to DoD on utilization of its innovator products that are dispensed through DoD’s Tricare network pharmacies to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP for the calendar year that the product was dispensed. A manufacturer that overcharges the government in connection with the FSS contract or Tricare Retail Pharmacy Rebate Program, whether due to a misstated FCP or otherwise, is required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations.

Our relationships with customers and third-party payors are subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians, distributors and third-party payors play a primary role in the distribution, recommendation and prescription of any pharmaceutical product for which we obtain marketing approval. Our arrangements with third-party payors and customers expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements through which we market, sell and distribute any products for which we have obtained or may obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The US federal healthcare Anti-Kickback Statute prohibits any person from, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in cash or in kind, to induce or

reward either the referral of an individual for, or the purchasing, leasing, ordering or arranging for or recommending of any good or service for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. The term “remuneration” has been broadly interpreted to include anything of value. The Anti-Kickback Statute is subject to evolving interpretation and has been applied by government enforcement officials to a number of common business arrangements in the pharmaceutical industry. The government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the statute or specific intent to violate it. There are a number of statutory exemptions and regulatory safe harbors protecting some common activities from prosecution; however, those exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute, but the legality of the arrangement will be evaluated on a case-by-case basis based on the totality of the facts and circumstances. We seek to comply with the available statutory exemptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient or product assistance programs.

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- The federal civil False Claims Act prohibits, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, or using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money to the federal government. Private individuals, commonly known as “whistleblowers,” can bring civil False Claims Act qui tam actions, on behalf of the government and such individuals and may share in amounts paid by the entity to the government in recovery or settlement. In recent years, several pharmaceutical and other healthcare companies have faced enforcement actions under the federal False Claims Act for, among other things, allegedly submitting false or misleading pricing information to government health care programs and providing free product to customers with the expectation that the customers would bill federal programs for the product. Federal enforcement agencies also have showed increased interest in pharmaceutical companies’ product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. Other companies have faced enforcement actions for causing false claims to be submitted because of the company’s marketing the product for unapproved, and thus non-reimbursable, uses. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false claim or statement for violations. Because of the potential for large monetary exposure, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. Companies may be required, however, to enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. Criminal penalties, including imprisonment and criminal fines, are also possible for making or presenting a false, fictitious or fraudulent claim to the federal government.
- HIPAA, among other things, imposes criminal and civil liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors, and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.
- The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the US Department of Health and Human Services, Centers for Medicare and Medicaid Services, information related to payments and other transfers of value, directly or indirectly, to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. A manufacturer’s failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of \$150,000 per year, and up to an aggregate of \$1 million per year for “knowing failures.” Manufacturers must submit reports by the 90th day of each calendar year.
- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third-party

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payors, including private insurers or patients. Several states also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-related activities, including the provision of gifts, meals, or other items to certain health care providers, and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Some states require the posting of information relating to clinical studies and their outcomes. Some states and cities require identification or licensing of sales representatives. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.

· Similar restrictions are imposed on the promotion and marketing of medicinal products in the EU Member States and other countries, including restrictions prohibiting the promotion of a compound prior to its approval. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct often are strictly enforced. Even in those countries where we may decide not to directly promote or market our products, inappropriate activity by our international distribution partners could have implications for us.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that we or our partners may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid in the US and similar programs outside the US, contractual damages, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other providers or entities with whom we do or 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. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

Our business and operations, including the use of hazardous and biological materials may result in liabilities with respect to environmental, health and safety matters.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials. In addition, our operations produce hazardous waste products, including hazardous waste. Federal, state and local laws and regulations govern the use, manufacture, management, storage, handling and disposal of hazardous materials and wastes. We may incur significant additional costs or liabilities to comply with, or for violations of, these and other applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. Further, in the event of a release of or exposure to hazardous materials, including at the sites we currently or formerly operate or at sites such as landfills where we send wastes for disposal, we could be held liable for cleanup costs or damages or subject to other costs or penalties and such liability could exceed our resources. We do not have any insurance for liabilities arising from hazardous materials or under environmental laws. Compliance with or liability under applicable environmental laws and regulations or with respect to hazardous materials may be expensive, and current or future

environmental regulations may impair our research, development and production efforts, which could harm our business, which could cause the price of our securities to fall.

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RISKS RELATING TO OUR ORDINARY SHARES

The market price for our shares has and may continue to fluctuate widely, and may result in substantial losses for purchasers of our ordinary shares.

Our ordinary shares began trading on June 3, 2014, and the market price for our shares has and may continue to fluctuate widely, and may result in substantial losses for purchasers of our ordinary shares. To the extent that historically low trading volumes for our ordinary shares continues, our stock price may fluctuate significantly more than the stock market as a whole or the stock prices of similar companies. Without a larger public float of actively traded shares, our ordinary shares are likely to be more sensitive to changes in sales volumes, market fluctuations and events or perceived events with respect to our business, than the shares of common stock of companies with broader public ownership, and as a result, the trading prices for our ordinary shares may be more volatile. Among other things, trading of a relatively small volume of ordinary shares may have a greater effect on the trading price than would be the case if our public float of actively traded shares were larger. In addition, as further described below under the risk factor entitled “—Concentration of ownership will limit your ability to influence corporate matters,” a number of shareholders hold large concentrations of our shares which, if sold within a relatively short timeframe, could cause the price of our shares to drop significantly.

Market prices for securities of biotechnology and biopharmaceutical companies have been highly volatile, and we expect such volatility to continue for the foreseeable future, so that investment in our ordinary shares involves substantial risk. Additionally, the stock market from time to time has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies.

The following are some of the factors that may have a significant effect on the market price of our ordinary shares:

- lower than expected sales of YUPELRI;
- any adverse developments or results or perceived adverse developments or results with respect to our key clinical programs, for example our JAK inhibitor program or ampreloxetine, including, without limitation, any delays in development in these programs, any halting of development in these programs, any difficulties or delays encountered with regard to the FDA or other regulatory authorities in these programs, or any indication from clinical or non-clinical studies that the compounds in such programs are not safe or efficacious;
- any adverse developments or results or perceived adverse developments or results with respect to the GSK-Partnered Respiratory Programs, including, without limitation, lower than expected sales of Trelegy Ellipta, any delays in development in these programs, any halting of development in these programs, any difficulties or delays encountered with regard to the FDA or other regulatory authorities in these programs, any indication from clinical or non-clinical studies that the compounds in such programs are not safe or efficacious;
- any announcements of developments with, or comments by, the FDA or other regulatory authorities with respect to products we or our partners have under development, are manufacturing or have commercialized;
- any adverse developments or agreements or perceived adverse developments or agreements with respect to our relationship with Innoviva, or the relationship of Innoviva or TRC on the one hand and GSK on the other hand, including any such developments or agreements resulting from or relating to the Spin-Off;
- any adverse developments or perceived adverse developments with respect to our relationship with any of our research, development or commercialization partners, including, without limitation, disagreements that may arise

between us and any of those partners;

- any adverse developments or perceived adverse developments in our programs with respect to partnering efforts or otherwise;

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- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;
- publicity regarding actual or potential study results or the outcome of regulatory review relating to products under development by us, our partners or our competitors;
- regulatory developments in the US and foreign countries;
- announcements with respect to governmental or private insurer reimbursement policies;
- announcements of equity or debt financings;
- possible impairment charges on non-marketable equity securities;
- economic and other external factors beyond our control, such as fluctuations in interest rates;
- loss of key personnel;
- likelihood of our ordinary shares to be more sensitive to changes in sales volume, market fluctuations and events or perceived events with respect to our business due to our small public float;
- low public market trading volumes for our ordinary shares related in part to the concentration of ownership of our shares;
- the sale of large concentrations of our shares;
- developments or disputes as to patent or other proprietary rights;
- approval or introduction of competing products and technologies;
- results of clinical trials;
 - failures or unexpected delays in timelines for our potential products in development, including the obtaining of regulatory approvals;
- delays in manufacturing adversely affecting clinical or commercial operations;
- fluctuations in our operating results;
- market reaction to announcements by other biotechnology or pharmaceutical companies;
- initiation, termination or modification of agreements with our collaborators or disputes or disagreements with collaborators;
- litigation or the threat of litigation;
- public concern as to the safety of product candidates or medicines developed by us; and
- comments and expectations of results made by securities analysts or investors.

If any of these factors causes us to fail to meet the expectations of securities analysts or investors, or if adverse conditions prevail or are perceived to prevail with respect to our business, the price of the ordinary shares would likely

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drop significantly. A significant drop in the price of a company's securities often leads to the filing of securities class action litigation against the company. This type of litigation against us could result in substantial costs and a diversion of management's attention and resources.

Concentration of ownership will limit your ability to influence corporate matters.

Based on our review of publicly available filings, as of December 31, 2018 our three largest shareholders collectively owned approximately 56.2% of our outstanding ordinary shares. These shareholders could control the outcome of actions taken by us that require shareholder approval, including a transaction in which shareholders might receive a premium over the prevailing market price for their shares. Based on our review of publicly available filings, as of December 31, 2018 our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 7.2% of our outstanding ordinary shares.

Certain provisions in our constitutional and other documents may discourage our acquisition by a third-party, which could limit your opportunity to sell shares at a premium.

Our constitutional documents include provisions that could limit the ability of others to acquire control of us, modify our structure or cause us to engage in change-of-control transactions, including, among other things, provisions that:

- require supermajority shareholder voting to effect certain amendments to our amended and restated memorandum and articles of association;
- establish a classified board of directors;
- restrict our shareholders from calling meetings or acting by written consent in lieu of a meeting;
- limit the ability of our shareholders to propose actions at duly convened meetings; and
- authorize our board of directors, without action by our shareholders, to issue preferred shares and additional ordinary shares.

In addition, in May 2018, our shareholders approved a resolution authorizing our board of directors to adopt a shareholder rights plan in the future intended to deter any person from acquiring more than 19.9% of our outstanding ordinary shares without the approval of our board of directors.

These provisions could have the effect of depriving you of an opportunity to sell your ordinary shares at a premium over prevailing market prices by discouraging third parties from seeking to acquire control of us in a tender offer or similar transaction.

Our shareholders may face difficulties in protecting their interests because we are incorporated under Cayman Islands law.

Our corporate affairs are governed by our amended and restated memorandum and articles of association, by the Companies Law (2016 Revision) of the Cayman Islands and by the common law of the Cayman Islands. The rights of

our shareholders and the fiduciary responsibilities of our directors under the laws of the Cayman Islands are different from those under statutes or judicial precedent in existence in jurisdictions in the US. Therefore, you may have more difficulty in protecting your interests than would shareholders of a corporation incorporated in a jurisdiction in the US, due to the different nature of Cayman Islands law in this area.

Shareholders of Cayman Islands exempted companies such as our Company have no general rights under Cayman Islands law to inspect corporate records and accounts or to obtain copies of lists of shareholders. Our directors have discretion under our amended and restated memorandum and articles of association to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them

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available to our shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

Our Cayman Islands counsel, Maples and Calder, is not aware of any reported class action having been brought in a Cayman Islands court. Derivative actions have been brought in the Cayman Islands courts, and the Cayman Islands courts have confirmed the availability for such actions. In most cases, the company will be the proper plaintiff in any claim based on a breach of duty owed to it, and a claim against (for example) our officers or directors usually may not be brought by a shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority and be applied by a court in the Cayman Islands, exceptions to the foregoing principle apply in circumstances in which:

- a company is acting, or proposing to act, illegally or beyond the scope of its authority;
- the act complained of, although not beyond the scope of the authority, could be effected if duly authorized by more than the number of votes which have actually been obtained; or
- those who control the company are perpetrating a “fraud on the minority.”

A shareholder may have a direct right of action against the company where the individual rights of that shareholder have been infringed or are about to be infringed.

There is uncertainty as to shareholders’ ability to enforce certain foreign civil liabilities in the Cayman Islands.

We are incorporated as an exempted company limited by shares with limited liability under the laws of the Cayman Islands. A material portion of our assets are located outside of the US. As a result, it may be difficult for our shareholders to enforce judgments against us or judgments obtained in US courts predicated upon the civil liability provisions of the federal securities laws of the US or any state of the US.

We have been advised by our Cayman Islands legal counsel, Maples and Calder, that the courts of the Cayman Islands are unlikely (i) to recognize or enforce against Theravance Biopharma judgments of courts of the US predicated upon the civil liability provisions of the securities laws of the US or any State; and (ii) in original actions brought in the Cayman Islands, to impose liabilities against Theravance Biopharma predicated upon the civil liability provisions of the securities laws of the US or any State, on the grounds that such provisions are penal in nature. However, in the case of laws that are not penal in nature, although there is no statutory enforcement in the Cayman Islands of judgments obtained in the US, the courts of the Cayman Islands will recognize and enforce a foreign money judgment of a foreign court of competent jurisdiction without retrial on the merits based on the principle that a judgment of a competent foreign court imposes upon the judgment debtor an obligation to pay the sum for which judgment has been given provided certain conditions are met. For a foreign judgment to be enforced in the Cayman Islands, such judgment must be final and conclusive and for a liquidated sum, and must not be in respect of taxes or a fine or penalty, inconsistent with a Cayman Islands’ judgment in respect of the same matter, impeachable on the grounds of fraud or obtained in a manner, and or be of a kind the enforcement of which is, contrary to natural justice or the public policy of the Cayman Islands (awards of punitive or multiple damages may well be held to be contrary to public policy). A Cayman Islands court, including the Grand Court of the Cayman Islands, may stay proceedings if

concurrent proceedings are being brought elsewhere, which would delay proceedings and make it more difficult for our shareholders to bring action against us.

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

The trading market for our ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our ordinary shares could be negatively affected. If one or more of the analysts who cover us downgrade our ordinary shares or publish inaccurate or unfavorable research about our business, the price of our 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 ordinary shares could decrease, which might cause our share price and trading volume to decline.

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We do not anticipate paying any cash dividends on our capital shares in the foreseeable future; as a result, capital appreciation, if any, of our ordinary shares will be your sole source of gain for the foreseeable future.

We have never declared or paid cash dividends on our capital shares. We do not anticipate paying any cash dividends on our capital shares in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. In addition, the terms of any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our ordinary shares. As a result, capital appreciation, if any, of our ordinary shares will be your sole source of gain for the foreseeable future.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our principal physical properties in the US consist of approximately 170,000 square feet of office and laboratory space leased in two buildings in South San Francisco, California. The South San Francisco lease expires in May 2030.

Our Irish subsidiary operates from approximately 6,100 square feet of leased office space in Dublin, Ireland, and the lease expires in April 2027. We believe our current space is sufficient for our needs.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material litigation or other material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

ITEM 5. MARKET FOR THE REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our ordinary shares have traded on The NASDAQ Global Market under the symbol “TBPH” since June 3, 2014. As of February 15, 2019, there were 72 shareholders of record of our ordinary shares. As many of our ordinary shares are held by brokers and other institutions on behalf of shareholders, we are unable to estimate the total number of shareholders represented by these record holders.

Dividend Policy

We currently intend to retain any future earnings to finance our research and development efforts. We have never declared or paid cash dividends on our ordinary shares and do not intend to declare or pay cash dividends on our ordinary shares in the foreseeable future.

Equity Compensation Plans

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2018:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Options	2,634,443	\$ 28.12	3,642,602
Restricted shares	3,069,403	n/a	n/a
Employee share purchase plan	n/a	n/a	1,153,357
Equity compensation plans approved by security holders	5,703,846	\$ 28.12	4,795,959
Options	428,726	\$ 17.95	132,415
Equity compensation plans not approved by security holders	428,726	\$ 17.95	132,415
Total	6,132,572	\$ 26.70	4,928,374

We have three equity compensation plans — our 2013 Equity Incentive Plan (the “2013 EIP”), our 2013 Employee Share Purchase Plan (the “2013 ESPP”), and our 2014 New Employee Equity Incentive Plan (the “2014 NEEIP”). At inception of the plans, we were authorized to issue 5,428,571 ordinary shares under the 2013 EIP and 857,142 ordinary shares under the 2013 ESPP, and 750,000 ordinary shares under the 2014 NEEIP.

The 2013 EIP provides for the issuance of share based awards, including restricted shares, restricted share units, options, share appreciation rights (“SARs”) and other equity based awards, to our employees, officers, directors and consultants. As of January 1 of each year, commencing on January 1, 2015 and ending on (and including) January 1, 2023, the aggregate number of ordinary shares that may be issued under the 2013 EIP shall automatically increase by a number equal to the least of 5% of the total number of ordinary shares outstanding on December 31 of the prior year, 3,428,571 ordinary shares, or a number of ordinary shares determined by our board of directors. Options may be granted with an exercise price not less than the fair market value of the ordinary shares on the grant date. Under the terms of our 2013 EIP, options granted to employees generally have a maximum term of 10 years and vest over a four year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three years. We may grant options with different vesting terms from time to time. Unless an employee’s termination of service is due to disability or death, upon termination of service, any unexercised vested options will generally be forfeited at the end of three months or the expiration of the option, whichever is earlier.

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Under the 2013 ESPP, our officers and employees may purchase ordinary shares through payroll deductions at a price equal to 85% of the lower of the fair market value of the ordinary share at the beginning of the offering period or at the end of each applicable purchase period. As of January 1 of each year, commencing on January 1, 2015 and ending on (and including) January 1, 2033, the aggregate number of ordinary shares that may be issued under the 2013 ESPP shall automatically increase by a number equal to the least of 1% of the total number of ordinary shares outstanding on December 31 of the prior year, 857,142 ordinary shares, or a number of ordinary shares determined by our board of directors. The ESPP generally provides for consecutive and overlapping offering periods of 24 months in duration, with each offering period generally composed of four consecutive six month purchase periods. The purchase periods end on either May 15 or November 15. ESPP contributions are limited to a maximum of 15% of an employee's eligible compensation.

Our 2013 ESPP also includes a feature that provides for the existing offering period to terminate and for participants in that offering period to automatically be enrolled in a new offering period when the fair market value of an ordinary share at the beginning of a subsequent offering period falls below the fair market value of an ordinary share on the first day of such offering period.

The 2014 NEEIP provides for the issuance of share based awards, including restricted shares, restricted share units, non qualified options and SARs, to our employees. Options may be granted with an exercise price not less than the fair market value of the ordinary shares on the grant date. Under the terms of our 2014 NEEIP, options granted to employees generally have a maximum term of 10 years and vest over a four year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three years. We may grant options with different vesting terms from time to time. Unless an employee's termination of service is due to disability or death, upon termination of service, any unexercised vested options will generally be forfeited at the end of three months or the expiration of the option, whichever is earlier.

Additional information regarding share based compensation is included in Note 1, "Organization and Summary of Significant Accounting Policies," and Note 11, "Share Based Compensation," to the consolidated financial statements appearing in this Annual Report on Form 10 K.

Share Performance Graph

The graph set forth below compares the cumulative total shareholder return on our ordinary shares for the period commencing on June 3, 2014, the date on which our ordinary shares began trading on The NASDAQ Global Market, through December 31, 2018, with the cumulative total return of (i) the NASDAQ Composite Index, (ii) the NYSE Arca Pharmaceutical Index (previously labeled as the NASDAQ Pharmaceutical Index) and (iii) the NASDAQ Biotechnology Index over the same period. This graph assumes the investment of \$100 on June 3, 2014 in each of (1) our ordinary shares, (2) the NASDAQ Composite Index, (3) the NYSE Arca Pharmaceutical Index and (4) the NASDAQ Biotechnology Index, and assumes the reinvestment of dividends, if any, although dividends have never been declared on our ordinary shares.

The comparisons shown in the graph below are based upon historical data. We caution that the price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our ordinary shares.

Notwithstanding anything to the contrary set forth in any of our previous or future filings under the Securities Act or the Exchange Act that might incorporate this Annual Report on Form 10 K or future filings made by us under those statutes, this Performance Graph section shall not be deemed filed with the SEC and shall not be deemed incorporated by reference into any of those prior filings or into any future filings made by us under those statutes.

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\$100 Investment in TBPH Shares or Index	TBPH	NASDAQ Composite Index	NYSE Arca Pharmaceutical Index	NASDAQ Biotechnology Index
June 3, 2014	\$ 100.00	\$ 100.00	\$ 100.00	\$ 100.00
December 31, 2014	63.46	112.66	105.29	126.47
December 31, 2015	69.72	120.66	109.68	141.35
December 31, 2016	135.60	131.49	100.53	111.17
December 31, 2017	118.63	170.57	117.20	135.22
December 31, 2018	108.85	165.78	125.98	123.24

ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated summary financial data below should be read in conjunction with Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Part II, Item 8, “Financial Statements and Supplementary Data”, in this Annual Report on Form 10 K.

The following table sets forth certain summary historical financial information as of and for each of the years in the five year period ended December 31, 2018, which have been derived from our (i) audited consolidated financial statements as of December 31, 2018 and 2017 and for the years ended December 31, 2018, 2017, and 2016, which are included in this Annual Report, (ii) audited combined financial statements as of December 31, 2016, 2015 and 2014 and for the years ended December 31, 2015, and 2014, which are not included in this Annual Report. The summary historical financial information may not be indicative of the results of operations or financial position that we would have obtained

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if we had been an independent company during the periods presented or of our future performance as an independent company.

