

Theravance Biopharma, Inc.  
Form 10-K  
March 11, 2016

Use these links to rapidly review the document

[Table of Contents](#)

[TABLE OF CONTENTS 2](#)

[TABLE OF CONTENTS 3](#)

[Table of Contents](#)

**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, 2015

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**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**98-1226628**  
(I.R.S. Employer  
Identification No.)

**PO 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**

---

Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 205 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark 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 registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act (Check One):

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

(Do not check if a smaller reporting company)

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, 2015 was \$219,238,494.

On February 29, 2016, there were 38,431,643 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 2016 Annual Meeting of Shareholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2015, 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.

Table of Contents

**THERAVANCE BIOPHARMA, INC.  
2015 Form 10-K Annual Report**

**Table of Contents**

<b><u>PART I</u></b>		
<u>Item 1.</u>	<u>Business</u>	<u>3</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>17</u>
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	<u>42</u>
<u>Item 2.</u>	<u>Properties</u>	<u>42</u>
<u>Item 3.</u>	<u>Legal Proceedings</u>	<u>43</u>
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	<u>43</u>
<b><u>PART II</u></b>		
<u>Item 5.</u>	<u>Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>44</u>
<u>Item 6.</u>	<u>Selected Financial Data</u>	<u>47</u>
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>49</u>
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>66</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>67</u>
<u>Item 9.</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	<u>108</u>
<u>Item 9A.</u>	<u>Controls and Procedures</u>	<u>108</u>
<u>Item 9B.</u>	<u>Other Information</u>	<u>108</u>
<b><u>PART III</u></b>		
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>109</u>
<u>Item 11.</u>	<u>Executive Compensation</u>	<u>109</u>
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>109</u>
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>109</u>
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	<u>109</u>
<b><u>PART IV</u></b>		
<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	<u>110</u>
<u>Signatures</u>		<u>111</u>
<u>Exhibit Index</u>		

Table of Contents

**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, expectations and objectives could be forward-looking statements. The words "aim," "anticipate," "believe," "contemplate," "continue," "could," "designed," "developed," "drive," "estimate," "expect," "goal," "intend," "may," "mission," "opportunities," "plan," "potential," "predict," "project," "pursue," "represent," "seek," "suggest," "should," "target," "will," "would" and 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.*

**PART I**

**ITEM 1. BUSINESS**

**Overview**

Theravance Biopharma, Inc. ("Theravance Biopharma") is a diversified biopharmaceutical company with the core purpose of creating medicines that make a difference in the lives of patients suffering from serious illness.

Our pipeline of internally discovered product candidates includes potential best-in-class medicines to address the unmet needs of patients being treated for serious conditions primarily in the acute care setting. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S., Europe and certain other countries for certain difficult-to-treat infections. Revefenacin (TD-4208) is a long-acting muscarinic antagonist ("LAMA") being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease ("COPD"). Our neprilysin ("NEP") inhibitor program is designed to develop selective NEP inhibitors for the treatment of a range of major cardiovascular and renal diseases, including acute and chronic heart failure, hypertension and chronic kidney diseases such as diabetic nephropathy. Our research efforts are focused in the areas of inflammation and immunology, with the goal of designing medicines that provide targeted drug delivery to tissues in the lung and gastrointestinal tract in order to maximize patient benefit and minimize risk. The first program to emerge from this research is designed to

Table of Contents

develop GI-targeted pan-Janus kinases ("JAK") inhibitors for the treatment of a range of inflammatory intestinal diseases.

In addition, we have an economic interest in future payments that may be made by Glaxo Group Limited or one of its affiliates ("GSK") pursuant to its agreements with Innoviva, Inc. ("Innoviva") (known as Theravance, Inc. prior to January 7, 2016) relating to certain drug development programs, including the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol).

On June 1, 2014, Innoviva separated its late-stage respiratory assets partnered with GSK from its biopharmaceutical operations by transferring its discovery, development and commercialization operations (the "Biopharmaceutical Business") and contributing \$393.0 million of cash, cash equivalents and marketable securities into its then wholly-owned subsidiary Theravance Biopharma. On June 2, 2014, Innoviva made a pro rata dividend distribution to its stockholders of record on May 15, 2014 of one ordinary share of Theravance Biopharma for every three and one half shares of Innoviva common stock outstanding on the record date (the "Spin-Off"). The Spin-Off resulted in Theravance Biopharma operating as an independent, publicly-traded company. Prior to June 2, 2014, Innoviva operated the Biopharmaceutical Business.

Theravance Biopharma was incorporated in the Cayman Islands in July 2013 under the name Theravance Biopharma, Inc. Our corporate address in the Cayman Islands is P.O. Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands and the principal office of our wholly-owned U.S. 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 subsidiary, Theravance Biopharma Ireland, Ltd., is Fitzwilliam Hall, Fitzwilliam Place, Dublin 2 Ireland.

**2015 Highlights**

In 2015, we accomplished a number of key corporate goals. We initiated Phase 1 clinical studies for two potentially best-in-class programs: our Neprilysin ("NEP") inhibitor program for cardiovascular and renal diseases and our GI-targeted pan-Janus kinase ("JAK") inhibitor program for inflammatory intestinal diseases. We initiated all three studies in the Phase 3 program for revefenacin (TD-4208) in COPD and established a strategic collaboration with Mylan Ireland Limited ("Mylan") to develop and commercialize nebulized revefenacin products for COPD and other respiratory diseases. We also continued to execute our commercial strategy for VIBATIV® including the hiring and training of additional field personnel and initiating clinical studies which, if successfully completed, are designed to expand the product's existing label.

**Our Programs**

The table below summarizes the status of our approved product and our most advanced product candidates for internal development or co-development. Our research and development activities are concentrated primarily on four therapeutic areas infectious disease, respiratory, gastrointestinal disease and cardiovascular and renal disease and our commercial infrastructure is focused primarily on the acute care setting. The table also includes the status of the respiratory programs in which we have an economic interest and are being developed by GSK pursuant to agreements between Innoviva and GSK ("GSK-Partnered Respiratory Programs"). These programs consist of the Closed Triple program, the Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist ("MABA") program and other future products that may be combined with Closed Triple or MABA. We have an economic interest in these programs through our interest in Theravance Respiratory Company, LLC ("TRC"), a limited liability company managed by Innoviva. The status of these programs reflects publically available information.

Table of Contents

---

\*

R-Pharm is conducting a Phase 3 clinical study of TD-1792 in complicated skin and soft tissues infections (cSSSI), caused by gram-positive bacteria with clinical sites in the Russian Federation and the country of Georgia.

\*\*

The information regarding the Closed Triple and the 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:**

**CNS:** Central Nervous System;

**COPD:** Chronic Obstructive Pulmonary Disease;

**cSSSI:** Complicated Skin and Skin Structure Infections;

Table of Contents

**FF:** Fluticasone Furoate;

**GI:** Gastrointestinal;

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

**HCV:** Hepatitis C Virus;

**ICS:** Inhaled Corticosteroid;

**MABA:** Bifunctional Muscarinic Antagonist-Beta<sub>2</sub> Agonist;

**MRSA:** Methicillin-Resistant *Staphylococcus Aureus*;

**nOH:** Neurogenic Orthostatic Hypotension;

**OIC:** Opioid Induced Constipation;

**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**

**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. VIBATIV is approved in the U.S. 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. VIBATIV is indicated in the European Union for the treatment of adults with nosocomial pneumonia, including ventilator-associated pneumonia, known or suspected to be caused by MRSA when other alternatives are not suitable. VIBATIV is also indicated in Canada and Russia for complicated skin and skin structure infections and HABP and VABP caused by Gram-positive bacteria, including MRSA. We plan to market VIBATIV outside the U.S. through a network of partners. To date, we have secured partners for VIBATIV in the following geographies: Europe, Canada, Middle East, North Africa, Israel, Russia, China and India.

*Commercial Program Expansion*

In 2014 and early 2015, we implemented a phased launch strategy for VIBATIV in the U.S. that focused on a limited number of targeted geographic territories across the country. In the second quarter of 2015, we announced our intention to expand our sales force to 50 representatives with the goal of further strengthening our commercial infrastructure comprised of experienced sales representatives and a



## Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

significant medical information component focused on the acute care market. We achieved our goal of hiring and training additional sales representatives by the end of the third quarter of 2015, and the newly expanded field force was fully deployed by the beginning of the fourth quarter of 2015.

### *Supplemental New Drug Application (sNDA) for Concurrent Staphylococcus aureus Bacteremia*

In September 2015, we announced that the Food and Drug Administration ("FDA") accepted for filing our sNDA to expand the VIBATIV label to include concurrent *Staphylococcus aureus* bacteremia. The sNDA submission was based on the combined data from our previously conducted pivotal trials of

Table of Contents

VIBATIV in its two approved indications cSSSI (ATLAS I and ATLAS II) and HABP/VABP (ATTAIN I and ATTAIN II). The trials were large, multi-center, multi-national, double-blind, randomized Phase 3 clinical studies enrolling and treating 3,370 adult patients, including a portion of patients with concurrent bacteremia. Importantly, these studies involved two of the largest cohorts of patients ever studied in these diseases and included one of the largest cohorts of patients with MRSA infections studied to date. Under the Prescription Drug User Fee Act ("PDUFA"), the FDA has set a target of the second quarter of 2016 to complete its review of the sNDA. Separately, we are conducting a Phase 3 registrational study in patients with *Staphylococcus aureus* bacteremia.

*Phase 3 Registrational Study in Staphylococcus aureus Bacteremia*

As part of our effort to explore additional settings in which VIBATIV may offer patients therapeutic benefit, in February 2015, we initiated a Phase 3 registrational study for the treatment of patients with *Staphylococcus aureus* bacteremia. The 250-patient registrational study is a multi-center, randomized, open-label study designed to evaluate the non-inferiority of telavancin in treating *Staphylococcus aureus* bacteremia as compared to standard therapy. Key secondary outcome measures of the study include an assessment of the duration of bacteremia post-randomization and the incidence of development of metastatic complications, as compared to standard therapy.

*Telavancin Observational Use Registry ("TOUR")*

Initiated in February 2015, the 1,000-patient TOUR observational use registry study is designed to assess the manner in which VIBATIV is used by healthcare practitioners to treat patients. By broadly collecting and examining data related to VIBATIV treatment patterns, as well as clinical and safety outcomes in the real world, we aim to create an expansive knowledge base to guide future development and optimal use of the drug.

***Long-Acting Muscarinic Antagonist Revefenacin (TD-4208)***

Revefenacin is an investigational long acting muscarinic antagonist ("LAMA") in development for the treatment of COPD. We believe that revefenacin may become a valuable addition to the COPD treatment regimen and that it represents a significant commercial opportunity. Our market research indicates there is an enduring population of COPD patients in the U.S. that either need or prefer nebulized delivery for maintenance therapy. LAMAs are a cornerstone of maintenance therapy for COPD, but existing LAMAs are only available in handheld devices that may not be suitable for every patient. Revefenacin has the potential to be a best-in-class once-daily single-agent product for COPD patients who require, or prefer, nebulized therapy. The therapeutic profile of revefenacin, together with its physical characteristics, suggest that this LAMA could serve as a foundation for combination products and for delivery in metered dose inhaler and dry powder inhaler products.

*Phase 3 Study in COPD*

In September 2015, we announced, with our partner Mylan Ireland Limited ("Mylan"), the initiation of the Phase 3 development program for revefenacin for the treatment of COPD. The Phase 3 development program, designed to support the registration of the product in the U.S., includes two replicate three-month efficacy studies and a single twelve-month safety study. The two efficacy studies will examine 2 doses (88 mcg and 175 mcg) of revefenacin inhalation solution administered once-daily via nebulizer in moderate to severe patients with COPD. The Phase 3 efficacy studies are replicate, randomized, double-blind, placebo-controlled, parallel-group trials designed to provide pivotal efficacy and safety data for once-daily revefenacin 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 is an open-label, active comparator study of 12 months duration. Together, the three studies will enroll approximately 2,300 patients. In February 2016, we announced the achievement of 50%

Table of Contents

enrollment in all three of the Phase 3 clinical studies for revefenacin. The achievement of 50% enrollment in the twelve-month safety study triggered a \$15.0 million milestone payment to Theravance Biopharma by Mylan.

*Mylan Collaboration*

In January 2015, Mylan and we established a strategic collaboration for the development and, subject to regulatory approval, 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 where we currently market VIBATIV. Funding of the Phase 3 development program by Mylan strengthens our capital position and enhances our financial flexibility to advance other high-value pipeline assets alongside revefenacin.

Under the terms of the Mylan Development and Commercialization Agreement (the "Mylan Agreement"), Mylan and we will co-develop nebulized revefenacin for COPD and other respiratory diseases. We are leading the U.S. Phase 3 development program and Mylan is responsible for reimbursement of our costs for that program up until the approval of the first new drug application, after which costs will be shared. If a product developed under the collaboration is approved in the U.S., Mylan will lead commercialization and we will retain the right to co-promote the product in the U.S. under a profit-sharing arrangement (65% Mylan/35% Theravance Biopharma). Outside the U.S. (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. Although China is not included in the ex-U.S. territory, Mylan has a right of first negotiation with respect to the development and commercialization of nebulized revefenacin in China.

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 ordinary share purchase agreement 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 early 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. As of December 31, 2015, we are eligible to receive from Mylan potential development and sales milestone payments totaling \$220.0 million in the aggregate, with \$175.0 million associated with revefenacin monotherapy and \$45.0 million for future potential combination products. In February 2016, we earned a \$15.0 million development milestone payment for achieving 50% enrollment in the Phase 3 twelve-month safety study.

We retain worldwide rights to revefenacin delivered through other dosage forms, such as a metered dose inhaler or dry powder inhaler ("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.

***Oral Peripherally-Acting Mu Opioid Receptor Antagonist Axelopran (TD-1211)***

*OIC Program*

Axelopran is an investigational, once-daily, oral peripherally active mu opioid receptor antagonist for OIC. The axelopran Phase 2 program demonstrated a clinically meaningful treatment effect in OIC patients compared to placebo. The goal for this program is to demonstrate the ability to normalize bowel function without impacting analgesia and improve a variety of GI symptoms associated with constipation, which could provide axelopran with a competitive advantage in the OIC market if demonstrated in Phase 3 studies and approved by regulatory authorities. We have developed a patient reported outcomes tool designed to measure patient symptoms which would be used in a Phase 3

Table of Contents

registrational program and potentially generate data that could differentiate the product from the competition. We are currently refining our development and commercial strategy for axelopran.

*Fixed Dose Combination*

In December 2014, we completed a Phase 1 study to determine the relative bioavailability of OxyContin® (oxycodone) and axelopran after oral administration as a fixed dose combination ("FDC") relative to the individual components administered together. The study examined a spray-coat application of axelopran to an opioid, OxyContin, to determine the effect of axelopran on OxyContin exposure. The study compared exposure of OxyContin alone, axelopran alone, OxyContin and axelopran administered as two separate tablets, and OxyContin spray-coated with axelopran in a FDC. Study results demonstrated that axelopran does not significantly alter systemic exposure to OxyContin when delivered as a FDC relative to when co-administered as individual tablets. A FDC of axelopran and an opioid could present an important market opportunity, as it has the potential to provide pain relief without constipation in a single abuse-deterrent pill for patients using opioids on a chronic basis.

*Velusetrag*

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-HT<sub>4</sub> receptor. Velusetrag is being developed in collaboration with Alfa Wassermann S.p.A. ("Alfa Wassermann") in a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis. Positive 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, were announced in April 2014. In March 2015, we initiated a Phase 2b study of velusetrag for the treatment of patients with gastroparesis and other gastrointestinal motility disorders. The 200-patient study is a multi-center, double-blind, randomized, placebo-controlled, parallel-group trial which will explore the efficacy and safety of multiple doses of velusetrag in patients with diabetic or idiopathic gastroparesis. The twelve-week study will test three doses: 5, 15, and 30 mg administered once-daily. The primary endpoint will be the effect of velusetrag on symptoms in subjects with gastroparesis. The study will also evaluate the effect of velusetrag on gastric emptying, and the psychometric properties of the Gastroparesis Rating Scale ("GRS"), a daily patient-reported outcome ("PRO") measure. Pursuant to our agreement with Alfa Wassermann, the first Phase 2 study was, and the bulk of the Phase 2b study is, funded by Alfa Wassermann.

*NS5A Inhibitor TD-6450*

TD-6450 is an internally discovered multivalent NS5A inhibitor designed to have improved antiviral activity against GT-1 resistance-associated variants ("RAV") resistant to first generation NS5A inhibitors. TD-6450 has successfully completed Phase 1 studies in both healthy volunteers and hepatitis C virus ("HCV") patients. In September 2015, Trek Therapeutics, PBC ("TREKtx") and we entered into a licensing agreement (the "TREKtx Agreement") granting TREKtx an exclusive worldwide license for the development, manufacturing, use, marketing and sale of TD-6450 as a component in combination HCV products (the "HCV Products"). Pursuant to the TREKtx Agreement, we received an upfront payment of \$8.0 million in the form of TREKtx's Series A preferred stock and will be eligible to receive future royalties based on net sales of the HCV Products. In October 2015, TREKtx and we announced that TREKtx had initiated a Phase 2a clinical trial to evaluate faldaprevir, an HCV protease inhibitor, combined with TD-6450 and ribavirin in patients infected with HCV genotype 4.

*Neprilysin (NEP) Inhibitor Program*

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

Table of Contents

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. Our primary objective is to develop a NEP inhibitor that could 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. We intend to create a platform for multiple combination products with our NEP inhibitor with features that are differentiated from currently available products. Specifically, compounds that are non-renally cleared, dosed once-daily, dosed alone or in combination with other medicines and that may be dosed orally or intravenously.

*Phase 1 Single Ascending Dose (SAD) Study*

In March 2016, we completed a Phase 1 clinical study of our most advanced NEP inhibitor compound, TD-0714. The Phase 1 trial was a randomized, double-blind, placebo-controlled, single ascending dose study in healthy volunteers. The study was designed to assess the safety, tolerability and pharmacokinetics of TD-0714, as well as measure biomarker evidence of target engagement and the amount of the drug that is eliminated via the kidneys. Results from the Phase 1 single-ascending dose study of TD-0714 demonstrate 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 safety and tolerability profile. These results met the Company's target product profile and provide confidence for future efficacy studies of TD-0714 in a broad range of cardiovascular and renal diseases, including in patients with compromised renal function. Theravance Biopharma is now conducting a Phase 1 multiple-ascending dose ("MAD") study of TD-0714 that is designed to supplement the findings of the SAD study and support the ongoing clinical development of the molecule.

***Gastrointestinal (GI)-Targeted Pan-Janus Kinase (JAK) Inhibitor Program***

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. This mechanism has previously demonstrated therapeutic benefit for patients with ulcerative colitis. Currently available treatments for ulcerative colitis have systemic safety liabilities and limited efficacy. Our goal is to develop an orally administered GI-targeted pan-JAK inhibitor designed to distribute adequately and exclusively to the tissues of the GI tract and minimize systemic exposure to treat ulcerative colitis and potentially other inflammatory intestinal disorders.

*Phase 1 Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) Studies*

In December 2015, we initiated a Phase 1 clinical study of TD-1473. The Phase 1 trial is a randomized, double-blind, placebo-controlled, single ascending dose and multiple ascending dose study in healthy subjects. The primary objective of the study will be evaluation of the safety and tolerability of single ascending doses and multiple ascending doses of TD-1473 in healthy subjects. A key secondary objective of the trial will be the characterization of pharmacokinetics related to TD-1473, which will help determine the amount of TD-1473 that enters systemic circulation following oral administration.

Table of Contents

**Other Programs**

***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 (pursuant to its agreements with Innoviva) relating to the GSK-Partnered Respiratory Programs consisting primarily of the Closed Triple 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 will not include any payments associated with RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® or vilanterol monotherapy. The following information regarding the Closed Triple and the MABA program is based solely upon publicly available information and may not reflect the most recent developments under the programs.

*"Closed Triple" or FF/UMEC/VI (fluticasone furoate/umeclidinium bromide/vilanterol)*

The Closed Triple program seeks 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. If the Closed Triple 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, which royalties are upward-tiering from 6.5% to 10%. Innoviva and GSK are conducting two global Phase 3 studies for the Closed Triple, which will enroll approximately 11,800 patients with COPD.

*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. Recently, GSK initiated two Phase 2 clinical trials in COPD patients and two pharmacology studies in healthy volunteers of batefenterol and batefenterol/FF.

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, 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 medicine. If a MABA medicine containing '081 is successfully developed and commercialized in multiple regions of the world, GSK will pay TRC contingent milestone payments of up to \$125.0 million for a single-agent medicine and up to \$250.0 million for both a single-agent and a combination medicine, and in each case we would be entitled to receive an 85% economic interest in any such payments.

*Theravance Respiratory Company, LLC*

Prior to the Spin-Off, Innoviva assigned to TRC its strategic alliance agreement with GSK and all of its rights and obligations under its LABA collaboration agreement with GSK other than with respect to RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® and vilanterol monotherapy. 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. The drug programs assigned to TRC include the Closed Triple 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.

Table of Contents

**Our Strategy**

Our mission is to create value from a diverse and unique set of assets: an approved product, a pipeline of late-stage assets, and a productive research platform designed for long-term growth. With our successful drug discovery and development track record, commercial infrastructure, experienced management team and efficient corporate structure, we believe that we are well positioned to create value for our shareholders and make a difference in the lives of patients.

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.

Our research and development activities are concentrated primarily on four therapeutic areas – infectious disease, respiratory, gastrointestinal disease and cardiovascular and renal disease – and we have established a commercial infrastructure focused primarily on the acute care setting. 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 U.S., predominantly in the acute care setting, or we may partner a product to extend our commercial reach beyond the acute care setting, to expand our geographic reach, and/or to manage the financial risk associated with the program. Alternatively, our strategy may be to monetize or 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 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 or commercialize our products as planned.

We have a single source of supply of telavancin API and another, separate single source of supply of VIBATIV drug product. If, for any reason, either the single-source third-party manufacturer of telavancin API or VIBATIV drug product is unable or unwilling to perform, or if its performance does not meet regulatory requirements, including maintaining current good manufacturing practice ("cGMP") compliance, we may not be able to locate alternative manufacturers, enter into acceptable agreements with them or obtain sufficient quantities of API or finished drug product in a timely manner. Any inability to acquire sufficient quantities of API or finished drug product in a timely manner from current or future sources would adversely affect the commercialization of VIBATIV.

**Government Regulation**

The development and commercialization of VIBATIV and our product candidates by us and our collaboration partners and our ongoing research are subject to extensive regulation by governmental authorities in the United States and other countries. Before marketing in the United States, any

Table of Contents

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 United States, the ability to market a product depends upon receiving a marketing authorization from the appropriate regulatory authorities. 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 medicines is permitted only if the appropriate regulatory authority is satisfied that we have presented adequate evidence of the safety, quality and efficacy of our medicines.