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(In thousands, except per share data)				
CONSOLIDATED STATEMENT OF OPERATIONS DATA					
Product sales	\$ 15,304	\$ 14,788	\$ 17,603	\$ 9,408	\$ 4,418
Collaboration revenue	41,791	598	31,045	32,718	7,270
Profit sharing revenue	3,275	—	—	—	—
Total revenue	60,370	15,386	48,648	42,126	11,688
Costs and expenses:					
Cost of goods sold (1)	715	6,030	2,894	4,657	4,058
Research and development	201,348	173,887	141,712	129,165	168,522
Selling, general and administrative	97,058	95,592	84,509	90,203	71,647
Total costs and expenses (2)	299,121	275,509	229,115	224,025	244,227
Loss from operations	(238,751)	(260,123)	(180,467)	(181,899)	(232,539)
Income from investment in TRC, LLC (3)	11,182	170	—	—	—
Interest expense	(10,482)	(8,547)	(1,404)	—	—
Other-than-temporary impairment loss	—	(8,000)	—	—	—
Interest and other income, net	11,966	4,789	1,312	631	1,865
Loss before income taxes	(226,085)	(271,711)	(180,559)	(181,268)	(230,674)
Provision for income tax benefit (expense)	10,561	(13,694)	(10,110)	(951)	(6,364)
Net loss	\$ (215,524)	\$ (285,405)	\$ (190,669)	\$ (182,219)	\$ (237,038)
Basic and diluted net loss per share	\$ (3.99)	\$ (5.45)	\$ (4.26)	\$ (5.34)	\$ (7.46)
Shares used to compute basic and diluted net loss per share (4)	53,969	52,352	44,711	34,150	31,755
	As of December 31,				
	2018	2017	2016	2015	2014
	(In thousands)				
CONSOLIDATED BALANCE SHEETS DATA					
Cash, cash equivalents and marketable securities	\$ 517,145	\$ 390,153	\$ 592,661	\$ 215,294	\$ 306,010
Working capital	434,269	316,197	479,235	188,002	234,114
Total assets	560,235	441,400	639,254	300,116	337,771
Convertible senior notes due 2023, net	224,818	223,746	222,676	—	—

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Non-recourse notes due 2033, net	229,535	—	—	—	—
Accumulated deficit	(1,012,145)	(797,740)	(512,225)	(321,556)	(139,337)
Total shareholders' (deficit) equity	(51,589)	115,178	350,231	243,065	289,787

(1)For the year ended December 31, 2018, cost of goods sold includes a reversal of a \$2.25 million charge related to excess inventory purchase commitments originally recognized in 2017. For the years ended December 31, 2017, 2016, 2015, and 2014 cost of goods sold includes charges of \$3.0 million, \$0.3 million, \$1.9 million, and \$2.9 million, respectively, arising from excess inventory.

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(2)The following table discloses the allocation of share based compensation expense included in total operating expenses:

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(In thousands)				
Research and development	\$ 25,563	\$ 22,691	\$ 20,202	\$ 25,770	\$ 21,191
Selling, general and administrative	25,750	26,454	20,967	28,280	22,043
Total share-based compensation	\$ 51,313	\$ 49,145	\$ 41,169	\$ 54,050	\$ 43,234

(3)75% of the income from our investment in TRC is available only for payment of the Non-Recourse 2033 Notes and is not available to pay our other obligations or the claims of our other creditors.

(4)Prior to the Spin Off in June 2014, we operated as part of Innoviva and not as a separate entity. As a result, the calculation of basic and diluted net loss per share assumes that the 32,260,105 ordinary shares issued to Innoviva stockholders in connection with the Spin Off, less the number of ordinary shares subject to forfeiture, were outstanding from the beginning of 2014.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Management's Discussion and Analysis ("MD&A") is intended to facilitate an understanding of our business and results of operations. This discussion and analysis should be read in conjunction with our consolidated financial statements and notes included in this Annual Report on Form 10 K. The information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10 K, including information with respect to our plans and strategy for our business, our operating expenses, and future payments under our collaboration agreements, includes forward looking statements within the meaning of Section 27A of the Securities Act of 1933 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). Such statements are based upon current expectations that involve risks and uncertainties. You should review the section entitled "Risk Factors" in Item 1A of Part I above for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward looking statements contained in the following discussion and analysis. See the section entitled "Special Note regarding Forward Looking Statements" above for more information.

Management Overview

Theravance Biopharma, Inc. ("Theravance Biopharma") is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines. Our purpose is to create transformational medicines to improve the lives of patients suffering from serious illnesses. Our research is focused in the areas of inflammation and immunology.

In pursuit of our purpose, we apply insights and innovation at each stage of our business and utilize our internal capabilities and those of partners around the world. We apply organ-selective expertise to biologically compelling targets to discover and develop medicines designed to treat underserved localized diseases and to limit systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing lung-selective medicines to treat respiratory disease, including FDA-approved YUPELRITM (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (“COPD”). Our pipeline of internally discovered programs is targeted to address significant patient needs.

We have an economic interest in potential future payments from Glaxo Group or one of its affiliates (“GSK”) pursuant to its agreements with Innoviva, Inc. (“Innoviva”) relating to certain programs, including TRELEGY ELLIPTA.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with US Generally Accepted Accounting Principles

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(“GAAP”). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management’s judgments and estimates.

Revenue Recognition

Effective January 1, 2018, we adopted Accounting Standards Codification, Topic 606, Revenue from Contracts with Customers (“ASC 606”) using the modified retrospective method. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, an entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of ASC 606, we identify the performance obligations in the contract by assessing whether the goods or services promised within each contract are distinct. We then recognize revenue for the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Sales

In our accompanying consolidated income statements, the comparative prior period product sales revenue remains reported under Accounting Standards Codification, Topic 605, Revenue Recognition (“ASC 605”), and our product sales revenue recognized in 2018 would not have been materially different under ASC 605 as compared to ASC 606.

On November 12, 2018, we completed the sale of our assets related to the manufacture, marketing and sale of the VIBATIV product to Cumberland Pharmaceuticals Inc. (“Cumberland”) pursuant to the Asset Purchase Agreement dated November 1, 2018. Up until that date, we sold VIBATIV in the US market by making the drug product available through a limited number of distributors, who sell VIBATIV to healthcare providers. Title and risk of loss transferred upon receipt by these distributors. We recognized VIBATIV product sales and related cost of product sales when the distributors obtained control of the drug product, which was at the time title transferred to the distributors.

We recorded sales on a net sales basis which includes estimates of variable consideration. The variable consideration results from sales discounts, government mandated rebates and chargebacks, distribution fees, estimated product

returns and other deductions for sales made by us prior to the November 12, 2018 sale to Cumberland. We reflected such reductions in revenue as either an allowance to the related account receivable from the distributor, or as an accrued liability, depending on the nature of the sales deduction. Sales deductions are based on management's estimates that considered payor mix in target markets, industry benchmarks and experience to date. In general, these estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in ASC 606. We monitored inventory levels in the distribution channel, as well as sales by distributors to healthcare providers, using product specific data provided by the distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of our agreements with customers, historical product returns of, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. We update our estimates and assumptions each quarter and if actual future results vary from our estimates, we may adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment.

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The following table summarizes activity in each of the product revenue allowance and reserve categories:

(In thousands)	Chargebacks, Discounts and Fees	Government and Other Rebates	Returns	Total
Balance at December 31, 2016	\$ 779	\$ 377	\$ 747	\$ 1,903
Provision related to current period sales	5,193	580	573	6,346
Adjustment related to prior period sales	(127)	75	561	509
Credit or payments made during the period	(4,853)	(680)	(935)	(6,468)
Balance at December 31, 2017	\$ 992	\$ 352	\$ 946	\$ 2,290
Provision related to current period sales	6,402	704	521	7,627
Adjustment related to prior period sales	(81)	168	(449)	(362)
Credit or payments made during the period	(6,938)	(932)	(157)	(8,027)
Balance at December 31, 2018	\$ 375	\$ 292	\$ 861	\$ 1,528

Collaborative Arrangements under ASC 606

We enter into collaborative arrangements with partners that fall under the scope of Accounting Standards Codification, Topic 808, Collaborative Arrangements (“ASC 808”). While these arrangements are in the scope of ASC 808, we may analogize to ASC 606 for some aspects of the arrangements. We analogize to ASC 606 for certain activities within the collaborative arrangement for the delivery of a good or service (i.e., a unit of account) that is part of our ongoing major or central operations. Revenue recognized by analogizing to ASC 606 is recorded as “collaboration revenue” whereas, revenue recognized in accordance with ASC 808, is recorded as “profit sharing revenue” in the consolidated statements of operations.

The terms of our collaborative arrangements typically include one or more of the following: (i) up-front fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; (iii) royalties on net sales of licensed products; (iv) reimbursements or cost-sharing of R&D expenses; and (v) profit/loss sharing arising from co-promotion arrangements. Each of these payments results in collaboration revenues or an offset against R&D expense. Where a portion of non-refundable up-front fees or other payments received is allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as deferred revenue and recognized as collaboration revenue when (or as) the underlying performance obligation is satisfied.

As part of the accounting for these arrangements, we must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price may include such estimates as, forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if they can be satisfied at a point in time or over time, and we measure the services delivered to our collaborative partner which are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated input component and, therefore revenue or expense recognized, would be recorded as a change in estimate. In addition,

variable consideration (e.g., milestone payments) must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Up-front Fees: If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize collaboration revenues from transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing collaboration revenue from the allocated transaction price. For example, when we receive up-front fees for the performance of research and development services, or when research and development services are not considered to be distinct from a license, we recognize collaboration revenue for those units of account over time using a measure of progress. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue or expense recognition as a change in estimate.

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Milestone Payments: At the inception of each arrangement that includes milestone payments (variable consideration), we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the collaborative partner's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of milestones that are within our or the collaborative partner's control, such as operational developmental milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and earnings in the period of adjustment. Revisions to our estimate of the transaction price may also result in negative collaboration revenues and earnings in the period of adjustment.

Royalties: For arrangements that include sales-based royalties, including commercial milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any material royalty revenue resulting from any of our collaborative arrangements.

Following the sale of VIBATIV to Cumberland in November 2018, VIBATIV royalties earned from Cumberland will be included within "interest and other income, net" on the consolidated statements of operations. In addition, our income earned related to TRELEGY ELLIPTA sales is included within "income from our investment in TRC, LLC" on the consolidated statements of operations.

Reimbursement, cost-sharing and profit-sharing payments: Under certain collaborative arrangements, we have been reimbursed for a portion of our R&D expenses or participate in the cost-sharing of such R&D expenses. Such reimbursements and cost-sharing arrangements have been reflected as a reduction of R&D expense in our consolidated statements of operations, as we do not consider performing research and development services for reimbursement to be a part of our ongoing major or central operations.

Research and Development Expenses

Research and development expenses are recorded in the period that services are rendered or goods are received. Research and development expenses consist of salaries and benefits, laboratory supplies and facility costs, as well as fees paid to third parties that conduct certain research and development activities on behalf of us, net of certain external research and development expenses reimbursed under our collaborative arrangements.

As part of the process of preparing financial statements, we are required to estimate and accrue certain research and development expenses. This process involves the following:

- identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost;
- estimating and accruing expenses in our financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and
- periodically confirming the accuracy of our estimates with selected service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that we accrue include:

- fees paid to clinical research organizations (“CROs”) in connection with preclinical and toxicology studies and clinical studies;

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- fees paid to investigative sites in connection with clinical studies;
- fees paid to contract manufacturing organizations (“CMOs”) in connection with the production of product and clinical study materials; and
- professional service fees for consulting and related services.

We base our expense accruals related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful enrollment of patients and the completion of clinical study milestones. Our service providers typically invoice us monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

To date, we have not experienced significant changes in our estimates of accrued research and development expenses after a reporting period. Such changes in estimates recorded after a reporting period have been less than 1% of our annual research and development expenses and have not been material. However, due to the nature of estimates, there is no assurance that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical studies and other research activities. Such changes in estimates will be recognized as research and development expenses in the period that the change in estimate occurs.

Theravance Respiratory Company, LLC (“TRC”)

Through our equity ownership of TRC, we are entitled to receive an 85% economic interest in any future payments that may be made by GSK relating to the GSK-Partnered Respiratory Programs (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). The GSK-Partnered Respiratory Programs consist primarily of the Trelegy Ellipta program and the inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (“MABA”) program.

We analyzed our ownership, contractual and other interests in TRC to determine if TRC is a variable interest entity (“VIE”), whether we have a variable interest in TRC and the nature and extent of that interest. We determined that TRC is a VIE. The party with the controlling financial interest, the primary beneficiary, is required to consolidate the entity determined to be a VIE. Therefore, we also assessed whether we are the primary beneficiary of TRC based on the power to direct its activities that most significantly impact its economic performance and our obligation to absorb its

losses or the right to receive benefits from it that could potentially be significant to TRC. Based on our assessment, we determined that we are not the primary beneficiary of TRC, and, as a result, we do not consolidate TRC in our consolidated financial statements. TRC is recognized in our consolidated financial statements under the equity method of accounting. Income related to our equity ownership of TRC is reflected in our consolidated statement of operations as non-operating income.

Income Taxes

We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax basis of assets and liabilities and are measured using enacted tax rates and laws that are anticipated to be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

Our total unrecognized tax benefits of \$52.4 million and \$41.8 million, as of December 31, 2018 and December 31, 2017, respectively, may reduce the effective tax rate in the period of recognition. As of December 31, 2018, we do not believe that it is reasonably possible that our unrecognized tax benefit will significantly decrease in the next

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twelve months. We currently have a full valuation allowance against our deferred tax assets, which would impact the timing of the effective tax rate benefit should any of these uncertain positions be favorably settled in the future.

We assess all material positions, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than 50% likely to be realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and we will determine whether the factors underlying the sustainability assertion have changed and whether the amount of the recognized tax benefit is still appropriate.

The recognition and measurement of tax benefits requires significant judgment. We have taken certain positions where we believe that our position is greater than 50% likely to be realized upon ultimate settlement and for which no reserve for uncertain tax positions has been recorded. If we do not ultimately realize the expected benefit of these positions, we will record additional income tax expenses in future periods. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

Results of Operations

Product Sales, Collaboration Revenue, and Profit Sharing Revenue

Product sales, collaboration revenue, and profit sharing revenue as compared to the prior years, were as follows:

(In thousands)	Year Ended December 31,			Change		2017	
	2018	2017	2016	2018		2017	
Product sales	\$ 15,304	\$ 14,788	\$ 17,603	\$ 516	3 %	\$ (2,815)	(16) %
Collaboration revenue	41,791	598	31,045	41,193	NM	(30,447)	(98)
Profit sharing revenue	3,275	—	—	3,275	NM	—	—
Total revenue	\$ 60,370	\$ 15,386	\$ 48,648	\$ 44,984	292 %	\$ (33,262)	(68) %

NM: Not Meaningful

Revenue from product sales was \$15.3 million in 2018 and represented our sales of VIBATIV through November 11, 2018, the date of the sale of VIBATIV to Cumberland. The increase in revenue of \$0.5 million in 2018 compared to 2017 was primarily due to an increase in sales volume and pricing.

Collaboration revenue increased by \$41.2 million in 2018 compared to 2017. The \$41.2 million increase was primarily due to \$31.1 million earned under the Janssen collaboration arrangement for TD-1473 and related back-up compounds that was entered into in February 2018 and \$10.0 million attributed to the April 2018 exercise by Alfasigma of its option to develop and commercialize velusetrag. The \$31.1 million from Janssen represented the

portion of revenue recognized in 2018 that was related to the total \$100.0 million upfront payment received in the same year.

We are entitled to a share of US profits and losses (65% to Mylan; 35% to Theravance Biopharma) received in connection with commercialization of YUPELRI, which was approved by the US Food and Drug Administration (“FDA”) in November 2018. Any reimbursement attributed to the 65% cost sharing of our R&D expense from Mylan is characterized as a reduction of R&D expense. If in any reporting period, the arrangement results in a receivable from Mylan after the Company’s R&D expenses have been reimbursed, then such a receivable is recognized as profit sharing revenue. Profit sharing revenue of \$3.3 million represents our share of the profit receivable from Mylan for the period from approval to December 31, 2018.

If in any reporting period, the arrangement results in a payable to Mylan after our R&D expenses have been reimbursed, then such payments will be recognized as collaboration expenses within operating expenses and no profit sharing revenue will be recognized.

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Revenue from product sales decreased by \$2.8 million in 2017 compared to 2016 primarily due to reduced sales volume attributed to increased competition from generic daptomycin in the US outpatient market, and revenue from collaboration arrangements decreased by \$30.4 million in 2017 compared to 2016 due to the absence of milestones achieved in 2017.

Cost of Goods Sold

Cost of goods sold, as compared to the prior years, were as follows:

(In thousands)	Year Ended December 31,			Change		2017	
	2018	2017	2016	2018	%	\$	%
Cost of goods sold	\$ 715	\$ 6,030	\$ 2,894	\$ (5,315)	(88) %	\$ 3,136	108 %

Cost of goods sold decreased by \$5.3 million in 2018 compared to 2017 primarily due to the reversal of an excess inventory charge that was originally recognized in 2017. In the fourth quarter of 2017, we accrued a \$2.25 million liability related to excess inventory purchase commitments based on our expected purchase obligations at the time. In the second quarter of 2018, we reversed the expense related to the \$2.25 million purchase commitment liability due to the waiver of our minimum purchase commitment by our third-party manufacturer. The 2018 decrease in cost of goods sold was also attributed to a separate \$0.7 million write-off of inventory taken early in 2017 and the sale of the VIBATIV product to Cumberland on November 12, 2018.

Cost of goods sold increased by \$3.1 million in 2017 compared to 2016 primarily due to a \$3.0 million charge arising from excess inventory.

Research & Development

Our research and development (“R&D”) expenses consist primarily of employee-related costs, external costs, and various allocable expenses. We budget total R&D expenses on an internal department level basis, and we manage and report our R&D activities across the following four cost categories:

- 1) Employee-related costs, which include salaries, wages and benefits;
- 2) Share-based compensation, which includes expenses associated with our equity plans;
- 3) External-related costs, which include clinical trial related expenses, other contract research fees, consulting fees, and contract manufacturing fees; and

- 4) Facilities and other, which include laboratory and office supplies, depreciation and other allocated expenses, which include general and administrative support functions, insurance and general supplies.

The following table summarizes our R&D expenses, net of reimbursements from collaboration partners, during the periods presented:

(In thousands)	Year Ended December 31,			Change		2017	
	2018	2017	2016	\$	%	\$	%
Employee-related	\$ 62,896	\$ 57,723	\$ 37,328	\$ 5,173	9 %	\$ 20,395	55 %
Share-based compensation	25,563	22,691	20,202	2,872	13	2,489	12
External-related	77,305	62,656	57,576	14,649	23	5,080	9
Facilities, depreciation and other allocated expenses	35,584	30,817	26,606	4,767	15	4,211	16
Total research & development	\$ 201,348	\$ 173,887	\$ 141,712	\$ 27,461	16 %	\$ 32,175	23 %

R&D expenses increased by \$27.5 million in 2018 compared to 2017. The increase was due to a \$14.6 million increase in external-related expenses, a \$5.2 million increase in employee-related expenses, a \$4.8 million increase in facilities, depreciation and other allocated expenses, and a \$2.9 million increase in share-based compensation.

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The \$14.6 million increase in external-related expenses was primarily due to the advancement of TD-1473 (our gut-selective pan-JAK inhibitor) into a Phase 2 study in Crohn’s disease and a Phase 2b/3 study in ulcerative colitis, continued development of ampreloxtine (TD-9855, a norepinephrine reuptake inhibitor (“NRI”)) in neurogenic orthostatic hypotension (“nOH”), and continued investment in our research and preclinical programs.

The \$5.2 million increase in employee-related expenses was primarily due to a \$7.3 million net increase in salaries, bonuses and other costs associated with incremental headcount and the achievement of goals related to our key programs and a \$5.5 million decrease in employee-related expense reimbursements under certain collaborative arrangements. These increases were partially offset by a \$7.6 million decrease in long-term retention and incentive cash bonus awards offered to certain employees in 2016 due to the probable achievement of certain performance conditions. The payout of such awards is dependent on the Company meeting its critical operating goals and objectives during a five-year period from 2016 to December 31, 2020.

R&D expenses increased by \$32.2 million in 2017 compared to 2016. The increase was primarily related to a \$25.5 million increase in employee-related and external-related costs due to progression of our key pipeline programs and continued investment in our research efforts.

Under certain of our collaborative arrangements, we receive partial reimbursement of employee related costs and external costs, which have been reflected as a reduction of R&D expenses of \$9.1 million, \$23.5 million and \$90.7 million for 2018, 2017 and 2016, respectively. The decreases in expense reimbursements in 2018 compared to 2017 and 2016 were primarily attributed to the completion of the Phase 3 pivotal program and submission and approval of the NDA for YUPELRI.

Due to later stage clinical development activities and continued investment in our research programs, we anticipate our R&D expenses will increase over current levels.

Selling, General & Administrative

Selling, general and administrative expenses, as compared to the prior years, were as follows:

(In thousands)	Year Ended December 31,			Change		2017	
	2018	2017	2016	2018	%	\$	%
Selling, general and administrative	\$ 97,058	\$ 95,592	\$ 84,509	\$ 1,466	2 %	\$ 11,083	13 %

Selling, general and administrative expenses increased by \$1.5 million in 2018 compared to 2017. The increase was primarily due a \$4.1 million increase in employee-related expenses primarily due to increases in salaries and bonuses, and a \$1.6 million increase in external-related expenses primarily due to information technology infrastructure projects. The increase was partially offset by a \$3.5 million decrease in facilities and other allocated expenses, and a \$0.7 million decrease in share-based compensation.

Selling, general and administrative expenses increased by \$11.1 million in 2017 compared to 2016 primarily due to higher incentive bonus costs. The higher incentive bonus costs were associated with the accrual of our long-term retention and incentive bonus awards granted to certain employees in 2016 due to the probable achievement of certain performance conditions, as further described below. The payout of such awards is dependent on meeting certain operating goals and objectives during a five-year period from 2016 to December 31, 2020.

Share-based compensation expenses related to selling, general and administrative expenses were \$25.8 million, \$26.5 million and \$21.0 million in 2018, 2017 and 2016, respectively.

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Income from Investment in TRC, LLC

Income from investment in TRC, as compared to the prior years, was as follows:

(In thousands)	Year Ended December 31,			Change		2017	
	2018	2017	2016	2018	%	\$	%
Income from investment in TRC, LLC	\$ 11,182	\$ 170	\$ —	\$ 11,012	NM	\$ 170	NM

NM: Not Meaningful

Income from investment in TRC was \$11.2 million in 2018 compared to \$0.2 million in 2017. The investment income in TRC was generated by royalty payments from GSK to TRC arising from the net sales of Trelegy Ellipta which was launched in the fourth quarter of 2017. There was no income from TRC in 2016.

In connection with the issuance of our \$237.5 million net principal amount of 9% non-recourse notes due 2033 (“Non-Recourse 2033 Notes”) that were issued in November 2018, 75% of the income from our investment in TRC is available only for payment of the Non-Recourse 2033 Notes and is not available to pay our other obligations or the claims of our other creditors.