Before commencing clinical studies in humans in the United States, 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 a new drug application ("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 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 ("REMS") 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, 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 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



Table of Contents

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 and our collaboration partners 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 United States our ability to market our 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.

**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 United States 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.

As of December 31, 2015, we or one of our wholly-owned subsidiaries owned 420 issued United States patents and 1,582 granted foreign patents, as well as additional pending United States patent applications and foreign patent applications. The claims in these various patents and patent applications are directed to compositions of matter, including claims covering product candidates, lead compounds and key intermediates, pharmaceutical compositions, methods of use and processes for making our compounds along with methods of design, synthesis, selection and use relevant to multivalency in general and to our research and development programs in particular. In particular, our wholly-owned subsidiary Theravance Biopharma Antibiotics IP, LLC owns the following U.S. patents which are listed in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) for telavancin: U.S. Patent No. 6,635,618 B2, expiring on September 11, 2023; U.S. Patent No. 6,858,584 B2, expiring on August 24, 2022; U.S. Patent No. 6,872,701 B2, expiring on June 5, 2021; U.S. Patent No. 7,008,923 B2, expiring on May 6, 2021; U.S. Patent No. 7,208,471 B2, expiring on May 1, 2021; U.S. Patent No. 7,351,691 B2, expiring on May 1, 2021; U.S. Patent No. 7,531,623 B2, expiring on January 1, 2027; U.S. Patent No. 7,544,364 B2, expiring on May 1, 2021; U.S. Patent No. 7,700,550 B2, expiring on May 1, 2021; U.S. Patent No. 8,101,575 B2, expiring on May 1, 2021; and U.S. Patent No. 8,158,580 B2, expiring on May 1, 2021. Thus, the last-to-expire patent currently listed in the Orange Book for telavancin expires on January 1, 2027.

Table of Contents

United States issued patents and foreign patents generally expire 20 years after filing. The patent rights relating to VIBATIV® (telavancin) currently consist of United States patents that expire between 2019 and 2027, additional pending United States patent applications and counterpart patents and patent applications in a number of jurisdictions, including Europe. 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.

We are party to a license agreement with Janssen Pharmaceutica ("Janssen") pursuant to which we have licensed rights under certain patents owned by Janssen covering an excipient used in the formulation of telavancin. Pursuant to the terms of this license agreement, we are obligated to pay royalties to Janssen based on any commercial sales of VIBATIV® (telavancin). The license is terminable by us upon prior written notice to Janssen or upon an uncured breach or a liquidation event of one of the parties.

**Competition**

Our marketed product and our research and development programs target four therapeutic areas – infectious disease, respiratory, gastrointestinal disease and cardiovascular and renal disease – and 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 and development to:

discover and develop medicines that are superior to other products in the market;

attract qualified scientific, product development and commercial personnel;

obtain patent and/or other proprietary protection for our medicines and technologies;

obtain required regulatory approvals; and

successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

*VIBATIV® (telavancin).* VIBATIV competes with vancomycin and linezolid, 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 products include but are not limited to Cubicin® (daptomycin) and Sivextro® (tedizolid) marketed by Merck & Co., Inc.; Teflaro® (ceftaroline) and Dalvance® (dalbavancin) marketed by Allergan; and Orbactiv® (oritavancin) marketed by The Medicines Company. To compete effectively with these medicines, and in particular with the relatively inexpensive generic options of vancomycin and linezolid, we will need to demonstrate to physicians that, based on experience, clinical data, side effect profiles and other factors, VIBATIV is a preferred

Table of Contents

injectable *Staphylococcus aureus* treatment for patients not likely to respond to current *Staphylococcus aureus* therapy.

*Revefenacin (TD-4208) long-acting muscarinic antagonist (LAMA)*. If successfully developed and approved as the first once-daily nebulized LAMA, revefenacin would be expected to compete predominantly with short-acting nebulized bronchodilators used 3 to 4 times per day and has the potential to be a first line prescription or complement to single agent nebulized long-acting beta agonist (LABA) products used two times per day.

**Research and Development**

We spent \$129.2 million, \$168.5 million, and \$120.6 million on research and development for the years ended December 31, 2015, 2014, and 2013, respectively. Additional information regarding these expenditures is included in Note 1, "Description of Operations and Summary of Significant Accounting Policies," to our consolidated financial statements in this Annual Report on Form 10-K.

**Employees**

As of December 31, 2015, we had 313 employees, of which 175 were engaged primarily in research and development activities. During 2015, some of our employees provided services to Innoviva pursuant to agreements between our companies. We consider our employee relations to be good.

**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 3, "Segment Information," to our consolidated financial statements in this Annual Report on Form 10-K.

**Available Information**

Our Internet address is [www.theravance.com](http://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 U.S. Securities and Exchange Commission ("SEC"). 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.

Table of Contents

**ITEM 1A. RISK FACTORS**

**RISKS RELATING TO THE COMPANY**

The risks described below and elsewhere in this Report 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 with Innoviva, Inc. (known as Theravance, Inc. prior to January 7, 2016), 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 or royalties on sales by our partners or via our interest in Theravance Respiratory Company, LLC ("TRC") to achieve profitability. During the years ended December 31, 2015, 2014 and 2013, we recognized losses of \$182.2 million, \$237.0 million and \$156.3 million, respectively, which are reflected in the Shareholders' Equity on our consolidated balance sheets. We reflect cumulative net loss incurred and retained after June 2, 2014, the effective date of the Spin-Off, as accumulated deficit on our consolidated balance sheets. We expect to continue to incur net losses over the next several years as we continue our drug discovery efforts and incur significant preclinical and clinical development costs related to our current product candidates and commercialization and development costs relating to VIBATIV® (telavancin). In particular, to the extent we advance our product candidates into and through later stage clinical studies without a partner, we will incur substantial expenses. We are also making additional investments in telavancin, our approved antibiotic. For example, in February 2015 we initiated a Phase 3 registrational study for bacteremia and a patient registry study. We are incurring all of the costs and expenses associated with the commercialization of VIBATIV in the U.S., including the creation of an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities, expansion of medical affairs presence, manufacturing and third party vendor logistics and consultant support, and post-marketing studies. Our commitment of resources to VIBATIV, to the continued development of our existing product candidates and to our discovery programs will require significant additional funding. Our operating expenses also will increase if:

our earlier stage potential products move into later stage clinical development, which is generally a more expensive stage of development;

additional preclinical product candidates are selected for clinical development;

we pursue clinical development of our potential products in new indications;

we increase the number of patents we are prosecuting or otherwise expend additional resources on patent prosecution or defense; or

we acquire additional technologies, product candidates, products or businesses.

Other than revenues from sales of VIBATIV, our only approved medicine, and potential payments under collaboration agreements, we do not expect to generate sales revenues from our programs for the foreseeable 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 may continue to exceed any revenues we may receive.

In the absence of substantial licensing, contingent payments or other revenues from third-party collaborators, royalties on sales of products licensed under our intellectual property rights, future revenues from our products in development or other sources of revenues, we will continue to incur

Table of Contents

operating losses and will require additional capital to fully execute our business strategy. The likelihood of reaching, and time required to reach, sustained 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.

*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. If our current operating plans or financial forecasts change, we may require or seek additional funding sooner in the form of public or private equity offerings, debt financings or additional collaborations and licensing arrangements. For example, if we choose to progress any of our product candidates into later-stage development on our own, our capital needs would increase substantially. We also are making additional investments in telavancin, our approved antibiotic, which will increase our operating expenses. For example, in February 2015 we announced initiation of a Phase 3 registrational study for bacteremia and initiation of a patient registry study. In addition, in 2015 we substantially increased the number of sales representatives and medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV and at the end of 2015, we had approximately 50 sales representatives in the field.

Although we expect that we will have sufficient cash to fund our operations and working capital requirements for at least the next twelve months based on current operating plans and financial forecasts, we may need to raise additional capital in the future to, among other things:

fund our discovery efforts, research and development programs;

fund our commercialization strategies for VIBATIV;

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 our product candidates;

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

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.

Table of Contents

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 very 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. If adequate funds are not available, we may have to sequence pre-clinical 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 debt, convertible debt 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. In such event, 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. 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. For example, in connection with entering into a collaboration agreement with Mylan for the development and commercialization of a nebulized formulation of our long-acting muscarinic antagonist ("LAMA") revefenacin (TD-4208) in February 2015, Mylan, Inc. made a \$30.0 million equity investment in us by purchasing 1,585,790 newly issued ordinary shares, which issuance resulted in dilution of ownership to our shareholders. By way of further example, in October 2015, funds managed by Woodford Investment Management LLP (collectively, the "Woodford Funds") made a \$55.0 million equity investment in us by purchasing 3,859,649 newly issued ordinary shares, which issuance resulted in dilution of ownership to our shareholders. In addition, if we seek to raise funds and this becomes known publicly, the market price of our shares could decline upon the expectation of dilution, regardless of whether dilution actually occurs. In July 2015, our shelf registration statement on Form S-3 for the potential offering, issuance and sale by us of up to a maximum aggregate offering price of \$250.0 million of our debt securities, ordinary shares, and/or warrants was declared effective. Up to \$50.0 million of the maximum aggregate offering price of \$250.0 million under the registration statement may be issued and sold pursuant to an at-the-market offering program for sales of our ordinary shares under a sales agreement with Cantor Fitzgerald & Co. In October 2015, we used \$55.0 million of the available financing capacity under the registration statement in the sale of ordinary shares to the Woodford Funds. 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 debt securities 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.

Table of Contents

***We do not control TRC and, in particular, have no control over or access to non-public information about the respiratory programs that Innoviva partnered with GSK and assigned to TRC in connection with the Spin-Off (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"). Our equity interest covers various drug programs including the Closed Triple combination of fluticasone furoate (FF)/umeclidinium (UMEC)/vilanterol (VI) (ICS/LAMA/LABA) 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 of 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 the GSK-Partnered Respiratory Programs in which we have a substantial economic interest, including the Closed Triple program and MABA program, encounter delays, do not demonstrate safety and efficacy, are terminated, or if there are any adverse developments or perceived adverse developments with respect to these programs, our business will be harmed, and the price of our securities could fall.***

We have no access to confidential information regarding the progress of, or plans for, the GSK-Partnered Respiratory Programs, including the Closed Triple program 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 economic interest in TRC, which is controlled by Innoviva. However, if any of the GSK-Partnered Respiratory Programs assigned to TRC in which we have a substantial economic interest, including the Closed Triple program and MABA program, encounter delays, do not demonstrate safety and efficacy, are terminated, or if there are any adverse developments or perceived adverse developments with respect to such programs, our business will be harmed, and the price of our securities could fall. Examples of such adverse developments include, but are not limited to:

GSK deciding to delay or halt development of any of the GSK-Partnered Respiratory Programs assigned to TRC in which we have a substantial economic interest, including the Closed Triple, GSK961081 ('081), the lead compound in the MABA program, or '081/FF;

the U.S. Food and Drug Administration ("FDA") and/or other regulatory authorities determining that any of the studies under these programs do not demonstrate adequate safety or efficacy, or that additional non-clinical or clinical studies are required with respect to such programs;

safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs; or



Table of Contents

any particular FDA requirements or changes in FDA policy or guidance regarding these programs.

***VIBATIV may not be broadly accepted by physicians, patients, third party payors, or the medical community in general, which would have a material, adverse effect on our business.***

The commercial success of VIBATIV depends upon its acceptance by physicians, patients, third party payors and the medical community in general. VIBATIV may not be sufficiently accepted by these parties. VIBATIV competes with vancomycin and linezolid, relatively inexpensive generic drugs that are manufactured by a variety of companies, and a number of existing antibacterials manufactured and marketed by major pharmaceutical companies and others, and may compete against new antibacterials that are not yet on the market. In addition, sales of a generic version of daptomycin could begin in 2016. If we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, VIBATIV for the treatment of complicated skin and skin structure infections ("cSSSI") and HAP/VABP caused by susceptible Gram-positive bacteria in adult patients is a preferred injectable *Staphylococcus aureus* treatment for patients not likely to respond to current *Staphylococcus aureus* therapy, we may never generate significant revenue from VIBATIV which could cause the price of our securities to fall. In addition, if we fail to meet expectations about our net sales of VIBATIV and our VIBATIV commercialization strategy, the price of our securities could fall. For example, we reduced our projected U.S. net sales target for VIBATIV for 2015 more than once.

The degree of market acceptance of VIBATIV and the rate of our VIBATIV sales depends on a number of factors, including, but not limited to:

the experiences of physicians, patients and payors with the use of VIBATIV;

the market price of VIBATIV relative to competing therapies and the timing, frequency and impact of price increases;

any adverse developments or perceived adverse developments with respect to whether Pfizer's acquisition of Hospira Worldwide, Inc. ("Hospira") may lead to changes in Hospira's operations which may adversely impact our single source of supply for VIBATIV drug product;

the advantages and disadvantages of VIBATIV compared to alternative therapies;

our ability to educate the medical community about the appropriate circumstances for use of VIBATIV;

the acceptance of VIBATIV onto formulary by multiple hospitals and healthcare systems;

our ability to attract, train and retain targeted numbers of sales and marketing personnel;

our ability to retain medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV;

the effectiveness of sales personnel to obtain access to or educate adequate numbers of physicians about prescribing VIBATIV in appropriate clinical situations;

the lack of complementary products to be offered by our sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

the reimbursement policies of government and third party payors, including the amount of chargebacks and government rebates; and

our customer mix.

Table of Contents

***We are developing the capability to market, sell and distribute VIBATIV in the U.S. without a partner and we may bear similar costs with respect to additional products in the future, which subjects us to certain risks.***

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.

VIBATIV was returned by Astellas Pharma Inc. ("Astellas"), our former VIBATIV collaboration partner, in January 2012, and Astellas is entitled to a ten-year, 2% royalty on future net sales of VIBATIV. On August 14, 2013, we (at the time with Innoviva) announced the reintroduction of VIBATIV to the U.S. market with the commencement of shipments into the wholesaler channel and as of the end of 2015 we had approximately 50 VIBATIV sales representatives in the U.S. The risks of commercializing VIBATIV in the U.S. without a partner include:

costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability, 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 from VIBATIV for several years;

our unproven ability to retain adequate numbers of effective sales and marketing personnel;

our unproven ability to retain medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV;

the unproven ability of sales personnel to obtain access to or educate adequate numbers of physicians about prescribing VIBATIV in appropriate clinical situations;

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; and

bearing the full costs of further U.S. development of telavancin.

If we are not successful in maintaining an internal sales and marketing organization with appropriate experience, technical expertise, supporting infrastructure, distribution capability and the ability to obtain access to or educate adequate numbers of physicians about prescribing VIBATIV in appropriate clinical situations, we will have difficulty commercializing VIBATIV in the U.S., which would adversely affect our business and financial condition and the price of our securities could fall. In the event we were to market, sell and distribute any additional products, we would face similar challenges and risks, which could adversely affect our business and financial condition and the price of our securities could fall.

***With regard to all of our programs, 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 or decisions to terminate programs.

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

### Table of Contents

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;

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 and changes in regulatory requirements, policy and guidelines;

failure of our partners to advance our product candidates through clinical development;

delays in patient enrollment and variability in the number and types of patients available for clinical studies;

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.

***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 U.S. 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 are safe and effective for a defined indication before they can be approved for commercial distribution. We will not obtain this approval for a product candidate unless and until the FDA approves a new drug application, or NDA. The processes by which regulatory approvals are obtained from the FDA to market and sell a new product are complex, require a number of years and involve the expenditure of substantial resources. 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.

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

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.

Table of Contents

Frequently, product candidates that have shown promising results in early preclinical or clinical studies have subsequently suffered significant setbacks or failed in later clinical or non-clinical studies. In addition, clinical and non-clinical studies of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates. If these studies are substantially delayed or fail to prove the safety and effectiveness of our product candidates in development, we may not receive regulatory approval of any of these product candidates. 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, over the past decade, the FDA has implemented additional standards for approval of new drugs, including recommended advisory committee meetings for new molecular entities, and formal risk evaluation and mitigation strategy at the FDA's discretion. These laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's review and approval of our and our collaborative partner's product candidates, which would materially harm our business and financial condition and the price of our securities could fall.

***We rely on a single manufacturer for the Active Pharmaceutical Ingredient ("API") for telavancin and a separate, single manufacturer for VIBATIV drug product supply. Our business will be harmed if either of these single-source manufacturers are not able to satisfy demand and alternative sources are not available.***

We have a single source of supply of API for telavancin and another, separate single source of supply of VIBATIV drug product. If, for any reason, either single-source third party manufacturer of telavancin API or of VIBATIV drug product is unable or unwilling to perform, or if its performance does not meet regulatory requirements, including maintaining current Good Manufacturing Practice ("cGMP") compliance, we may not be able to locate alternative manufacturers, enter into acceptable agreements with them or obtain sufficient quantities of API or finished drug product in a timely manner. Any inability to acquire sufficient quantities of API or finished drug product in a timely manner from current or future sources would adversely affect the commercialization of VIBATIV and our obligations to our partners and the price of our securities could fall.

Our previous VIBATIV commercialization partner (at the time with Innoviva) failed to maintain a reliable source of drug product supply which resulted in critical product shortages and, eventually, suspension of commercialization for well over a year. We currently have an agreement with Hospira to supply VIBATIV drug product, which was entered into May 2012. In June 2013, the FDA approved Hospira as a VIBATIV drug product manufacturer, and this agreement with Hospira has been assigned to us. Although we believe that Hospira will continue to be a reliable supplier of VIBATIV drug product, if it cannot perform or if its performance does not meet regulatory requirements, including maintaining cGMP compliance, and if commercial manufacture of VIBATIV drug product cannot be arranged elsewhere on a timely basis, the commercialization of VIBATIV will be adversely affected. In addition, Pfizer acquired Hospira in 2015 and we cannot predict whether the acquisition will lead to changes in Hospira's operations which may adversely impact our single source of supply for VIBATIV drug product. Given the time required to locate and qualify another acceptable drug product manufacturer, any supply delay, suspension or cessation by Hospira (whether or not resulting from or related to the acquisition by Pfizer) would adversely affect the commercialization of VIBATIV and our obligations to our partners and the price of our securities could 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 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

Table of Contents

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 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 commercial 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 U.S., there may be difficulties in importing our APIs and drug products or their components into the U.S. as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging.

***Even if our product candidates receive regulatory approval, as VIBATIV has, commercialization of such products may be adversely affected by regulatory actions and oversight.***

Even if we receive regulatory approval for our product candidates, this approval may include 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. For example, the U.S. labeling for VIBATIV contains a boxed warnings. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. In addition, the VIBATIV labeling for hospital-acquired and ventilator associated bacterial pneumonia ("HABP/VABP") in the U.S. and the European Union specifies that VIBATIV should be reserved for use when alternative treatments are not suitable. These restrictions limit how broadly VIBATIV can be marketed. With VIBATIV approved in certain countries, we are subject to continuing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of promotion and marketing.

In addition, the manufacturing, labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for the approved product remain subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with an approved product in the U.S. 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 U.S. Department of Health and Human Services and other regulatory bodies with respect to VIBATIV, as

Table of Contents

well as governmental authorities in those foreign countries in which any of our product candidates are 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. Any failure to maintain regulatory approval will limit our ability to commercialize our product candidates, which would materially and adversely affect our business and financial condition and the price of our securities could fall.

The risks identified in this risk factor relating to regulatory actions and oversight by agencies in the U.S. and throughout the world also apply to the commercialization of any partnered products by our collaboration partners, and such regulatory actions and oversight may limit our collaboration partners' ability to commercialize such products, which could materially and adversely affect our business and financial condition, which may cause the price of our securities to fall.

***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 Alfa Wassermann S.p.A. ("Alfa Wassermann") for velusetrag, our lead compound in the 5-HT4 program, covering the European Union, Russia, China, Mexico and certain other countries. In October 2012, we (at the time with Innoviva) also entered into a research collaboration and license agreement with Merck to discover, develop and commercialize novel small molecule therapeutics for the treatment of cardiovascular disease, which Merck terminated in September 2013. We also have a commercialization agreement with Clinigen Group plc ("Clinigen") for VIBATIV in the European Union and certain other European countries (including Switzerland and Norway). In connection with these agreements, these parties have certain rights regarding the use of its patents and technology with respect to the compounds in our development programs, including development and marketing rights. The Alfa Wassermann and Clinigen agreements were assigned to us in the Spin- Off. The Alfa Wassermann agreement provides research and development funding for the program under license. In January 2015, we entered into a collaboration agreement with Mylan for the development and commercialization of a nebulized formulation of our LAMA revefenacin (TD-4208). Under the terms of the agreement, we and Mylan will co-develop nebulized revefenacin for COPD and other respiratory diseases.

Our partners might not fulfill all of their obligations under these agreements, and, in certain circumstances, they may terminate our partnership with them as Astellas did in January 2012 with its VIBATIV agreement and as Merck did in September 2013 with the cardiovascular disease collaboration. In either event, we may be unable to assume the development and commercialization of the product candidates 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 its own products and product candidates in preference to those licensed from us, 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



Table of Contents

could be materially and adversely affected. 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.

***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, 2015, GSK beneficially owned approximately 22.0% of our outstanding ordinary shares. GSK is also a strategic partner to Innoviva with rights and obligations under the strategic alliance agreement and under the collaboration agreement assigned to TRC (the "GSK-Innoviva Agreements") that may cause GSK's interests to differ from the interests of us and our other shareholders. In particular, if the Closed Triple or a MABA/ICS in either the U.S. or the European Union is approved, GSK's diligent efforts obligations under the GSK- Innoviva Agreements with regard to commercialization matters will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK-Innoviva Agreements. Following such regulatory approval, GSK's commercialization efforts will be 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-Innoviva 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-Innoviva Agreements. Also, given the potential future royalty payments GSK may be obligated to pay under the GSK-Innoviva 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 the true value of the Company, though the actions GSK may take to acquire us are limited under our governance agreement with GSK which will expire on December 31, 2017 (the "Governance Agreement"). 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-Innoviva 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-Innoviva Agreements, including by violating the confidentiality provisions of those agreements or the master agreement between GSK, Innoviva and us entered into in connection with the Spin-Off, or otherwise violating its legal rights. While we believe our operations fully comply with the GSK-Innoviva 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 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-Innoviva Agreements or the relationship/partnership between

Table of Contents

Innoviva and GSK could result in significant reduction in the market price of our securities and other material harm to our business.

***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 a three-way master agreement (the "Master Agreement") that, among other things, requires GSK's consent to make any changes to (A) the 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, among other things, provides share purchase rights to GSK and exempts GSK from triggering our Rights Agreement until 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-Innoviva Agreements. There can be no assurance that these restrictions will not materially harm our business, particularly given that GSK's interests may not be aligned with the interests of our business or our other shareholders.

***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 Alfa Wassermann for velusetrag, with Clinigen for VIBATIV for the European Union, and with other companies for regional development and commercialization of VIBATIV. Also, through our interest in TRC we may participate economically in Innoviva's collaborations with GSK with respect to the GSK-Partnered Respiratory Programs. In addition, by way of example, in January 2015 we entered into a collaboration agreement with Mylan for the development and commercialization of a nebulized formulation of revefenacin (TD-4208), our LAMA compound. We received non-marketable equity securities in connection with the TREKtx Agreement, and recognized those investments at their estimated fair market value at the time of receipt, and we may receive similar non-marketable equity securities in the future, which could subject us to future impairment charges up to the amount recognized for such assets. Additional collaborations will likely be needed to fund later-stage development of our product candidates that have not been licensed to a collaborator, such as axelopran (TD-1211) for opioid-induced constipation or for a territory that is not covered by existing collaborations, and to commercialize these product candidates if approved by the necessary regulatory authorities. In some instances, we may seek additional third parties with which to pursue collaboration arrangements for the development and commercialization of our development programs and for the future commercialization of VIBATIV in regions where it is not currently partnered. Collaborations with third parties regarding these programs or our other 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

Table of Contents

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. Our inability to successfully collaborate with third parties would increase our development costs and would limit the likelihood of successful commercialization of our product candidates and the price of our securities could 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 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 practices ("GCPs") and other regulations as required by the FDA and foreign regulatory authorities, and the applicable protocol. Failure by these parties to comply with applicable regulations, GCPs and protocols 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 enforces GCPs 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 GCPs, 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 we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs, could result in significant additional costs and the price of our securities could fall.

***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 patent and/or other proprietary protection for our medicines and technologies;

obtain required regulatory approvals;

develop and effectively implement commercialization strategies, with or without collaborative partners; and

Table of Contents

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 approval 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. VIBATIV must demonstrate these advantages in certain circumstances, as it competes with vancomycin and linezolid, relatively inexpensive generic drugs that are manufactured by a number of companies, and a number of existing antibacterial drugs marketed by major and other pharmaceutical companies. In addition, sales of a generic version of daptomycin could begin in 2016. 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.

***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 our officers and most of our 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 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 VIBATIV and any other products that may be approved in the future 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.

The Spin-Off represented a significant organizational change and our employees may have continuing concerns about our prospects as a stand-alone company, including our ability to successfully operate the new entity over the long-term, and our ability to maintain our independence after the Spin-Off. If we are not successful in assuring our employees of our prospects as an independent company, our employees may seek other employment, which could materially adversely affect our

Table of Contents

business. 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.

In addition, our U.S. 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.

***Our business and operations would suffer in the event of system failures or security breaches.***

Although we have security measures in place, our internal computer systems and those of our CROs and other service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any material system failure, accident or security breach could result in a material disruption to our business or other losses. We rely extensively on computer systems to process payment transactions, maintain information and manage our business. Although we have security and fraud prevention measures in place, we have been subject to immaterial payment fraud activity. If we suffered material electronic security breaches, we could incur significant liability or significant disruption to our business. 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. If a disruption or security breach results in a loss of or damage to our data or regulatory applications, inadvertent disclosure of confidential or proprietary information, or other harm to our business, we could incur liability, the further development of our product candidates could be delayed and the price of our securities could fall.

***Our U.S. 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 U.S. 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 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.

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

We are an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Where appropriate, we plan to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be

Table of Contents

subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

For as long as we continue to be an emerging growth company, we also intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory shareholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). Therefore, the information that we intend to provide shareholders will be different than what is available with respect to some other public companies. We cannot predict if investors will find our ordinary shares less attractive because we rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

We were an emerging growth company for all of 2015 and will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our ordinary shares that is held by non-affiliates exceeds \$700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenues of \$1 billion or more during such fiscal year, (iii) the date on which we issue more than \$1 billion in non-convertible debt in a three-year period or (iv) December 31, 2019, the end of the fiscal year following the fifth anniversary of the date of the first sale of our ordinary shares pursuant to an effective registration statement filed under the Securities Act.

***Our historical financial information prior to the Spin-Off may not reflect what our financial position, results of operations or cash flows would have been as a stand-alone company during the periods presented and is not necessarily indicative of our future financial position, future results of operations or future cash flows.***

Our historical financial information prior to the Spin-Off does not necessarily reflect what our financial position, results of operations or cash flows would have been as a stand-alone company during the periods presented and is not necessarily indicative of our future financial position, future results of operations or future cash flows. This is primarily a result of the following factors:

prior to the Spin-Off, our business was operated by Innoviva as part of its broader corporate organization rather than as a stand-alone company, and our business was able to leverage Innoviva's financial resources and creditworthiness;

prior to the Spin-Off, certain general administrative functions were performed by Innoviva for the combined entity. Our historical consolidated financial statements reflect allocations of costs for services shared with Innoviva. These allocations may differ from the costs we will incur for these services as an independent company;

holding other factors constant, our cost of capital as a stand-alone company is likely higher on average than Innoviva's cost of capital was as a combined business prior to the Spin-Off;

following the Spin-Off, we are responsible for the additional costs associated with being an independent, public company, including costs related to corporate governance and listed and registered securities; and

having separating from Innoviva, there is a risk that we may be more susceptible to market fluctuations and other adverse events than we would have been were we still a part of Innoviva.

Table of Contents

Our accounting and other management systems and resources may not be adequately prepared to meet the financial reporting and other requirements to which we became subject following the Spin-Off. If we are unable to achieve and 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 will require annual management assessments of the effectiveness of our internal control over financial reporting. When and if we become a "large accelerated filer" and are no longer an "emerging growth company," each as defined in the Exchange Act, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. These reporting and other obligations will place significant demands on our management and administrative and operational resources, including accounting resources.

In addition, we are currently replacing our existing enterprise resource planning ("ERP") software system. Our ERP system is critical to our ability to accurately maintain books and records, record transactions, provide important information to our management and prepare our financial statements. Such an implementation is complex and difficult and will require us to address a number of challenges including data conversion, system cutover and user training. As a result, it represents a major undertaking financially and from a management and personnel perspective. Our business and results of operations may be adversely affected if we experience operating problems and/or cost overruns during the ERP implementation process, or if the ERP system and the associated process changes do not give rise to the benefits that we expect. Additionally, if we do not effectively implement the ERP system as planned or if the system does not operate as intended, it could be disruptive and adversely affect our operations and results of operations, including our ability to report accurate and timely financial results and 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 United States. Any failure to achieve and maintain effective internal controls could have an adverse effect on our business, financial position and results of operations.

***We have only been operating as a stand-alone entity since June 2, 2014 and therefore we have a limited history operating as an independent company upon which you can evaluate us.***

We have only been operating as a stand-alone entity since June 2, 2014 and therefore we have a limited operating history as an independent company upon which you can evaluate us. While our biopharmaceutical business has constituted a substantial part of the historic operations of Innoviva, we did not operate as a stand-alone company without the right to receive potential royalty revenue derived from Innoviva's GSK Partnered Respiratory Program (the "Royalty Business") until the Spin-Off. As a new independent company, our ability to satisfy our obligations and achieve profitability will be primarily dependent upon the future performance of our biopharmaceutical business, and we do not rely upon the revenues, capital resources and cash flows of the Royalty Business remaining with Innoviva.

***We may be treated as a U.S. corporation for U.S. federal income tax purposes.***

For U.S. 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-U.S.

Table of Contents

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 U.S. corporation for U.S. 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 U.S. will be treated as a U.S. corporation for U.S. federal tax purposes, when (i) the foreign corporation directly or indirectly acquires substantially all of the properties held directly or indirectly by a U.S. corporation, (ii) the former shareholders of the acquired U.S. corporation hold at least 80% of the vote or value of the shares of the foreign acquiring corporation by reason of holding stock in the U.S. 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 U.S. 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 IRS 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 U.S. corporate tax residence and there could be changes to Section 7874 of the Code or the Treasury Regulations promulgated thereunder that could result in Theravance Biopharma being treated as a U.S. corporation.

If it were determined that we should be treated as a U.S. corporation for U.S. federal income tax purposes, we could be liable for substantial additional U.S. federal income tax on our post-Spin-Off taxable income. In addition, payments of dividends to non-U.S. holders may be subject to U.S. 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, United States, 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. 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.



Table of Contents

***We were a passive foreign investment company, or "PFIC," for 2014 but we believe that we will not be a PFIC for 2015.***

For U.S. 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 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 during the course of 2015, we do not believe that our company is a PFIC for 2015. For any taxable year (or portion thereof) in which our company is a PFIC that is included in the holding period of a U.S. holder, the U.S. holder is generally subject to additional U.S. 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 R&D, Inc. U.S. 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. U.S. 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 required to indemnify Innoviva, or if we are not able to collect on indemnification rights from Innoviva, 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, the Transition Services Agreement, the Employee Matters Agreement, the Tax Matters Agreement, and the 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 collect on indemnification rights from Innoviva, our business prospects and financial condition may be harmed.

Table of Contents

**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 market.*

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, 2015, we or one of our wholly-owned subsidiaries owned 420 issued United States patents and 1,582 granted foreign patents, as well as additional pending United States 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 disclosed 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 United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States 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 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.

Table of Contents

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 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. Prosecution of these claims to enforce our rights against others would involve substantial litigation expenses and divert substantial employee resources from our business. 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 United States 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 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 and have likely increased with the commercial reintroduction of VIBATIV. 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. The VIBATIV prescribing information describes several potential adverse effects observed during clinical trials, including increased mortality versus vancomycin in patients with HABP/VABP who had pre-existing moderate to severe renal impairment, decreased clinical response in patients with cSSSI who had pre-existing moderate/severe renal impairment, and other renal adverse events. The prescribing information includes a black box warning regarding increased mortality in patients with pre-existing moderate/severe renal impairment who were treated with VIBATIV for HABP/VABP, new onset or worsening renal impairment, use in women of childbearing potential or during pregnancy and adverse developmental outcomes observed in 3 animal species. 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. Also, changes in laws outside the U.S. are expanding our potential liability for injuries that occur during clinical trials. 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.

Table of Contents

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. The cost of defending any product liability litigation or other proceeding, even if resolved in our favor, could be substantial and uncertainties resulting from the initiation and continuation of product liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Product liability claims could also harm our reputation, which may adversely affect our and our partners' ability to commercialize our products successfully and the price of our securities could fall.

***Government restrictions on pricing and reimbursement, as well as other healthcare payor cost-containment initiatives, may negatively impact our ability to generate revenues.***

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 one or more of the following:

our or our collaborators' ability to set and collect a price we believe is reasonable for our product;

our ability to generate revenues and achieve profitability; and

the availability of capital.

The Patient Protection and Affordable Care Act, the Veterans Health Care Act and other existing and potential legislative or regulatory actions, such as the discounted pricing offered to Public Health Service ("PHS") and government managed Medicaid programs referred to in the Note to our Consolidate Financial Statements, regarding healthcare and insurance matters, along with the trend toward managed healthcare in the United States, could influence the purchase of healthcare products and reduce demand and prices for our product. This could harm our or our collaborators' ability to market our existing and potential medicines and generate revenues. Cost containment measures that health care payors and providers are instituting and the effect of the Patient Protection and Affordable Care Act, the Veterans Health Care Act, the discounted pricing offered to Public Health Service ("PHS") and government managed Medicaid programs, and any additional agency regulations that may emerge in the future could significantly reduce potential revenues from the sale of VIBATIV and any product candidates approved in the future. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures at the state and federal level, as well as internationally, will continue and may increase, which may make it difficult for us to sell VIBATIV and any other potential medicines that may be approved in the future at a price acceptable to us or our collaborators and which may cause the price of our securities to fall.

***If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

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. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may incur significant additional costs to comply with 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. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability

Table of Contents

could exceed our resources. We do not have any insurance for liabilities arising from hazardous materials. Compliance with applicable environmental laws and regulations is 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.

**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 date, there is limited securities analyst coverage of our company. Limited securities analyst coverage of our company and shares is likely to reduce demand for our shares from potential investors, which likely will reduce the market price for our 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.

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. By separating from Innoviva, there is a risk that our company may be more susceptible to market fluctuations and other adverse events than we would have been were we still a part of Innoviva. 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:

any adverse developments or results or perceived adverse developments or results with respect to the GSK-Partnered Respiratory Programs, 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 further adverse developments or perceived adverse developments with respect to the commercialization of VIBATIV, including whether Pfizer's acquisition of Hospira in 2015 will lead to changes in Hospira's operations which may adversely impact our single source of supply for VIBATIV drug product;

whether we achieve increased sales for VIBATIV;

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 or have commercialized;

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

### Table of Contents

any adverse developments or agreements or perceived adverse developments or agreements with respect to 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, including any such developments resulting from or relating to the Spin-Off;

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

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 United States and foreign countries;

announcements of equity or debt financings;

economic and other external factors beyond our control;

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;

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;

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

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 drugs 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 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.

Table of Contents

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

Based on our review of publicly available filings, as of December 31, 2015 GSK beneficially owned approximately 22.0% of our outstanding ordinary shares and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 4.3% of our outstanding ordinary shares. Based on our review of publicly available filings, as of December 31, 2015 our three largest shareholders other than GSK collectively owned approximately 36.4% of our outstanding ordinary shares. These shareholders and GSK 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.

***Certain provisions in our constitutional 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.

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 (2013 Revision) (as amended) 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 U.S. Therefore, you may have more difficulty in protecting your interests than would shareholders of a corporation incorporated in a jurisdiction in the U.S., 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 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,



Table of Contents

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) the company's 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 United States. As a result, it may be difficult for our shareholders to enforce judgments against us or judgments obtained in U.S. courts predicated upon the civil liability provisions of the federal securities laws of the United States or any state of the United States.

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 United States predicated upon the civil liability provisions of the securities laws of the United States 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 United States 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 United States, 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 may stay enforcement proceedings if concurrent proceedings are being brought elsewhere. 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.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**ITEM 2. PROPERTIES**

Our principal physical properties in the U.S. consist of approximately 150,000 square feet of office and laboratory space leased in two buildings in South San Francisco, CA. The lease expires in May

Table of Contents

2020 and we may extend the terms for two additional five-year periods. Our Irish subsidiary operates from a leased office in Dublin, Ireland. We believe our current space is sufficient for our needs.

**ITEM 3. LEGAL PROCEEDINGS**

We are not a party to any material legal proceedings.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

Table of Contents**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. Prior to this date, there was no public market for our ordinary shares. The following table sets forth the high and low closing prices of our ordinary shares on a per share basis for the periods indicated and as reported on The NASDAQ Global Market:

Calendar Quarter	High	Low
<b>2015</b>		
Fourth Quarter	\$ 19.51	\$ 11.13
Third Quarter	\$ 14.80	\$ 10.88
Second Quarter	\$ 18.63	\$ 12.57
First Quarter	\$ 21.73	\$ 14.70
<b>2014</b>		
Fourth Quarter	\$ 24.06	\$ 13.11
Third Quarter	\$ 34.07	\$ 23.01
Second Quarter	\$ 35.67	\$ 14.75

As of February 29, 2016, there were 111 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, 2015:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	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))
	(a)	(b)	(c)
Options	1,827,614	\$ 25.55	2,147,461
RSU	2,988,041	n/a	n/a
ESPP	n/a	n/a	929,143
Equity compensation plans approved by security holders	4,815,655	\$ 25.55	3,076,604
Options	483,550	\$ 13.70	266,450
Equity compensation plans not approved by security holders	483,550	\$ 13.70	266,450
<b>Total</b>	<b>5,299,205</b>	<b>\$ 23.07</b>	<b>3,343,054</b>

Table of Contents

Upon the completion of the Spin-Off, we had two equity compensation plans our 2013 Equity Incentive Plan (the "2013 EIP") and our 2013 Employee Share Purchase Plan (the "2013 ESPP"). 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. In October 2014, we adopted the 2014 New Employee Equity Incentive Plan (the "2014 NEEIP"). We are authorized to issue 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.

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, "Description of Operations and Summary of Significant Accounting Policies," and Note 7, "Share-Based Compensation," to the consolidated financial statements appearing in this Annual Report on Form 10-K.

Table of Contents

*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, 2015, with the cumulative total return of (i) the NASDAQ Composite Index, (ii) 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 NASDAQ 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.

**COMPARISON OF CUMULATIVE TOTAL RETURN\***

Among Theravance Biopharma, Inc., the NASDAQ Composite Index,  
the NASDAQ Pharmaceutical Index and the NASDAQ Biotechnology Index

---

\*

Shows the cumulative return on investment assuming an investment of \$100 in our ordinary shares or the indices on June 3, 2014, including the reinvestment of dividends.

Table of Contents**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, 2015, which have been derived from our (i) audited consolidated financial statements as of December 31, 2015, and 2014 and for the years ended December 31, 2015, 2014, and 2013, which are included in this Annual Report, (ii) audited combined financial statements as of December 31, 2013, 2012, and 2011 and for the years ended December 31, 2012, and 2011, which are not included in this Annual Report. In our opinion, the summary historical financial information derived from our unaudited combined financial statements is presented on a basis consistent with the information in our audited consolidated financial statements. The summary historical financial information may not be indicative of the results of operations or financial position that we would have obtained if we had been an independent company during the periods presented or of our future performance as an independent company.

	Year Ended December 31,				
	2015	2014	2013	2012	2011
(In thousands, except per share data)					
<b>CONSOLIDATED STATEMENTS OF OPERATIONS DATA</b>					
Product sales	\$ 9,408	\$ 4,418	\$	\$	\$
Revenue from collaborative arrangements(1)	32,718	7,270	226	130,145	14,854
Total revenue	42,126	11,688	226	130,145	14,854
Costs and expenses:					
Cost of goods sold(2)	4,657	4,058			
Research and development	129,165	168,522	120,579	113,995	98,850
Selling, general and administrative	90,203	71,647	35,931	25,725	25,339
Total costs and expenses(3)	224,025	244,227	156,510	139,720	124,189
Loss from operations	(181,899)	(232,539)	(156,284)	(9,575)	(109,335)
Interest and other income	631	1,865			
Loss before income taxes	(181,268)	(230,674)	(156,284)	(9,575)	(109,335)
Provision for income taxes	951	6,364			
Net loss	\$ (182,219)	\$ (237,038)	\$ (156,284)	\$ (9,575)	\$ (109,335)
Basic and diluted net loss per share	\$ (5.34)	\$ (7.46)	\$ (4.92)	\$ (0.30)	\$ (3.44)
Shares used to compute basic and diluted net loss per share(4)	34,150	31,755	31,741	31,741	31,741

Table of Contents

	As of December 31,				
	2015	2014	2013	2012	2011
(In thousands)					
<b>CONSOLIDATED BALANCE SHEETS DATA</b>					
Cash, cash equivalents and marketable securities(5)	\$ 215,294	\$ 306,010	\$	\$	\$
Working capital	188,002	234,114	(22,747)	(11,837)	(33,565)
Total assets	300,116	337,771	25,177	20,962	13,821
Long-term liabilities(6)	7,581	6,728	5,359	5,280	118,664
Accumulated deficit	(321,556)	(139,337)			
Parent company deficit			(17,035)	(6,990)	(140,724)
Total shareholders' equity and parent company deficit	\$ 243,065	\$ 289,787	\$ (17,035)	\$ (6,990)	\$ (140,724)

- (1) In 2012, there was an acceleration of deferred revenue of \$125.8 million from our global collaboration agreement with Astellas Pharma Inc. ("Astellas") for the development and commercialization of VIBATIV, which resulted from the termination of the Astellas agreement in January 2012.
- (2) For the years ended December 31, 2015 and 2014, cost of goods sold includes charges of \$1.9 million and \$2.9 million, respectively, for the write-down of VIBATIV inventory due to the dating of the product.
- (3) The following table discloses the allocation of shared-based compensation expense included in total operating expenses:

	Year Ended December 31,				
	2015	2014	2013	2012	2011
(In thousands)					
Research and development	\$ 25,770	\$ 21,191	\$ 15,444	\$ 13,192	\$ 12,696
Selling, general and administrative	28,280	22,043	7,032	8,131	8,767
Total share-based compensation	\$ 54,050	\$ 43,234	\$ 22,476	\$ 21,323	\$ 21,463

- (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 2013 and 2014.
- (5) Cash, cash equivalents and marketable securities were not allocated to us prior to the Spin-Off.
- (6) Long-term liabilities include the long-term portion of deferred revenue as follows:

As of December 31,				
2015	2014	2013	2012	2011
(In thousands)				

Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

Deferred revenue	\$	952	\$	712	\$	585	\$	206	\$	112,843
------------------	----	-----	----	-----	----	-----	----	-----	----	---------

---

48



Table of Contents

**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 and Section 21E of 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 with the core purpose of creating medicines that make a difference in the lives of patients suffering from serious illness.

Our pipeline of internally discovered product candidates includes potential best-in-class medicines to address the unmet needs of patients being treated for serious conditions primarily in the acute care setting. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S., Europe and certain other countries for certain difficult-to-treat infections. Revefenacin (TD-4208) is a long-acting muscarinic antagonist ("LAMA") being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease ("COPD"). Our neprilysin ("NEP") inhibitor program is designed to develop selective NEP inhibitors for the treatment of a range of major cardiovascular and renal diseases, including acute and chronic heart failure, hypertension and chronic kidney diseases such as diabetic nephropathy. Our research efforts are focused in the areas of inflammation and immunology, with the goal of designing medicines that provide targeted drug delivery to tissues in the lung and gastrointestinal tract in order to maximize patient benefit and minimize risk. The first program to emerge from this research is designed to develop GI-targeted pan-Janus kinases ("JAK") inhibitors for the treatment of a range of inflammatory intestinal diseases.

In addition, we have an economic interest in future payments that may be made by Glaxo Group Limited or one of its affiliates ("GSK") pursuant to its agreements with Innoviva, Inc. ("Innoviva") (known as Theravance, Inc. prior to January 7, 2016) relating to certain drug development programs, including the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol).

In 2015, our net loss was \$182.2 million, a decrease of \$54.8 million from \$237.0 million in 2014. Our research and development expenses were \$129.2 million in 2015, an decrease of \$39.3 million from \$168.5 million in 2014, primarily due to the reimbursement of external costs under certain collaborative arrangements. Our selling, general and administrative expenses were \$90.2 million in 2015, an increase of \$18.6 million from \$71.6 million in 2014, primarily due to the expansion of our VIBATIV commercial infrastructure and an increase in share-based compensation expense. Cash, cash equivalents, and marketable securities, excluding restricted cash, totaled \$215.3 million on December 31, 2015.