Interest Expense

Interest expense, as compared to the prior years, was as follows:

(In thousands)	Year Ended December 31,			Change		2017	
	2018	2017	2016	2018	%	\$	%
Interest expense	\$ 10,482	\$ 8,547	\$ 1,404	\$ 1,935	23 %	\$ 7,143	509 %

Interest expense increased to \$10.5 million in 2018 compared to \$8.5 million in 2017 and \$1.4 million in 2016. The \$1.9 million increase in 2018 compared to 2017 was primarily due to additional interest expense related to the issuance of the Non-Recourse 2033 Notes in November 2018. The \$7.1 million increase in 2017 compared to 2016 was due to a full year of interest expense associated with the November 2016 issuance of \$230.0 million in aggregate principal amount of 3.25% convertible senior notes due 2023 (the “Convertible Senior 2023 Notes”).

Other-Than-Temporary Impairment Loss

Other-than-temporary impairment loss, as compared to the prior years, was as follows:

(In thousands)	Year Ended December 31,			Change		2017	
	2018	2017	2016	\$	%	\$	%
Other-than-temporary impairment loss	\$ —	\$ 8,000	\$ —	\$ (8,000)	NM	\$ 8,000	NM

NM: Not Meaningful

In 2017, we recognized an impairment loss of \$8.0 million on our investment in Trek Therapeutics, PBC, a non-marketable equity security, which we determined to be other-than-temporary. We had no such loss recorded in the comparable periods in 2018 and 2016.

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Interest and Other Income

Interest and other income, as compared to the prior years, were as follows:

(In thousands)	Year Ended December 31,			Change		2017	
	2018	2017	2016	2018	%	2017	%
Interest and other income, net	\$ 11,966	\$ 4,789	\$ 1,312	\$ 7,177	150 %	\$ 3,477	265 %

Interest and other income increased to \$12.0 million in 2018 compared to \$4.8 million in 2017 and \$1.3 million in 2016. The \$7.2 million increase in 2018 compared to 2017 was primarily due to a \$6.1 million net gain recorded for the sale of the VIBATIV product to Cumberland on November 12, 2018. We expect to record the royalties receivable from future US net sales by Cumberland within other income. The \$3.5 million increase in 2017 compared to 2016 was primarily due to the additional income earned from higher investment balances following our public equity and convertible debt offerings in November 2016.

Provision for Income Tax Benefit (Expense)

(In thousands)	Year Ended December 31,			Change		2017	
	2018	2017	2016	2018	%	2017	%
Provision for income tax benefit (expense)	\$ 10,561	\$ (13,694)	\$ (10,110)	\$ 24,255	(177) %	\$ (3,584)	35 %

The 2018 benefit for income taxes of \$10.6 million was primarily due to additional tax loss generated in 2017 by the US entity as a result of the finalization of transfer pricing policy, current year US research and development credit, and the release of previously recorded contingent tax liabilities due to the lapse of the statute of limitations. The provision for income tax recorded in 2017 and 2016 primarily resulted from contingent tax liabilities related to uncertain tax positions taken with respect to transfer pricing and tax credits.

Although we incurred operating losses on a consolidated basis, we operate in multiple jurisdictions and certain jurisdictions generated taxable income. In contrast to 2017 and 2016, we recorded a tax benefit in 2018 because of the aforementioned tax benefits.

Liquidity and Capital Resources

We have financed our operations primarily through public offering of equity and debt securities, private placements of equity and debt, revenue from collaboration arrangements and, to a lesser extent, revenue from product sales. As of December 31, 2018, we had approximately \$517.1 million in cash, cash equivalents, and investments in marketable

securities. Also, as of December 31, 2018, we had outstanding \$230.0 million in aggregate principal Convertible Senior 2023 Notes and \$237.5 million in net principal Non-Recourse 2033 Notes.

The Non-Recourse 2033 Notes are secured by all of the issuer's right, title and interest as a holder of certain membership interests (the "Issuer Class C Units") in TRC. The primary source of funds to make payments on the Non-Recourse 2033 Notes will be the 63.75% economic interest of the issuer (evidenced by the Issuer Class C Units) in any future payments that may be made by GSK to TRC under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC by Innoviva (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters) relating to the GSK-Partnered Respiratory Programs, including the Trelegy Ellipta program. The sole source of principal and interest payments for the Non-Recourse 2033 Notes are the future royalty payments generated from the TRELEGY ELLIPTA program, and as a result, the holders of the Non-Recourse 2033 Notes have no recourse against Theravance Biopharma even if the TRELEGY ELLIPTA payments are insufficient to cover the principal and interest payments for the Non-Recourse 2033 Notes.

We expect to continue to incur net losses over at least the next several years due to significant expenditures relating to our continuing drug discovery efforts, preclinical and clinical development of our current product candidates and commercialization costs relating to YUPELRI. In particular, to the extent we advance our product candidates into and

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through later stage clinical studies without a partner, we will incur substantial expenses. We expect the clinical development of our key development programs will require significant investment in order to continue to advance in clinical development. In addition, we expect to invest strategically in our research efforts to continue to grow our development pipeline. In the past, we have received a number of significant payments from collaboration agreements and other significant transactions. In the future, we may continue to receive potential substantial payments from future collaboration transactions if the drug candidates in our pipeline achieve positive clinical or regulatory outcomes. In addition, we recently began recognizing investment income arising from our economic interest in royalties payable by GSK to TRC. Our current business plan is subject to significant uncertainties and risks as a result of, among other factors, clinical program outcomes, whether, when and on what terms we are able to enter into new collaboration arrangements, expenses being higher than anticipated, the sales levels of any approved products, unplanned expenses, cash receipts being lower than anticipated, and the need to satisfy contingent liabilities, including litigation matters and indemnification obligations.

Adequacy of cash resources to meet future needs

We expect our cash and cash equivalents and marketable securities will be sufficient to fund our operations for at least the next 12 months from the issuance date of these consolidated financial statements based on current operating plans and financial forecasts.

We may seek to obtain additional financing in the form of public or private equity offerings, debt financing or additional collaborations and licensing arrangements. However, future financing may not be available in amounts or on terms acceptable to us, if at all.

Without adequate financial resources to fund our operations as presently conducted, we may be required to relinquish rights to our technologies, product candidates or territories, or grant licenses on terms that are not favorable to us, in order to raise additional funds through collaborations or licensing arrangements. We may also have to sequence preclinical and clinical studies as opposed to conducting them concomitantly in order to conserve resources, or delay, reduce or eliminate one or more of our research or development programs and reduce overall overhead expenses. In addition, we may have to make reductions in our workforce and may be prevented from continuing our discovery, development and commercialization efforts and exploiting other corporate opportunities.

Cash Flows

Cash flows, as compared to the prior years, were as follows:

(In thousands)	Year Ended December 31,			Change	
	2018	2017	2016	2018	2017
Net cash used in operating activities	\$ (112,867)	\$ (201,052)	\$ (98,989)	\$ 88,185	\$ (102,063)
	176,708	(56,333)	(148,235)	233,041	91,902

Net cash provided by (used in) investing activities					
Net cash provided by financing activities	225,200	1,656	479,226	223,544	(477,570)

Net cash flows used in operating activities

Net cash used in operating activities was \$112.9 million in 2018, consisting primarily of net loss of \$215.5 million, adjusted for non-cash items such as \$51.3 million for share-based compensation expense, and \$59.4 million of net cash inflow related to changes in operating assets and liabilities primarily driven by the \$100.0 million upfront payment in February 2018 from the Janssen collaborative arrangement.

Net cash used in operating activities was \$201.1 million in 2017, consisting primarily of net loss of \$285.4 million, adjusted for non-cash items such as \$49.1 million for share-based compensation expense, \$8.0 million for other-than-temporary impairment loss on our non-marketable equity securities and \$22.4 million of net cash inflow related to changes in operating assets and liabilities. The \$22.4 million net cash inflow related to changes in operating assets and liabilities was primarily attributable to a \$36.6 million increase in our accounts payable, accrued personnel-related and clinical/development expenses, and other long-term liabilities. This was partially offset by a \$15.2 million increase in our inventory and long-term tax receivable related to the prepayment of corporate taxes and tax withholdings.

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Net cash used in operating activities was \$99.0 million in 2016, consisting primarily of net loss of \$190.7 million, adjusted for non-cash items such as \$41.2 million for share-based compensation expense and \$46.9 million of net cash inflow related to changes in operating assets and liabilities. The \$46.9 million net cash inflow related to changes in operating assets and liabilities was primarily attributable to a \$26.2 million net decrease in receivables from collaboration partners, principally Mylan, and \$9.5 million in net tax refunds in 2016.

Net cash flows provided by (used in) investing activities

Net cash provided by investing activities was \$176.7 million in 2018, consisting of maturities of marketable securities of \$347.2 million and \$20.0 million in proceeds from the VIBATIV sale. These inflows were partially offset by outflows related to purchases of marketable securities of \$183.3 million and the acquisition of property and equipment of \$7.2 million.

Net cash used in investing activities was \$56.3 million in 2017, consisting primarily of purchases of marketable securities of \$288.8 million partially offset by maturities of marketable securities of \$234.9 million.

Net cash used in investing activities was \$148.2 million in 2016, consisting primarily of purchases of marketable securities of \$237.6 million partially offset by maturities of marketable securities of \$91.5 million.

Net cash flows provided by financing activities

Net cash provided by financing activities was \$225.2 million in 2018, consisting of net proceeds from the issuance of our Non-Recourse 2033 Notes of \$229.4 million, \$5.6 million in share option exercises and employee share plan purchases, and partially offset by \$9.8 million related to the repurchase of shares to satisfy tax withholdings associated with vested options.

Net cash provided by financing activities was \$1.7 million in 2017, consisting of net proceeds arising from share option exercises, employee share plan purchases, and partially offset by the repurchase of shares to satisfy tax withholdings associated with vested options.

Net cash provided by financing activities was \$479.2 million in 2016, consisting primarily of the sales of ordinary shares for total net proceeds of \$253.0 million and the issuance of our Convertible Senior 2023 Notes for a total net proceeds of \$222.5 million.

Contractual Obligations and Commercial Commitments

In the table below, we set forth our significant obligations and future commitments, as well as obligations related to all contracts that we are likely to continue, regardless of the fact that they were cancelable as of December 31, 2018. Some of the figures that we include in this table are based on management's estimate and assumptions about these obligations, including their duration. Because these estimates and assumptions are necessarily subjective, the amount of the obligations we will actually pay in future periods may vary from those reflected in the table.

(In thousands)	Years				
	Total	Within 1	Over 1 to 3	Over 3 to 5	After 5
3.25% Convertible senior notes due 2023 - principal	\$ 230,000	\$ —	\$ —	\$ 230,000	\$ —
3.25% Convertible senior notes due 2023 - interest	36,150	7,475	14,950	13,725	—
9.0% Non-recourse notes due 2033 - principal *	237,500	*	*	*	*
Facility operating leases (1)	113,912	7,817	16,048	19,810	70,237
Purchase obligations (2)	282,827	139,132	104,946	26,027	12,722
Total	\$ 900,389	\$ 154,424	\$ 135,944	\$ 289,562	\$ 82,959

*The Non-Recourse 2033 Notes are secured by Triple Royalty Sub LLC's (the "Issuer") right, title, and interest in TRC. The primary source of funds to make payments on the Non-Recourse 2033 Notes is the 63.75% economic

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interest of the Issuer in any future payments made by GSK under the collaboration agreement, dated as of November 14, 2002, by and between Innoviva and GSK relating to the Trelegy Ellipta program. In addition, prior to October 15, 2020, in the event that the distributions received by the Issuer from TRC in a quarter is less than the interest accrued for the quarter, the principal amount of the Non-Recourse 2033 Notes will increase by the interest shortfall amount for that period. Since the timing of the principal and interest payments on the Non-Recourse 2033 Notes are ultimately based on royalties from TRELEGY ELLIPTA product sales, which will vary from quarter to quarter and are unknown to us, only the total net principal payment amount at issuance is included in the above table. See Note 8, "Long-Term Debt" of the accompanying consolidated financial statements for further information.

(1)As security for performance of certain obligations under the operating leases for our principal physical properties, we issued a letter of credit in the amount of \$0.8 million, collateralized by an equal amount of restricted cash.

(2)Substantially all of this amount was subject to open purchase orders, as of December 31, 2018, that were issued under existing contracts. This amount does not represent any minimum contract termination liabilities for our existing contracts.

Commitments and Contingencies

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recognized any liabilities relating to these agreements as of December 31, 2018.

Performance-Contingent Awards

In 2016, we granted long-term retention and incentive restricted share awards ("RSAs") and restricted share units ("RSUs") to members of senior management and long-term retention and incentive cash bonus awards to certain employees. The vesting and payout of such awards is dependent on meeting certain operating goals and objectives during a five-year period from 2016 to December 31, 2020. These goals are strategically important for us, and we believe the goals, if achieved, will increase shareholder value. The awards have dual triggers of vesting based upon the achievement of these goals and continued employment, and they are broken into three separate tranches.

We determined that achievement of the requisite performance conditions for the first tranche were completed as of June 30, 2018. The maximum potential remaining expense associated with the second and third tranches of this program is \$17.8 million related to share-based compensation expense and \$21.0 million related to cash bonus expense, which would be recognized in increments based on achievement of the performance conditions. With the completed achievement of the first tranche's requisite performance conditions and the second tranche being probable due to achievement of certain performance conditions and multiple advancements of programs within our development pipeline, we have recognized \$4.3 million in share-based compensation expense and \$5.4 million in cash bonus expense for the year ended December 31, 2018, respectively. We determined that the remaining third tranche was not probable of vesting and, as a result, no compensation expense related to this tranche has been recognized to date.

In 2017, we approved the grant of 50,000 performance-contingent RSUs to a newly appointed member of senior management. The RSUs have dual triggers of vesting based upon the achievement of certain corporate operating milestones in specified timelines, as well as a requirement for continued employment. Share-based compensation expense related to this grant is broken into two separate tranches and recognized when the associated performance goals are deemed to be probable of achievement. The maximum expense associated with the first tranche was \$0.8 million. In 2017, we recognized \$0.4 million in share-based compensation expense as we determined that the performance conditions associated with the first tranche was probable of vesting, and in 2018, we recognized the remaining \$0.4 million of share-based compensation expense as the performance conditions associated with the first tranche of this award were met. We have determined that the second tranche was not probable of vesting as of December 31, 2018 and, as a result, no compensation expense related to the second tranche has been recognized to date.

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Off Balance Sheet Arrangements

Our equity interest in TRC constitutes an off balance sheet arrangement. Under the agreement governing TRC, the manager of TRC may request quarterly capital contributions from us to fund the operating costs of TRC; however, we are not obligated to make such contributions. Our equity interest in TRC entitles us to an 85% economic interest in any future payments, which includes royalties and milestone payments, made by GSK under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC by Innoviva (the “GSK Agreements”). We have determined TRC to be a variable interest entity that is not consolidated in our financial statements. The potential importance of TRC to our future financial condition and results of operations is dependent upon the progression of drug candidates covered by the GSK Agreements through development to commercialization and the rate of commercialization for approved drugs covered by the GSK Agreements. We rely on publicly available information about those drug candidates as we do not have access to confidential information regarding their progression or status.

Recent Accounting Pronouncements

The information required by this item is included in Item 8, Note 1, “Organization and Summary of Significant Accounting Policies,” in our consolidated financial statements included in this Annual Report on Form 10 K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. These risks primarily include risk related to interest rate sensitivities.

Interest Rate Sensitivity

We have invested primarily in money market funds, federal agency notes, corporate debt securities, commercial papers and US treasury notes. To reduce the volatility relating to these exposures, we have put investment and risk management policies and procedures in place. The securities in our investment portfolio are not leveraged and are classified as available for sale due to their short term nature. We currently do not engage in hedging activities.

We performed a sensitivity analysis to determine the impact a change in interest rates would have on the value of our investment portfolio. As of December 31, 2018 and 2017, we have estimated that a hypothetical 100 basis point increase in interest rates would have resulted in a decrease in the fair market value of our investment portfolio of \$0.5 million and \$1.8 million, respectively. Such losses would only be realized if we sold the investments prior to maturity.

We are also subject to interest rate sensitivity on our outstanding Convertible Senior 2023 Notes that were issued in November 2016 and our Non-Recourse 2033 Notes that were issued in November 2018. Increases in interest rates would result in a decrease in the fair value of our outstanding debt and decreases in interest rates would result in an increase in the fair value of our outstanding debt. These increases or decreases in the fair value of our outstanding debt would be partially offset by corresponding increases or decreases in our investment portfolio. The Convertible Senior 2023 Notes pay interest semi annually, and the \$230.0 million of principal is scheduled to be repaid in 2023. The

Non-Recourse 2033 Notes pay interest and principal quarterly, and the final payment of the \$237.5 million of net principal is due by 2033.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Theravance Biopharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Theravance Biopharma, Inc. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows, for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated February 28, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2013.

San Jose, California

February 28, 2019

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THERAVANCE BIOPHARMA, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	December 31, 2018	2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 378,021	\$ 88,980
Short-term marketable securities	127,255	259,586
Accounts receivable, net of allowances of \$0 and \$992 at December 31, 2018 and 2017, respectively	620	2,253
Receivables from collaborative arrangements	10,053	7,109
Prepaid taxes	310	291
Other prepaid and current assets	16,564	3,700
Inventories	—	16,830
Total current assets	532,823	378,749
Property and equipment, net	13,176	10,157
Long-term marketable securities	11,869	41,587
Tax receivable	—	8,191
Restricted cash	833	833
Other assets	1,534	1,883
Total assets	\$ 560,235	\$ 441,400
Liabilities and Shareholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	\$ 9,028	\$ 5,924
Accrued personnel-related expenses	23,803	24,136
Accrued clinical and development expenses	11,876	20,657
Other accrued liabilities	10,445	11,710
Deferred revenue	43,402	125
Total current liabilities	98,554	62,552
Convertible senior notes due 2023, net	224,818	223,746
Non-recourse notes due 2033, net	229,535	—
Deferred rent	7,976	3,668
Long-term deferred revenue	26,179	1,436
Other long-term liabilities	24,762	34,820
Commitments and contingencies (Notes 2, 11, and 13)		
Shareholders' (Deficit) Equity		
Preferred shares, \$0.00001 par value: 230 shares authorized, no shares issued or outstanding at December 31, 2018 and 2017, respectively	—	—
Ordinary shares, \$0.00001 par value: 200,000 shares authorized; 55,681 and 54,381 shares issued and outstanding at December 31, 2018 and 2017,	1	1

respectively

Additional paid-in capital	960,721	913,650
Accumulated other comprehensive loss	(166)	(733)
Accumulated deficit	(1,012,145)	(797,740)
Total shareholders' (deficit) equity	(51,589)	115,178
Total liabilities and shareholders' (deficit) equity	\$ 560,235	\$ 441,400

See accompanying notes to consolidated financial statements

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THERAVANCE BIOPHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Year Ended December 31,		
	2018	2017	2016
Revenue:			
Product sales	\$ 15,304	\$ 14,788	\$ 17,603
Collaboration revenue	41,791	598	31,045
Profit sharing revenue	3,275	—	—
Total revenue	60,370	15,386	48,648
Costs and expenses:			
Cost of goods sold	715	6,030	2,894
Research and development (1)	201,348	173,887	141,712
Selling, general and administrative (1)	97,058	95,592	84,509
Total costs and expenses	299,121	275,509	229,115
Loss from operations	(238,751)	(260,123)	(180,467)
Income from investment in TRC, LLC (Note 7)	11,182	170	—
Interest expense	(10,482)	(8,547)	(1,404)
Other-than-temporary impairment loss	—	(8,000)	—
Interest and other income, net	11,966	4,789	1,312
Loss before income taxes	(226,085)	(271,711)	(180,559)
Provision for income tax benefit (expense) (Note 12)	10,561	(13,694)	(10,110)
Net loss	\$ (215,524)	\$ (285,405)	\$ (190,669)
Net loss per share:			
Basic and diluted net loss per share	\$ (3.99)	\$ (5.45)	\$ (4.26)
Shares used to compute basic and diluted net loss per share	53,969	52,352	44,711

(1) Amounts include share-based compensation expense as follows:

(In thousands)	Year Ended December 31,		
	2018	2017	2016
Research and development	\$ 25,563	\$ 22,691	\$ 20,202
Selling, general and administrative	25,750	26,454	20,967
Total share-based compensation expense	\$ 51,313	\$ 49,145	\$ 41,169

See accompanying notes to consolidated financial statements.

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THERAVANCE BIOPHARMA, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,		
	2018	2017	2016
Net loss	\$ (215,524)	\$ (285,405)	\$ (190,669)
Other comprehensive income (loss):			
Net unrealized gain (loss) on available-for-sale investments, net of tax	567	(480)	(183)
Comprehensive loss	\$ (214,957)	\$ (285,885)	\$ (190,852)

See accompanying notes to consolidated financial statements.

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THERAVANCE BIOPHARMA, INC.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)

(In thousands)

	Ordinary Shares		Additional	Other	Comprehensive Accumulated	Total
	Shares	Amount	Paid-In Capital	Comprehensive Income (Loss)	Deficit	Shareholders' Equity (Deficit)
Balances at December 31, 2015	37,981	\$ —	\$ 564,691	\$ (70)	\$ (321,556)	\$ 243,065
Net proceeds from sale of ordinary shares	11,978	1	253,027	—	—	253,028
Proceeds from ESPP purchases	245	—	3,172	—	—	3,172
Employee share-based compensation expense	—	—	41,290	—	—	41,290
Issuance of restricted shares	2,466	—	—	—	—	—
Option exercises	197	—	4,378	—	—	4,378
Repurchase of shares to satisfy tax withholding	(34)	—	(3,871)	—	—	(3,871)
Excess tax benefit of share-based compensation	—	—	21	—	—	21
Net unrealized loss on marketable securities	—	—	—	(183)	—	(183)
Net loss	—	—	—	—	(190,669)	(190,669)
Balances at December 31, 2016	52,833	1	862,708	(253)	(512,225)	350,231
Net proceeds from sale of ordinary shares	—	—	1	—	—	1
Proceeds from ESPP purchases	250	—	3,980	—	—	3,980
Employee share-based compensation expense	—	—	49,175	—	—	49,175
Issuance of restricted shares	1,025	—	—	—	—	—
Option exercises	276	—	6,236	—	—	6,236
Cumulative effect upon the adoption of ASU 2016-09	—	—	110	—	(110)	—
Repurchase of shares to satisfy tax withholding	(3)	—	(8,560)	—	—	(8,560)
Net unrealized loss on marketable securities	—	—	—	(480)	—	(480)
Net loss	—	—	—	—	(285,405)	(285,405)

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Balances at						
December 31, 2017	54,381	1	913,650	(733)	(797,740)	115,178
Proceeds from ESPP						
purchases	204	—	4,173	—	—	4,173
Employee share-based						
compensation expense	—	—	51,313	—	—	51,313
Issuance of restricted shares	1,168	—	—	—	—	—
Option exercises	75	—	1,393	—	—	1,393
Cumulative effect upon the						
adoption of ASC 606	—	—	—	—	1,119	1,119
Repurchase of shares to						
satisfy tax withholding	(147)	—	(9,808)	—	—	(9,808)
Net unrealized gain on						
marketable securities	—	—	—	567	—	567
Net loss	—	—	—	—	(215,524)	(215,524)
Balances at						
December 31, 2018	55,681	\$ 1	\$ 960,721	\$ (166)	\$ (1,012,145)	\$ (51,589)

See accompanying notes to consolidated financial statements.