Theravance Biopharma was incorporated in the Cayman Islands in July 2013. While we are incorporated under Cayman Island law, we became an Irish tax resident effective July 1, 2015.

Table of Contents

**The Separation of Theravance Biopharma from Innoviva, Inc. and Basis of Historical Presentation**

On June 2, 2014, Theravance Biopharma became an independent, publicly-traded company as a result of a pro rata dividend distribution by Innoviva of one ordinary share of Theravance Biopharma for every three and one half shares of Innoviva common stock outstanding (the "Spin-Off"). The Spin-Off was designed to separate Innoviva's late-stage respiratory assets partnered with GSK from its biopharmaceutical business.

For the periods prior to June 2, 2014, the consolidated financial statements have been prepared using Innoviva's historical cost basis of the assets, liabilities, revenues, and expenses of the various activities that comprise the biopharmaceutical business as a component of Innoviva and reflect the results of operations, financial condition and cash flows of the biopharmaceutical business as a component of Innoviva. The statements of operations include expense allocations for general corporate overhead functions historically shared with Innoviva, including finance, legal, human resources, information technology and other administrative functions, which include the costs of salaries, benefits and other related costs, as well as consulting and other professional services. Where appropriate, these allocations were made on a specific identification basis. Otherwise, the expenses related to services provided to the biopharmaceutical business by Innoviva were allocated to Theravance Biopharma based on the relative percentages, as compared to Innoviva's other businesses, of headcount or square footage usage. The costs historically allocated to us by Innoviva for the services it has shared with us may not be indicative of the costs we have incurred or will incur for these services following the Spin-Off.

**Program Highlights**

**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. VIBATIV is approved in the U.S. 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. VIBATIV is indicated in the European Union for the treatment of adults with nosocomial pneumonia, including ventilator-associated pneumonia, known or suspected to be caused by MRSA when other alternatives are not suitable. VIBATIV is also indicated in Canada and Russia for complicated skin and skin structure infections and HABP and VABP caused by Gram-positive bacteria, including MRSA. We plan to market VIBATIV outside the U.S. through a network of partners. To date, we have secured partners for VIBATIV in the following geographies: Europe, Canada, Middle East, North Africa, Israel, Russia, China and India.

*Commercial Program Expansion*

In 2014 and early 2015, we implemented a phased launch strategy for VIBATIV in the U.S. that focused on a limited number of targeted geographic territories across the country. In the second quarter of 2015, we announced our intention to expand our sales force to 50 representatives with the goal of further strengthening our commercial infrastructure comprised of experienced sales representatives and a significant medical information component focused on the acute care market. We achieved our goal of hiring and training additional sales representatives by the end of the third quarter of 2015, and the newly expanded field force was fully deployed by the beginning of the fourth quarter of 2015.

Table of Contents

*Supplemental New Drug Application (sNDA) for Concurrent Staphylococcus aureus Bacteremia*

In September 2015, we announced that the Food and Drug Administration ("FDA") accepted for filing our sNDA to expand the VIBATIV label to include concurrent *Staphylococcus aureus* bacteremia. The sNDA submission was based on the combined data from our previously conducted pivotal trials of VIBATIV in its two approved indications cSSSI (ATLAS I and ATLAS II) and HABP/VABP (ATTAIN I and ATTAIN II). The trials were large, multi-center, multi-national, double-blind, randomized Phase 3 clinical studies enrolling and treating 3,370 adult patients, including a portion of patients with concurrent bacteremia. Importantly, these studies involved two of the largest cohorts of patients ever studied in these diseases and included one of the largest cohorts of patients with MRSA infections studied to date. Under the Prescription Drug User Fee Act ("PDUFA"), the FDA has set a target of the second quarter of 2016 to complete its review of the sNDA. Separately, we are conducting a Phase 3 registrational study in patients with *Staphylococcus aureus* bacteremia.

*Phase 3 Registrational Study in Staphylococcus aureus Bacteremia*

As part of our effort to explore additional settings in which VIBATIV may offer patients therapeutic benefit, in February 2015, we initiated a Phase 3 registrational study for the treatment of patients with *Staphylococcus aureus* bacteremia. The 250-patient registrational study is a multi-center, randomized, open-label study designed to evaluate the non-inferiority of telavancin in treating *Staphylococcus aureus* bacteremia as compared to standard therapy. Key secondary outcome measures of the study include an assessment of the duration of bacteremia post-randomization and the incidence of development of metastatic complications, as compared to standard therapy.

*Telavancin Observational Use Registry ("TOUR")*

Initiated in February 2015, the 1,000-patient TOUR observational use registry study is designed to assess the manner in which VIBATIV is used by healthcare practitioners to treat patients. By broadly collecting and examining data related to VIBATIV treatment patterns, as well as clinical and safety outcomes in the real world, we aim to create an expansive knowledge base to guide future development and optimal use of the drug.

***Long-Acting Muscarinic Antagonist Revefenacin (TD-4208)***

Revefenacin is an investigational long acting muscarinic antagonist ("LAMA") in development for the treatment of COPD. We believe that revefenacin may become a valuable addition to the COPD treatment regimen and that it represents a significant commercial opportunity. Our market research indicates there is an enduring population of COPD patients in the U.S. that either need or prefer nebulized delivery for maintenance therapy. LAMAs are a cornerstone of maintenance therapy for COPD, but existing LAMAs are only available in handheld devices that may not be suitable for every patient. Revefenacin has the potential to be a best-in-class once-daily single-agent product for COPD patients who require, or prefer, nebulized therapy. The therapeutic profile of revefenacin, together with its physical characteristics, suggest that this LAMA could serve as a foundation for combination products and for delivery in metered dose inhaler and dry powder inhaler products.

*Phase 3 Study in COPD*

In September 2015, we announced, with our partner Mylan Ireland Limited ("Mylan"), the initiation of the Phase 3 development program for revefenacin for the treatment of COPD. The Phase 3 development program, designed to support the registration of the product in the U.S., includes two replicate three-month efficacy studies and a single twelve-month safety study. The two efficacy studies will examine 2 doses (88 mcg and 175 mcg) of revefenacin inhalation solution administered once-daily via nebulizer in moderate to severe patients with COPD. The Phase 3 efficacy studies are

Table of Contents

replicate, randomized, double-blind, placebo-controlled, parallel-group trials designed to provide pivotal efficacy and safety data for once-daily revefenacin 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 is an open-label, active comparator study of 12 months duration. Together, the three studies will enroll approximately 2,300 patients. In February 2016, we announced the achievement of 50% enrollment in all three of the Phase 3 clinical studies for revefenacin. The achievement of 50% enrollment in the twelve-month safety study triggered a \$15.0 million milestone payment to Theravance Biopharma by Mylan.

*Mylan Collaboration*

In January 2015, Mylan and we established a strategic collaboration for the development and, subject to regulatory approval, 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 where we currently market VIBATIV. Funding of the Phase 3 development program by Mylan strengthens our capital position and enhances our financial flexibility to advance other high-value pipeline assets alongside revefenacin.

Under the terms of the Mylan Development and Commercialization Agreement (the "Mylan Agreement"), Mylan and we will co-develop nebulized revefenacin for COPD and other respiratory diseases. We are leading the U.S. Phase 3 development program and Mylan is responsible for reimbursement of our costs for that program up until the approval of the first new drug application, after which costs will be shared. If a product developed under the collaboration is approved in the U.S., Mylan will lead commercialization and we will retain the right to co-promote the product in the U.S. under a profit-sharing arrangement (65% Mylan/35% Theravance Biopharma). Outside the U.S. (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. Although China is not included in the ex-U.S. territory, Mylan has a right of first negotiation with respect to the development and commercialization of nebulized revefenacin in China.

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 ordinary share purchase agreement 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 early 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. As of December 31, 2015, we are eligible to receive from Mylan potential development and sales milestone payments totaling \$220.0 million in the aggregate, with \$175.0 million associated with revefenacin monotherapy and \$45.0 million for future potential combination products. In February 2016, we earned a \$15.0 million development milestone payment for achieving 50% enrollment in the Phase 3 twelve-month safety study.

We retain worldwide rights to revefenacin delivered through other dosage forms, such as a metered dose inhaler or dry powder inhaler ("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.

***Oral Peripherally-Acting Mu Opioid Receptor Antagonist Axelopran (TD-1211)***

*OIC Program*

Axelopran is an investigational, once-daily, oral peripherally active mu opioid receptor antagonist for OIC. The axelopran Phase 2 program demonstrated a clinically meaningful treatment effect in OIC patients compared to placebo. The goal for this program is to demonstrate the ability to normalize

Table of Contents

bowel function without impacting analgesia and improve a variety of GI symptoms associated with constipation, which could provide axelopran with a competitive advantage in the OIC market if demonstrated in Phase 3 studies and approved by regulatory authorities. We have developed a patient reported outcomes tool designed to measure patient symptoms which would be used in a Phase 3 registrational program and potentially generate data that could differentiate the product from the competition. We are currently refining our development and commercial strategy for axelopran.

*Fixed Dose Combination*

In December 2014, we completed a Phase 1 study to determine the relative bioavailability of OxyContin® (oxycodone) and axelopran after oral administration as a fixed dose combination ("FDC") relative to the individual components administered together. The study examined a spray-coat application of axelopran to an opioid, OxyContin, to determine the effect of axelopran on OxyContin exposure. The study compared exposure of OxyContin alone, axelopran alone, OxyContin and axelopran administered as two separate tablets, and OxyContin spray-coated with axelopran in a FDC. Study results demonstrated that axelopran does not significantly alter systemic exposure to OxyContin when delivered as a FDC relative to when co-administered as individual tablets. A FDC of axelopran and an opioid could present an important market opportunity, as it has the potential to provide pain relief without constipation in a single abuse-deterrent pill for patients using opioids on a chronic basis.

***Velusetrag***

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-HT<sub>4</sub> receptor. Velusetrag is being developed in collaboration with Alfa Wassermann S.p.A. ("Alfa Wassermann") in a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis. Positive 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, were announced in April 2014. In March 2015, we initiated a Phase 2b study of velusetrag for the treatment of patients with gastroparesis and other gastrointestinal motility disorders. The 200-patient study is a multi-center, double-blind, randomized, placebo-controlled, parallel-group trial which will explore the efficacy and safety of multiple doses of velusetrag in patients with diabetic or idiopathic gastroparesis. The twelve-week study will test three doses: 5, 15, and 30 mg administered once-daily. The primary endpoint will be the effect of velusetrag on symptoms in subjects with gastroparesis. The study will also evaluate the effect of velusetrag on gastric emptying, and the psychometric properties of the Gastroparesis Rating Scale ("GRS"), a daily patient-reported outcome ("PRO") measure. Pursuant to our agreement with Alfa Wassermann, the first Phase 2 study was, and the bulk of the Phase 2b study is, funded by Alfa Wassermann.

***NS5A Inhibitor TD-6450***

TD-6450 is an internally discovered multivalent NS5A inhibitor designed to have improved antiviral activity against GT-1 resistance-associated variants ("RAV") resistant to first generation NS5A inhibitors. TD-6450 has successfully completed Phase 1 studies in both healthy volunteers and hepatitis C virus ("HCV") patients. In September 2015, we entered into a licensing agreement with Trek Therapeutics, PBC ("TREKtx") (the "TREKtx Agreement") granting TREKtx an exclusive worldwide license for the development, manufacturing, use, marketing and sale of TD-6450 as a component in combination HCV products (the "HCV Products"). Pursuant to the TREKtx Agreement, we received an upfront payment of \$8.0 million in the form of TREKtx's Series A preferred stock and will be eligible to receive future royalties based on net sales of the HCV Products. In October 2015, TREKtx and we announced that TREKtx had initiated a Phase 2a clinical trial to evaluate faldaprevir, an HCV protease inhibitor, combined with TD-6450 and ribavirin in patients infected with HCV genotype 4.

Table of Contents

***Neprilysin (NEP) Inhibitor Program***

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. Our primary objective is to develop a NEP inhibitor that could 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. We intend to create a platform for multiple combination products with our NEP inhibitor with features that are differentiated from currently available products. Specifically, compounds that are non-renally cleared, dosed once-daily, dosed alone or in combination with other medicines and that may be dosed orally or intravenously.

***Phase 1 Single Ascending Dose (SAD) Study***

In March 2016, we completed a Phase 1 clinical study of our most advanced NEP inhibitor compound, TD-0714. The Phase 1 trial was a randomized, double-blind, placebo-controlled, single ascending dose study in healthy volunteers. The study was designed to assess the safety, tolerability and pharmacokinetics of TD-0714, as well as measure biomarker evidence of target engagement and the amount of the drug that is eliminated via the kidneys. Results from the Phase 1 single-ascending dose study of TD-0714 demonstrate 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 safety and tolerability profile. These results met the Company's target product profile and provide confidence for future efficacy studies of TD-0714 in a broad range of cardiovascular and renal diseases, including in patients with compromised renal function. Theravance Biopharma is now conducting a Phase 1 multiple-ascending dose ("MAD") study of TD-0714 that is designed to supplement the findings of the SAD study and support the ongoing clinical development of the molecule.

***Gastrointestinal (GI)-Targeted Pan-Janus Kinase (JAK) Inhibitor Program***

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. This mechanism has previously demonstrated therapeutic benefit for patients with ulcerative colitis. Currently available treatments for ulcerative colitis have systemic safety liabilities and limited efficacy. Our goal is to develop an orally administered GI-targeted pan-JAK inhibitor designed to distribute adequately and exclusively to the tissues of the GI tract and minimize systemic exposure to treat ulcerative colitis and potentially other inflammatory intestinal disorders.

***Phase 1 Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) Studies***

In December 2015, we initiated a Phase 1 clinical study of TD-1473. The Phase 1 trial is a randomized, double-blind, placebo-controlled, single ascending dose and multiple ascending dose study in healthy subjects. The primary objective of the study will be evaluation of the safety and tolerability of single ascending doses and multiple ascending doses of TD-1473 in healthy subjects. A key secondary objective of the trial will be the characterization of pharmacokinetics related to TD-1473, which will help determine the amount of TD-1473 that enters systemic circulation following oral administration.

Table of Contents

**Other Programs**

***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 (pursuant to its agreements with Innoviva) relating to the GSK-Partnered Respiratory Programs consisting primarily of the Closed Triple 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 will not include any payments associated with RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® or vilanterol monotherapy. The following information regarding the Closed Triple and the MABA program is based solely upon publicly available information and may not reflect the most recent developments under the programs.

*"Closed Triple" or FF/UMEC/VI (fluticasone furoate/umeclidinium bromide/vilanterol)*

The Closed Triple program seeks 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. If the Closed Triple 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, which royalties are upward-tiering from 6.5% to 10%. Innoviva and GSK are conducting two global Phase 3 studies for the Closed Triple, which will enroll approximately 11,800 patients with COPD.

*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. Recently, GSK initiated two Phase 2 clinical trials in COPD patients and two pharmacology studies in healthy volunteers of batefenterol and batefenterol/FF.

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, 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 medicine. If a MABA medicine containing '081 is successfully developed and commercialized in multiple regions of the world, GSK will pay TRC contingent milestone payments of up to \$125.0 million for a single-agent medicine and up to \$250.0 million for both a single-agent and a combination medicine, and in each case we would be entitled to receive an 85% economic interest in any such payments.

*Theravance Respiratory Company, LLC*

Prior to the Spin-Off, Innoviva assigned to TRC its strategic alliance agreement with GSK and all of its rights and obligations under its LABA collaboration agreement with GSK other than with respect to RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® and vilanterol monotherapy. 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. The drug programs assigned to TRC include the Closed Triple 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.

Table of Contents

**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 U.S. generally accepted accounting principles ("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.

*Product Sales*

In 2013, we reintroduced VIBATIV into the U.S. market by making the drug product available through a limited number of distributors who sell VIBATIV to healthcare providers. Title and risk of loss transfer upon receipt by these distributors.

Outside of the U.S., we make VIBATIV available through a limited number of collaborative partners who sell VIBATIV in their respective geographies.

Prior to the fourth quarter of 2014, as a result of VIBATIV's limited sales history, we could not reliably estimate expected returns, rebates and chargebacks of the product at the time the product was sold to the distributors. Therefore, we deferred the recognition of revenue on sales to the VIBATIV distributors, and instead, recognized revenue at the time the product was sold through to healthcare providers, the end customers, or the right of return no longer existed, whichever occurred earlier.

Beginning in the fourth quarter of 2014, we had developed sufficient historical experience and data to reasonably estimate future returns, rebates and chargebacks of VIBATIV and as a result, effective October 1, 2014, we began recognizing VIBATIV product sales and related cost of product sales at the time title transfers to the wholesalers, otherwise known as a sell-in basis. The impact of this change resulted in additional product sales recognition of \$0.3 million in 2014 in our consolidated statements of operations.

Product sales are recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. We reflect 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 consider payer mix in target markets, industry benchmarks and experience to date. We monitor inventory levels in the distribution channel, as well as sales of VIBATIV 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 VIBATIV experienced by Innoviva's former collaborative partner, Astellas Pharma Inc. ("Astellas"), 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.

Sales Discounts: We offer cash discounts to certain customers in the U.S. as an incentive for prompt payment. We expect our customers to comply with the prompt payment terms to earn the cash



Table of Contents

discount. In addition, we offer contract discounts to certain direct customers. We estimate sales discounts based on contractual terms, historical utilization rates, as available, and our expectations regarding future utilization rates. We account for sales discounts by reducing accounts receivable by the full amount and recognizing the discount as a reduction of revenue in the same period the related revenue is recognized.

**Chargebacks and Government Rebates:** For VIBATIV sales in the U.S., we estimate 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. Our 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. Our accrual for Medicaid is based upon statutorily-defined discounts, estimated payer mix, expected sales to qualified healthcare providers, and our expectation about future utilization. The Medicaid accrual and government rebates that are invoiced directly to us are recorded in other accrued liabilities on the consolidated balance sheets. For qualified programs that can purchase our products through distributors at a lower contractual government price, the distributors charge back to us the difference between their acquisition cost and the lower contractual government price, which we record as an allowance against accounts receivable.

**Distribution Fees and Product Returns:** We have written contracts with our distributors in the U.S. that include terms for distribution-related fees. We record distribution-related fees based on a percentage of the product sales price. We offer our distributors a right to return product purchased directly from us, which is principally based upon the product's expiration date. Our policy is to accept product returns during the six months prior to and twelve months after the product expiration date on product that had been sold to our distributors. We have developed estimates for VIBATIV product returns based upon historical VIBATIV sales. We record distribution fees and product returns as an allowance against accounts receivable.

**Allowance for Doubtful Accounts:** We record allowances for potentially doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. Based on our history, we deem the risk of loss associated with these receivables to be low. As of December 31, 2015 and 2014, there was no allowance for doubtful accounts related to customer payments.

Our reserve activity for sales & return allowances, discounts, chargebacks and rebates is summarized as follows:

<b>(In thousands)</b>	<b>Balance at</b>		<b>Charges</b>		<b>Deductions</b>		<b>Balance at</b>	
	<b>December 31, 2014</b>						<b>December 31, 2015</b>	
Sales & returns allowances, discounts, chargebacks and rebates	\$	180	\$	3,257	\$	(2,576)	\$	861
<i>Inventories</i>								

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 we incur 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 commercialization agreements, we may sell VIBATIV packaged in unlabeled vials that are recorded in work-in-process. Inventories are stated at the lower of cost or market value. We determine the cost of inventory using the average-cost method for each manufacturing batch.

Table of Contents

We assess our inventory levels quarterly and write down inventory that is expected to become obsolete, that has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. This assessment requires management to utilize judgement in formulating estimates and assumptions that we believe to be reasonable under the circumstances. Actual results may differ from those estimates and assumptions.

When we recognize a loss on such inventory, 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 the products making up that inventory. In 2015 and 2014, we recognized charges of \$1.9 million and \$2.9 million, respectively, to write-down inventory due to dating of the product. Finished goods is the portion of our inventory that is most at risk for product dating issues and the carrying value of our finished goods inventory was \$3.1 million as of December 31, 2015. In order to realize the value of our recorded inventory, we will be dependent upon continued increases in the sales volumes of VIBATIV. Refer to Note 5, "Inventories," to the consolidated financial statements appearing in this Annual Report on Form 10-K for further information regarding the components of our inventories.

*Income Taxes*

The provision for income taxes in 2015 is a result of recording certain contingent tax liabilities pertaining primarily to uncertain tax positions taken with respect to transfer pricing and tax credits.

During 2015, we adopted FASB Accounting Standards Update 2015-17, *Balance Sheet Classification of Deferred Income Taxes*, which requires that the Consolidated Balance Sheets reflect all deferred income tax assets and liabilities as non-current. We elected to retrospectively apply the provisions of the standard, and the adoption had no impact on our consolidated financial position or results of operations.

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. We continue to maintain a full valuation allowance against our deferred tax assets. We reassess our valuation allowance for deferred income taxes at each reporting period. If we determine that it is more likely than not that the benefit of those assets will be realized, a reversal of a portion or all of the valuation allowance would occur and result in a corresponding benefit to earnings.

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. The provision for income taxes, including the effective tax rates, the determination of deferred tax assets and liabilities and related valuation allowance evaluation, and the analysis of potential tax exposure items, if any, requires significant judgment. Our filings, including the positions taken therein, may be subject to audit by various taxing authorities. 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.

At December 31, 2015 and 2014, we had total federal, state and foreign unrecognized tax benefits of \$9.2 million and \$1.1 million, respectively. Our unrecognized tax benefits would reduce our effective income tax rate if recognized. As of December 31, 2015, we do not anticipate the total amount of

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

### Table of Contents

unrecognized income tax benefits relating to uncertain tax positions existing at December 31, 2015 to decrease in the next 12 months.

### *Accrued Research and Development Expenses*

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

communicating with our applicable personnel to identify 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;

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 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. 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.

### *Non-Marketable Equity Securities*

As a result of entering into a licensing agreement with Trek Therapeutics, PBC ("TREKtx") in September 2015, we hold an \$8.0 million minority investment in TREKtx, a non-public company. We recorded this non-marketable equity investment at cost in long-term assets, and we periodically review our non-marketable equity securities for impairment by determining whether impairment indicators are present. Common impairment indicators include a significant adverse change in the regulatory or economic environment in which the investee entity operates or cash used in operating activities and other working capital deficiencies.



Table of Contents

If we conclude that any of the non-marketable equity securities are impaired, we determine whether such impairment is other-than-temporary. Factors we consider to make such determination include the duration and severity of the impairment, the reason for the decline in value and the potential recovery period and our intent to sell. If any impairment is considered other-than-temporary, we will write down the asset to its fair value and record the corresponding charge as interest and other income (loss).