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THERAVANCE BIOPHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2018	2017	2016
Operating activities			
Net loss	\$ (215,524)	\$ (285,405)	\$ (190,669)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,166	4,027	3,119
Share-based compensation	51,313	49,145	41,169
Net gain from the sale of VIBATIV business	(6,056)	—	—
Other-than-temporary impairment loss	—	8,000	—
Inventory write-down	—	740	303
Excess tax benefits from share-based compensation	—	—	(21)
Undistributed earnings from investment in TRC, LLC	(5,152)	—	—
Other	(43)	10	182
Changes in operating assets and liabilities:			
Accounts receivable	1,633	(1,607)	1,276
Receivables from collaborative arrangements	(2,944)	1,967	26,156
Prepaid taxes	—	2,788	9,522
Other prepaid and current assets	(2,400)	(1,489)	2,710
Inventories	(1,629)	(7,301)	(3,182)
Tax receivable	8,191	(7,890)	—
Other assets	45	(354)	184
Accounts payable	3,575	3,796	(16,436)
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	(10,516)	8,353	17,192
Deferred rent	4,308	(298)	(632)
Deferred revenue	69,224	17	448
Other long-term liabilities	(10,058)	24,449	9,690
Net cash used in operating activities	(112,867)	(201,052)	(98,989)
Investing activities			
Purchases of property and equipment	(7,240)	(2,406)	(2,135)
Purchases of marketable securities	(183,261)	(288,791)	(237,567)
Maturities of marketable securities	347,192	234,864	91,467
Proceeds from the sale of VIBATIV business, net	20,000	—	—
Proceeds from the sales of fixed assets	17	—	—
Net cash provided by (used in) investing activities	176,708	(56,333)	(148,235)
Financing activities			
Proceeds from sale of ordinary shares, net	—	—	253,028

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Proceeds from issuance of notes, net	229,441	—	222,498
Proceeds from ESPP purchases	4,173	3,980	3,172
Proceeds from option exercises	1,393	6,236	4,378
Excess tax benefits from share-based compensation	—	—	21
Repurchase of shares to satisfy tax withholding	(9,807)	(8,560)	(3,871)
Net cash provided by financing activities	225,200	1,656	479,226
Net increase (decrease) in cash, cash equivalents, and restricted cash	289,041	(255,729)	232,002
Cash, cash equivalents, and restricted cash at beginning of period	89,813	345,542	113,540
Cash, cash equivalents, and restricted cash at end of period	\$ 378,854	\$ 89,813	\$ 345,542
Supplemental disclosure of cash flow information			
Cash paid for interest	\$ 7,475	\$ 7,454	\$ —
Cash (received) paid for income taxes, net	\$ (7,316)	\$ 4,929	(9,488)

See accompanying notes to consolidated financial statements.

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THERAVANCE BIOPHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

Theravance Biopharma, Inc. (“Theravance Biopharma” or the “Company”) is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines to improve the lives of patients suffering from serious illnesses.

Basis of Presentation

The Company’s consolidated financial statements have been prepared in conformity with US Generally Accepted Accounting Principles (“GAAP”), and the US Securities and Exchange (“SEC”) regulations for annual reporting.

Principles of Consolidation

The consolidated financial statements include the accounts of Theravance Biopharma and its wholly-owned subsidiaries, all of which are denominated in US dollars. All intercompany balances and transactions have been eliminated in consolidation.

Use of Management’s Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. On an ongoing basis, management evaluates its significant accounting policies or estimates. Management based its estimates on historical experience and other relevant assumptions that it believes to be reasonable under the circumstances. These estimates also form the basis for making judgments about the carrying values of assets and liabilities when these values are not readily apparent from other sources.

Segment Reporting

The Company operates in a single segment, which is the discovery (research), development and commercialization of human therapeutics. The Company’s business offerings have similar economics and other characteristics, including the nature of products and manufacturing processes, types of customers, distribution methods and regulatory environment. The Company is comprehensively managed as one business segment by the Company’s Chief Executive Officer and the management team. Product sales are attributed to regions based on ship to location and revenue from collaborative arrangements, including royalty revenue, are attributed to regions based on the location of the collaboration partner. Revenue from profit sharing arrangements are attributed to the geographic market in which the products are sold. Capitalized property and equipment is predominantly located in the US.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with a maturity of three months or less on the date of purchase to be cash equivalents. Cash equivalents are carried at fair value.

Restricted Cash

Under certain lease agreements and letters of credit, the Company has pledged cash and cash equivalents as collateral. As of December 31, 2018 and 2017, restricted cash related to such agreements was \$0.8 million.

Investments in Marketable Securities

The Company invests in marketable securities, primarily corporate notes, government, government agency, and municipal bonds. The Company classifies its marketable securities as available for sale securities and reports them at

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fair value in cash equivalents or marketable securities on the consolidated balance sheets with related unrealized gains and losses included as a component of shareholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income on the consolidated statements of operations. Realized gains and losses and declines in value judged to be other than temporary, if any, on available for sale securities are included in interest and other income (loss). The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available for sale are included in interest income.

The Company regularly reviews all of its investments for other than temporary declines in estimated fair value. The Company's review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that the Company will be required to sell the securities before the recovery of their amortized cost basis. When the Company determines that the decline in estimated fair value of an investment is below the amortized cost basis and the decline is other than temporary, the Company reduces the carrying value of the security and records a loss for the amount of such decline.

Fair Value of Financial Instruments

The Company defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The Company's valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect the Company's market assumptions. The Company classifies these inputs into the following hierarchy:

Level 1 — Quoted prices for identical instruments in active markets.

Level 2 — Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 — Unobservable inputs and little, if any, market activity for the assets.

Financial instruments include cash equivalents, marketable securities, non-marketable securities, accounts receivable, accounts payable, accrued liabilities, and debt. The Company's cash equivalents and marketable securities are carried at estimated fair value and remeasured on a recurring basis. The carrying value of accounts receivable, receivables from collaborative arrangements, accounts payable, and accrued liabilities approximate their estimated fair value due to the relatively short term nature of these instruments.

Accounts Receivable

Trade accounts receivable are recorded net of allowances for wholesaler chargebacks related to government rebate programs, cash discounts for prompt payment, distribution fees, and sales discounts. Estimates for wholesaler chargebacks for government rebates and cash discounts are based on contractual terms, historical trends and the Company's expectations regarding the utilization rates for these programs. When appropriate, the Company provides for an allowance for doubtful accounts by reserving for specifically identified doubtful accounts. For the periods presented, the Company did not have any material write offs of trade accounts receivable. The Company performs periodic credit evaluations of its customers and generally does not require collateral.

On November 12, 2018, the Company completed the sale of its assets related to the manufacture, marketing and sale of the VIBATIV product to Cumberland Pharmaceuticals Inc. ("Cumberland") pursuant to the Asset Purchase Agreement dated November 1, 2018. As a result, the remaining accounts receivable balance at December 31, 2018 related to product sales recognized prior to November 12, 2018.

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Concentration of Credit Risks

The Company invests in a variety of financial instruments and, by its policy, limits the amount of credit exposure with any one issuer, industry or geographic area for investments other than instruments backed by the US federal government.

Inventories

Inventories consist of raw materials, work in process and finished goods related to the production of VIBATIV. Raw materials include VIBATIV active pharmaceutical ingredient (“API”) and other raw materials. Work in process and finished goods include third party manufacturing costs and labor and indirect costs the Company incurred in the production process. Included in inventories are raw materials and work in process that may be used as clinical products, which are charged to research and development (“R&D”) expense when consumed. In addition, under certain prior commercialization agreements, the Company sold VIBATIV packaged in unlabeled vials that were recorded in work in process. Inventories are stated at the lower of cost or net realizable value. The Company determines the cost of inventory using the average cost method for each manufacturing batch.

The Company assesses its inventory levels each reporting period and writes down inventory that is expected to be at risk for expiration, that has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. In evaluating the sufficiency of its inventory reserves or liabilities for firm purchase commitments, the Company also takes into consideration its firm purchase commitments for future inventory production. If the Company were to decide to cancel its manufacturing commitment, such cancellation would trigger the payment of a cancellation fee. If the Company projects to have excess inventories and that it would be more cost-efficient to pay the cancellation fee, it may accrue the cancellation fee as a liability. The Company’s assessment of excess inventories, including future firm purchase commitments, requires management to utilize judgement in formulating estimates and assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates and assumptions.

When the Company recognizes a loss on such inventory or firm purchase commitments, it establishes a new, lower cost basis for that inventory, and subsequent changes in facts and circumstances will not result in the restoration or increase in that newly established cost basis. If inventory with a lower cost basis is subsequently sold, it will result in higher gross margin for those sales. In 2017, the Company recognized a charge of \$3.0 million arising from excess inventory of which \$2.25 million was attributed to an expected purchase obligation at the time. In 2018, the Company reversed the expense related to the \$2.25 million purchase obligation due to the waiver of its minimum purchase commitment by the third-party manufacturer.

As a result of the VIBATIV sale to Cumberland in November 2018, the Company did not have any inventory as of December 31, 2018.

Property and Equipment

Property, equipment and leasehold improvements are stated at cost, net of accumulated depreciation and depreciated using the straight line method as follows:

Leasehold improvements	Shorter of remaining lease terms or useful life
Equipment, furniture and fixtures	5 - 7 years
Software and computer equipment	3 - 5 years

Capitalized Software

The Company capitalizes certain costs related to direct material and service costs for software obtained for internal use. For the year ended December 31, 2017, the Company capitalized costs for the implementation of its new procurement software system of \$0.5 million. Upon being placed in service, these costs and other future capitalizable costs related to the internal use software system integration will be depreciated over five years. There was no additional capitalized software costs recorded for the year ended December 31, 2018.

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Impairment of Long Lived Assets

Long lived assets include property and equipment. The carrying value of long lived assets is reviewed for impairment whenever events or changes in circumstances indicate that the asset may not be recoverable. An impairment loss is recognized when the total of estimated future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount.

Deferred Rent

Deferred rent consists of the difference between cash payments and the recognition of rent expense on a straight line basis for the buildings the Company occupies. Rent expense is recognized ratably over the life of the leases. Because the Company's facility operating leases provide for rent increases over the terms of the leases, average annual rent expense during the initial years of the leases exceeded the Company's actual cash rent payments. Also included in deferred rent are lease incentives which are being recognized ratably over the life of the leases.

Revenue Recognition

Prior to January 1, 2018, the Company recognized revenue under Accounting Standards Codification ("ASC"), Topic 605, Revenue Recognition ("ASC 605"). Under ASC 605, revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Where the revenue recognition criteria was not met, the Company delayed the recognition of revenue by recording deferred revenue until such time that all criteria are met.

Effective January 1, 2018, the Company adopted ASC, Topic 606, Revenue from Contracts with Customers ("ASC 606") using the modified retrospective method. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, an entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company identifies the performance obligations in the contract by assessing whether the goods or services promised within each contract are distinct. The Company then recognizes revenue for the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. The Company recorded a reduction to the opening balance of accumulated deficit of approximately \$1.1 million and a corresponding reduction in deferred revenue as of January 1, 2018 due to ASC 606's cumulative adoption impact on the Company's collaborative arrangements. The Company's revenue recognized in 2018 would not have been materially different under ASC 605 as compared to ASC 606.

Product Sales

On November 12, 2018, the Company completed the sale of its assets related to the manufacture, marketing and sale of the VIBATIV product to Cumberland pursuant to the Asset Purchase Agreement dated November 1, 2018. Up until that date, the Company sold VIBATIV in the US market by making the drug product available through a limited number of distributors, who sold VIBATIV to healthcare providers. Title and risk of loss transferred upon receipt by these distributors. The Company recognized VIBATIV product sales and related cost of product sales when the distributors obtained control of the drug product, which was at the time title transferred to the distributors.

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The Company recorded sales on a net sales basis which includes estimates of variable consideration. The variable consideration results from sales discounts, government mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. The Company reflected such reductions in revenue as either an allowance to the related account receivable from the distributor, or as an accrued liability, depending on the nature of the sales deduction. Sales deductions are based on management's estimates that considered payor mix in target markets, industry benchmarks and experience to date. In general, these estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in ASC 606. The Company monitored inventory levels in the distribution channel, as well as sales by distributors to healthcare providers, using product specific data provided by the distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of the Company's agreements with customers, historical product returns of, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. The Company updates its estimates and assumptions each quarter and if actual future results vary from its estimates, the Company may adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment.

Sales Discounts: The Company offers cash discounts to certain customers as an incentive for prompt payment. The Company expects its customers to comply with the prompt payment terms to earn the cash discount. In addition, the Company offers contract discounts to certain direct customers. The Company estimates sales discounts based on contractual terms, historical utilization rates, as available, and its expectations regarding future utilization rates. The Company accounts for sales discounts by reducing accounts receivable by the expected discount and recognizing the discount as a reduction of revenue in the same period the related revenue is recognized.

Chargebacks and Government Rebates: The Company estimates reductions to product sales for qualifying federal and state government programs including discounted pricing offered to Public Health Service ("PHS"), as well as government managed Medicaid programs. The Company's reduction for PHS is based on actual chargebacks that distributors have claimed for reduced pricing offered to such healthcare providers and our expectation about future utilization rates. The Company's accrual for Medicaid is based upon statutorily defined discounts, estimated payor mix, expected sales to qualified healthcare providers, and the Company's expectation about future utilization. The Medicaid accrual and government rebates that are invoiced directly to the Company are recorded in other accrued liabilities on the consolidated balance sheets. For qualified programs that can purchase the Company's products through distributors at a lower contractual government price, the distributors charge back to the Company the difference between their acquisition cost and the lower contractual government price, which the Company records as an allowance against accounts receivable.

Distribution Fees: The Company has contracts with its distributors in the US that include terms for distribution related fees. The Company determines distribution related fees based on a percentage of the product sales price, and it records the distribution fees as an allowance against accounts receivable.

Product Returns: The Company offers its distributors a right to return product purchased directly from the Company, which is principally based upon the product's expiration date. The Company's policy is to accept product returns during

the six months prior to and twelve months after the product expiration date on product that has been sold to its distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of our agreements with customers, historical product returns, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. The Company records its product return reserves as other accrued liabilities.

Allowance for Doubtful Accounts: The Company records allowances for potentially doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. As of December 31, 2018, there was no allowance for doubtful accounts related to trade accounts receivable.

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The following table summarizes activity in each of the product revenue allowance and reserve categories:

(In thousands)	Chargebacks, Discounts and Fees	Government and Other Rebates	Returns	Total
Balance at December 31, 2016	\$ 779	\$ 377	\$ 747	\$ 1,903
Provision related to current period sales	5,193	580	573	6,346
Adjustment related to prior period sales	(127)	75	561	509
Credit or payments made during the period	(4,853)	(680)	(935)	(6,468)
Balance at December 31, 2017	\$ 992	\$ 352	\$ 946	\$ 2,290
Provision related to current period sales	6,402	704	521	7,627
Adjustment related to prior period sales	(81)	168	(449)	(362)
Credit or payments made during the period	(6,938)	(932)	(157)	(8,027)
Balance at December 31, 2018	\$ 375	\$ 292	\$ 861	\$ 1,528

Collaborative Arrangements Under ASC 606 (Effective January 1, 2018)

The Company enters into collaborative arrangements with partners that fall under the scope of ASC, Topic 808, Collaborative Arrangements (“ASC 808”). While these arrangements are in the scope of ASC 808, the Company may analogize to ASC 606 for some aspects of the arrangements. The Company analogizes to ASC 606 for certain activities within the collaborative arrangement for the delivery of a good or service (i.e., a unit of account) that is part of its ongoing major or central operations. Revenue recognized by analogizing to ASC 606 is recorded as “collaboration revenue” whereas, revenue recognized in accordance with ASC 808, is recorded as “profit sharing revenue” in the consolidated statements of operations.

The terms of the Company’s collaborative arrangements typically include one or more of the following: (i) up-front fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; (iii) royalties on net sales of licensed products; (iv) reimbursements or cost-sharing of R&D expenses; and (v) profit/loss sharing arising from co-promotion arrangements. Each of these payments results in collaboration revenues or an offset against R&D expense. Where a portion of non-refundable up-front fees or other payments received is allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as deferred revenue and recognized as collaboration revenue when (or as) the underlying performance obligation is satisfied.

As part of the accounting for these arrangements, the Company must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price may include such estimates as, forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation to determine if they can be satisfied at a point in time or over time, and it measures the services delivered to the collaborative partner which are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated input component and, therefore revenue or expense recognized, would be recorded as a change in estimate.

In addition, variable consideration (e.g., milestone payments) must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Up-front Fees: If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes collaboration revenues from the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing collaboration revenue from the allocated transaction price. For example, when the Company receives up-front fees for the performance of research and development services, or when research and development services are not considered to be distinct from a license, the Company recognizes collaboration revenue for those units of account over time using a measure of progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue or expense recognition as a change in estimate.

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Milestone Payments: At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the collaborative partner's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of milestones that are within its or the collaborative partner's control, such as operational developmental milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and earnings in the period of adjustment. Revisions to the Company's estimate of the transaction price may also result in negative collaboration revenues and earnings in the period of adjustment.

Royalties: For arrangements that include sales-based royalties, including commercial milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any material royalty revenue resulting from any of our collaborative arrangements.

Following the sale of VIBATIV to Cumberland in November 2018, VIBATIV royalties earned from Cumberland are included within "interest and other income, net" on the consolidated statements of operations. In addition, the Company's income earned related to TRELEGY ELLIPTA sales is included within "income from our investment in TRC, LLC" on the consolidated statements of operations.

Reimbursement, cost-sharing and profit-sharing payments: Under certain collaborative arrangements, the Company has been reimbursed for a portion of its R&D expenses or participates in the cost-sharing of such R&D expenses. Such reimbursements and cost-sharing arrangements have been reflected as a reduction of R&D expense in the Company's consolidated statements of operations, as the Company does not consider performing research and development services for reimbursement to be a part of its ongoing major or central operations.

Collaborative Arrangements under ASC 605 (Effective Prior to January 1, 2018)

Revenue from non-refundable, up-front license or technology access payments under license and collaborative arrangements that were not dependent on any future performance by the Company was recognized when such amounts were earned. If the Company had continuing obligations to perform under the arrangement, such fees were recognized over the estimated period of continuing performance obligation.

The Company accounted for multiple element arrangements, such as license and development agreements in which it may have provided several deliverables, in accordance with ASC, Subtopic 605-25, Multiple Element Arrangements. For new or materially amended multiple element arrangements, the Company identified the deliverables at the inception of the arrangement and each deliverable within a multiple deliverable revenue arrangement was accounted for as a separate unit of accounting if both of the following criteria were met: (1) the delivered item or items had value to the customer on a standalone basis and (2) for an arrangement that included a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) was considered probable and substantially in the Company's control. The Company allocated revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, the Company determined the selling price for each deliverable using vendor-specific objective evidence ("VSOE") of selling price, if it existed, or third-party evidence ("TPE") of selling price, if it existed. If neither VSOE nor TPE of selling price existed for a deliverable, the Company used the best estimated selling price for that deliverable. Revenue allocated to each element was then recognized based on when the basic four revenue recognition criteria were met for each element.

Where a portion of non-refundable upfront fees or other payments received were allocated to continuing performance obligations under the terms of a collaborative arrangement, they were recorded as deferred revenue and recognized as revenue ratably over the term of the Company's estimated performance period under the agreement. The

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Company determined the estimated performance periods, and they were periodically reviewed based on the progress of the related program. The effect of any change made to an estimated performance period and, therefore revenue recognized, would occur on a prospective basis in the period that the change was made.

Under certain collaborative arrangements, the Company was reimbursed for a portion of its R&D expenses. These reimbursements were reflected as a reduction of R&D expense in the Company's consolidated statements of operations, as it did not consider performing research and development services to be a customer relationship in the context of those collaborative arrangements. Therefore, the reimbursement of research and development services were recorded as a reduction of R&D expense.

The Company recognized revenue from milestone payments when (i) the milestone event was substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) the Company did not have ongoing performance obligations related to the achievement of the milestone. Milestone payments were considered substantive if all of the following conditions were met: the milestone payment (a) was commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (b) related solely to past performance, and (c) was reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

Research and Development Expenses

Research and development expenses are recorded in the period that services are rendered or goods are received. Research and development expenses consist of salaries and benefits, laboratory supplies and facility costs, as well as fees paid to third parties that conduct certain research and development activities on behalf of the Company, net of certain external research and development expenses reimbursed under the Company's collaborative arrangements.

As part of the process of preparing financial statements, the Company is required to estimate and accrue certain research and development expenses. This process involves the following:

- identifying services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual cost;
- estimating and accruing expenses in the Company's financial statements as of each balance sheet date based on facts and circumstances known to it at the time; and

- periodically confirming the accuracy of the Company's estimates with selected service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that the Company accrues include:

- fees paid to clinical research organizations ("CROs") in connection with preclinical and toxicology studies and clinical studies;

- fees paid to investigative sites in connection with clinical studies;

- fees paid to contract manufacturing organizations ("CMOs") in connection with the production of product and clinical study materials; and

- professional service fees for consulting and related services.

The Company bases its expense accruals related to clinical studies on its estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies on the Company's behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful enrollment

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of patients and the completion of clinical study milestones. The Company's service providers invoice it monthly in arrears for services performed. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the Company does not identify costs that it has begun to incur or if it underestimates or overestimates the level of services performed or the costs of these services, the Company's actual expenses could differ from its estimates.