As of December 31, 2015, we reviewed our TREKtx investment for impairment and determined that no impairment indicators were present and no impairment charges were necessary.

**Results of Operations**

***Product Sales and Revenue from Collaborative Arrangements***

Product sales and revenues from collaborative arrangements, as compared to the prior years, were as follows:

(In thousands)	Year Ended December 31,			Change			
	2015	2014	2013	2015		2014	
	\$	\$	\$	\$	%	\$	%
Product sales	\$ 9,408	\$ 4,418	\$	\$ 4,990	113%	\$ 4,418	NM
Revenue from collaborative arrangements	32,718	7,270	226	25,448	350	7,044	NM
Total revenue	\$ 42,126	\$ 11,688	\$ 226	\$ 30,438	260%	\$ 11,462	NM

---

NM: Not Meaningful

Revenue from product sales increased to \$9.4 million in 2015 compared to \$4.4 million in 2014 due to the continued growth in VIBATIV. The growth was primarily due to an increase in number of customer accounts and increase in sales volume, driven in part by the continued expansion of our sales infrastructure. U.S. product sales accounted for 93% and 96% of total product sales in 2015 and 2014, respectively.

We did not recognize any revenue from product sales in 2013 as VIBATIV was only available through a limited number of distributors, and we accounted for such sales on a sell-through basis. In October 2014, we began recognizing VIBATIV product sales at the time title transfers to the wholesalers, otherwise known as a sell-in basis as a result of developing sufficient historical experience and data to reasonably estimate future returns, rebates and chargebacks.

Revenue from collaborative arrangements increased significantly in 2015 to \$32.7 million compared to \$7.3 million in 2014 and \$0.2 million in 2013. The increase was primarily due to the recognition of \$19.2 million of upfront payment from Mylan for the delivery of a license and technological know-how for revefenacin (TD-4208) and \$8.0 million of upfront non-cash consideration from TREKtx for the TD-6450 licensing agreement.

Revenue from collaborative arrangements increased in 2014 from 2013 primarily due to the recognition of previously deferred revenue from the Clinigen Group plc collaborative arrangement of \$5.0 million and JSC R-Pharm (formerly R-Pharm CSJC) collaborative arrangement of \$2.1 million. Recognition of both resulted from the completion of the technical transfer of the license in 2014.

Table of Contents**Cost of Goods Sold**

(In thousands)	Year Ended December 31,			Change			
	2015	2014	2013	2015		2014	
	\$	\$	\$	\$	%	\$	%
Costs of goods sold	\$ 4,657	\$ 4,058	\$	\$ 599	15%	\$ 4,058	NM

NM: Not Meaningful

Cost of goods sold was \$4.7 million in 2015 which includes a charge of \$1.9 million for the write down of short-dated VIBATIV inventory. This is compared to cost of goods sold of \$4.1 million in 2014 which included a similar write down of \$2.9 million. Excluding the write downs in both years, cost of goods sold increased \$1.6 million due to the increase in VIBATIV product sales. If our VIBATIV sales are higher than expected in the near future, we may be able to sell, prior to expiration, a portion of the inventory that has been written down. In the event that we sell inventory that has been previously written down, our gross margins in future periods will be favorably affected.

There were no costs of goods sold in 2013 as there were no product sales recognized in 2013.

**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, as we do not have program level reporting capabilities. 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 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 incurred during the periods presented:

(In thousands)	Year Ended December 31,			Change			
	2015	2014	2013	2015		2014	
	\$	\$	\$	\$	%	\$	%
Employee-related	\$ 38,621	\$ 57,427	\$ 36,917	\$ (18,806)	(33)%	\$ 20,510	56%
Share-based compensation	25,770	21,191	15,444	4,579	22	5,747	37
External-related	38,151	62,975	45,926	(24,824)	(39)	17,049	37
Facilities, depreciation and other allocated	26,623	26,929	22,292	(306)	(1)	4,637	21
<b>Total Research &amp; Development</b>	<b>\$ 129,165</b>	<b>\$ 168,522</b>	<b>\$ 120,579</b>	<b>\$ (39,357)</b>	<b>(23)%</b>	<b>\$ 47,943</b>	<b>40%</b>

R&D expenses decreased \$39.4 million in 2015 compared to 2014 primarily due to decreases in employee-related costs and external-related costs. The decrease in employee-related costs was primarily due to lower costs associated with the long-term retention and incentive awards granted to certain employees in 2011. The decrease in external-related costs was primarily due to the reimbursement of R&D costs for the revefenacin program under the Mylan collaboration agreement. Both decreases were



## Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

### Table of Contents

partially offset by an increase in share-based compensation expense compared to 2014, due primarily to new equity awards issued under our equity plans post Spin-Off.

R&D expenses increased in 2014 compared to 2013 primarily due to progression of clinical studies in our key programs. The expenditures for clinical trials in 2014 were primarily related to the initiation of our telavancin Phase 3 registrational study in bacteremia and Phase 4 registry study for VIBATIV, completion of Phase 2 studies for revefenacin and Phase 1 studies in our earlier stage programs. In 2013, our key clinical trials primarily consisted of Phase 2 clinical studies in our MARIN program with TD-9855 for ADHD and fibromyalgia, a Phase 2 study for revefenacin and Phase 1 studies in our earlier stage programs. Employee-related expenses, including share-based compensation, increased primarily due to the achievement of performance conditions under special long-term retention and incentive awards granted to certain employees in 2011, prior to the Spin-Off. In 2013, employee-related expenses were partially offset by R&D reimbursements received from our collaborative partners.

Under certain of our collaborative arrangements we receive partial reimbursement of external costs and employee-related costs, which have been reflected as a reduction of R&D expenses of \$55.2 million, \$1.9 million and \$6.5 million for 2015, 2014 and 2013, respectively.

### ***Selling, General & Administrative***

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

(In thousands)	Year Ended December 31,			Change			
	2015    2014    2013			2015		2014	
	2015	2014	2013	\$	%	\$	%
Selling, general and administrative	\$ 90,203	\$ 71,647	\$ 35,931	\$ 18,556	26%	\$ 35,716	99%

Selling, general and administrative expenses increased \$18.6 million in 2015 compared to 2014 and \$35.7 million in 2014 compared to 2013. The increases are primarily due to costs associated with the continued expansion of our internal sales and marketing organization supporting VIBATIV commercialization and due to an increase in share-based compensation expense. Share-based compensation expenses were \$28.3 million, \$22.0 million and \$7.0 million in 2015, 2014 and 2013, respectively. Share-based compensation increased primarily due to new equity awards issued under our equity plans post Spin-Off.

### ***Interest and Other Income***

Interest and other income was not significant in 2015. In 2014, interest and other income of \$1.9 million primarily consisted of interest income of \$0.3 million and reimbursement for transition services rendered to Innoviva of \$1.6 million. There was no interest and other income in 2013.

### ***Provision for Income Taxes***

(In thousands)	Year Ended December 31,			Change			
	2015    2014    2013			2015		2014	
	2015	2014	2013	\$	%	\$	%
Provision for income taxes	\$ 951	\$ 6,364	\$ (5,413)	\$ (5,413)	(85)%	\$ 6,364	NM

NM: Not Meaningful

The provision for income taxes decreased \$5.4 million in 2015 compared to 2014 due to changes in our transfer pricing. The provision for income taxes was \$1.0 million and \$6.4 million in 2015 and 2014, respectively, although we incurred operating losses on a consolidated basis. The provision for 2015 resulted from recording contingent tax liabilities pertaining primarily to uncertain tax positions taken



Table of Contents

with respect to transfer pricing and tax credits. The 2014 provision was a result of generating taxable income in our U.S. operations. There was no provision for income taxes in 2013.

As of December 31, 2015, we had \$10.9 million of federal net operating loss carryforwards, as well as \$2.7 million of federal research and development tax credit carryforwards that expire in 2035. We had state operating loss carryforwards of \$23.4 million which begin to expire in 2034, and state research and development credit carryforwards of \$4.4 million to be carried forward indefinitely. We had unrecognized tax benefits of \$9.2 million as of December 31, 2015. Our unrecognized tax benefits would reduce our effective income tax rate if recognized.

**Liquidity and Capital Resources**

We expect to continue to incur net losses over the next several years as we continue our drug discovery efforts and incur significant preclinical and clinical development costs related to our current product candidates and commercialization and development costs relating to VIBATIV. In particular, to the extent we advance our product candidates into and through later stage clinical studies without a partner, we will incur substantial expenses. In 2015, we have made additional investments in telavancin, our approved antibiotic. For example, in February 2015, we initiated a Phase 3 registrational study for bacteremia and a patient registry study. In addition, we have increased the number of VIBATIV sales representatives and medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV. We are incurring all of the costs and expenses associated with the commercialization of VIBATIV in the U.S., including the creation of an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities, expansion of medical affairs presence, manufacturing and third party vendor logistics and consultant support, and post-marketing studies.

*Adequacy of cash resources to meet future needs*

We expect our cash and cash equivalents and marketable securities will fund our operations for at least the next 12 months based on current operating plans and financial forecasts.

If our current operating plans or financial forecasts change, we may require additional funding sooner in the form of public or private equity offerings, debt financings or additional collaborations and licensing arrangements. In July 2015, our shelf registration statement on Form S-3 for the potential offering, issuance and sale by us of up to a maximum aggregate offering price of \$250.0 million of our debt securities, ordinary shares, and/or warrants was declared effective (the "Form S-3"). Up to \$50.0 million of the maximum aggregate offering price of \$250.0 million under the registration statement may be issued and sold pursuant to an at-the-market offering program for sales of our ordinary shares under a sales agreement with Cantor Fitzgerald & Co. ("ATM Agreement"), who would act as our sales agent and underwriter. In October 2015, we entered into an Ordinary Share Purchase Agreement (the "Purchase Agreement") with funds managed by Woodford Investment Management LLP for the registered direct offering of an aggregate of 3,859,649 of our ordinary shares, \$0.00001 par value (the "Shares"), at a purchase price of \$14.25 per Share. The Shares were issued pursuant to a prospectus supplement filed with the Securities and Exchange Commission ("SEC") on October 26, 2015, in connection with a takedown from our shelf registration statement on Form S-3. The closing of the transaction occurred on October 29, 2015 and the net offering proceeds were approximately \$53.0 million. As favorable financing opportunities arise, we may seek to raise capital under the Form S-3, including under the ATM Agreement to fund our operations. 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

Table of Contents

arrangements. We may also have to sequence pre-clinical 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	
	2015	2014	2013	2015	2014
Net cash used in operating activities	\$ (168,857)	\$ (175,155)	\$ (120,959)	\$ 6,298	\$ (54,196)
Net cash provided by (used in) investing activities	111,039	(106,251)	(2,634)	217,290	(103,617)
Net cash provided by financing activities	81,310	370,621	123,593	(289,311)	247,028

*Net cash flows used in operating activities*

Net cash used in operating activities was \$168.9 million in 2015, consisting primarily of net loss of \$182.2 million, adjusted for non-cash items such as \$54.1 million for share-based compensation expense and \$8.0 million for non-cash revenue from collaborative agreements, and \$37.8 million of net cash outflow related to changes in operating assets and liabilities. The \$37.8 million net cash outflow related to changes in operating assets and liabilities was primarily attributable to receivables due from the Mylan collaboration agreement that was established in January 2015 and prepaid taxes in 2015.

Net cash used in operating activities was \$175.2 million in 2014, consisting primarily of net loss of \$237.0 million, adjusted for non-cash items such as \$43.2 million for share-based compensation expense, and \$12.8 million of net cash inflow related to changes in operating assets and liabilities.

Net cash used in operating activities was \$121.0 million in 2013, consisting primarily of net loss of \$156.3 million, adjusted for non-cash items such as \$22.5 million for share-based compensation expense, and \$10.2 million of net cash inflow related to changes in operating assets and liabilities.

*Net cash flows provided by (used in) investing activities*

Net cash provided by investing activities was \$111.0 million in 2015, consisting primarily of maturities of marketable securities of \$186.7 million partially offset by purchases of marketable securities of \$73.0 million.

Net cash used in investing activities was \$106.3 million in 2014, consisting primarily of purchases of marketable securities of \$168.9 million partially offset by maturities of marketable securities of \$65.6 million.

Net cash used in investing activities was \$2.6 million in 2013, consisting primarily of capital expenditures for property and equipment of \$2.7 million.

*Net cash flows provided by financing activities*

Net cash provided by financing activities was \$81.3 million in 2015, consisting primarily of the sales of ordinary shares to Mylan and Woodford Investment Management LLP for a total net proceeds of \$79.0 million.

Net cash provided by financing activities was \$370.6 million in 2014, consisting primarily of \$277.5 million in cash and cash equivalents contributed from Innoviva as a result of the Spin-Off.

Table of Contents

Net cash provided by financing activities was \$123.6 million in 2013, consisting solely of transfers from Innoviva to Theravance Biopharma, its former biopharmaceutical business before the Spin-Off.

***Commitments and Contingencies***

In 2011, Innoviva granted special long-term retention and incentive restricted stock awards to members of senior management. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year time frame from 2011 through December 31, 2016 and continued employment.

In May 2014, Innoviva's Compensation Committee approved the modification of the remaining tranches related to these awards contingent upon the Spin-Off. The modification acknowledged the Spin-Off and permitted recognition of achievement of the original performance conditions that were met prior to the Spin-Off, triggering 12-month service-based vesting for a portion of the equity awards. The share-based compensation expense of \$6.9 million associated with a portion of these awards after the modification was fully recognized as of June 30, 2015.

During the fourth quarter of 2014, we determined that it was probable that the performance conditions associated with the remaining Innoviva RSAs would be achieved. In addition, the remaining RSAs outstanding are entitled to the pro rata dividend distribution made by Innoviva on June 2, 2014 of one ordinary share of Theravance Biopharma for every three and one half shares of Innoviva common stock. As a result, for the year ended December 31, 2015, we recognized \$7.1 million of the total share-based compensation expense of \$9.5 million related to these remaining RSAs and pro rata dividends. The RSAs and pro rata dividend were subject to a twelve-month service period, which commenced in February 2015 and was completed in February 2016.

***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. See Note 11, "Contractual Agreements with Innoviva, Inc." in the notes to our consolidated financial statements for further information regarding our interest in TRC. 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. We rely on publicly available information about those drug candidates as we do not have access to confidential information regarding their progression or status.

***Contractual Obligations and Commercial Commitments***

In the table below, we set forth our enforceable and legally binding, 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, 2015. Some of the figures that we include in this table are based on management's estimate and assumptions about these obligations, including their duration, the possibility of renewal, anticipated actions by third parties, and other

Table of Contents

factors. Because these estimates and assumptions are necessarily subjective, the obligations we will actually pay in future periods may vary from those reflected in the table.

(In thousands)	Total	Within 1	Years		
			Over 1 to 3	Over 3 to 5	After 5
Facility operating leases(1)	\$ 27,663	\$ 5,985	\$ 12,426	\$ 9,252	\$
Purchase obligations	127,629	127,520	107	2	
<b>Total</b>	<b>\$ 155,292</b>	<b>\$ 133,505</b>	<b>\$ 12,533</b>	<b>\$ 9,254</b>	<b>\$</b>

---

(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.

**Recent Accounting Pronouncements**

The information required by this item is included in Item 8, Note 1, "Description of Operations 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 U.S. 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. Based on our investment positions as of December 31, 2015, a hypothetical 100 basis point increase in interest rates would result in a \$0.9 million decline in the fair market value of our portfolio. Such losses would only be realized if we sold the investments prior to maturity.

Table of Contents

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

<u>Consolidated Balance Sheets as of December 31, 2015 and 2014</u>	<u>68</u>
<u>Consolidated Statements of Operations for each of the three years in the period ended December 31, 2015</u>	<u>69</u>
<u>Consolidated Statements of Comprehensive Loss for each of the three years in the period ended December 31, 2015</u>	<u>70</u>
<u>Consolidated Statements of Shareholders' Equity and Parent Company Deficit for each of the three years in the period ended December 31, 2015</u>	<u>71</u>
<u>Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2015</u>	<u>72</u>
<u>Notes to Consolidated Financial Statements</u>	<u>73</u>
<u>Supplementary Financial Data (unaudited)</u>	<u>106</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>107</u>

Table of Contents**THERAVANCE BIOPHARMA, INC.****CONSOLIDATED BALANCE SHEETS****(In thousands, except per share data)**

	December 31,	
	2015	2014
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 112,707	\$ 89,215
Short-term marketable securities	59,727	165,396
Accounts receivable, net of allowances of \$758 and \$87 at December 31, 2015 and 2014, respectively	1,922	289
Receivables from collaborative arrangements	35,232	1,840
Prepaid taxes	12,764	
Other prepaid and current assets	5,115	6,084
Inventories	10,005	12,546
Total current assets	237,472	275,370
Property and equipment, net	9,873	9,663
Long-term marketable securities	42,860	51,399
Other investments	8,000	
Restricted cash	833	833
Other assets	1,078	506
Total assets	\$ 300,116	\$ 337,771
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 18,804	\$ 9,921
Accrued personnel-related expenses	10,866	18,156
Accrued clinical and development expenses	14,709	7,871
Other accrued liabilities	4,947	5,219
Deferred revenue	144	89
Total current liabilities	49,470	41,256
Deferred rent	4,598	5,150
Other long-term liabilities	2,983	1,578
Commitments and contingencies (Note 2, 7, and 9)		
Shareholders' equity		
Preferred shares, \$0.00001 par value: 230 shares authorized, no shares issued or outstanding at December 31, 2015 and 2014, respectively		
Ordinary shares, \$0.00001 par value: 200,000 shares authorized at December 31, 2015 and 2014; 37,981 and 32,221 shares issued and outstanding at December 31, 2015 and 2014, respectively		
Additional paid-in capital	564,691	429,206
Accumulated other comprehensive income (loss)	(70)	(82)
Accumulated deficit	(321,556)	(139,337)
Total shareholders' equity	243,065	289,787

Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

Total liabilities and shareholders' equity	\$	300,116	\$	337,771
--	----	---------	----	---------

See accompanying notes to consolidated financial statements.

Table of Contents**THERAVANCE BIOPHARMA, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS****(In thousands, except per share data)**

	Year Ended December 31,		
	2015	2014	2013 (Note 1)
<b>Revenue:</b>			
Product sales	\$ 9,408	\$ 4,418	\$
Revenue from collaborative arrangements	32,718	7,270	226
<b>Total revenue</b>	<b>42,126</b>	<b>11,688</b>	<b>226</b>
<b>Costs and expenses:</b>			
Cost of goods sold	4,657	4,058	
Research and development(1)	129,165	168,522	120,579
Selling, general and administrative(1)	90,203	71,647	35,931
<b>Total costs and expenses</b>	<b>224,025</b>	<b>244,227</b>	<b>156,510</b>
Loss from operations	(181,899)	(232,539)	(156,284)
Interest and other income	631	1,865	
Loss before income taxes	(181,268)	(230,674)	(156,284)
Provision for income taxes	951	6,364	
<b>Net loss</b>	<b>\$ (182,219)</b>	<b>\$ (237,038)</b>	<b>\$ (156,284)</b>
<b>Net loss per share:</b>			
Basic and diluted net loss per share	\$ (5.34)	\$ (7.46)	\$ (4.92)
<b>Shares used to compute basic and diluted net loss per share</b>	<b>34,150</b>	<b>31,755</b>	<b>31,741</b>

(1)

Amounts include share-based compensation expense as follows:

<b>(In thousands)</b>	Year Ended December 31,		
	2015	2014	2013
Research and development	\$ 25,770	\$ 21,191	\$ 15,444
Selling, general and administrative	28,280	22,043	7,032
<b>Total share-based compensation expense</b>	<b>\$ 54,050</b>	<b>\$ 43,234</b>	<b>\$ 22,476</b>



See accompanying notes to consolidated financial statements.

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**(In thousands)**

	<b>Year Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
			<b>(Note 1)</b>
Net loss	\$ (182,219)	\$ (237,038)	\$ (156,284)
Other comprehensive income (loss):			
Net unrealized gain (loss) on marketable securities	12	(173)	
Comprehensive loss	\$ (182,207)	\$ (237,211)	\$ (156,284)

See accompanying notes to consolidated financial statements.

Table of Contents**THERAVANCE BIOPHARMA, INC.****CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY AND PARENT COMPANY DEFICIT**

(In thousands, except share data)

	Ordinary Shares		Additional	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Parent Company Deficit	Total Shareholders' Equity and Parent Company Deficit
	Shares	Amount	Paid-In Capital				
Balances at December 31, 2012 (Note 1)		\$	\$	\$	\$	\$ (6,990)	\$ (6,990)
Net loss						(156,284)	(156,284)
Employee share-based compensation expense						22,646	22,646
Net transfers from parent						123,593	123,593
Balances at December 31, 2013 (Note 1)						(17,035)	(17,035)
Contribution of net assets from Innoviva, Inc.	32,260,105		402,787	91		(402,878)	
Cash contribution from Innoviva, Inc.						277,541	277,541
Net transfers from parent						222,934	222,934
Employee share-based compensation expense			26,315			17,139	43,454
Cancellation of shares distributed	(31,285)						
Repurchase of shares to satisfy tax withholding	(7,737)		(178)				(178)
Excess tax benefit of share-based compensation			282				282
Net unrealized loss on marketable securities				(173)			(173)
Net loss					(139,337)	(97,701)	(237,038)
Balances at December 31, 2014	32,221,083		429,206	(82)	(139,337)		289,787
Net proceeds from sale of ordinary shares	5,490,013		79,017				79,017
Proceeds from ESPP purchases	250,209		3,124				3,124
Employee share-based compensation expense			54,175				54,175
Issuance of restricted shares	71,365						
Repurchase of shares to satisfy tax withholding	(51,534)		(756)				(756)
Excess tax benefit of share-based compensation			(75)				(75)
Net unrealized gain (loss) on marketable securities				12			12
Net loss					(182,219)		(182,219)
Balances at December 31, 2015	37,981,136	\$	\$ 564,691	\$ (70)	\$ (321,556)	\$	\$ 243,065

See accompanying notes to consolidated financial statements.



Table of Contents**THERAVANCE BIOPHARMA, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****(In thousands)**

	<b>Year Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
			<b>(Note 1)</b>
<b>Operating activities</b>			
Net loss	\$ (182,219)	\$ (237,038)	\$ (156,284)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,989	3,274	2,653
Share-based compensation	54,050	43,234	22,476
Inventory write-down	2,096	2,887	
Excess tax benefits from share-based compensation	75	(282)	
Non-cash revenue from collaborative arrangements	(8,000)		
Other	(65)		20
Changes in operating assets and liabilities:			
Accounts receivable	(1,633)	(90)	(199)
Receivables from collaborative arrangements	(33,392)	(906)	7
Receivable from Innoviva, Inc.		14,635	
Prepaid taxes	(12,764)		
Other prepaid and current assets	963	(2,878)	19
Inventories	1,030	(6,628)	(3,101)
Other assets	(572)	(211)	
Accounts payable	8,717	3,917	2,113
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	(1,039)	11,680	4,170
Deferred rent	(552)	376	(300)
Deferred revenue	295	(7,991)	7,467
Other long-term liabilities	1,164	866	
<b>Net cash used in operating activities</b>	<b>(168,857)</b>	<b>(175,155)</b>	<b>(120,959)</b>
<b>Investing activities</b>			
Changes in restricted cash		(833)	
Purchases of property and equipment	(2,647)	(3,107)	(2,734)
Purchases of marketable securities	(73,011)	(168,893)	
Maturities of marketable securities	186,697	65,564	
Sale of short-term investments and marketable securities		878	
Payments received on notes receivable, net of issuances		140	100
<b>Net cash provided by (used in) investing activities</b>	<b>111,039</b>	<b>(106,251)</b>	<b>(2,634)</b>
<b>Financing activities</b>			
Net proceeds from sale of ordinary shares under private placements	79,017		
Proceeds from ESPP purchases	3,124		
Excess tax benefits from share-based compensation	(75)	282	
Repurchase of shares to satisfy tax withholding	(756)	(178)	
Cash and cash equivalents contributed from Innoviva, Inc. (Note 1)		277,541	
Transfers from Innoviva, Inc.		92,976	123,593
<b>Net cash provided by financing activities</b>	<b>81,310</b>	<b>370,621</b>	<b>123,593</b>
<b>Net increase in cash and cash equivalents</b>	<b>23,492</b>	<b>89,215</b>	
<b>Cash and cash equivalents at beginning of period</b>	<b>89,215</b>		
<b>Cash and cash equivalents at end of period</b>	<b>\$ 112,707</b>	<b>\$ 89,215</b>	<b>\$</b>

Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

**Supplemental disclosure of cash flow information**

Cash paid for income taxes	\$	13,389	\$	4,550	\$
----------------------------	----	--------	----	-------	----

**Supplemental disclosure of non-cash information**

Contribution of net assets, excluding cash and cash equivalents, from Innoviva, Inc. (Note 10)	\$		\$	125,337	\$
--	----	--	----	---------	----

See accompanying notes to consolidated financial statements.

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Description of Operations and Summary of Significant Accounting Policies**

*Description of Operations*

Theravance Biopharma, Inc. ("Theravance Biopharma", the "Company", or "we" and other similar pronouns) is a diversified biopharmaceutical company with the core purpose of creating medicines that make a difference in the lives of patients suffering from serious illness.

Our pipeline of internally discovered product candidates includes potential best-in-class medicines to address the unmet needs of patients being treated for serious conditions primarily in the acute care setting. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S., Europe and certain other countries for certain difficult-to-treat infections. Revefenacin (TD-4208) is a long-acting muscarinic antagonist ("LAMA") being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease ("COPD"). Our neprilysin ("NEP") inhibitor program is designed to develop selective NEP inhibitors for the treatment of a range of major cardiovascular and renal diseases, including acute and chronic heart failure, hypertension and chronic kidney diseases such as diabetic nephropathy. Our research efforts are focused in the areas of inflammation and immunology, with the goal of designing medicines that provide targeted drug delivery to tissues in the lung and gastrointestinal tract in order to maximize patient benefit and minimize risk. The first program to emerge from this research is designed to develop GI-targeted pan-Janus kinases ("JAK") inhibitors for the treatment of a range of inflammatory intestinal diseases.

In addition, we have an economic interest in future payments that may be made by Glaxo Group Limited or one of its affiliates ("GSK") pursuant to its agreements with Innoviva, Inc. ("Innoviva") (known as Theravance, Inc. prior to January 7, 2016) relating to certain drug development programs, including the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol).

On June 1, 2014, pursuant to a Separation and Distribution Agreement between Innoviva and Theravance Biopharma (the "Separation and Distribution Agreement"), Innoviva separated its late-stage respiratory assets partnered with GSK from its biopharmaceutical operations by transferring its discovery, development and commercialization operations (the "Biopharmaceutical Business") and contributing \$393.0 million of cash, cash equivalents and marketable securities into its then wholly-owned subsidiary Theravance Biopharma. On June 2, 2014, Innoviva made a pro rata dividend distribution to its stockholders of record on May 15, 2014 of one ordinary share of Theravance Biopharma for every three and one half shares of Innoviva common stock outstanding on the record date (the "Spin-Off"). The Spin-Off resulted in Theravance Biopharma operating as an independent, publicly-traded company. Prior to June 2, 2014, Innoviva operated the Biopharmaceutical Business. While Theravance Biopharma is incorporated under Cayman Island law, the Company became an Irish tax resident effective July 1, 2015.

*Basis of Presentation*

For the periods prior to June 2, 2014, the consolidated financial statements have been prepared using Innoviva's historical cost basis of the assets and liabilities of the various activities that comprised the Biopharmaceutical Business of Innoviva and reflect the consolidated results of operations, financial condition and cash flows of Theravance Biopharma as a wholly-owned subsidiary of Innoviva prior to the Spin-Off. The various assets, liabilities, revenues and expenses associated with Innoviva have been allocated to the historical consolidated financial statements of Theravance Biopharma in a manner consistent with the Separation and Distribution Agreement, discussed in Note 11, "Contractual

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. Description of Operations and Summary of Significant Accounting Policies (Continued)**

Agreements with Innoviva, Inc.". Changes in parent company deficit represent Innoviva's net investment in Theravance Biopharma, after giving effect to Theravance Biopharma's net loss, parent company expense allocations, and net cash transfers to and from Innoviva.

For purposes of preparing the consolidated financial statements, the Biopharmaceutical Business was derived from Innoviva's historical consolidated financial statements, allocations of revenues, research and development ("R&D") expenses, and non-operating income and expenses to Theravance Biopharma were made on a specific identification basis. For purposes of allocating general and administrative expenses from Innoviva's historical consolidated financial statements, costs directly related to the Biopharmaceutical Business were allocated to Theravance Biopharma on a specific identification basis or based on the estimated underlying effort. Theravance Biopharma's general and administrative expenses also include allocations of Innoviva's general corporate overhead expenses, including finance, legal, human resources, information technology and other administrative functions. These allocations of general corporate overhead expenses were primarily based on the estimated underlying effort or an estimated number of full-time employees that worked with the Biopharmaceutical Business. The consolidated balance sheets of Theravance Biopharma include assets and liabilities that were allocated to Theravance Biopharma principally on a specific identification basis.

Management believes that the consolidated statements of operations and comprehensive loss include a reasonable allocation of costs incurred by Innoviva which benefited Theravance Biopharma. However, such expenses may not be indicative of the actual level of expense that would have been incurred by Theravance Biopharma if it had operated as an independent, publicly traded company or of the costs expected to be incurred in the future. As such, the financial information herein for periods prior to the Spin-Off may not necessarily reflect the financial position, results of operations, and cash flows of Theravance Biopharma in the future or what it would have been had Theravance Biopharma been an independent, publicly traded company during such periods.

As Theravance Biopharma was a wholly owned subsidiary of Innoviva until June 2, 2014, no separate cash accounts for the Biopharmaceutical Business were historically maintained prior to the Spin-Off and, therefore, Innoviva is presumed to have funded Theravance Biopharma's operating, investing and financing activities as necessary. For purposes of the historical consolidated financial statements prior to the Spin-Off, funding of Theravance Biopharma's expenditures is reflected in the consolidated financial statements as a component of parent company investment. In connection with the assets transfer and Spin-Off discussed above, Innoviva contributed to Theravance Biopharma cash, cash equivalents and marketable securities of \$393.0 million.

We describe the Biopharmaceutical Business transferred to us by Innoviva in connection with the Spin-Off as though the Biopharmaceutical Business were our business for all historical periods described. However, Theravance Biopharma did not conduct any operations prior to the Spin-Off.

***Principles of Consolidation***

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



Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. Description of Operations and Summary of Significant Accounting Policies (Continued)**

*Use of Management's Estimates*

The preparation of consolidated financial statements in conformity with U.S. Generally Accepted Accounting Principles ("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. We base our estimates on historical experience and other relevant assumptions that we believe 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*

We have determined that we operate in a single segment, which is the discovery (research), development and commercialization of human therapeutics. We operate in one segment because our business offerings have similar economics and other characteristics, including the nature of products and manufacturing processes, types of customers, distribution methods and regulatory environment. We are comprehensively managed as one business segment by our Chief Executive Officer and his 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.

All property and equipment is maintained in the United States.

*Cash and Cash Equivalents*

We consider 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, we have pledged cash and cash equivalents as collateral. As of December 31, 2015, restricted cash related to such agreements was \$0.8 million.

*Investments in Marketable Securities*

We invest in marketable securities, primarily corporate notes, government, government agency, and municipal bonds. We classify our marketable securities as available-for-sale securities and report them at 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.

We regularly review all of our investments for other-than-temporary declines in estimated fair value. Our review includes the consideration of the cause of the impairment, including the

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. Description of Operations and Summary of Significant Accounting Policies (Continued)**

creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether we have the intent to sell the securities and whether it is more likely than not that we will be required to sell the securities before the recovery of their amortized cost basis. When we determine that the decline in estimated fair value of an investment is below the amortized cost basis and the decline is other-than-temporary, we reduce the carrying value of the security and record a loss for the amount of such decline.

***Investments in Non-Marketable Equity Securities***

As a result of entering into a licensing agreement with Trek Therapeutics, PBC ("TREKtx") in September 2015, we hold an \$8.0 million minority investment in TREKtx, a non-public company. We recorded this non-marketable equity investment at cost in long-term assets, and we periodically review our non-marketable equity securities for impairment by determining whether impairment indicators are present. Common impairment indicators include a significant adverse change in the regulatory or economic environment in which the investee entity operates or cash used in operating activities and other working capital deficiencies.

If we conclude that any of the non-marketable equity securities are impaired, we determine whether such impairment is other-than-temporary. Factors we consider to make such determination include the duration and severity of the impairment, the reason for the decline in value and the potential recovery period and our intent to sell. If any impairment is considered other-than-temporary, we will write down the asset to its fair value and record the corresponding charge as interest and other income (loss).

***Fair Value of Financial Instruments***

We define 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.

Our valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect our market assumptions. We classify 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, accounts receivable, receivables from Innoviva, accounts payable, and accrued liabilities. Our 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.

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. Description of Operations and Summary of Significant Accounting Policies (Continued)**

***Accounts Receivable***

Trade accounts receivable are recorded net of allowances for wholesaler chargebacks related to government rebate programs, cash discounts for prompt payment and sales returns. Estimates for wholesaler chargebacks for government rebates, cash discounts and sales returns are based on contractual terms, historical trends and our expectations regarding the utilization rates for these programs. When appropriate, we provide for an allowance for doubtful accounts by reserving for specifically identified doubtful accounts. For the periods presented, we did not have any write-offs of accounts receivable. We perform ongoing credit evaluations of our customers and generally do not require collateral.

***Concentration of Credit Risks***

We invest in a variety of financial instruments and, by our policy, limit the amount of credit exposure with any one issuer, industry or geographic area for investments other than instruments backed by the U.S. federal government.

We depend on a single-source supplier of the active pharmaceutical ingredient ("API") in VIBATIV® (telavancin) and one supplier to provide fill-finish services related to the manufacturing of VIBATIV. If any of our suppliers were to limit or terminate production or otherwise fail to meet the quality or delivery requirements needed to supply VIBATIV at levels to meet market demand, we could experience a loss of revenue, which could materially and adversely impact our results of operations.

***Inventories***

Inventories consist of raw materials, work-in-process and finished goods related to the production of VIBATIV. Raw materials include VIBATIV API and other raw materials. Work-in-process and finished goods include third-party manufacturing costs and labor and indirect costs we incur 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 expense when consumed. In addition, under certain commercialization agreements, we may sell VIBATIV packaged in unlabeled vials that are recorded in work-in-process. Inventories are stated at the lower of cost or market value. We determine the cost of inventory using the average-cost method for each manufacturing batch.

We assess our inventory levels quarterly and write down inventory that is expected to become obsolete, that has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. This assessment requires management to utilize judgement in formulating estimates and assumptions that we believe to be reasonable under the circumstances. Actual results may differ from those estimates and assumptions.

When we recognize a loss on such inventory, 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 the products making up that inventory. In order to realize the value of our recorded inventory, we will be dependent upon continued increases in the sales volumes of VIBATIV.

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****1. Description of Operations and Summary of Significant Accounting Policies (Continued)*****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 years

***Capitalized Software***

We capitalize certain costs related to direct material and service costs for software obtained for internal use. For the year ended December 31, 2015, we capitalized costs for the replacement of our enterprise resource planning software system ("ERP System") of \$0.3 million. Upon being placed in service, these costs and other future capitalizable costs related to the ERP System integration will be depreciated over three years.

***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 we occupy. Rent expense is being recognized ratably over the life of the leases. Because our facility operating leases provide for rent increases over the terms of the leases, average annual rent expense during the first 2.5 years of the leases exceeded our actual cash rent payments. Also included in deferred rent are lease incentives of \$1.2 million as of December 31, 2015, which is being recognized ratably over the life of the leases.

***Revenue Recognition***

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 are not met, we defer the recognition of revenue by recording deferred revenue until such time that all criteria are met.

***Product Sales***

In 2013, we reintroduced VIBATIV into the U.S. market by making the drug product available through a limited number of distributors, who sell VIBATIV to healthcare providers. Title and risk of loss transfer upon receipt by these distributors.

Prior to the fourth quarter of 2014, as a result of VIBATIV's limited sales history, we could not reliably estimate expected returns, rebates and chargebacks of the product at the time the product was

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. Description of Operations and Summary of Significant Accounting Policies (Continued)**

sold to the distributors. Therefore, we deferred the recognition of revenue on sales to the VIBATIV distributors, and instead, recognized revenue at the time the product was sold through to healthcare providers, the end customers, or the right of return no longer existed, whichever occurred earlier.

Beginning in the fourth quarter of 2014, we had developed sufficient historical experience and data to reasonably estimate future returns, rebates and chargebacks of VIBATIV and as a result, effective October 1, 2014, we began recognizing VIBATIV product sales and related cost of product sales at the time title transfers to the wholesalers.

Product sales are recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. We reflect 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 consider payer mix in target markets, industry benchmarks and experience to date. We monitor inventory levels in the distribution channel, as well as sales of VIBATIV 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 VIBATIV experienced by Innoviva's former collaborative partner, Astellas Pharma Inc. ("Astellas"), 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.

Sales Discounts: We offer cash discounts to certain customers as an incentive for prompt payment. We expect our customers to comply with the prompt payment terms to earn the cash discount. In addition, we offer contract discounts to certain direct customers. We estimate sales discounts based on contractual terms, historical utilization rates, as available, and our expectations regarding future utilization rates. We account for sales discounts by reducing accounts receivable by the full amount and recognizing the discount as a reduction of revenue in the same period the related revenue is recognized.

Chargebacks and Government Rebates: For VIBATIV sales in the U.S., we estimate 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. Our 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. Our accrual for Medicaid is based upon statutorily-defined discounts, estimated payer mix, expected sales to qualified healthcare providers, and our expectation about future utilization. The Medicaid accrual and government rebates that are invoiced directly to us are recorded in other accrued liabilities on the consolidated balance sheets. For qualified programs that can purchase our products through distributors at a lower contractual government price, the distributors charge back to us the difference between their acquisition cost and the lower contractual government price, which we record as an allowance against accounts receivable.

Distribution Fees and Product Returns: We have written contracts with our distributors that include terms for distribution-related fees. We record distribution-related fees based on a percentage of the

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****1. Description of Operations and Summary of Significant Accounting Policies (Continued)**

product sales price. We offer our distributors a right to return product purchased directly from us, which is principally based upon the product's expiration date. Our policy is to accept product returns during the six months prior to and twelve months after the product expiration date on product that had been sold to our distributors. We have developed estimates for VIBATIV product returns based upon historical VIBATIV sales. We record distribution fees and product returns as an allowance against accounts receivable.

Allowance for Doubtful Accounts: We maintain a policy to record allowances for potentially doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. As of December 31, 2015 and 2014, there was no allowance for doubtful accounts related to customer payments.

Our reserve activity for sales & return allowances, discounts, chargebacks and rebates is summarized as follows:

(In thousands)	Balance at December 31, 2014	Charges	Deductions	Balance at December 31, 2015
Sales & returns allowances, discounts, chargebacks and rebates	\$ 180	\$ 3,257	\$ (2,576)	\$ 861
<i>Collaborative Arrangements and Multiple-Element Arrangements</i>				

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

We account for multiple element arrangements, such as license and development agreements in which a customer may purchase several deliverables, in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Subtopic 605-25, *Multiple Element Arrangements*. For new or materially amended multiple element arrangements, we identify the deliverables at the inception of the arrangement and each deliverable within a multiple deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. We allocate revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, we determine the selling price for each deliverable using vendor-specific objective evidence ("VSOE") of selling price, if it exists, or third-party evidence ("TPE") of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, we use the best estimated selling price for that deliverable. Revenue allocated to each element is then recognized based on when the basic four revenue recognition criteria are met for each element.

For multiple-element arrangements entered into prior to January 1, 2011, we determined the delivered items under our collaborative arrangements did not meet the criteria to be considered separate accounting units for the purposes of revenue recognition. As a result, we recognized revenue from non-refundable, upfront fees and development contingent payments in the same manner as the final deliverable, which is ratably over the expected term of our performance of R&D services under

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. Description of Operations and Summary of Significant Accounting Policies (Continued)**

the agreements. These upfront or contingent payments received, pending recognition as revenue, are recorded as deferred revenue and are classified as a current or non-current liability on the consolidated balance sheets and recognized over the estimated period of performance. We periodically review the estimated performance periods of our contracts based on the progress of our programs.

Where a portion of non-refundable upfront fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as deferred revenue and recognized as revenue or as an accrued liability and recognized as a reduction of R&D expenses ratably over the term of our estimated performance period under the agreement. We determine the estimated performance periods, and they are 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, we have been reimbursed for a portion of our R&D expenses. These reimbursements 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 to be a part of our ongoing and central operations. Therefore, the reimbursement of research and development services and any amounts allocated to our research and development services are recorded as a reduction of R&D expense.

Amounts deferred under a collaborative arrangement in which the performance obligations are terminated will result in an immediate recognition of any remaining deferred revenue and accrued liability in the period that termination occurred, provided that there are no remaining performance obligations.

We recognize revenue from milestone payments when (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) we do not have ongoing performance obligations related to the achievement of the milestone. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment (a) is commensurate with either our 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 our performance to achieve the milestone, (b) relates solely to past performance, and (c) is 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 us, net of certain external research and development expenses reimbursed under our collaborative arrangements.

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. Description of Operations and Summary of Significant Accounting Policies (Continued)**

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

communicating with our applicable personnel to identify 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;

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 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.

***Advertising Expenses***

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses were \$4.0 million, \$1.1 million and \$1.4 million in 2015, 2014 and 2013, respectively.

***Fair Value of Share-Based Compensation Awards***

We use the Black-Scholes-Merton option pricing model to estimate the fair value of options granted under our equity incentive plans and rights to acquire shares granted under our 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. We use the "simplified" method as



## Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

described in Staff Accounting Bulletin No. 107, *Share-Based Payment*, for the expected option term since our shares started trading on June 3, 2014 after the Spin-Off. We use peer company price volatility to estimate expected share price volatility due to our limited historical ordinary share price volatility since our shares started trading on June 3, 2014 after the Spin-Off.

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****1. Description of Operations and Summary of Significant Accounting Policies (Continued)**

Share-based compensation expense is calculated based on awards ultimately expected to vest and is reduced for estimated forfeitures at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Our estimated annual forfeiture rates for options are based on historical forfeiture experience of peer companies.

Compensation expense for purchases under the ESPP is recognized based on the fair value of the ordinary share on the date of offering, less the purchase discount percentage provided for in the plan.

***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 common shares had been issued for other dilutive securities.

For the years ended December 31, 2015, 2014 and 2013, diluted and basic net loss per share was identical since potential common shares were excluded from the calculation, as their effect was anti-dilutive. 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 2013 and 2014.

***Anti-dilutive Securities***

The following common 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,		
	2015	2014	2013
Share issuances under equity incentive plan and ESPP	4,537	3,475	
Forfeitable shares	202	424	
	4,739	3,899	

***Other Income, net***

For the years ended December 31, 2015 and 2014, other income includes \$0.2 million and \$1.6 million, respectively, related to transition services rendered to Innoviva. Refer to Note 11, "Contractual Agreements with Innoviva, Inc." for further information on transition services.

***Income Taxes***

During 2015, we adopted FASB Accounting Standards Update 2015-17, *Balance Sheet Classification of Deferred Income Taxes*, which requires that the Consolidated Balance Sheets reflect all deferred income tax assets and liabilities as non-current. We elected to retrospectively apply the provisions of this standard, and the adoption had no impact on our consolidated financial position or results of operations.

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

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

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. Description of Operations and Summary of Significant Accounting Policies (Continued)**

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 unrecognized tax benefits would reduce our effective income tax rate if recognized. As of December 31, 2015, we do not anticipate the total amount of unrecognized income tax benefits relating to uncertain tax positions existing at December 31, 2015 to significantly increase or decrease in the next 12 months.

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. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

***Comprehensive Loss***

Comprehensive loss is comprised of net loss and changes in unrealized gains and losses on our marketable securities.

***Related Parties***

GSK owned 22.0% of our shares outstanding as of December 31, 2015.

Robert V. Gunderson, Jr. is a member of our board of directors. We have engaged Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, of which Mr. Gunderson is a partner, as our primary legal counsel. Fees incurred were \$1.1 million in 2015, \$1.1 million in 2014, and \$1.4 million in 2013.

***Recently Issued Accounting Pronouncements Not Yet Adopted***

In May 2014, the FASB issued Accounting Standards Update 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which converges the FASB and the International Accounting Standards Board standards on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. In August 2015, the FASB issued Accounting Standards Update 2015-14 which defers the effective date of ASU 2014-09 by one year. As a result, the standard will become effective for public companies for the fiscal years and interim reporting periods beginning after December 15, 2017, at which time we may adopt the new standard under the full retrospective method or the modified retrospective method. Early adoption is permitted for fiscal years and interim reporting period beginning after December 15, 2016 which was the original effective date of the standard. We are currently evaluating the impact of adopting ASU 2014-09 on our consolidated financial statements and related disclosures.