To date, the Company has not experienced significant changes in its estimates of accrued research and development expenses after a reporting period. Such changes in estimates recorded after a reporting period have been less than 1% of the Company's annual research and development expenses and have not been material. However, due to the nature of estimates, there is no assurance that the Company will not make changes to its estimates in the future as it becomes aware of additional information about the status or conduct of its clinical studies and other research activities. Such changes in estimates will be recognized as research and development expenses in the period that the change in estimate occurs.

Advertising Expenses

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses were \$1.9 million, \$3.2 million and \$2.5 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Fair Value of Share Based Compensation Awards

The Company uses the Black-Scholes-Merton option pricing model to estimate the fair value of options granted under its equity incentive plans and rights to acquire shares granted under its employee share purchase plan ("ESPP"). The Black-Scholes-Merton option valuation model requires the use of assumptions, including the expected term of the award and the expected share price volatility. The Company uses the "simplified" method as described in Staff Accounting Bulletin No. 107, Share Based Payment, to estimate the expected option term.

Share based compensation expense is calculated based on awards ultimately expected to vest and is reduced for actual forfeitures as they occur, as allowed under Accounting Standards Update ("ASU") 2016-09, Compensation—Stock Compensation (Topic 718) ("ASU 2016-09"). Prior to the adoption of ASU 2016-09 on January 1, 2017, forfeitures were estimated at the time of grant and revised, if necessary, in subsequent periods if the actual forfeitures differed from those estimates.

Compensation expense for purchases under the ESPP is recognized based on the fair value of the award on the date of offering.

Amortization of Debt Issuance Costs

Debt issuance costs are amortized to interest expense over the estimated life of the related debt based on the effective interest method.

Theravance Respiratory Company, LLC (“TRC”)

Through its equity ownership of TRC, the Company is entitled to receive an 85% economic interest in any future payments that may be made by Glaxo Group or one of its affiliates (“GSK”) relating to the GSK-Partnered Respiratory Programs (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). The GSK-Partnered Respiratory Programs consist primarily of the Trelegy Ellipta program and the inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (“MABA”) program.

The Company analyzed its ownership, contractual and other interests in TRC to determine if TRC is a variable interest entity (“VIE”), whether the Company has a variable interest in TRC and the nature and extent of that interest. The Company determined that TRC is a VIE. The party with the controlling financial interest, the primary beneficiary, is required to consolidate the entity determined to be a VIE. Therefore, the Company also assessed whether the Company is the primary beneficiary of TRC based on the power to direct its activities that most significantly impact

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its economic performance and the Company's obligation to absorb its losses or the right to receive benefits from it that could potentially be significant to TRC. Based on the Company's assessment, it determined that it is not the primary beneficiary of TRC, and, as a result, the Company does not consolidate TRC in its consolidated financial statements. TRC is recognized in the Company's consolidated financial statements under the equity method of accounting. Income related to the Company's equity ownership of TRC is reflected in its consolidated statement of operations as non-operating income.

Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax basis of assets and liabilities and are measured using enacted tax rates and laws that are anticipated to be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Company's total unrecognized tax benefits of \$52.4 million and \$41.8 million, as of December 31, 2018 and December 31, 2017, respectively, may reduce the effective tax rate in the period of recognition. As of December 31, 2018, the Company does not believe that it is reasonably possible that its unrecognized tax benefit will significantly decrease in the next twelve months. The Company currently has a full valuation allowance against its deferred tax assets, which would impact the timing of the effective tax rate benefit should any of these uncertain positions be favorably settled in the future.

The Company assesses all material positions, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than 50% likely to be realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether the factors underlying the sustainability assertion have changed and whether the amount of the recognized tax benefit is still appropriate.

The recognition and measurement of tax benefits requires significant judgment. The Company has taken certain positions where it believes that its position is greater than 50% likely to be realized upon ultimate settlement and for which no reserve for uncertain tax positions has been recorded. If the Company does not ultimately realize the expected benefit of these positions, it will record additional income tax expenses in future periods. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of outstanding, less ordinary shares subject to forfeiture. Diluted net loss per share is computed by dividing net loss by the

weighted-average number of shares outstanding, less ordinary shares subject to forfeiture, plus all additional ordinary shares that would have been outstanding, assuming dilutive potential ordinary shares had been issued for other dilutive securities.

For the years ended December 31, 2018, 2017 and 2016, diluted and basic net loss per share was identical since potential ordinary shares were excluded from the calculation, as their effect was anti-dilutive.

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Anti dilutive Securities

The following ordinary equivalent shares were not included in the computation of diluted net loss per share because their effect was anti dilutive:

(In thousands)	Year Ended December 31,		
	2018	2017	2016
Share issuances under equity incentive plans and ESPP	3,492	3,369	3,709
Restricted shares	2	6	33
Share issuances upon the conversion of convertible senior notes	6,676	6,676	6,676
Total	10,170	10,051	10,418

In addition, there were 978,750 and 1,305,000 shares that are subject to performance based vesting criteria which have been excluded from the ordinary equivalent shares table above for the years ended December 31, 2018 and 2017, respectively.

Comprehensive Loss

Comprehensive loss is comprised of net loss and changes in unrealized gains and losses on the Company's available-for-sale investments.

Related Parties

GSK owned 17.3% of the Company's ordinary shares outstanding as of December 31, 2018. On March 17, 2016, GSK purchased from the Company 1,301,015 of its ordinary shares for an aggregate purchase price of approximately \$23.0 million pursuant to a Share Purchase Agreement between GSK and the Company dated March 14, 2016. The Share Purchase Agreement was entered into pursuant to Section 2.1(d)(ii) of the Governance Agreement between GSK and the Company dated March 3, 2014 (the "Governance Agreement"), which until December 31, 2017 afforded GSK, on a quarterly basis, the opportunity to purchase from the Company ordinary shares sufficient to maintain GSK's Percentage Interest (as defined in the Governance Agreement) at the same level as prior to any exercise of share options and vesting of restricted shares that occurred during the prior quarter, and pursuant to the Company's approval to GSK to make additional purchases, which approval was required by Section 2.1(a) of the Governance Agreement. The Governance Agreement expired on December 31, 2017.

Robert V. Gunderson, Jr. is a member of the Company's board of directors. The Company has engaged Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, of which Mr. Gunderson is a partner, as its primary legal counsel. Fees incurred were \$0.5 million, \$0.3 million, and \$1.1 million for the years ended December 31, 2018, 2017,

and 2016, respectively.

Dr. Smaldone Alsup is a member of the Company's board of directors and is also the Chief Operating Officer and Chief Scientific Officer of NDA Group. The Company engaged NDA Group in 2017 to perform consulting services related to the regulatory plans for one of the Company's drug candidates. There were no fees incurred for the year ended December 31, 2018 and \$0.1 million in fees incurred for the year ended December 31, 2017.

Recently Adopted Accounting Pronouncements

Effective January 1, 2018, the Company adopted ASC, Topic 606, Revenue from Contracts with Customers ("ASC 606") using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018 and recognized the cumulative effect of ASC 606 at the date of initial application. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. The Company recorded a reduction to the opening balance of accumulated deficit of approximately \$1.1 million and a corresponding reduction in deferred revenue as of January 1, 2018 due to ASC 606's cumulative adoption impact on its collaborative arrangements. The Company's product sales

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revenue under ASC 606 would not have been materially different under the legacy Accounting Standards Codification, Topic 605, Revenue Recognition (“ASC 605”).

Effective January 1, 2018, the Company adopted ASU 2016-16, Income Taxes (Topic 740), Intra-Entity Transfers of Assets Other Than Inventory (“ASU 2016-16”) using the modified retrospective approach. ASU 2016-16 requires immediate recognition of income tax consequences of intra-company asset transfers, other than inventory transfers. Legacy GAAP prohibited recognition of income tax consequences of intra-company asset transfers whereby the seller defers any net tax effect and the buyer is prohibited from recognizing a deferred tax asset on the difference between the newly created tax basis of the asset in its tax jurisdiction and its financial statement carrying amount as reported in the consolidated financial statements. An example of an inter-company asset transfers included in ASU 2016-16’s scope is intellectual property. The adoption of ASU 2016-16 did not have a material impact on the Company’s balance sheet or statement of operations as its deferred tax assets are fully offset by a valuation allowance.

Effective January 1, 2018, the Company adopted ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (“ASU 2016-18”) that changed the presentation of restricted cash and cash equivalents on the consolidated statements of cash flows. Restricted cash balances are now included with cash and cash equivalents when reconciling the beginning of period and end of period total amounts shown on the consolidated statements of cash flows. To conform to the presentation under ASU 2016-18, the Company revised the amounts previously reported on the consolidated statements of cash flows for the comparable prior year periods.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the Financial Accounting Standards Board (“FASB”) issued ASU 2016 02, Leases (Topic 842) (“ASU 2016 02”). ASU 2016 02 is aimed at making leasing activities more transparent and comparable, and requires leases with terms greater than one year to be recognized by lessees on their balance sheet as a right of use asset and corresponding lease liability. ASU 2016 02 is effective for all interim and annual reporting periods beginning after December 15, 2018, with early adoption permitted, and is required to be adopted using a modified retrospective approach. In July 2018, the FASB issued supplemental adoption guidance that allows for an optional transition method to initially account for the impact of the adoption with a cumulative adjustment to accumulated deficit on the effective date of ASU 2016-02, January 1, 2019, rather than applying the transition provisions in the earliest period presented.

Based on the Company’s assessment of ASU 2016-02, it elected the optional transition method described above and a package of practical expedients that allows entities to not (i) reassess whether any expired or existing contracts are considered or contain leases; (ii) reassess the lease classification for any expired or existing leases; and (iii) reassess initial direct costs for any existing leases. In addition, the Company elected other practical expedients that allow entities to (iv) use hindsight in determining the term of a lease when the lease includes an option to extend the lease term; (v) exclude all leases, on a go forward basis, that have a lease term of 12-month or less; and (vi) combine lease and non-lease components (e.g., office common area maintenance expenses) when recognizing a lease on an entity’s balance sheet on a go forward basis.

The Company will adopt ASU 2016-02 in January 2019, and the Company has substantially completed the evaluation of its existing lease arrangements in order to determine the full impact that the adoption of ASU 2016-02 will have on its balance sheet, financial statement disclosures, and related internal controls. The most significant impact to the Company's balance sheet upon adoption will be from recognizing a right-of-use asset and corresponding lease liability related to its office leases in South San Francisco and Dublin, Ireland. The Company currently anticipates that it will record a right-to-use asset and corresponding lease liability ranging between appropriately \$47 million to \$50 million. Based on the review of the Company's existing lease arrangements, ASU 2016-02 will not have a material impact on the Company's results of operations or cash flows.

In May 2017, the FASB issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting (“ASU 2017-09”). ASU 2017-09 was issued to provide clarity and reduce both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, Compensation—Stock Compensation, to a change to the terms or conditions of a share-based payment award. The amendments in ASU 2017-09 provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification

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accounting in Topic 718. Essentially, an entity will not have to account for the effects of a modification if: (1) the fair value of the modified award is the same immediately before and after the modification; (2) the vesting conditions of the modified award are the same immediately before and after the modification; and (3) the classification of the modified award as either an equity instrument or liability instrument is the same immediately before and after the modification. The amendments in ASU 2017-09 will become effective for the Company as of January 1, 2019. Early adoption is permitted, including adoption in any interim period. The adoption of this guidance is not expected to have a material impact upon the Company's consolidated financial statements and related disclosures.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. The Company anticipates its first presentation of changes in stockholders' equity as required under the new SEC guidance will be included in its Form 10-Q for the three month period ending March 31, 2019.

The Company has evaluated other recently issued accounting pronouncements and does not believe that any of these pronouncements will have a material impact on its consolidated financial statements and related disclosures.

2. Collaborative Arrangements

Revenues from Collaboration and Profit Sharing Arrangements

The Company recognized collaboration revenue as follows:

(In thousands)	Year Ended December 31,		
	2018	2017	2016
Janssen	\$ 31,053	\$ —	\$ —
Alfasigma	10,678	—	—
Mylan	24	102	15,102
R-Pharm	32	491	109
Takeda Pharmaceuticals	—	—	15,075
Various VIBATIV collaborative partners	4	5	259
Other	—	—	500
Total collaboration revenue	\$ 41,791	\$ 598	\$ 31,045

In addition, the Company recognized \$3.3 million in profit sharing revenue from its YUPELRI™ (revefenacin) collaborative arrangement with Mylan for the year ended December 31, 2018.

Under the legacy revenue guidance ASC 605, the Company's collaboration revenue for the year ended December 31, 2018 would not have differed materially.

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Changes in Deferred Revenue Balances

The Company recognized the following revenue from collaborative arrangements as a result of changes in its deferred revenue balance during the periods below:

(In thousands)	Year Ended December 31, 2018
Collaboration revenue recognized in the period from:	
Amounts included in deferred revenue at the beginning of the period	\$ 130
Performance obligations satisfied in the previous period	—

Janssen Biotech

In February 2018, the Company entered into a global co-development and commercialization agreement with Janssen Biotech, Inc. (“Janssen”) for TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease (the “Janssen Agreement”). Under the terms of the Janssen Agreement, the Company received an upfront payment of \$100.0 million. The Company has dosed first patients a Phase 2 (DIONE) study in Crohn's disease and initiated sites in the registrational Phase 2b/3 (RHEA) induction and maintenance study in ulcerative colitis. Following completion of the Phase 2 Crohn's study and the Phase 2b induction portion of an ulcerative colitis study, Janssen can elect to obtain an exclusive license to develop and commercialize TD-1473 and certain related compounds by paying us a fee of \$200.0 million. Upon any such election, the Company and Janssen will jointly develop and commercialize TD-1473 in inflammatory intestinal diseases and share profits in the US and expenses related to a potential Phase 3 program (67% to Janssen; 33% to Theravance Biopharma). The Company would receive royalties on ex-US sales at double-digit tiered percentage royalty rates, and the Company would be eligible to receive up to an additional \$700.0 million in development and commercialization milestone payments from Janssen.

The Janssen Agreement is considered to be within the scope of ASC 808, as the parties are active participants and exposed to the risks and rewards of the collaborative activity. The Company evaluated the terms of the Janssen Agreement and have analogized to ASC 606 for the research and development activities to be performed through the initial Phase 2 development period of the collaborative arrangement that are considered to be part of the Company's ongoing major or central operations. Using the concepts of ASC 606, the Company has identified research and development activities as its only performance obligation. The Company further determined that the transaction price under the arrangement was the \$100.0 million upfront payment which was allocated to the single performance obligation.

The \$900.0 million in future potential payments is considered variable consideration if Janssen elects to remain in the collaboration arrangement following completion of certain Phase 2 activities, as described above and, as such, was not included in the transaction price, as the potential payments were all determined to be fully constrained under ASC 606. As part of the Company's evaluation of this variable consideration constraint, it determined that the potential

payments are contingent upon developmental and regulatory milestones that are uncertain and are highly susceptible to factors outside of its control. The Company expects that any consideration related to royalties and sales-based milestones will be recognized when the subsequent sales occur.

For the year ended December 31, 2018, the Company recognized \$31.1 million as revenue from collaboration arrangements related to the Janssen Agreement. The remaining transaction price of \$68.9 million was recorded in deferred revenue on the consolidated balance sheets and is expected to be recognized as collaboration revenue as the research and development services are delivered over the Phase 2 development period. Collaboration revenue is recognized for the research and development services based on a measure of the Company's efforts toward satisfying the performance obligation relative to the total expected efforts or inputs to satisfy the performance obligation (e.g., costs incurred compared to total budget). For the year ended December 31, 2018, the Company incurred \$38.6 million in research and development costs related to the Janssen Agreement. In future reporting periods, the Company will reevaluate the Company's estimates related to its efforts towards satisfying the performance obligation and may record a change in estimate if deemed necessary.

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Alfasigma

Development and Collaboration Agreement

Under an October 2012 development and collaboration agreement for velusetrag, the Company and Alfasigma S.p.A (“Alfasigma”) agreed to collaborate in the execution of a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis (a medical condition consisting of a paresis (partial paralysis) of the stomach, resulting in food remaining in the stomach for a longer time than normal) (the “Alfasigma Agreement”). As part of the Alfasigma Agreement, Alfasigma funded the majority of the costs associated with the Phase 2 gastroparesis program, which consisted of a Phase 2 study focused on gastric emptying and a Phase 2 study focused on symptoms. Alfasigma had an exclusive option to develop and commercialize velusetrag in the European Union (“EU”), Russia, China, Mexico and certain other countries, while the Company retained full rights to velusetrag in the US, Canada, Japan and certain other countries.

In April 2018, Alfasigma exercised its exclusive option to develop and commercialize velusetrag, and the Company elected not to pursue further development of velusetrag. As a result, the Company is transferring global rights for velusetrag to Alfasigma under the terms of the existing collaboration agreement. The Company received a \$10.0 million option exercise fee and a \$1.0 million non-refundable reimbursement from Alfasigma, and the Company is eligible to receive future potential development, regulatory and sales milestone payments of up to \$26.8 million, and tiered royalties on global net sales ranging from high single digits to the mid-teens.

The Alfasigma Agreement is considered to be within the scope of ASC 808, as the parties are active participants and exposed to the risks and rewards of the collaborative activity. The Company has historically received reimbursements related to R&D services performed under the Alfasigma Agreement. Performing R&D services for reimbursement is considered to be a collaborative activity under the scope of ASC 808. Reimbursable program costs are accounted for as reductions to R&D expense. For this unit of account, the Company does not recognize revenue or analogize to ASC 606 and, as such, the reimbursable program costs are excluded from the transaction price.

As a result of Alfasigma’s election to exercise its exclusive option to develop and commercialize velusetrag in April 2018, Alfasigma paid the Company a total of \$11.0 million, comprised of the \$10.0 million option exercise fee and the \$1.0 million non-refundable reimbursement. The Company analogized to ASC 606 for the delivery of the following identified performance obligations: (i) delivery of the velusetrag license; (ii) transfer of technical know-how; (iii) delivery of clinical study reports (“CSRs”); (iv) delivery of registration batches, including drug substances; and (v) joint steering committee participation. The Company determined that all of the five performance obligations were distinct, and it allocated the transaction price based on the estimated stand-alone selling prices of each of the performance obligations. The stand-alone selling price of the license was based on a discounted cash flow approach and considered several factors including, but not limited to: discount rate, development timeline, regulatory risks, estimated market demand and future revenue potential.

The Company determined that any potential development or regulatory milestones were to be fully constrained as prescribed under ASC 606. As part of its evaluation of this variable consideration constraint, the Company determined

that the potential payments are contingent upon developmental and regulatory milestones that are uncertain and are highly susceptible to factors outside of the Company's control. In addition, the Company expects that any consideration related to sales-based milestones would be recognized when the subsequent sales occur.

For the year ended December 31, 2018, the Company recognized \$10.7 million as revenue from collaboration arrangements related to the Alfasigma Agreement. As of December 31, 2018, \$0.3 million was recorded in deferred revenue on the consolidated balance sheets and is expected to be recognized as collaboration revenue over approximately the next four years.

Mylan

Development and Commercialization Agreement

In January 2015, the Company and Mylan Ireland Limited ("Mylan") established a strategic collaboration (the "Mylan Agreement") for the development and commercialization of revefenacin, including YUPELRI inhalation

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solution. The Company entered into the collaboration to expand the breadth of its revefenacin development program and extend its commercial reach beyond the acute care setting.

Under the Mylan Agreement, Mylan paid the Company an up-front fee of \$15.0 million for the delivery of the revefenacin license in 2015 and, in 2016, Mylan paid the Company a milestone payment \$15.0 million for the achievement of 50% enrollment in the Phase 3 twelve-month safety study. Separately, pursuant to an agreement to purchase ordinary shares entered into on January 30, 2015, Mylan Inc., a subsidiary of Mylan N.V., made a \$30.0 million equity investment in the Company, buying 1,585,790 ordinary shares from the Company in February 2015 in a private placement transaction at a price of approximately \$18.918 per share, which represented a 10% premium, equal to \$4.2 million, over the volume weighted average price per share of the Company's ordinary shares for the five trading days ending on January 30, 2015.

As of December 31, 2018, the Company is eligible to receive from Mylan additional potential development, regulatory and sales milestone payments totaling up to \$205.0 million in the aggregate, with \$160.0 million associated with YUPELRI monotherapy, and \$45.0 million associated with future potential combination products. Of the \$160.0 million associated with monotherapy, \$150.0 million relates to sales milestones based on achieving certain levels of net sales and \$10.0 million relates to regulatory actions in the EU.

The Mylan Agreement is considered to be within the scope of ASC 808, as the parties are active participants and exposed to the risks and rewards of the collaborative activity. Under the terms of the Mylan Agreement, Mylan was responsible for reimbursement of the Company's costs related to the registrational program up until the approval of the first new drug application in November 2018. Performing R&D services for reimbursement is considered to be a collaborative activity under the scope of ASC 808. Reimbursable program costs are recognized proportionately with the performance of the underlying services and accounted for as reductions to R&D expense. For this unit of account, the Company did not recognize revenue or analogize to ASC 606 and, as such, the reimbursable program costs are excluded from the transaction price.

The Company analogized to ASC 606 for the accounting for two performance obligations: (1) delivery of the license to develop and commercialize revefenacin; and (2) joint steering committee participation. The Company determined the license to be distinct from the joint steering committee participation. The Company further determined that the transaction price under the arrangement was comprised of the following: (1) \$15.0 million up-front license fee received in 2015; (2) \$4.2 million premium related to the ordinary share purchase agreement received in 2015; and (3) \$15.0 million milestone for 50% enrollment in the Phase 3 twelve-month safety study received in 2016. The total transaction price of \$34.2 million was allocated to the two performance obligations based on the Company's best estimate of the relative stand-alone selling price. For the delivery of the license, the Company based the stand-alone selling price on a discounted cash flow approach and considered several factors including, but not limited to: discount rate, development timeline, regulatory risks, estimated market demand and future revenue potential. For the committee participation, the Company based the stand-alone selling price on the average compensation of its committee members estimated to be incurred over the performance period. The Company expects to recognize collaboration revenue from the committee participation ratably over the performance period of approximately seventeen years.

The future potential milestone amounts were not included in the transaction price, as they were all determined to be fully constrained following the concepts of ASC 606. As part of the Company's evaluation of the development and regulatory milestones constraint, the Company determined that the achievement of such milestones are contingent upon success in future clinical trials and regulatory approvals which are not within its control and uncertain at this stage. The Company expects that the sales-based milestone payments and royalty arrangements will be recognized when the sales occur or the milestone is achieved. The Company will re-evaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur.

As of December 31, 2018, \$0.3 million was recorded in deferred revenue on the consolidated balance sheets under the Mylan Agreement. This amount reflects revenue allocated to joint steering committee participation and will be recognized as collaboration revenue over the course of the remaining performance period of approximately fourteen years. For the year ended December 31, 2018, the Company recognized \$24,000 in collaboration revenue from the recognition of previously deferred revenue under the Mylan collaborative arrangement.

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The Company is also entitled to a share of US profits and losses (65% to Mylan; 35% to Theravance Biopharma) received in connection with commercialization of YUPELRI, and the Company is entitled to low double-digit royalties on ex-US net sales (excluding China). Mylan is the principal in the sales transactions, and as a result, the Company will not reflect the product sales in its financial statements. Net amounts payable to or receivable from Mylan each quarter under the profit sharing structure are disaggregated according to their individual components. The reimbursement received from Mylan for the Company's R&D expense is characterized as a reduction of R&D expense, as the Company does not consider performing research and development services for reimbursement to be a part of its ongoing major or central operations. For the year ended December 31, 2018, the Company recorded \$7.5 million as a reduction to R&D expense comprised of \$4.5 million related to registrational activities conducted in support of the NDA and \$3.0 million related to the YUPELRI profit sharing payments receivable from Mylan which were attributed to R&D services. There were no reductions to R&D expense related to such profit sharing payments for the year ended December 31, 2017.

If in any reporting period, the arrangement results in a receivable from Mylan after the Company's R&D expenses have been reimbursed, then such a receivable is recognized as profit sharing revenue. For the year ended December 31, 2018, the Company recorded \$3.3 million as collaboration profit sharing revenue related to profit sharing payments receivable from Mylan. There was no collaboration profit sharing revenue for the year ended December 31, 2017. If in any reporting period, the arrangement results in a payable to Mylan after the Company's R&D expenses have been reimbursed, then such payments are recognized as collaboration expenses within operating expenses.

Takeda Pharmaceuticals

License and Collaboration Agreement

In June 2016, the Company entered into a License and Collaboration Agreement with Millennium Pharmaceuticals, Inc., a Delaware corporation ("Millennium") (the "Takeda Agreement"), in order to establish a collaboration for the development and commercialization of TD-8954 (TAK-954), a selective 5-HT₄ receptor agonist. Millennium is an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (TSE: 4502), a publicly-traded Japanese corporation listed on the Tokyo Stock Exchange (collectively with Millennium, "Takeda").

Under the terms of the Takeda Agreement, Takeda is responsible for worldwide development and commercialization of TD-8954. The Company received an upfront cash payment of \$15.0 million and will be eligible to receive success based development, regulatory and sales milestone payments by Takeda. The Company will also be eligible to receive a tiered royalty on worldwide net sales by Takeda at percentage royalty rates ranging from low double-digits to mid-teens.

The Takeda Agreement was finalized in the third quarter of 2016, and the Company recognized \$15.1 million in revenue for the year ended December 31, 2016.

Reimbursement of R&D Costs

The following table summarizes the reductions to R&D expenses related to reimbursement payments:

(In thousands)	Year Ended December 31,		
	2018	2017	2016
Mylan	\$ 7,515	\$ 23,427	\$ 83,490
Janssen	1,597	—	—
Alfasigma	—	—	7,113
Other	—	113	134
Total reduction to R&D expense	\$ 9,112	\$ 23,540	\$ 90,737

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3. Sale of VIBATIV

On November 12, 2018, the Company completed the sale of its assets related to the manufacture, marketing and sale of VIBATIV to Cumberland Pharmaceutical Inc. (“Cumberland”) pursuant to the Asset Purchase Agreement dated November 1, 2018 (the “APA”). At the closing of the transaction, the Company received \$20.0 million in cash. Pursuant to the terms of the APA, an additional \$5.0 million in cash will be paid by the Cumberland to the Company on or before April 1, 2019. In addition, the Company is entitled to receive tiered royalties of up to 20% of US net sales of VIBATIV until such time as royalties cumulatively total \$100.0 million.

In connection with the closing of the transaction, Cumberland acquired, among other things, (i) intellectual property rights relating to VIBATIV, (ii) active pharmaceutical ingredient for VIBATIV, work-in-process and finished drug product, (iii) the US marketing authorization for VIBATIV, (iv) certain assigned contracts relating to the manufacture and commercialization of VIBATIV, and (v) books and records related to VIBATIV. Cumberland also assumed certain clinical study obligations related to VIBATIV and certain post-closing liabilities and obligations as described in the APA.

The Company retained financial responsibility for any liabilities relating to products sold prior to the closing of the transaction, and Cumberland assumed financial responsibility for any liabilities relating to products sold on or after the closing of the transaction. The Company has agreed to provide transition services to Cumberland for limited periods of time following the closing of the transaction. The Company has also agreed for a limited period not to engage in specified activities that would compete with the manufacture, marketing and sale of VIBATIV.

The Company recognized a net gain of approximately \$6.1 million upon the sale of VIBATIV within “interest and other income, net” on the consolidated statements of operations. The Company will record the royalties receivable from future US net sales by Cumberland within other income. Transition-related costs of approximately \$1.1 million were recognized concurrently and included as a reduction to the net gain on the sale.

4. Segment Information

The Company operates in a single segment, which is the discovery (research), development and commercialization of human therapeutics. The following table summarizes total revenue by geographic region:

(In thousands)	Year Ended December 31,		
	2018	2017	2016
US	\$ 49,239	\$ 14,272	\$ 33,179
Europe	11,117	1,109	15,211
Asia	14	5	254
Other	—	—	4

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Total revenue \$ 60,370 \$ 15,386 \$ 48,648

The following table summarizes total revenue from each of the Company's customers or collaboration partners who individually accounted for 10% or more of the Company's total revenue (as a percentage of total revenues) during the most recent three years:

(% of total revenue)	Year Ended		
	December 31,		
	2018	2017	2016
Janssen	51 %	—	—
Alfasigma	18 %	—	—
Cardinal Health	—	28 %	—
AmerisourceBergen Drug Corp.	—	25 %	—
McKesson Corp.	—	23 %	—
Besse Medical	—	13 %	—
Mylan	—	—	31 %
Takeda	—	—	31 %

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5. Cash, Cash Equivalents, and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheets that sum to the total of the same such amount shown on the consolidated statements of cash flows.

(In thousands)	December 31,	
	2018	2017
Cash and cash equivalents	\$ 378,021	\$ 88,980
Restricted cash	833	833
Total cash, cash equivalents, and restricted cash shown on the consolidated statements of cash flows	\$ 378,854	\$ 89,813

6. Investments and Fair Value Measurements

Available-for-Sale Securities

The estimated fair value of marketable securities is based on quoted market prices for these or similar investments that were based on prices obtained from a commercial pricing service. The fair value of marketable securities classified within Level 2 is based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including market research publications.

Available-for-sale securities are summarized below:

(In thousands)		December 31, 2018			
		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
US government securities	Level 1	\$ 48,807	\$ —	\$ (86)	\$ 48,721
US government agency securities	Level 2	9,852	2	—	9,854
Corporate notes	Level 2	57,508	6	(88)	57,426
Commercial paper	Level 2	90,919	—	—	90,919
Marketable securities		207,086	8	(174)	206,920
Money market funds	Level 1	294,751	—	—	294,751
Total		\$ 501,837	\$ 8	\$ (174)	\$ 501,671

December 31, 2017

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(In thousands)		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
US government securities	Level 1	\$ 89,896	\$ —	\$ (342)	\$ 89,554
US government agency securities	Level 2	50,891	—	(113)	50,778
Corporate notes	Level 2	141,226	2	(280)	140,948
Commercial paper	Level 2	19,893	—	—	19,893
Marketable securities		301,906	2	(735)	301,173
Money market funds	Level 1	69,055	—	—	69,055
Total		\$ 370,961	\$ 2	\$ (735)	\$ 370,228

As of December 31, 2018, all of the available-for-sale securities had contractual maturities within two years and the weighted average maturity of marketable securities was approximately four months. There were no transfers between Level 1 and Level 2 during the periods presented, and there have been no changes to the Company's valuation techniques during the years ended December 31, 2018 and 2017.

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In general, the Company invests in debt securities with the intent to hold such securities until maturity at par value. The Company does not intend to sell the investments that are currently in an unrealized loss position, and it is unlikely that it will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. The Company has determined that the gross unrealized losses on its marketable securities, as of December 31, 2018, were temporary in nature and primarily due to increases in short-term interest rates in the capital markets. There were no material unrealized losses on investments which have been in a loss position for more than twelve months as of December 31, 2018.

As of December 31, 2018, the Company's accumulated other comprehensive loss on its consolidated balance sheets consisted of net unrealized losses on available-for-sale investments. During the years ended December 31, 2018 and 2017, the Company did not sell any of its marketable securities.

Non-Marketable Equity Securities and Other-Than-Temporary Impairment

In September 2015, the Company and Trek Therapeutics, PBC ("TREKtx") entered into a licensing agreement (the "TREKtx Agreement") granting TREKtx an exclusive worldwide license for the development, manufacturing, use, marketing and sale of the Company's NS5A inhibitor known as TD-6450 as a component in combination hepatitis C virus ("HCV") products (the "HCV Products"). Pursuant to the TREKtx Agreement, the Company received an upfront payment of \$8.0 million in the form of TREKtx's Series A preferred stock and would be eligible to receive future royalties based on net sales of the HCV Products. TREKtx is solely responsible for all future costs associated with the supply, manufacture, development, sale and marketing of the licensed compound.

At the date of the acquisition of the investment, the Company estimated the fair value of the consideration received to be \$8.0 million based upon the price of similar Series A preferred stock that TREKtx sold to an independent third-party for cash consideration. The Company accounted for this investment using the cost method of accounting and recorded it in other investments on the Company's consolidated balance sheets. The Company is not considered to be the primary beneficiary of TREKtx and therefore, does not consolidate the financial results of the company into its financial statements. The Company's equity investments is reviewed at least annually for impairment or whenever events or changes in circumstances indicate that the carrying value of the investment might not be recoverable.

During 2017, the Company identified indicators of impairment were present for its investment in TREKtx. The Company concluded that the impairment of this investment was other-than-temporary due to TREKtx's challenges in securing additional funding and, as a result, the Company recorded an impairment charge. Due to the uncertainty in the recovery of the investment, the Company recorded an impairment charge for the full carrying value of the investment. The \$8.0 million other-than-temporary impairment charge was reported as "Other-than-temporary impairment loss" on the consolidated statements of operations for the year ended December 31, 2017. As the inputs utilized for the assessment were not based on observable market data, the determination of fair value of this cost-method investment was classified within Level 3 of the fair value hierarchy. To determine the fair value of this investment, the Company used all available financial information related to the investee, including liquidity, rate of cash use, and ability to secure additional funding.

7. Theravance Respiratory Company, LLC ("TRC")

Prior to the June 2014 spin-off from Innoviva, Inc. (the "Spin-Off"), the Company's former parent company, Innoviva, Inc. ("Innoviva"), assigned to TRC, a Delaware limited liability company formed by Innoviva, its strategic alliance

agreement with GSK and all of its rights and obligations under its collaboration agreement with GSK other than with respect to RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® and vilanterol monotherapy. Through the Company's 85% equity interests in TRC, the Company is entitled to receive an 85% economic interest in any future payments made by GSK under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). The drug programs assigned to TRC include Trelegy Ellipta and the MABA program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid ("ICS"), and any other product or combination of products that may be discovered and developed in the future under the GSK agreements.

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In May 2014, the Company entered into the TRC LLC Agreement with Innoviva that governs the operation of TRC. Under the TRC LLC Agreement, Innoviva is the manager of TRC, and the business and affairs of TRC are managed exclusively by the manager, including (i) day to day management of the drug programs in accordance with the existing GSK agreements; (ii) preparing an annual operating plan for TRC; and (iii) taking all actions necessary to ensure that the formation, structure and operation of TRC complies with applicable law and partner agreements. The Company is responsible for its proportionate share of TRC's administrative expenses incurred by Innoviva.

The Company analyzed its ownership, contractual and other interests in TRC to determine if it is a variable interest entity ("VIE"), whether the Company has a variable interest in TRC and the nature and extent of that interest. The Company determined that TRC is a VIE. The party with the controlling financial interest, the primary beneficiary, is required to consolidate the entity determined to be a VIE. Therefore, the Company also assessed whether it is the primary beneficiary of TRC based on the power to direct TRC's activities that most significantly impact TRC's economic performance and its obligation to absorb TRC's losses or the right to receive benefits from TRC that could potentially be significant to TRC. Based on the Company's assessment, the Company determined that it is not the primary beneficiary of TRC, and, as a result, the Company does not consolidate TRC in its consolidated financial statements. TRC is recognized in the Company's consolidated financial statements under the equity method of accounting, and the value of the Company's equity investment in TRC was \$5.4 million and \$0.2 million as of December 31, 2018 and 2017, respectively. These amounts are comprised of undistributed earnings from the Company's investment in TRC which are recorded within "other prepaid and current assets" on the consolidated balance sheets. Pursuant to the TRC operating agreement, the cash from the TRELEGY ELLIPTA royalties, net of any expenses, is distributed to the equity holders quarterly.

For the years ended December 31, 2018 and 2017, the Company recognized \$11.2 million and \$0.2 million, respectively, in income from its investment in TRC which was generated by royalty payments from GSK to TRC arising from the net sales of Trelegy Ellipta.

8. Long-Term Debt

Long-term debt consists of the following liability components:

(In thousands)	December 31,	
	2018	2017
3.25% Convertible notes due 2023		
Principal amount	\$ 230,000	\$ 230,000
Unamortized debt issuance costs	(5,182)	(6,254)
9.0% Non-recourse notes due 2033		
Principal amount, net of 5% retained by the Company	237,500	—
Unamortized debt issuance costs	(7,965)	—
Total long-term debt	\$ 454,353	\$ 223,746

Long-term debt interest expense consists of the following components:

(In thousands)	Year Ended December 31,		
	2018	2017	2016
Stated coupon interest	\$ 9,316	\$ 7,475	\$ 1,225
Amortization of debt issuance costs	1,166	1,072	179
Total long-term debt interest expense	\$ 10,482	\$ 8,547	\$ 1,404

3.25% Convertible Senior Notes Due 2023

In November 2016, the Company completed an underwritten public offering of \$230.0 million of 3.25% convertible senior notes, due 2023 (the "Convertible Senior 2023 Notes") for net proceeds of approximately \$222.5 million. The Company incurred approximately \$7.5 million in debt issuance costs, which are being amortized to interest expense over the estimated life of the Convertible Senior 2023 Notes. The Convertible Senior 2023 Notes bear an annual

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interest rate of 3.25%, payable semi-annually in arrears, on November 1 and May 1 of each year, which commenced on May 1, 2017.

The Convertible Senior 2023 Notes are senior unsecured obligations and rank senior in right of payment to any of the Company's indebtedness that is expressly subordinated in right of payment to the Convertible Senior 2023 Notes; equal in right of payment to any of the Company's indebtedness that is not so subordinated; effectively junior in right of payment to any of the Company's secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of the Company's subsidiaries.

The Convertible Senior 2023 Notes will mature on November 1, 2023, unless earlier redeemed or repurchased by the Company or converted. Holders may convert their Convertible Senior 2023 Notes into ordinary shares at an initial conversion rate of 29.0276 shares for each \$1,000 principal amount of Convertible Senior 2023 Notes, which is equivalent to an initial conversion price of approximately \$34.45 per share, subject to adjustment, in certain circumstances (including upon the occurrence of a fundamental change), at any time prior to the close of business on the second business day immediately preceding the maturity date. Upon the occurrence of a fundamental change involving the Company, holders of the Convertible Senior 2023 Notes may require the Company to repurchase all or a portion of their Convertible Senior 2023 Notes for cash at a redemption price equal to 100% of the principal amount of the Convertible Senior 2023 Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. In addition, in some circumstances, the conversion rate of the Convertible Senior 2023 Notes will increase with a make whole premium for conversions in connection with certain fundamental changes.

The debt issuance costs related to the Convertible Senior 2023 Notes offering were capitalized as deferred financing costs and presented as a reduction of the carrying value of the financial liability on the Company's consolidated balance sheets at December 31, 2018 and 2017.

The estimated fair value of the Convertible Senior 2023 Notes was \$235.0 million and \$251.0 million at December 31, 2018 and 2017, respectively. The estimated fair value was primarily based upon the underlying price of Theravance Biopharma's publicly traded shares and other observable inputs as of December 31, 2018 and 2017. The inputs to determine fair value of the Convertible Senior 2023 Notes are categorized as Level 2 inputs. Level 2 inputs include quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

9.0% Non-Recourse Notes Due 2033

In November 2018, the Company entered into note purchase agreements relating to the private placement of \$250.0 million aggregate principal amount of 9.0% non-recourse notes, due on or before 2033 (the "Non-Recourse 2033 Notes") issued by the Company's wholly-owned subsidiary, Triple Royalty Sub LLC (the "Issuer"). The Issuer was formed in October 2018 and is governed as a special purpose bankruptcy remote entity under Delaware law by the Amended and Restated Limited Liability Agreement, dated as of November 30, 2018, entered into by Theravance Biopharma R&D, Inc., a wholly-owned subsidiary of the Company, as the initial sole equity member of the Issuer.

The Non-Recourse 2033 Notes are secured by all of the Issuer's right, title and interest as a holder of certain membership interests (the "Issuer Class C Units") in TRC. The primary source of funds to make payments on the Non-Recourse 2033 Notes will be the 63.75% economic interest of the Issuer (evidenced by the Issuer Class C Units)

in any future payments made by GSK under the collaboration agreement, dated as of November 14, 2002, by and between Innoviva, Inc. and GSK, as amended from time to time (net of the amount of cash, if any, expected to be used in TRC LLC pursuant to the TRC LLC Agreement over the next four fiscal quarters) relating to the Trelegy Ellipta program. The sole source of principal and interest payments for the Non-Recourse 2033 Notes are the future royalty payments generated from the TRELEGY ELLIPTA program, and as a result, the holders of the Non-Recourse 2033 Notes have no recourse against the Company even if the TRELEGY ELLIPTA payments are insufficient to cover the principal and interest payments for the Non-Recourse 2033 Notes.

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The Non-Recourse 2033 Notes are not convertible into Company equity and have no security interest in nor rights under any agreement with GSK. The Non-Recourse 2033 Notes may be redeemed at any time prior to maturity, in whole or in part, at specified redemption premiums. The Non-Recourse 2033 Notes bear an annual interest rate of 9.0%, with interest and principal paid quarterly beginning April 15, 2019. Prior to October 15, 2020, in the event that the distributions received by the Issuer from TRC in a quarter is less than the interest accrued for the quarter, the principal amount of the Non-Recourse 2033 Notes will increase by the interest shortfall amount for that period. Since the principal and interest payments on the Non-Recourse 2033 Notes are ultimately based on royalties from Trelegy ELLIPTA product sales, which will vary from quarter to quarter, the Non-Recourse 2033 Notes may be repaid prior to the final maturity date in 2033.

In order to comply with Regulation RR – Credit Risk Retention (17 C.F.R. Part 246), 5% of the principal amount of the Non-Recourse 2033 Notes were retained by Theravance Biopharma R&D, Inc. and eliminated in the Company’s consolidated financial statements. Excluding the \$12.5 million of retained Non-Recourse 2033 Notes and other fees related to the transaction, net proceeds of the offering were approximately \$229.4 million. The Company incurred approximately \$8.1 million in debt issuance costs, which were capitalized as deferred financing costs and are being amortized to interest expense over the estimated life of the Non-Recourse 2033 Notes.

The estimated fair value of the Non-Recourse 2033 Notes, net, was \$237.5 million at December 31, 2018. The inputs to determine fair value of the Non-Recourse 2033 Notes are categorized as Level 2 inputs. Level 2 inputs include quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

9. Inventories

As a result of the VIBATIV sale to Cumberland in November 2018, the Company did not have any inventory as of December 31, 2018. Inventory as of December 31, 2017 consisted of the following:

(In thousands)	December 31, 2017
Raw materials	\$ 11,729
Work-in-process	66
Finished goods	5,035
Total inventories	\$ 16,830

10. Property and Equipment

Property and equipment are held predominantly in the US and consist of the following:

(In thousands)	December 31,	
	2018	2017
Computer equipment	\$ 2,522	\$ 1,866
Software	3,577	3,432
Furniture and fixtures	3,759	3,759

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Laboratory equipment	31,164	28,371
Leasehold improvements	21,849	19,444
Subtotal	62,871	56,872
Less: accumulated depreciation	(49,695)	(46,715)
Property and equipment, net	\$ 13,176	\$ 10,157

For the years ended December 31, 2018, 2017 and 2016, depreciation expense for property and equipment was \$3.0 million, \$2.5 million and \$2.2 million, respectively.

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11. Share-Based Compensation

Theravance Biopharma Equity Plans

The Company has three equity compensation plans — its 2013 Equity Incentive Plan (the “2013 EIP”), its 2013 Employee Share Purchase Plan (the “2013 ESPP”) and its 2014 New Employee Equity Incentive Plan (the “2014 NEEIP”). At inception, the Company was authorized to issue 5,428,571 ordinary shares under the 2013 EIP, 857,142 ordinary shares under the 2013 ESPP, and 750,000 ordinary shares under the 2014 NEEIP.

The 2013 EIP provides for the issuance of share-based awards, including restricted shares, restricted share units, options, share appreciation rights (“SARs”) and other equity-based awards, to Company employees, officers, directors and consultants. As of January 1 of each year, commencing on January 1, 2015 and ending on (and including) January 1, 2023, the aggregate number of ordinary shares that may be issued under the 2013 EIP shall automatically increase by a number equal to the least of 5% of the total number of ordinary shares outstanding on December 31 of the prior year, 3,428,571 ordinary shares, or a number of ordinary shares determined by the Company’s board of directors. Options may be granted with an exercise price not less than the fair market value of the ordinary shares on the grant date. Under the terms of the Company’s 2013 EIP, options granted to employees generally have a maximum term of 10 years and vest over a four-year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three years. The Company may grant options with different vesting terms from time to time. Unless an employee’s termination of service is due to disability or death, upon termination of service, any unexercised vested options will generally be forfeited at the end of three months or the expiration of the option, whichever is earlier.