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Collaborative Arrangements***Revenues from Collaborative Arrangements*

We recognized revenue from our collaborative arrangements as follows:

(In thousands)	Year Ended December 31,		
	2015	2014	2013
Mylan	\$ 19,175	\$	\$
Trek Therapeutics	8,216		
SciClone Pharmaceuticals	2,902		
R-Pharm	2,049	2,259	
Pendopharm	350		
Clinigen		5,011	
Other	26		226
Total revenue from collaborative arrangements	\$ 32,718	\$ 7,270	\$ 226

*Mylan**Development and Commercialization Agreement*

In January 2015, Mylan and we established a strategic collaboration for the development and, subject to regulatory approval, commercialization of revefenacin (TD-4208), our investigational LAMA in development for the treatment of COPD. We entered into this collaboration to expand the breadth of our revefenacin development program and extend our commercial reach beyond the acute care setting where we currently market VIBATIV.

Under the terms of the Mylan Development and Commercialization Agreement (the "Mylan Agreement"), Mylan and we will co-develop nebulized revefenacin for COPD and other respiratory diseases. We are leading the U.S. Phase 3 development program and Mylan is responsible for reimbursement of our costs for that program up until the approval of the first new drug application, after which costs will be shared. If a product developed under the collaboration is approved in the U.S., Mylan will lead commercialization and we will retain the right to co-promote the product in the U.S. under a profit-sharing arrangement (65% Mylan/35% Theravance Biopharma). Outside the U.S. (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. Although China is not included in the ex-U.S. territory, Mylan has a right of first negotiation with respect to the development and commercialization of nebulized revefenacin in China. We retain worldwide rights to revefenacin delivered through other dosage forms, such as a metered dose inhaler or dry powder inhaler ("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.

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 ordinary share purchase agreement entered into on January 30, 2015, Mylan Inc., a subsidiary of Mylan N.V., made a \$30.0 million equity investment in us, buying 1,585,790 ordinary shares from us in early 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. As

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. Collaborative Arrangements (Continued)**

of December 31, 2015, we are eligible to receive from Mylan potential development and sales milestone payments totaling \$220.0 million in the aggregate, with \$175.0 million associated with revefenacin monotherapy and \$45.0 million for future potential combination products. Development milestones are deemed to be substantive milestones and will be recognized as revenue in the period upon achievement of each respective milestone. Sales milestones are considered contingent payments and are not deemed to be substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to Mylan's performance of future commercial activities.

Under the Mylan Agreement, the significant deliverables were determined to be the license, development responsibilities and committee participation. We determined that the license represents a separate unit of accounting as the license, which includes rights to our underlying technologies for revefenacin, has standalone value because the rights conveyed permit Mylan to perform all efforts necessary to use our technologies to bring the compounds through development and, upon regulatory approval, commercialization. We based the best estimate of selling price for the license using a discounted cash flow approach. We determined that development responsibilities and committee participation represent separate units of accounting as Mylan could negotiate for and/or acquire each of these services from other third parties and we based the best estimates of the respective selling prices on the nature and timing of the services to be performed.

As payments are received from Mylan, they are allocated to the three units of accounting based on the relative selling price method. Amounts allocated to the license are recognized as collaborative revenue when delivered. Amounts allocated to the development responsibilities under the Mylan Agreement are recognized proportionately with the performance of the underlying services and accounted for as reductions to R&D expense. Amounts allocated to committee participation are recognized ratably over the estimated performance periods as revenue from collaborative arrangements.

In the first quarter of 2015, upfront payments totaling \$19.2 million from Mylan were allocated to the license and committee participation based on the relative selling price method. The \$19.2 million consists of the initial payment of \$15.0 million in cash and the \$4.2 million premium related to the equity investment, which represents the difference between the closing price on January 30, 2015 and the issued price of \$18.918 per share.

For the year ended December 31, 2015, we recognized \$19.2 million in revenue from collaborative arrangements related primarily to the license and technological know-how delivered in the first quarter of 2015, and we recorded reductions to R&D expense of \$52.6 million representing reimbursements for our development responsibilities.

***Trek Therapeutics***

***Licensing Agreement***

In September 2015, TREKtx and we entered into a licensing agreement (the "TREKtx Agreement") granting TREKtx an exclusive worldwide license for the development, manufacturing, use, marketing and sale of our NS5A inhibitor known as TD-6450 as a component in combination hepatitis C virus ("HCV") products (the "HCV Products"). Pursuant to the TREKtx Agreement, we received an upfront payment of \$8.0 million in the form of TREKtx's Series A preferred stock and will be eligible to receive future royalties based on net sales of the HCV Products. Other terms of the licensing transaction have not been disclosed.

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. Collaborative Arrangements (Continued)**

Based on the accounting guidance for non-monetary transactions, if the value of the consideration can be measured within reasonable limits, we measure the assets exchanged at either the fair value of the asset given up or the fair value of the asset acquired, depending on which can be more reliably measured. We estimated the fair value of the preferred stock received based upon the price of similar Series A preferred stock that TREKtx had recently sold to an independent third party for cash consideration. Based on this approach, we estimated the fair value of the consideration received to be \$8.0 million which we believe is a more reliable measure of the non-monetary assets exchanged.

Under the TREKtx Agreement, the significant deliverable was determined to be the license, which includes rights to our underlying technologies for TD-6450. We transferred the license and technological know-how upon execution of the TREKtx Agreement, and we recognized \$8.0 million as revenue from collaborative arrangements for the year ended December 31, 2015. TREKtx will be solely responsible for all future costs associated with the supply, manufacture, development, sale and marketing of the licensed compound. As such, our maximum exposure to loss as a result of entering into the TREKtx Agreement is our \$8.0 million investment in TREKtx's Series A preferred stock.

We determined TREKtx to be a variable interest entity. Based on the contractual terms of the arrangement, we do not have the power to direct the activities of TREKtx that most significantly impact its economic performance. As a result, we are not considered to be the primary beneficiary of TREKtx and therefore, do not consolidate the financial results of the company into our financial statements. In addition, we do not have significant influence over TREKtx. Accordingly, we accounted for this investment using the cost method of accounting and recorded it in other investments on our consolidated balance sheets. As of December 31, 2015, we reviewed our TREKtx investment for impairment and determined that no impairment indicators were present.

***SciClone Pharmaceuticals***

***Development and Commercialization Agreement***

In May 2015, SciClone and we entered into a development and commercialization agreement (the "SciClone Agreement") granting SciClone exclusive development and commercial rights for VIBATIV in China, as well as the Hong Kong SAR, the Macau SAR, Taiwan and Vietnam. Under the SciClone Agreement, the companies plan to pursue the development and commercialization of VIBATIV in hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia ("HABP"/"VABP"). Additional indications may include complicated skin and skin structure infections ("cSSSI"), and potentially bacteremia.

In exchange for the exclusive development and commercial rights granted to SciClone, we received an upfront payment of \$3.0 million and will be eligible to receive a \$3.0 million milestone payment upon a regulatory approval event. This regulatory milestone is considered to be a contingent payment and not deemed to be a substantive milestone due to the fact that the achievement of the event underlying the payment predominantly relates to SciClone's performance of future development activities. SciClone will be responsible for all aspects of development and commercialization in the partnered regions, including pre- and post-launch activities and product registration. We will sell to SciClone all clinical and commercial product required to develop and commercialize VIBATIV in China.

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. Collaborative Arrangements (Continued)**

Under the SciClone Agreement, the significant deliverables were determined to be the license, manufacturing of clinical product and committee participation. We determined that the license represents a separate unit of accounting as the license, which includes rights to our underlying technologies for VIBATIV, has standalone value because the rights conveyed permit SciClone to perform all efforts necessary to use our technologies to bring the compounds through development and, upon regulatory approval, commercialization. We based the best estimate of selling price for the license using a discounted cash flow approach. We determined that manufacturing of clinical product represents a separate unit of accounting as SciClone could acquire manufacturing services from third parties. We based the best estimates of the respective selling prices on the nature and timing of the services to be performed.

The upfront payment of \$3.0 million was received in the second quarter of 2015 and was allocated to the three units of accounting based on the relative selling price method. For the year ended December 31, 2015, we recognized \$2.9 million as revenue from collaborative arrangements in the consolidated statements of operations as we delivered the license and technological know-how during the period. The amount allocated to the manufacturing responsibilities will be recognized proportionately with the performance of the underlying services. The amount allocated to committee participation is being recognized ratably over the estimated performance period as revenue from collaborative arrangements.

***JSC R-Pharm (formerly R-Pharm CSJC) ("R-Pharm")***

***VIBATIV Development and Commercialization Agreement***

In October 2012, Innoviva entered into a development and commercialization agreement with R-Pharm to develop and commercialize VIBATIV (the "R-Pharm VIBATIV Agreement"). Under the R-Pharm VIBATIV Agreement, Innoviva granted R-Pharm exclusive rights to develop and commercialize VIBATIV in Russia, Ukraine, other member countries of the Commonwealth of Independent States, and Georgia. Innoviva received \$1.1 million in upfront payments for the R-Pharm VIBATIV Agreement. The R-Pharm VIBATIV Agreement was transferred to us as a result of the Spin-Off from Innoviva. We are eligible to receive contingent payments potentially totaling up to \$10.0 million, of which we have recognized \$2.0 million, and royalties of 25% on net sales of VIBATIV by R-Pharm. The contingent payments are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to R-Pharm's performance of future development and commercialization activities.

Under the R-Pharm VIBATIV Agreement, the significant deliverables were determined to be the license, committee participation and a contingent obligation to supply R-Pharm with API at R-Pharm's expense, subject to entering into a future supply agreement. Innoviva determined that the license represents a separate unit of accounting as the license, which includes rights to Innoviva's underlying technologies for VIBATIV, has standalone value because the rights conveyed permit R-Pharm to perform all efforts necessary to use Innoviva's technologies to bring the compounds through development and, upon regulatory approval, commercialization and Innoviva based the best estimate of selling price for the license based on potential future cash flows under the arrangement over the estimated performance period. Innoviva determined that the committee participation represents a separate unit of accounting as R-Pharm could negotiate for and/or acquire these services from other



Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Collaborative Arrangements (Continued)**

third parties and Innoviva based the best estimate of selling price on the nature and timing of the services to be performed.

The \$1.1 million upfront payment received for the R-Pharm VIBATIV Agreement was allocated to two units of accounting based on the relative selling price method. The amount allocated to the license was recognized by us as revenue in the second quarter of 2014 due to the completion of technical transfer. The amount allocated to committee participation was deferred and will be recognized as revenue over the estimated performance period.

In June 2015, the Ministry of Health of the Russian Federation granted marketing authorization for VIBATIV for the treatment of complicated skin and soft tissue infections, as well as nosocomial pneumonia (including artificial lung ventilation-associated pneumonia), caused by Gram-positive bacteria, including methicillin-resistance *Staphylococcus aureus* ("MRSA"). As a result, we recognized \$2.0 million in revenue in the second quarter of 2015 for regulatory milestone payments from R-Pharm.

***Reimbursement of R&D Costs***

Under certain collaborative arrangements, we are entitled to reimbursement of certain R&D costs. Our policy is to account for the reimbursement payments by our collaboration partners as reductions to R&D expense.

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

(In thousands)	Year Ended December 31,		
	2015	2014	2013
Mylan	\$ 52,551	\$	\$
Alfa Wassermann	2,122	1,764	1,500
R-Pharm	483		
Merck			4,937
Other		120	86
Total reduction to R&D expense	\$ 55,156	\$ 1,884	\$ 6,523

**3. Segment Information**

We operate in a single segment, which is the discovery (research), development and commercialization of human therapeutics. The following table summarizes total revenue by geographic region for the most recent two years:

(In thousands)	Year Ended December 31,	
	2015	2014
U.S.	\$ 16,981	\$ 4,231
Europe	21,354	7,456
Asia	2,902	
Other	889	1
Total revenue	\$ 42,126	\$ 11,688



Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. Segment Information (Continued)**

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

(In thousands)	Year Ended December 31, 2015
Mylan	46%
Trek Therapeutics	20%

(In thousands)	Year Ended December 31, 2014
Clinigen	43%
R-Pharm	19%

**4. Available-for-Sale Securities and Fair Value Measurements***Available-for-Sale Securities*

The following table summarizes the classification of the available-for-sale securities in our consolidated balance sheets:

(In thousands)	December 31,	
	2015	2014
Cash equivalents	\$ 69,126	\$ 69,866
Short-term marketable securities	59,727	165,396
Long-term marketable securities	42,860	51,399
Restricted cash	833	833
<b>Total</b>	<b>\$ 172,546</b>	<b>\$ 287,494</b>

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 our 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. Gross unrealized gains and losses were not significant at either December 31, 2015 or December 31, 2014.

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. Available-for-Sale Securities and Fair Value Measurements (Continued)**

Available-for-sale securities are summarized below:

(In thousands)		Amortized Cost	December 31, 2015		Estimated Fair Value
			Gross Unrealized Gains	Gross Unrealized Losses	
Money market funds	Level 1	\$ 69,959	\$	\$	\$ 69,959
U.S. government securities	Level 1	47,068	4	(29)	47,043
U.S. government agency securities	Level 2	31,502		(37)	31,465
Corporate notes	Level 2	19,098	2	(11)	19,089
Commercial paper	Level 2	4,990			4,990
Total		\$ 172,617	\$ 6	\$ (77)	\$ 172,546

(In thousands)		Amortized Cost	December 31, 2014		Estimated Fair Value
			Gross Unrealized Gains	Gross Unrealized Losses	
Money market funds	Level 1	\$ 70,699	\$	\$	\$ 70,699
U.S. government securities	Level 1	32,515	26		32,541
U.S. government agency securities	Level 2	39,598	4	(14)	39,588
Corporate notes	Level 2	97,779	12	(110)	97,681
Commercial paper	Level 2	46,985			46,985
Total		\$ 287,576	\$ 42	\$ (124)	\$ 287,494

At December 31, 2015, all of the available-for-sale securities had contractual maturities within two years and the weighted average maturity of marketable securities was approximately 10 months. There were no transfers between Level 1 and Level 2 during the periods presented.

We do not intend to sell the investments that are in an unrealized loss position, and it is unlikely that we will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. We have determined that the gross unrealized losses on our marketable securities at December 31, 2015 were temporary in nature. All marketable securities with unrealized losses at December 31, 2015 have been in a loss position for less than twelve months or the loss is not material.

During 2014, we sold available-for-sale securities totaling \$0.9 million, and the related realized gains and losses were not material. There were no sales during 2015 or 2013.

**5. Inventories**

Inventory consists of the following:

(In thousands)	December 31,	
	2015	2014

Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

Raw materials	\$	6,869	\$	6,830
Work-in-process				145
Finished goods		3,136		5,571
Total inventories	\$	10,005	\$	12,546

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****5. Inventories (Continued)**

In 2015 and 2014, we recorded within costs of goods sold charges of \$1.9 million and \$2.9 million, respectively, for the write-down of VIBATIV inventory due to the dating of the product.

**6. Property and Equipment**

Property and equipment consists of the following:

(In thousands)	December 31,	
	2015	2014
Computer equipment	\$ 1,434	\$ 3,152
Software	3,776	5,435
Furniture and fixtures	3,656	3,897
Laboratory equipment	25,603	33,790
Leasehold improvements	17,639	17,857
Subtotal	52,108	64,131
Less: accumulated depreciation	(42,235)	(54,468)
Property and equipment, net	\$ 9,873	\$ 9,663

For the years ended December 31, 2015, 2014 and 2013, depreciation expense for property and equipment was \$2.5 million, \$2.7 million and \$2.7 million, respectively.

**7. Share-Based Compensation*****Theravance Biopharma Equity Plans***

Upon the completion of the Spin-Off, we had two equity compensation plans our 2013 Equity Incentive Plan (the "2013 EIP") and our 2013 Employee Share Purchase Plan (the "2013 ESPP"). At inception, we were authorized to issue 5,428,571 ordinary shares under the 2013 EIP and 857,142 ordinary shares under the 2013 ESPP. In October 2014, we adopted the 2014 New Employee Equity Incentive Plan (the "2014 NEEIP"). We are authorized to issue 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.

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**7. Share-Based Compensation (Continued)**

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, 571,428 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.

***Innoviva's Equity Plans***

Many of our employees have in the past received Innoviva stock-based compensation awards, and, therefore, the following disclosures include information regarding share-based compensation expense allocated to Theravance Biopharma that related to Innoviva stock-based equity awards. Accordingly, the amounts presented are not necessarily indicative of future performance and do not necessarily reflect the results that we would have experienced as an independent, publicly-traded company for the periods presented.

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

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

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**7. Share-Based Compensation (Continued)**

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.

On June 2, 2014, Innoviva made a pro rata dividend distribution to its stockholders of record on May 15, 2014 of one ordinary share of Theravance Biopharma for every three and one half shares of Innoviva common stock outstanding on the record date. Innoviva's outstanding stock options and RSUs, which were not entitled to the dividend distribution were adjusted for the Spin-Off. Specifically, the number of shares and exercise price for Innoviva's outstanding stock options were adjusted and the number of shares underlying Innoviva's outstanding RSUs was adjusted. All other terms of these options and RSUs remained the same; provided, however, that the vesting and expiration of these grants are based on the holder's continuing employment or service with Innoviva or us, as applicable.

Although the anti-dilution adjustments were required pursuant to the terms of each equity plan, the anti-dilution adjustments were calculated using a volume-weighted average stock price, rather than the stock price as of the date of the dividend distribution, which resulted in incremental compensation expense. The accounting impact of the adjustment to the outstanding Innoviva stock options and RSUs that occurred in connection with the Spin-Off of Theravance Biopharma was measured by comparing the fair values of the modified stock options and RSUs to our employees and directors immediately before and after the adjustment. As a result, we will recognize total incremental share-based compensation expense of \$0.7 million associated with this adjustment over the remaining service period as it pertains to unvested stock options and RSUs held by individuals in service with us. The incremental expense recognized in 2014 was not material.

*Innoviva Performance-Contingent Restricted Stock Awards*

Over the past three years, the Compensation Committee of Innoviva's board of directors ("Innoviva's Compensation Committee") has approved grants of performance-contingent RSAs to its senior management and a non-executive officer. Generally, these awards have dual triggers of vesting based upon the achievement of certain performance goals by a pre-specified date, as well as a requirement for continued employment. When the performance goals are deemed achieved for these types of awards, time-based vesting and, as a result, recognition of stock-based compensation expense commence. Included in these performance-contingent RSAs is the grant of 1,290,000 special long-term retention and incentive performance-contingent RSAs to senior management in 2011. The awards had dual triggers of vesting based upon the achievement of certain performance conditions over a six-year time frame from 2011 through December 31, 2016 and require continued employment.

In May 2014, Innoviva's Compensation Committee determined that the requisite performance conditions for the first tranche of the awards were achieved and, as a result, \$7.0 million in share-based compensation expense was recognized by us during the year ended December 31, 2014.

In May 2014, Innoviva's Compensation Committee approved the modification of the remaining tranches related to these awards contingent upon the Spin-Off. The modification acknowledged the Spin-Off and permitted recognition of achievement of the original performance conditions that were met prior to the Spin-Off, triggering twelve-month service-based vesting for a portion of the equity



Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. Share-Based Compensation (Continued)**

awards. Share-based compensation expense of \$6.9 million associated with this portion of the awards after the modification was fully recognized as of June 30, 2015.

During the fourth quarter of 2014, we determined that it was probable that the performance conditions associated with the vesting of the remaining RSAs outstanding under these awards would be achieved. In addition, the remaining RSAs outstanding under these awards are entitled to the pro rata dividend distribution made by Innoviva on June 2, 2014 of one ordinary share of Theravance Biopharma for every three and one half shares of Innoviva common stock. As a result, for the year ended December 31, 2015, we recognized \$7.1 million of the total share-based compensation expense of \$9.5 million related to these remaining RSAs and pro rata dividends. The RSAs and pro rata dividends remain subject to a twelve-month service period, which ends in February 2016.

***Employee Share Option Exchange Program***

On August 28, 2015, we gave eligible option holders of the Company and its subsidiaries the opportunity to exchange some or all of their outstanding options granted under our 2013 EIP or our NEEIP before August 4, 2015, whether vested or unvested, for restricted share units (the "Exchange Program"). The Exchange Program was designed to restore the intended employee retention and incentive value of our 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 our 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 our 2013 EIP. The RSUs granted under the Exchange Program will vest over a three or four year service period depending on the grant date of the original option exchanged. Our executive officers and members of our board of directors were not eligible to participate in the Exchange Program.

The Exchange Program closed on September 25, 2015 and we 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 is considered a modification to the terms of the original equity award. As such, the Exchange Program resulted in an 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 year ended December 31, 2015, we recognized \$0.1 million of the \$1.4 million in incremental share-based compensation costs.

***Share-Based Compensation Expense***

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

(In thousands)	Year Ended December 31,		
	2015	2014	2013
Research and development	\$ 25,770	\$ 21,191	\$ 15,444
Selling, general and administrative	28,280	22,043	7,032
<b>Total share-based compensation expense</b>	<b>\$ 54,050</b>	<b>\$ 43,234</b>	<b>\$ 22,476</b>

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. Share-Based Compensation (Continued)**

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

(In thousands)	Year Ended December 31,		
	2015	2014	2013
Transferred from parent	\$	\$ 17,043	\$ 22,476
Innoviva equity:			
Options	5,199	4,378	
RSUs	3,292	3,169	
RSAs	7,590	3,796	
Performance RSAs	11,166	4,490	
Theravance Biopharma equity:			
Options	14,063	9,404	
RSUs	10,471		
ESPP	2,269	954	
Total share-based compensation expense	\$ 54,050	\$ 43,234	\$ 22,476

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

As of December 31, 2015, the unrecognized share-based compensation cost, net of expected 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	\$ 7,338	2.0
RSUs	1,778	1.0
RSAs	4,114	1.4
Performance RSAs	1,040	0.2
Theravance Biopharma equity:		
Options	19,498	2.8
RSUs	42,508	3.0
ESPP	1,751	1.0
	\$ 78,027	

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. Share-Based Compensation (Continued)***Compensation Awards*

The following table summarizes option activity under the 2013 EIP and 2014 NEEIP for the years ended December 31, 2015 and 2014:

	Number of Shares Subject to Outstanding Options	Weighted-Average Exercise Price of Outstanding Options
Balance at June 2, 2014		\$
Granted	4,235,059	24.75
Forfeited	(272,633)	25.01
Outstanding at December 31, 2014	3,962,426	24.73
Granted	750,775	14.26
Forfeited	(2,402,037)	23.05
Outstanding at December 31, 2015	2,311,164	\$ 23.07

As of December 31, 2015, the aggregate intrinsic value of the options outstanding was \$1.4 million and the aggregate intrinsic value of the options exercisable was not material. As of December 31, 2014, the aggregate intrinsic value of the options outstanding and the aggregate intrinsic value of the options exercisable were not material. The total estimated fair value of options vested (excluding vested options that have expired) was \$10.7 million in 2015 and \$1.0 million in 2014.