Under the 2013 ESPP, the Company’s officers and employees may purchase ordinary shares through payroll deductions at a price equal to 85% of the lower of the fair market value of the ordinary share at the beginning of the offering period or at the end of each applicable purchase period. As of January 1 of each year, commencing on January 1, 2015 and ending on (and including) January 1, 2033, the aggregate number of ordinary shares that may be issued under the 2013 ESPP shall automatically increase by a number equal to the least of 1% of the total number of ordinary shares outstanding on December 31 of the prior year, 571,428 ordinary shares or a number of ordinary shares determined by the Company’s board of directors. The ESPP generally provides for consecutive and overlapping offering periods of 24 months in duration, with each offering period generally composed of four consecutive six-month purchase periods. The purchase periods end on either May 15 or November 15. ESPP contributions are limited to a maximum of 15% of an employee’s eligible compensation.

The 2013 ESPP also includes a feature that provides for the existing offering period to terminate and for participants in that offering period to automatically be enrolled in a new offering period when the fair market value of an ordinary share at the beginning of a subsequent offering period falls below the fair market value of an ordinary share on the first day of such offering period.

The 2014 NEEIP provides for the issuance of share-based awards, including restricted shares, restricted share units, non-qualified options and SARs, to the Company’s employees. Options may be granted with an exercise price not less than the fair market value of the ordinary shares on the grant date. Under the terms of the 2014 NEEIP, options granted to employees generally have a maximum term of 10 years and vest over a four-year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three years. The Company may grant options with different vesting terms from time to time. Unless an employee’s termination of service is due to disability or death, upon termination of service, any unexercised vested options will generally be forfeited at the end of three months or the expiration of the option, whichever is earlier.

Innoviva’s Equity Plans

Prior to the Spin-Off, the Company's employees may have received Innoviva stock-based compensation awards, and, therefore, the following disclosures include information regarding stock-based compensation expense allocated to Theravance Biopharma that relates to Innoviva stock-based equity awards.

At the time of the Spin-Off, Innoviva had one active stock-based incentive plan under which it granted stock-based awards to employees, officers and consultants, the 2012 Equity Incentive Plan. All outstanding stock options and

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restricted stock units (“RSUs”) held by (1) Innoviva employees who became the Company’s employees, and (2) members of the board of directors of Innoviva who became members of the Company’s board of directors, in connection with the Spin-Off were adjusted for the Spin-Off. Such awards, along with outstanding restricted stock awards (“RSAs”) held by Innoviva employees who became the Company’s employees in connection with the Spin-Off, will continue to vest and remain outstanding based on continuing employment or service with the Company.

The 2012 Equity Incentive Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, stock unit awards and SARs to employees, non-employee directors and consultants. Stock options were granted with an exercise price not less than the fair market value of the common stock on the grant date. Stock options granted to employees generally have a maximum term of 10 years and vest over a four year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three years. However, Innoviva granted options with different vesting terms from time to time. Unless an employee’s termination of service is due to disability or death, upon termination of service, any unexercised vested options will be forfeited at the end of three months or the expiration of the option, whichever is earlier.

Innoviva Performance-Contingent Restricted Stock Awards

In connection with performance-contingent RSAs granted to members of the Company’s senior management by Innoviva’s board of directors prior to the Spin-Off in 2014, the Company recognized \$1.0 million in share-based compensation expense for the year ended December 31, 2016. The expense recognition pertaining to these RSAs was completed in 2016.

Employee Share Option Exchange Program

On August 28, 2015, the Company gave eligible share option holders of the Company and its subsidiaries the opportunity to exchange some or all of their outstanding options granted under the 2013 EIP or the 2014 NEEIP before August 4, 2015, whether vested or unvested, for RSUs (the “Exchange Program”). The Exchange Program was designed to restore the intended employee retention and incentive value of the equity awards.

In accordance with the terms of the Exchange Program, employees who held options that had an exercise price above the market price of the Company’s ordinary shares at the offer expiration date were eligible to exchange two shares subject to eligible options for one RSU granted under the terms of the 2013 EIP. The RSUs granted under the Exchange Program vests over a three or four year service period depending on the grant date of the original option exchanged. The Company’s executive officers and members of the board of directors were not eligible to participate in the Exchange Program.

The Exchange Program closed on September 25, 2015, and the Company exchanged 1,975,009 outstanding options for 987,496 RSUs with a fair value of \$12.43 per share. The exchange of options for RSUs was considered a modification to the terms of the original equity award. As such, the Exchange Program resulted in incremental share-based compensation costs of \$1.4 million to be recognized, concurrently with the unamortized original compensation costs of the exchanged option awards, ratably over the new vesting period of three years. For the years ended December 31, 2018, 2017, and 2016, the Company recognized \$0.3 million, \$0.5 million, and \$0.5 million, respectively, of the \$1.4 million in incremental share-based compensation costs.

Performance-Contingent Awards

In the first quarter of 2016, the Compensation Committee of the Company’s board of directors (“Compensation Committee”) approved the grant of 1,575,000 performance-contingent RSAs and 135,000 performance-contingent restricted share units RSUs to senior management. The vesting of such awards is dependent on the Company meeting

its critical operating goals and objectives during a five-year period from 2016 to December 31, 2020. The goals that must be met in order for the performance-contingent RSAs and RSUs to vest are strategically important for the Company, and the Compensation Committee believes the goals, if achieved, will increase shareholder value. The awards have dual triggers of vesting based upon the achievement of these goals and continued employment. As of December 31, 2018, there were 978,750 of these performance-contingent RSAs and 101,250 of these performance-contingent RSUs

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outstanding, and as of December 31, 2017, there were 1,305,000 performance-contingent RSAs and 135,000 performance-contingent RSUs outstanding.

Expense associated with these awards is broken into three separate tranches and may be recognized during the years 2016 to 2020 depending on the probability of meeting the performance conditions. Compensation expense relating to awards subject to performance conditions is recognized if it is considered probable that the performance goals will be achieved. The probability of achievement is reassessed at each quarter-end reporting period.

The performance conditions associated with the first tranche of these awards were completed in the second quarter of 2018, and the Company recognized \$1.7 million and \$2.6 million of share-based compensation expense for the years ended December 31, 2018 and 2017, respectively, associated with these awards.

For years ended December 31, 2018 and 2017, the Company recognized \$2.6 million and \$6.3 million, respectively, of share-based compensation expense related to its assessment of the probability that the performance conditions associated with the second tranche of these awards was considered to be probable of vesting. As of December 31, 2018, the Company determined that the remaining third tranche was not probable of vesting and, as a result, no compensation expense related to the third tranche has been recognized to date.

The maximum potential expense associated with the remaining second and third tranches could be up to \$17.8 million (allocated as \$7.4 million for research and development expense and \$10.4 million for selling, general and administrative expense) if the performance conditions for the second and third tranches are achieved.

In 2017, the Compensation Committee approved the grant of 50,000 performance-contingent RSUs to a newly appointed member of senior management. The RSUs have dual triggers of vesting based upon the achievement of certain corporate operating milestones in specified timelines, as well as a requirement for continued employment. Share-based compensation expense related to this grant is broken into two separate tranches and recognized when the associated performance goals are deemed to be probable of achievement. The maximum expense associated with the first tranche was \$0.8 million. In 2017, the Company recognized \$0.4 million in share-based compensation expense as it determined that the performance conditions associated with the first tranche were probable of vesting, and in 2018, the Company recognized the remaining \$0.4 million of share-based compensation expense as the performance conditions associated with the first tranche of this award were met. The Company has determined that the second tranche was not probable of vesting as of December 31, 2018 and, as a result, no compensation expense related to the second tranche has been recognized to date.

Share-Based Compensation Expense

The allocation of share-based compensation expense included in the consolidated statements of operations was as follows:

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(In thousands)	Year Ended December 31,		
	2018	2017	2016
Research and development	\$ 25,563	\$ 22,691	\$ 20,202
Selling, general and administrative	25,750	26,454	20,967
Total share-based compensation expense	\$ 51,313	\$ 49,145	\$ 41,169

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Share-based compensation expense included in the consolidated statements of operations by award type was as follows:

(In thousands)	Year Ended December 31,		
	2018	2017	2016
Innoviva equity:			
Options	\$ 280	\$ 2,973	\$ 3,973
RSUs	—	224	1,547
RSAs	457	660	2,597
Performance RSAs	—	1	1,005
Theravance Biopharma equity:			
Options	8,441	7,969	7,591
RSUs	34,077	25,959	20,946
Performance RSAs and RSUs	4,707	9,224	1,808
ESPP	3,351	2,135	1,702
Total share-based compensation expense	\$ 51,313	\$ 49,145	\$ 41,169

Total share-based compensation expense capitalized to inventory was not material for any of the periods presented.

As of December 31, 2018, the unrecognized share-based compensation cost, net of actual forfeitures, and the estimated weighted average amortization period, using the straight-line attribution method, was as follows:

(In thousands, except amortization period)	Unrecognized Compensation Cost	Weighted Average Amortization Period (Years)
Innoviva equity:		
Options	\$ —	—
RSAs	64	0.23
Theravance Biopharma equity:		
Options	18,147	2.84
RSUs	62,718	2.49
Performance RSAs and RSUs (1)	3,604	1.14
ESPP	2,322	1.03
Total	\$ 86,855	

(1) Represents unrecognized share-based compensation cost associated with the Theravance Biopharma performance-contingent awards described above that are probable of vesting.

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Compensation Awards

The following table summarizes option activity under the 2013 EIP and 2014 NEEIP for the years ended December 31, 2018, 2017 and 2016:

	Number of Shares Subject to Outstanding Options	Weighted-Average Exercise Price of Outstanding Options
Outstanding at December 31, 2015	2,311,164	\$ 23.07
Granted	474,675	24.06
Exercised	(197,328)	22.18
Forfeited	(357,716)	19.83
Outstanding at December 31, 2016	2,230,795	\$ 23.88
Granted	720,350	32.60
Exercised	(275,776)	22.61
Forfeited	(166,800)	25.70
Outstanding at December 31, 2017	2,508,569	\$ 26.40
Granted	755,800	27.10
Exercised	(74,692)	18.65
Forfeited	(126,508)	27.95
Outstanding at December 31, 2018	3,063,169	\$ 26.70

As of December 31, 2018, 2017, and 2016, the aggregate intrinsic value of the options outstanding was \$5.1 million, \$8.0 million and \$18.1 million, respectively. As of December 31, 2018, the aggregate intrinsic value of the options exercisable was \$3.9 million. The total estimated fair value of options vested (excluding vested options that have expired) was \$8.4 million, \$8.2 million, and \$7.7 million in 2018, 2017, and 2016, respectively.

The following table summarizes total RSU and RSA activity (including performance RSUs and RSAs) for the years ended December 31, 2018, 2017 and 2016:

	Number of Shares Subject to Outstanding RSUs	Number of Shares Outstanding Subject to Performance Conditions (RSAs)
Outstanding at December 31, 2015	2,988,041	—
Granted	2,344,034	1,575,000
Released	(1,185,905)	—
Forfeited	(537,052)	(135,000)
Outstanding at December 31, 2016	3,609,118	1,440,000
Granted	1,165,578	—
Released	(1,420,485)	—
Forfeited	(456,453)	(135,000)
Outstanding at December 31, 2017	2,897,758	1,305,000
Granted	1,772,263	—
Released	(1,405,294)	(326,250)
Forfeited	(195,324)	—
Outstanding at December 31, 2018	3,069,403	978,750

As of December 31, 2018, the aggregate intrinsic value of the RSUs and RSAs outstanding was \$78.5 million and \$25.0 million, respectively. The total estimated fair value of RSUs vested was \$31.6 million, \$25.1 million, and \$21.4 million in 2018, 2017, and 2016, respectively.

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Valuation Assumptions

The range of assumptions used to estimate the fair value of options granted and rights granted under the 2013 ESPP was as follows:

	Year Ended December 31,		
	2018	2017	2016
Options			
Risk-free interest rate	2.3% - 3.0%	2.0% - 2.1%	1.1% - 1.9%
Expected term (in years)	6.0	6.0	6.0
Volatility	53% - 54%	54% - 56%	53% - 73%
Dividend yield	—	—	—
Weighted-average estimated fair value 2013 ESPP	\$ 14.32	\$ 17.29	\$ 13.28
Risk-free interest rate	2.1% - 2.8%	0.9% - 1.7%	0.4% - 1.0%
Expected term (in years)	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0
Volatility	42% - 53%	41% - 56%	54% - 65%
Dividend yield	—	—	—
Weighted-average estimated fair value	\$ 9.13	\$ 7.09	\$ 9.63

12. Income Taxes

Theravance Biopharma was incorporated in the Cayman Islands in July 2013 under the name Theravance Biopharma, Inc. as a wholly-owned subsidiary of Innoviva and began operations subsequent to the Spin-Off with wholly-owned subsidiaries in the Cayman Islands, US, United Kingdom, and Ireland. Effective July 1, 2015, Theravance Biopharma became an Irish tax resident, therefore, the loss before income taxes of Theravance Biopharma, the parent company, are included in Ireland in the tables below.

The components of the loss before income taxes were as follows:

(In thousands)	Year Ended December 31,		
	2018	2017	2016
Income (loss) before provision for income taxes:			
Cayman Islands	\$ 14,838	\$ (163,770)	\$ (185,099)
United States	(69,695)	(33,374)	(18,441)
Ireland	(171,134)	(74,472)	23,323
United Kingdom	(94)	(95)	(342)
Total	\$ (226,085)	\$ (271,711)	\$ (180,559)

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The components of provision for income tax benefit (expense) were as follows:

(In thousands)	Year Ended December 31,		
	2018	2017	2016
Provision for income tax benefit (expense):			
Current:			
Cayman Islands	\$ —	\$ —	\$ —
United States	10,563	(13,091)	(9,859)
Ireland	—	(566)	(219)
United Kingdom	(2)	(37)	(32)
Subtotal	10,561	(13,694)	(10,110)
Deferred	—	—	—
Total	\$ 10,561	\$ (13,694)	\$ (10,110)
Effective tax rate	4.67 %	(5.04) %	(5.60) %

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The provision for income tax benefit (expense) was \$10.6 million, (\$13.7) million, and (\$10.1) million for the years ended December 31, 2018, 2017, and 2016 respectively.

The 2018 benefit for income taxes was primarily due to additional tax loss generated in 2017 by the US entity as a result of the finalization of transfer pricing policy, current year US research and development credit, and the release of previously recorded contingent tax liabilities due to the lapse of the statute of limitations. The provision for income tax recorded in 2017 and 2016 primarily resulted from contingent tax liabilities related to uncertain tax positions taken with respect to transfer pricing and tax credits.

No provision for income taxes has been recognized on undistributed earnings of the Company's foreign subsidiaries because it considers such earnings to be indefinitely reinvested. In the event of a distribution of these earnings in the form of dividends or otherwise, the Company may be liable for income taxes, subject to an adjustment, if any, for foreign tax credits and foreign withholdings taxes payable to certain foreign tax authorities. As of December 31, 2018, there were no undistributed earnings.

For 2018 and 2017, as a result of the Company becoming an Irish tax resident effective July 1, 2015, the tax rates reflect the Irish statutory rate of 25%. The differences between the Irish statutory income tax rate and the Company's effective tax rates were as follows:

	Year Ended December 31,					
	2018		2017		2016	
Provision at statutory income tax rate	25.00	%	25.00	%	25.00	%
Foreign rate differential	(7.51)		(18.17)		(23.11)	
Share-based compensation	0.28		1.52		(0.27)	
Non-deductible executive compensation	(0.72)		(1.03)		(1.07)	
Uncertain tax positions	(4.00)		(6.55)		(8.55)	
Research and development tax credit carryforwards	1.79		1.21		1.93	
Federal tax reform - Tax rate change	—		(4.66)		—	
Foreign exchange loss	8.52		—		—	
Change in valuation allowance	(18.82)		(5.15)		(0.89)	
Other	0.13		2.79		1.36	
Effective tax rate	4.67	%	(5.04)	%	(5.60)	%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities were as follows:

(In thousands)	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	\$ 33,396	\$ 15,834
Capital loss carryforwards	19,409	—
Research and development tax credit carryforwards	8,508	6,504
Fixed assets and intangibles	285,821	3,746
Share-based compensation	12,479	11,140
Accruals	8,343	5,293

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Other	—	248
Subtotal	367,956	42,765
Valuation allowance	(367,748)	(42,613)
Total deferred tax assets	208	152
Deferred tax liabilities:		
Prepaid assets	(208)	(152)
Total deferred tax liabilities	(208)	(152)
Net deferred tax assets/liabilities	\$ —	\$ —

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Realization of deferred tax assets is dependent upon future taxable income in the respective jurisdictions, if any, the timing and the amount of which are uncertain. Accordingly, the deferred tax assets have been fully offset by a valuation allowance.

On January 1, 2018, the Company adopted ASU 2016-16, Income Taxes (Topic 740), Intra-Entity Transfers of Assets Other Than Inventory (“ASU 2016-16”) using the modified retrospective approach. ASU 2016-16 requires immediate recognition of income tax consequences of intra-company asset transfers, other than inventory transfers. Legacy GAAP prohibited recognition of income tax consequences of intra-company asset transfers whereby the seller defers any net tax effect and the buyer is prohibited from recognizing a deferred tax asset on the difference between the newly created tax basis of the asset in its tax jurisdiction and its financial statement carrying amount as reported in the consolidated financial statements. An example of an inter-company asset transfers included in ASU 2016-16’s scope is intellectual property. On October 2, 2017, Theravance Biopharma R&D, Inc. (Cayman Islands) transferred its economic interests in certain intellectual property to Theravance Biopharma Ireland Limited. The transfer was classified as an intra-company sale of assets for both financial reporting and income tax purposes. The Company recorded a deferred tax asset of \$282.7 million fully offset by a valuation allowance as a result of the sale of intellectual property. The adoption of this pronouncement did not have a material impact on the Company’s balance sheet or statement of operations.

The valuation allowance as of December 31, 2018 increased from \$42.6 million (the valuation allowance as of December 31, 2017) to \$367.7 million, primarily as a result of additional tax loss generated in various jurisdictions during the current year, the transfer of intellectual property to Ireland, and a capital loss carryforward generated in Ireland. Valuation allowances require an assessment of both positive and negative evidence when determining whether it is more likely than not that the deferred tax assets are recoverable. As required, the Company prepares its assessment of the realizability of deferred tax assets on a jurisdiction-by-jurisdiction basis.

As of December 31, 2018, the Company had \$101.8 million of US federal net operating loss carryforwards and \$10.6 million of federal research and development tax credit carryforwards which expire beginning in 2035. After the enactment of the Tax Cut and Jobs Act (the “Tax Act”) in December 2017, the operating losses of \$56.9 million generated in 2018 have an indefinite carryforward life, but are limited to 80% of taxable income when utilized. The Company had state net operating loss carryforwards of \$76.6 million which generally begin to expire in 2034 and state research and development credit carryforwards of \$13.3 million to be carried forward indefinitely.

The Company also had Irish net operating loss carryforwards of \$210.7 million with no expiration date and capital loss carryforwards of \$58.8 million to be carried forward indefinitely.

Utilization of net operating loss and tax credit carryforwards may be subject to an annual limitation due to ownership change limitations provided by the Internal Revenue Code and similar state provisions. Annual limitations may result in expiration of net operating loss and tax credit carryforwards before some or all of such amounts have been utilized.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The amount of tax expense related to interest or penalties was immaterial for the years ended December 31, 2018 and 2017.

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Uncertain Tax Positions

A reconciliation of the beginning and ending balances of the total amounts of unrecognized tax benefits were as follows:

(In thousands)	
Unrecognized tax benefits as of December 31, 2016	\$ 23,254
Gross decrease in tax positions for prior years	(51)
Gross increase in tax positions for current year	18,591
Unrecognized tax benefits as of December 31, 2017	41,794
Gross decrease in tax positions for prior years	(685)
Gross increase in tax positions for current year	11,295
Unrecognized tax benefits as of December 31, 2018	\$ 52,404

The total unrecognized tax benefits of \$52.4 million and \$41.8 million, as of December 31, 2018 and December 31, 2017, respectively, may reduce the effective tax rate in the period of recognition. As of December 31, 2018, the Company does not believe that it is reasonably possible that its unrecognized tax benefit will significantly decrease in the next twelve months. The Company currently has a full valuation allowance against its deferred tax assets, which would impact the timing of the effective tax rate benefit should any of these uncertain positions be favorably settled in the future.

The Company is subject to taxation in Ireland, the US, and various other jurisdictions. The tax years 2015 and forward remain open to examination in Ireland, tax years 2015 and forward remain open to examination in the US, and the tax years 2012 and forward remain open to examination in other jurisdictions.

US Tax Reform

In December 2017, the US government enacted the Tax Act. The Tax Act significantly revises the US corporate income tax laws by, amongst other things, reducing the corporate income tax rate from 35% to 21% and implementing a modified territorial tax system that includes a one-time repatriation tax on accumulated undistributed foreign earnings.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (“SAB 118”), which allowed the Company to record provisional amounts for the Tax Act during a measurement period not to extend beyond one year of the enactment date, with further clarifications made recently with the issuance of amendments to SAB 118. The Company has completed its assessment of the Tax Act and did not have any significant adjustments to its provisional amount of \$12.4 million related to the reduction in the corporate income tax rate from 35% to 21%.

The Company's future income tax expense may be affected by such factors as changes in tax laws, its business, regulations, tax rates, interpretation of existing laws or regulations, the impact of accounting for share-based compensation, the impact of accounting for business combinations, its international organization, shifts in the amount of income before tax earned in the US as compared with other regions in the world, and changes in overall levels of income before tax.

13. Commitments and Contingencies

Operating Leases and Subleases

The Company leases approximately 170,000 square feet of office and laboratory space in two buildings in South San Francisco, California, under a non-cancelable operating lease that ends in May 2030. In addition, the

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Company's Irish subsidiary leases approximately 6,100 square feet of office space in Dublin, Ireland. Future minimum lease payments under the leases, exclusive of executory costs, as of December 31, 2018, are as follows:

(In thousands)	
Years ending December 31:	
2019	\$ 7,817
2020	6,547
2021	9,501
2022	9,766
Thereafter	80,281
Total	\$ 113,912

Rent expense (net of sublease income) and sublease income associated with operating leases were as follows:

	Year Ended December 31,		
(In thousands)	2018	2017	2016
Rent expense, net	\$ 9,965	\$ 7,740	\$ 6,865
Sublease income	\$ 73	\$ 209	\$ 244

Performance-Contingent Awards

In 2016, the Company granted long-term retention RSAs and RSUs to members of senior management and incentive cash bonus awards to certain employees. The vesting and payout of such awards is dependent on the Company meeting its critical operating goals and objectives during a five-year period from 2016 to December 31, 2020. These goals are strategically important for the Company, and it believes the goals, if achieved, will increase shareholder value. The awards have dual triggers of vesting based upon the achievement of these goals and continued employment, and they are broken into three separate tranches.

The Company determined that achievement of the requisite performance conditions for the first tranche were completed as of June 30, 2018. The maximum potential remaining expense associated with the second and third tranches of this program is \$17.8 million related to share-based compensation expense and \$21.0 million related to cash bonus expense, which would be recognized in increments based on achievement of the performance conditions. With the completed achievement of the first tranche's requisite performance conditions and the second tranche being probable due to achievement of certain performance conditions and multiple advancements of programs within the Company's development pipeline, the Company recognized \$4.3 million in share-based compensation expense and \$5.4 million in cash bonus expense for the year ended December 31, 2018. For the year ended December 31, 2017, the Company recognized \$8.9 million in share-based compensation expense and \$18.2 million in cash bonus expense. The Company determined that the remaining third tranche was not probable of vesting and, as a result, no compensation expense related to this tranche has been recognized to date.

Guarantees and Indemnifications

The Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recognized any liabilities relating to these agreements as of December 31, 2018.

14. Subsequent Events

In January 2019, the Company announced a reduction in workforce to align with its focus on continued execution of key strategic programs, and advancement of selected late-stage research programs toward clinical development. The Company reduced its overall headcount by approximately 50 individuals, with the affected employees primarily focused on early research or the infrastructure in support of VIBATIV which was sold by the Company to Cumberland Pharmaceuticals Inc. in November 2018. The workforce reduction is expected to be substantially completed in the first quarter of 2019.

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As a result of the workforce reduction, the Company expects to record severance related charges totaling approximately \$3.5 million to \$4.0 million including compensation expense that will continue to be made to affected employees during any minimum statutory notice periods. A significant majority of the cash payments relating to personnel-related restructuring charges will be paid during the first quarter of 2019.

The charges that the Company expects to incur in connection with the workforce reduction are estimates and subject to a number of assumptions, and actual results may differ materially. The Company may incur additional costs not currently contemplated due to events associated with or resulting from the workforce reduction.

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SUPPLEMENTARY FINANCIAL DATA (UNAUDITED)

(In thousands, except per share data)

The following table presents certain unaudited consolidated quarterly financial information for the eight quarters in the periods ended December 31, 2018 and 2017. This information has been prepared on the same basis as the audited consolidated financial statements and includes all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the unaudited quarterly results of operations set forth herein.

	For the Quarters Ended			
	March 31,	June 30,	September 30,	December 31,
2018				
Total revenue	\$ 8,319	\$ 23,476	\$ 12,838	\$ 15,737
Costs and expenses	73,295	72,180	75,288	78,358
Loss from operations	(64,976)	(48,704)	(62,450)	(62,621)
Net loss	(65,087)	(40,818)	(59,433)	(50,186)
Basic and diluted net loss per share	\$ (1.22)	\$ (0.76)	\$ (1.10)	\$ (0.92)
2017				
Total revenue	\$ 3,087	\$ 3,509	\$ 4,275	\$ 4,515
Costs and expenses	61,916	68,630	61,272	83,691
Loss from operations	(58,829)	(65,121)	(56,997)	(79,176)
Net loss	(65,319)	(66,287)	(66,877)	(86,922)
Basic and diluted net loss per share	\$ (1.27)	\$ (1.27)	\$ (1.27)	\$ (1.64)

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures.

We conducted an evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act as of December 31, 2018, under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined under Rule 13a-15(e) of the Exchange Act), which are controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Principal Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. In connection with the preparation of this Annual Report, our management, including our Chief Executive Officer and Principal Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2018 based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the "COSO criteria"). Based on its assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2018.

The effectiveness of our internal control over financial reporting as of December 31, 2018 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

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Limitations on the Effectiveness of Controls

Our management, including our Chief Executive Officer and Principal Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Theravance Biopharma have been detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act, which occurred during the fourth quarter of the year ended December 31, 2018 which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Theravance Biopharma, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Theravance Biopharma, Inc.'s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Theravance Biopharma, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows, for each of the three years in the period ended December 31, 2018 and related notes and our report dated February 28, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Jose, California

February 28, 2019

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ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

For the information required by this Item, see “Questions and Answers About Procedural Matters”, “Election of Directors”, “Nominees”, “Audit Committee”, “Meetings of the Board of Directors”, “Code of Conduct”, “Executive Officers” “Section 16(a) Beneficial Ownership Reporting Compliance” in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

For the information required by this Item, see “Director Compensation”, “Executive Compensation” and “Compensation Committee Interlocks and Insider Participation” in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

For the information required by this Item, see “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

For the information required by this Item, see “Director Independence” and “Policies and Procedures for Related Party Transactions” in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

For the information required by this Item, see “Ratification of the Appointment of Independent Registered Public Accounting Firm” and “Pre Approval of Audit and Non Audit Services” in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)The following documents are filed as part of this Annual Report on Form 10 K:

1. Financial Statements:

The following financial statements and schedules of the Registrant are contained in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on Form 10 K:

<u>Report of Independent Registered Public Accounting Firm</u>	73
<u>Consolidated Balance Sheets as of December 31, 2018 and 2017</u>	74
<u>Consolidated Statements of Operations for each of the three years in the period ended December 31, 2018</u>	75
<u>Consolidated Statements of Comprehensive Loss for each of the three years in the period ended December 31, 2018</u>	76
<u>Consolidated Statements of Shareholders’ Equity (Deficit) for each of the three years in the period ended December 31, 2018</u>	77
<u>Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2018</u>	78
<u>Notes to Consolidated Financial Statements</u>	79
<u>Supplementary Financial Data (unaudited)</u>	113

2. Financial Statement Schedules:

All schedules have been omitted because of the absence of conditions under which they are required or because the required information, where material, is shown in the financial statements, financial notes or supplementary financial information.

(b)Exhibits required by Item 601 of Regulation S K

The information required by this Item is set forth on the exhibit index that precedes the signature page of this report.

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Exhibit Index

Exhibit Number	Description	Incorporated by Reference	
		Filing Date/Period Form	End Date
2.1	<u>Separation and Distribution Agreement by and between Theravance Biopharma, Inc. and Innoviva, Inc., dated June 1, 2014</u>	8 K	June 3, 2014
2.2*	<u>Asset Purchase Agreement, dated as of November 1, 2018, by and among Cumberland Pharmaceuticals Inc. on the one hand, and Theravance Biopharma Ireland Limited and Theravance Biopharma US, Inc. on the other hand.</u>	8-K	November 16, 2018
3.1	<u>Amended and Restated Memorandum and Articles of Association</u>	10 12B	April 30, 2014
4.1	<u>Specimen Share Certificate</u>	10 12B	April 30, 2014
4.2	<u>Registration Rights Agreement, dated March 3, 2014</u>	10 12B	April 8, 2014
4.3	<u>Form of Rights Agreement by and between Theravance Biopharma, Inc. and Computershare Inc.</u>	10 12B	April 8, 2014
4.4	<u>First Amendment to Rights Agreement by and between Theravance Biopharma, Inc. and Computershare Inc., dated November 10, 2015</u>	8 K	November 10, 2015
4.5	<u>Controlled Equity OfferingSM Sales Agreement, dated June 26, 2015, by and between Theravance Biopharma, Inc. and Cantor Fitzgerald & Co.</u>	S 3	June 26, 2015
4.6	<u>Indenture, dated as of November 2, 2016, between Theravance Biopharma, Inc. and Wells Fargo Bank, National Association, as trustee</u>	8 K	November 2, 2016
4.7	<u>First Supplemental Indenture, dated as of November 2, 2016, between Theravance Biopharma, Inc. and Wells Fargo Bank, National Association, as trustee</u>	8 K	November 2, 2016
4.8	<u>Form of 3.25% Convertible Senior Note due 2023 (included in Exhibit 4.7)</u>	8 K	November 2, 2016
4.9	<u>Indenture, dated as of November 30, 2018, between Triple Royalty Sub LLC, as issuer, and U.S. Bank National Association, as trustee</u>	8 K	December 3, 2018
4.10	<u>Form of 9.0% PhARMA 9% Fixed-Rate Term Notes due 2033 (included in Exhibit 4.9)</u>	8 K	December 3, 2018
10.1	<u>Transition Services Agreement by and between Theravance Biopharma, Inc. and Innoviva, Inc., dated June 2, 2014</u>	8 K	June 3, 2014
10.2	<u>Tax Matters Agreement by and between Theravance Biopharma, Inc. and Innoviva, Inc., dated June 2, 2014</u>	8 K	June 3, 2014
10.3	<u>Employee Matters Agreement by and between Theravance Biopharma, Inc. and Innoviva, Inc., dated June 1, 2014</u>	8 K	June 3, 2014
10.4+	<u>2013 Equity Incentive Plan</u>	S 8	August 18, 2014
10.5+	<u>UK Addendum to the 2013 Equity Incentive Plan</u>	10 Q	August 14, 2014
10.6+	<u>2014 New Employee Equity Incentive Plan</u>	S 8	November 14, 2014
10.7+	<u>2013 Employee Share Purchase Plan, as amended</u>	S 8	Aug. 18, 2014
10.8+	<u>Forms of award agreements under the 2013 Equity Incentive Plan and 2014 New Employee Equity Incentive Plan</u>	10 Q	May 10, 2016
10.9+	<u>Forms of Equity Award Amendment</u>	10 12B	May 7, 2014
10.10+	<u>Form of TFIO Cash Award Amendment</u>	10 12B	May 7, 2014
10.11+	<u>Form of Acknowledgment for Irish Non-Employee Directors</u>	10 K	March 11, 2016

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10.12+	<u>Irish Addendum to the 2013 Equity Incentive Plan</u>	10	K	March 11, 2016
10.13+	<u>Irish Addendum to the 2014 New Employee Equity Incentive Plan</u>	10	K	March 11, 2016
10.14+	<u>UK and Irish Addendums to the 2013 Employee Share Purchase Plan</u>	10	K	March 11, 2016
10.15+	<u>Theravance Biopharma, Inc. Performance Incentive Plan</u>	8	K	May 6, 2016
10.16+	<u>Form of Notice of Option Grant and Option Agreement under the Company's Performance Incentive Plan</u>			November 8,
		10	Q	2017
10.17+	<u>Form of Notice of Performance Restricted Share Unit Award and Restricted Share Unit Agreement under the Company's Performance Incentive Plan</u>			November 8,
		10	Q	2017

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Exhibit Number	Description	Incorporated by Reference	
		Filing Date/Period	Form End Date
	<u>Change in Control Severance Plan</u>		
10.18+		10 12B	April 8, 2014
10.19+	<u>Cash Bonus Program</u>		November 22, 2013
10.20+	<u>Form of Indemnity Agreement</u>	10 12B	April 30, 2014
10.21	<u>Amended and Restated Lease Agreement, 951 Gateway Boulevard, between Innoviva, Inc. and HMS Gateway Office L.P., dated January 1, 2001</u>	10 12B	August 1, 2013
10.22	<u>First Amendment to Lease for 951 Gateway Boulevard effective as of June 1, 2010 between Innoviva, Inc. and ARE 901/951 Gateway Boulevard, LLC</u>	10 12B	August 1, 2013
10.23	<u>Lease Agreement, 901 Gateway Boulevard, between Innoviva, Inc. and HMS Gateway Office L.P., dated January 1, 2001</u>	10 12B	August 1, 2013
10.24	<u>First Amendment to Lease for 901 Gateway Boulevard effective as of June 1, 2010 between Innoviva, Inc. and ARE 901/951 Gateway Boulevard, LLC</u>	10 12B	August 1, 2013
10.25	<u>Consent to Assignment by and among ARE 901/951 Gateway Boulevard, LLC, Innoviva, Inc. and Theravance Biopharma, Inc. and Assignment and Assumption of Lease for 901 Gateway Blvd.</u>	10 Q	August 14, 2014
10.26	<u>Consent to Assignment by and among ARE 901/951 Gateway Boulevard, LLC, Innoviva, Inc. and Theravance Biopharma, Inc. and Assignment and Assumption of Lease for 951 Gateway Blvd.</u>	10 Q	August 14, 2014
10.27	<u>Theravance Respiratory Company, LLC Limited Liability Company Agreement, dated May 31, 2014</u>	8 K	June 3, 2014
10.28*	<u>Technology Transfer and Supply Agreement, dated as of May 22, 2012 between Innoviva, Inc. and Hospira Worldwide, Inc.</u>	10 12B	May 7, 2014
10.29*	<u>First Amendment to the Technology Transfer and Supply Agreement by and between Innoviva, Inc. and Hospira Worldwide, Inc., dated May 16, 2013</u>	10 Q	November 9, 2016
10.30*	<u>Second Amendment to the Technology Transfer and Supply Agreement by and between Theravance Biopharma Antibiotics, Inc. and Hospira Worldwide, Inc., dated October 17, 2014</u>	10 Q	November 9, 2016
10.31*	<u>Third Amendment to the Technology Transfer and Supply Agreement by and between Theravance Biopharma Ireland Limited and Hospira Worldwide, Inc., dated April 14, 2016</u>	10 Q	November 9, 2016
10.32*	<u>Fourth Amendment to the Technology Transfer and Supply Agreement by and between Theravance Biopharma Ireland Limited and Pfizer CentreOne group of Pfizer, Inc., dated September 29, 2016</u>	10 Q	November 9, 2016
10.33	<u>Amendment No. 1 to the License, Development, and Commercialization Agreement by and between Theravance Biopharma Ireland Limited and Clinigen Group PLC dated August 4, 2016</u>	10 Q	August 9, 2016
10.34	<u>License Agreement with Janssen Pharmaceutica, dated as of May 14, 2002</u>	10 Q	August 14, 2014
10.35	<u>Collaboration Agreement between Innoviva, Inc. and Glaxo Group Limited, dated November 14, 2002 (1)</u>		
10.36	<u>Strategic Alliance Agreement by and between Innoviva, Inc. and Glaxo Group Limited, dated March 30, 2004 (2)</u>		
10.37	<u>Amendment to Strategic Alliance Agreement by and between Innoviva, Inc. and Glaxo Group Limited, dated October 3, 2011 (3)</u>		

- 10.38 Collaboration Agreement Amendment by and between Innoviva, Inc. and Glaxo Group Limited dated, March 3, 2014 (4)
- 10.39 Strategic Alliance Agreement Amendment by and between Innoviva, Inc. and Glaxo Group Limited dated, March 3, 2014 (4)
- 10.40 Master Agreement by and between Innoviva, Inc., Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014 (4)

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Exhibit Number	Description	Incorporated by Reference	
		Filing Date/Period Form	End Date
10.41	<u>Extension Agreement by and between the Company and Glaxo Group Limited, dated March 3, 2014</u>	10 12BA	April 8, 2014
10.42	<u>Governance Agreement by and between Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014</u>	10 12BA	April 8, 2014
10.43+	<u>Amended Offer Letter with Rick E Winningham dated August 5, 2014</u>	10 Q	November 12, 2014
10.44+	<u>Offer Letter with Frank Pasqualone May 12, 2014</u>	10 Q	August 14, 2014
10.45+	<u>Offer Letter with Brett K. Haumann dated May 12, 2014</u>	10 Q	August 14, 2014
10.46+	<u>Offer Letter with Renee D. Gala dated May 12, 2014</u>	10 Q	November 12, 2014
10.47+	<u>Offer Letter with Brad Shafer dated August 20, 2014</u>	10 Q	November 12, 2014
10.48+	<u>Offer Letter with Sharath Hegde May 12, 2014</u>	10 Q	May 10, 2016
10.49+	<u>Offer Letter with Ken Pitzer September 15, 2014</u>	10 Q	May 10, 2016
10.50+	<u>Offer Letter with Phil Worboys September 9, 2014</u>	10 Q	May 10, 2016
10.51+	<u>Offer Letter with Shehnaaz Suliman dated May 31, 2017</u>	10 Q	November 8, 2017
10.52*	<u>Development and Commercialization Agreement by and between Theravance Biopharma R&D, Inc. and Mylan Ireland Limited, dated January 30, 2015</u>	8 K/A	April 24, 2015
10.53*	<u>License and Collaboration Agreement by and between Theravance Biopharma Ireland Limited and Millennium Pharmaceuticals, Inc. dated June 8, 2016</u>	10 Q	August 9, 2016
10.54	<u>Form of Note Purchase Agreement, dated November 30, 2018, among Theravance Biopharma R&D, Inc., Triple Royalty Sub LLC, and the note purchasers</u>	8 K	December 3, 2018
10.55	<u>Sale and Contribution Agreement, dated November 30, 2018, among Theravance Biopharma R&D, Inc., as the transferor, Triple Royalty Sub LLC, as the transferee, and Theravance Biopharma, Inc.</u>	8 K	December 3, 2018
10.56	<u>Pledge and Security Agreement, dated November 30, 2018, between Theravance Biopharma R&D, Inc., as the pledgor, and U.S. Bank National Association, as the pledgee</u>	8 K	December 3, 2018
10.57	<u>Servicing Agreement, dated November 30, 2018, between Triple Royalty Sub LLC, as the issuer and Theravance Biopharma R&D, Inc., as the servicer</u>	8 K	December 3, 2018
10.58	<u>Account Control Agreement, dated November 30, 2018, among Triple Royalty Sub LLC, as the issuer, Theravance Biopharma R&D, Inc., as the servicer, U.S. Bank National Association, as the secured party, and U.S. Bank National Association, as the financial institution</u>	8 K	December 3, 2018
10.59	<u>Amended and Restated Limited Liability Company Agreement of Triple Royalty Sub LLC, dated November 30, 2018, by Theravance Biopharma R&D, Inc., as the initial sole equity member, including Annex A — Rules of Construction and Defined Terms, dated November 30, 2018</u>	8 K	December 3, 2018
10.60*	<u>License and Collaboration Agreement by and between Theravance Biopharma Ireland Limited and Janssen Biotech, Inc. dated as of February 5, 2018</u>	10-Q	May 9, 2018
10.61+		10-Q	August 2, 2018

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Memorandum to Brett K. Haumann regarding Transfer to Theravance Biopharma
US, Inc., executed April 5, 2018

10.62	<u>Amendments to Lease for 901 Gateway Boulevard between Theravance Biopharma US, Inc. and ARE-901/951 Gateway Boulevard, LLC</u>	10-Q	August 2, 2018
10.63	<u>Amendments to Lease for 951 Gateway Boulevard between Theravance Biopharma US, Inc. and ARE-901/951 Gateway Boulevard, LLC</u>	10-Q	August 2, 2018
21.1	<u>Subsidiaries of Theravance Biopharma, Inc.</u>		
23.1	<u>Consent of Independent Registered Public Accounting Firm</u>		
24.1	Power of Attorney (see signature page to this Annual Report on Form 10 K)		

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Exhibit Number	Description	Incorporated by Reference Filing Date/Period Form End Date
31.1	<u>Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934</u>	
31.2	<u>Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934</u>	
32	<u>Certifications Pursuant to 18 U.S.C. Section 1350</u>	
101	The following materials from Registrant's Annual Report on Form 10-K for the year ended December 31, 2018, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Shareholders' Equity (Deficit), (v) Consolidated Statements of Cash Flows, and (vi) Notes to Consolidated Financial Statements.	

+Management contract or compensatory plan or arrangement required to be filed pursuant to Item 15(b) of Form 10-K.

*Portions of this exhibit have been omitted and the omitted information has been filed separately with the Securities and Exchange Commission pursuant to an order granting confidential treatment.

(1)Incorporated by reference to an exhibit filed with the quarterly report on Form 10-Q of Innoviva, Inc., filed with the Securities and Exchange Commission on August 7, 2014.

(2)Incorporated by reference to an exhibit filed with the annual report on Form 10-K of Innoviva, Inc., filed with the Commission on March 3, 2014.

(3)Incorporated by reference to an exhibit filed with the annual report on Form 10-K of Innoviva, Inc., filed with the Commission on February 27, 2012.

(4)Incorporated by reference to an exhibit filed with the current report on Form 8-K/A of Innoviva, Inc., filed with the Commission on March 6, 2014.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

THERAVANCE
BIOPHARMA, INC.

Date: February 28, 2019 By: /s/ RICK E WINNINGHAM
Rick E Winningham
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Rick E Winningham as their true and lawful attorney in fact and agent, each with full power of substitution and resubstitution, for such person and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to the annual report on Form 10 K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney in fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she could do in person, hereby ratifying and confirming all that said attorney in fact and agent, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Rick E Winningham	Chairman of the Board and Chief Executive Officer	February 28, 2019
Rick E Winningham	(Principal Executive Officer and Principal Financial Officer)	
/s/ Laurie Smaldone	Director	February 28, 2019

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Alsup, MD

Laurie
Smaldone
Alsup, MD

/s/ Eran Broshy
Director February 28,
Eran Broshy 2019

/s/ Robert V.
Gunderson, Jr. Director February 28,
Robert V. 2019
Gunderson, Jr.

/s/ Donal
O'Connor Director February 28,
Donal 2019
O'Connor

/s/ Burton G.
Malkiel, Ph.D. Director February 28,
Burton G. 2019
Malkiel, Ph.D.

/s/ Dean J.
Mitchell Director February 28,
Dean J. 2019
Mitchell

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Signature	Title	Date
/s/ Susan M. Molineaux, Ph.D.	Director	February 28, 2019
Susan M. Molineaux, Ph.D.		
/s/ Peter S. Ringrose, Ph.D.	Director	February 28, 2019
Peter S. Ringrose, Ph.D.		
/s/ George M. Whitesides, Ph.D.	Director	February 28, 2019
George M. Whitesides, Ph.D.		
/s/ William D. Young	Director	February 28, 2019
William D. Young		