The following table summarizes RSU activity for the year ended December 31, 2015:

	Number of Shares Subject to Outstanding RSUs
Outstanding at December 31, 2014	
Granted	3,399,924
Forfeited	(411,883)
Outstanding at December 31, 2015	2,988,041

As of December 31, 2015, the aggregate intrinsic value of the RSUs outstanding was \$49.0 million and the total estimated fair value of RSUs vested was \$1.6 million in 2015.

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. Share-Based Compensation (Continued)***Valuation Assumptions*

The range of assumptions we used to estimate the fair value of options granted under the 2013 EIP, 2014 NEEIP and rights granted under the 2013 ESPP was as follows:

	Year Ended December 31,	
	2015	2014
<b><i>Options Under the 2013 EIP and 2014 NEEIP</i></b>		
Risk-free interest rate	1.4% - 1.9%	1.7% - 2.0%
Expected term (in years)	6	5 - 6
Volatility	71% - 78%	64% - 70%
Dividend yield		
Weighted-average estimated fair value	\$9.16	\$15.55
<b><i>2013 ESPP</i></b>		
Risk-free interest rate	0.1% - 0.9%	0.1% - 0.7%
Expected term (in years)	0.5 - 2.0	0.6 - 2.2
Volatility	46% - 62%	58% - 66%
Dividend yield		
Weighted-average estimated fair value	\$5.91	\$10.95

The range of assumptions Innoviva used to estimate the fair value of stock options granted prior to the Spin-Off was as follows:

	Year Ended December 31,	
	2014	2013
<b><i>Options under the 2012 Equity Incentive Plan</i></b>		
Risk-free interest rate	1.6% - 2.1%	0.7% - 2.0%
Expected term (in years)	5 - 6	5 - 6
Volatility	52% - 61%	58% - 60%
Dividend yield		
Weighted-average estimated fair value	\$16.14	\$19.96
<b><i>Employee stock purchase plan issuances</i></b>		
Risk-free interest rate		0.1% - 0.3%
Expected term (in years)		0.5 - 2
Volatility		56% - 61%
Dividend yield		
Weighted-average estimated fair value	\$	\$16.44

**8. 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, U.S., 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.

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. Income Taxes (Continued)**

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

(In thousands)	2015	December 31, 2014	2013
Income (loss) before provision for income taxes:			
Cayman Islands	\$ (107,074)	\$ (235,306)	\$
United States	(45,960)	5,189	
Ireland	(27,013)		
Other	(1,221)	(557)	(156,284)
Total	\$ (181,268)	\$ (230,674)	\$ (156,284)

The components of provision for income taxes were as follows:

Provision for income taxes:			
Current			
Cayman Islands	\$	\$	\$
United States	883	6,223	
Ireland	45		
Other	23	141	
Subtotal	951	6,364	
Deferred			
Total	\$ 951	\$ 6,364	\$
Effective tax rate	(0.52)%	(2.76)%	0.00%

The provision for income taxes was \$1.0 million and \$6.4 million in 2015 and 2014, respectively, although we incurred operating losses on a consolidated basis. In general, the provision for 2015 resulted from recording contingent tax liabilities pertaining primarily to uncertain tax positions taken with respect to transfer pricing and tax credits. The 2014 provision was a result of generating taxable income in our U.S. operations.

No provision for income taxes has been recognized on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested. In the event of a distribution of these earnings in the form of dividends or otherwise, we 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, 2015, there were no undistributed earnings.

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. Income Taxes (Continued)**

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 our deferred tax assets and liabilities are as follows:

(In thousands)	December 31,	
	2015	2014
Deferred tax assets:		
Net operating loss carryforwards	\$ 4,541	\$ 181
Research and development tax credit carryforwards	2,405	821
Fixed assets and acquired intangibles	7,275	8,088
Share-based compensation	10,895	7,489
Accruals	2,285	2,563
Other	21	29
Subtotal	27,422	19,171
Valuation allowance	(26,822)	(18,787)
Total deferred tax assets	600	384
Deferred tax liabilities:		
Prepaid assets	(600)	(384)
Total deferred tax liabilities	(600)	(384)
Net deferred tax assets/liabilities	\$	\$

As discussed in Note 1, "Description of Operations and Summary of Significant Accounting Policies", during the year ended December 31, 2015, we retrospectively adopted ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes*. The adoption had no impact on our consolidated financial position or results of operations.

In the table below, the U.S. statutory tax rate of 34% was used for 2013 and the Cayman tax rate of 0% was used in 2014. For 2015, as a result of the Company becoming an Irish tax resident effective July 1, 2015, the tax rate reflects the Irish statutory rate of 25%. The differences between the Ireland (2015), Cayman Islands (2014) and the United States (2013) federal statutory income tax rate and our effective tax rates are as follows:

	Year Ended December 31,		
	2015	2014	2013
Provision at statutory income tax rate	25.00%	0.00%	34.00%
Foreign rate differential	(14.62)	(0.99)	
Change in valuation allowance	(4.42)	(2.42)	(35.89)
Share-based compensation	(4.15)		
Uncertain tax positions	(3.88)	(0.25)	
Research and development tax credit carryforwards	2.05	1.00	2.87
Other	(0.50)	(0.10)	(0.98)
Effective tax rate	(0.52)%	(2.76)%	0.00%



Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. Income Taxes (Continued)**

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. The valuation allowance as of December 31, 2015 increased from \$18.8 million (the valuation allowance as of December 31, 2014) to \$26.8 million, primarily as a result of changes to temporary differences in share-based compensation, and increases to net operating loss and tax credit carryforwards. Valuation allowances require an assessment of both positive and negative evidence when determining whether it is more likely than not deferred tax assets are recoverable. Such assessment is required on a jurisdiction-by-jurisdiction basis.

As of December 31, 2015, we had \$10.9 million of federal net operating losses and \$2.7 million federal research and development tax credit carryforwards which expire in 2035. We had state net operating losses of \$23.4 million which generally begin to expire in 2034, and state research and development credit carryforwards of \$4.4 million to be carried forward indefinitely.

The net operating loss deferred tax asset balances as of December 31, 2015 do not include excess tax benefits from option exercises. Shareholders' equity and parent company deficit will be credited if and when such excess tax benefits are ultimately realized.

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.

Our 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, 2015 and 2014.

***Uncertain Tax Positions***

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

**(In thousands)**

Unrecognized tax benefits as of December 31, 2013	\$ 41
Gross increase in tax positions for prior years	
Gross increase in tax positions for current year	1,018
Unrecognized tax benefits as of December 31, 2014	\$ 1,059
Gross increase in tax positions for prior years	108
Gross increase in tax positions for current year	8,031
Unrecognized tax benefits as of December 31, 2015	\$ 9,198

The total unrecognized tax benefits of \$9.2 million and \$1.1 million at December 31, 2015 and 2014, respectively, if recognized, would reduce the effective tax rate in the period of recognition. As of December 31, 2015, we do not believe that it is reasonably possible that our unrecognized tax benefit will significantly increase or decrease in the next twelve months. We currently have a full valuation



Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. Income Taxes (Continued)**

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 are subject to taxation in Ireland, the U.S., and various other jurisdictions. The tax years 2015 and forward remain open to examination in Ireland, tax years 2013 and forward remain open to examination in the U.S., and the tax years 2012 and forward remain open to examination in other jurisdictions.

**9. Commitments and Contingencies***Operating Leases and Subleases*

We lease approximately 150,000 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 2020. We may extend the terms of this lease for two additional five-year periods. In addition, our Irish subsidiary leases an office in Dublin, Ireland. Future minimum lease payments under the leases, exclusive of executory costs, at December 31, 2015, were as follows:

<b>(In thousands)</b>	
Years ending December 31:	
2016	\$ 5,985
2017	6,121
2018	6,305
2019	6,494
2020	2,758
Thereafter	
<b>Total</b>	<b>\$ 27,663</b>

Expenses and income associated with operating leases were as follows:

<b>(In thousands)</b>	<b>Year Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
Rent expense	\$ 6,522	\$ 6,616	\$ 5,763
Sublease income, net	\$ 186	\$	\$

***Special Long-Term Retention and Incentive Cash Awards Program***

In 2011, Innoviva granted special long-term retention and incentive restricted stock awards to members of senior management. The awards had dual triggers of vesting based upon the achievement of certain performance conditions over a six-year time frame from 2011 through December 31, 2016 and continued employment.

In May 2014, Innoviva's Compensation Committee approved the modification of the remaining tranches related to these awards contingent upon the Spin-Off. The modification acknowledged the Spin-Off and permitted recognition of achievement of the original performance conditions that were met prior to the Spin-Off, triggering 12-month service-based vesting for a portion of the equity awards.

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****9. Commitments and Contingencies (Continued)**

The share-based compensation expense of \$6.9 million associated with a portion of these awards after the modification was fully recognized as of June 30, 2015.

During the fourth quarter of 2014, we determined that it was probable that the performance conditions associated with the remaining Innoviva RSAs would be achieved. In addition, the remaining RSAs outstanding are entitled to the pro rata dividend distribution made by Innoviva on June 2, 2014 of one ordinary share of Theravance Biopharma for every three and one half shares of Innoviva common stock. As a result, for the year ended December 31, 2015, we recognized \$7.1 million of the total share-based compensation expense of \$9.5 million related to these remaining RSAs and pro rata dividends. The RSAs and pro rata dividend are subject to a twelve-month service period, which ends in February 2016.

***Guarantees and Indemnifications***

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, 2015.

**10. Spin-Off from Innoviva, Inc.**

On June 1, 2014, Innoviva separated its late-stage respiratory assets partnered with GSK from its biopharmaceutical operations by transferring its discovery, development and commercialization operations (the "Biopharmaceutical Business") into its then wholly-owned subsidiary Theravance Biopharma. Innoviva also contributed certain assets and liabilities from the Biopharmaceutical Business and \$393.0 million of cash, cash equivalents and marketable securities to us. In connection with the Spin-Off, on June 2, 2014, Innoviva made a pro rata dividend distribution to its stockholders of record on May 15, 2014 of one ordinary share of Theravance Biopharma for every three and one half shares of Innoviva common stock outstanding on the record date. The Spin-Off resulted in Theravance Biopharma operating as an independent, publicly traded company.

The net book value of the net assets that were transferred to us in connection with the Spin-Off was as follows:

<b>(In thousands)</b>	<b>June 2, 2014</b>
Cash and cash equivalents	\$ 277,541
Marketable investment securities	115,129
Accounts receivable	125
Reimbursement of certain liabilities	16,983
Prepaid and other current assets	3,172
Inventories	14,328
Property and equipment, net	9,580
Accrued liabilities	(22,342)
Deferred revenue	(6,694)
Other liabilities	(4,944)
<b>Net book value of assets transferred</b>	<b>\$ 402,878</b>

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**11. Contractual Agreements with Innoviva, Inc.**

***Separation and Distribution Agreement***

In connection with the Spin-Off, on June 1, 2014, Innoviva and Theravance Biopharma entered into the Separation and Distribution Agreement which set forth the principal transactions necessary to separate the companies. The Separation and Distribution Agreement identifies the assets transferred, liabilities assumed and contracts assigned to us as part of the Spin-Off, and describes when and how these transfers, assumptions and assignments occurred. In particular, all of the assets and liabilities associated or primarily used in connection with the Biopharmaceutical Business operations were transferred to us.

In addition, in connection with the Spin-Off, we were capitalized with \$393.0 million in cash, cash equivalents and marketable securities. Except as expressly set forth in the Separation and Distribution Agreement or any ancillary agreement, all assets were transferred to us on an "as is," "where is" basis. Under the terms of the Separation and Distribution Agreement, we will indemnify Innoviva, and Innoviva will indemnify us from and after the Spin-Off with respect to all debts, liabilities and obligations transferred to Innoviva in connection with the Spin-Off (including failure to pay, perform or otherwise promptly discharge any such debts, liabilities or obligations after the Spin-Off) and any breach by us of the Separation and Distribution Agreement, the Transition Services Agreement, the Tax Matters Agreement and the Employee Matters Agreement and.

***Transition Services Agreement***

On June 2, 2014, we also entered into a Transition Services Agreement with Innoviva pursuant to which Innoviva and we will provide each other with a variety of administrative services, including financial, tax, accounting, information technology, legal and human resources services. In connection with the services performed under the Transition Services Agreement, each party shall pay a monthly fee to the performing party. For the year ended December 31, 2015, we billed Innoviva \$0.4 million, and Innoviva billed us \$0.5 million under the Transition Services Agreement. As of December 31, 2015, we had no material receivables due from or payables due to Innoviva.

***Tax Matters Agreement***

On June 2, 2014, we also entered into a Tax Matters Agreement with Innoviva that governs Innoviva's and our respective rights, responsibilities and obligations after the Spin-Off with respect to taxes. Under the Tax Matters Agreement, all tax liabilities (including tax refunds and credits) (i) attributable to Innoviva's Biopharmaceutical Business for any and all periods or portions thereof ending prior to or on, the date of the Spin-Off, (ii) resulting or arising from the contribution of Innoviva's Biopharmaceutical Business to us, the distribution of our ordinary shares and the other separation transactions and (iii) otherwise attributable to Innoviva, will be borne solely by Innoviva. As a result, we should generally expect to be liable only for tax liabilities attributable to, or incurred with respect to, the Biopharmaceutical Business after the date of the Spin-Off.

***Employee Matters Agreement***

On June 1, 2014, we also entered into an Employee Matters Agreement with Innoviva, which governs the employee benefit obligations of Innoviva and us as they relate to current and former employees. The Employee Matters Agreement allocates liabilities and responsibilities relating to employee benefit matters, including 401(k) plan matters that are subject to ERISA in connection with

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**11. Contractual Agreements with Innoviva, Inc. (Continued)**

the separation, as well as other employee benefit programs. The Employee Matters Agreement also provides the mechanics for the adjustment of equity awards (including stock options, restricted stock, and restricted stock units) granted under Innoviva's equity compensation programs in connection with the Spin-Off.

*Limited Liability Company Agreement of Theravance Respiratory Company, LLC*

Prior to the Spin-Off, Innoviva assigned to Theravance Respiratory Company, LLC ("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. 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 drug programs assigned to TRC include the Closed Triple or FF/UMEC/VI 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 will not include any payments associated with RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® or vilanterol monotherapy.

On May 31, 2014, we 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.

We analyzed our ownership, contractual and other interests in TRC to determine if it 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 and determined we are not the primary beneficiary of TRC. As a result, we do not consolidate TRC.

**12. Subsequent Events**

*Mylan Milestone Payment*

In February 2016, we announced the achievement of 50% enrollment in all three of the Phase 3 clinical studies for revefenacin. The achievement of 50% enrollment in the twelve-month safety study triggered a \$15.0 million milestone payment to Theravance Biopharma by Mylan.

Table of Contents

**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, 2015 and 2014. 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. 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 all periods in 2014.

	For the Quarters Ended			
	March 31	June 30	September 30	December 31
<b>2015</b>				
Total revenue	\$ 20,401	\$ 7,134	\$ 10,698	\$ 3,893
Costs and expenses	58,138	52,427	53,793	59,667
Loss from operations	(37,737)	(45,293)	(43,095)	(55,774)
Net loss(1)	(42,474)	(47,603)	(47,314)	(44,828)
Basic and diluted net loss per share	\$ (1.29)	\$ (1.42)	\$ (1.40)	\$ (1.23)
<b>2014</b>				
Total revenue(2)	\$ 945	\$ 2,974	\$ 6,336	\$ 1,433
Operating expenses	60,963	59,680	56,398	67,186
Loss from operations	(60,018)	(56,706)	(50,062)	(65,753)
Net loss	(60,018)	(58,215)	(54,495)	(64,310)
Basic and diluted net loss per share	\$ (1.89)	\$ (1.83)	\$ (1.72)	\$ (2.02)

- (1) In the fourth quarter of 2015, we recognized a \$10.8 million reduction in our 2015 provision for income taxes primary due to changes in the Company's transfer pricing.
- (2) Commencing in the first quarter of 2014, we recognized revenue from sales of VIBATIV. In the second quarter of 2014, previously deferred revenue from the R-Pharm collaborative arrangement of \$2.1 million was recognized. In the third quarter of 2015, previously deferred revenue from the Clinigen collaborative arrangement of \$5.0 million was recognized.

Table of Contents

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**The Board of Directors and Shareholders of Theravance Biopharma, Inc.**

We have audited the accompanying consolidated balance sheets of Theravance Biopharma, Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, shareholders' equity and parent company deficit and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Theravance Biopharma, Inc. at December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

San Jose, California  
March 11, 2016

Table of Contents

**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, 2015, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief 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 Chief 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 Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2015 using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control Integrated Framework. Based on its assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2015.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting pursuant to the transition rules under the JOBS Act.

*Limitations on the Effectiveness of Controls*

Our management, including our Chief Executive Officer and Chief 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, 2015 which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

Table of Contents

**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" and "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 ACCOUNTING 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.



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>Consolidated Balance Sheets as of December 31, 2015 and 2014</u>	<u>68</u>
<u>Consolidated Statements of Operations for each of the three years in the period ended December 31, 2015</u>	<u>69</u>
<u>Consolidated Statements of Comprehensive Loss for each of the three years in the period ended December 31, 2015</u>	<u>70</u>
<u>Consolidated Statements of Shareholders' Equity and Parent Company Deficit for each of the three years in the period ended December 31, 2015</u>	<u>71</u>
<u>Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2015</u>	<u>72</u>
<u>Notes to Consolidated Financial Statements</u>	<u>73</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>107</u>

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 follows the signature page of this report.



Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

Table of Contents

Signature	Title	Date
<u>/s/ ROBERT V. GUNDERSON, JR.</u> Robert V. Gunderson, Jr.	Director	March 11, 2016
<u>/s/ DONAL O'CONNOR</u> Donal O'Connor	Director	March 11, 2016
<u>/s/ BURTON G. MALKIEL, PH.D.</u> Burton G. Malkiel, Ph.D.	Director	March 11, 2016
<u>/s/ DEAN J. MITCHELL</u> Dean J. Mitchell	Director	March 11, 2016
<u>/s/ SUSAN M. MOLINEAUX, PH.D</u> Susan M. Molineaux, Ph.D.	Director	March 11, 2016
<u>/s/ PETER S. RINGROSE, PH.D.</u> Peter S. Ringrose, Ph.D.	Director	March 11, 2016
<u>/s/ GEORGE M. WHITESIDES, PH.D.</u> George M. Whitesides, Ph.D.	Director	March 11, 2016
<u>/s/ WILLIAM D. YOUNG</u> William D. Young	Director	March 11, 2016

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

### Table of Contents

#### Exhibit Index

Exhibit Number	Description	Incorporated by Reference	
		Filing Form	Date/Period End Date
2.1	Separation and Distribution Agreement by and between Theravance Biopharma, Inc. and Innoviva, Inc., dated June 1, 2014.	8-K	June 3, 2014
3.1	Amended and Restated Memorandum and Articles of Association	10-12B	April 30, 2014
4.1	Specimen Share Certificate	10-12B	April 30, 2014
4.2	Registration Rights Agreement, dated March 3, 2014	10-12B	April 8, 2014
4.3	Form of Rights Agreement by and between Theravance Biopharma, Inc. and Computershare Inc.	10-12B	April 8, 2014
4.4	First Amendment to Rights Agreement by and between Theravance Biopharma, Inc. and Computershare Inc., dated November 10, 2015	8-K	Nov. 10, 2015
4.5	Controlled Equity Offering <sup>SM</sup> Sales Agreement, dated June 26, 2015, by and between Theravance Biopharma, Inc. and Cantor Fitzgerald & Co.	S-3	June 26, 2015
10.1	Transition Services Agreement by and between Theravance Biopharma, Inc. and Innoviva, Inc., dated June 2, 2014.	8-K	June 3, 2014
10.2	Tax Matters Agreement by and between Theravance Biopharma, Inc. and Innoviva, Inc., dated June 2, 2014.	8-K	June 3, 2014
10.3	Employee Matters Agreement by and between Theravance Biopharma, Inc. and Innoviva, Inc., dated June 1, 2014.	8-K	June 3, 2014
10.4+	2013 Equity Incentive Plan	S-8	Aug. 18, 2014
10.5+	UK Addendum to the 2013 Equity Incentive Plan	10-Q	Aug. 14, 2014
10.6+	Forms of award agreements under the 2013 Equity Incentive Plan and 2014 New Employee Equity Incentive Plan		
10.7+	2014 New Employee Equity Incentive Plan	S-8	Nov. 14, 2014
10.8+	2013 Employee Share Purchase Plan, as amended	S-8	Aug. 18, 2014
10.9+	Change in Control Severance Plan	10-12B	April 8, 2014
10.10+	Cash Bonus Program	10-12B	Nov. 22, 2013
10.11+	Form of Indemnity Agreement	10-12B	April 30, 2014
10.12	Amended and Restated Lease Agreement, 951 Gateway Boulevard, between Innoviva, Inc. and HMS Gateway Office L.P., dated January 1, 2001	10-12B	Aug. 8, 2013
10.13	First Amendment to Lease for 951 Gateway Boulevard effective as of June 1, 2010 between Innoviva, Inc. and ARE-901/951 Gateway Boulevard, LLC	10-12B	Aug. 8, 2013

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

### Table of Contents

Exhibit Number	Description	Incorporated by Reference	
		Form	Filing Date/Period End Date
10.14	Lease Agreement, 901 Gateway Boulevard, between Innoviva, Inc. and HMS Gateway Office L.P., dated January 1, 2001	10-12B	Aug. 8, 2013
10.15	First Amendment to Lease for 901 Gateway Boulevard effective as of June 1, 2010 between Innoviva, Inc. and ARE-901/951 Gateway Boulevard, LLC	10-12B	Aug. 8, 2013
10.16	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.	10-Q	Aug. 14, 2014
10.17	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.	10-Q	Aug. 14, 2014
10.18	Theravance Respiratory Company, LLC Limited Liability Company Agreement, dated May 31, 2014.	8-K	June 3, 2014
10.19*	Technology Transfer and Supply Agreement, dated as of May 22, 2012 between Innoviva, Inc. and Hospira Worldwide, Inc.	10-12B	May 7, 2014
10.20*	Commercialization Agreement between Innoviva, Inc. and Clinigen Group plc, dated March 8, 2013	10-12B	May 7, 2014
10.21	License Agreement with Janssen Pharmaceutica, dated as of May 14, 2002	10-Q	Aug. 14, 2014
10.22	Collaboration Agreement between Innoviva, Inc. and Glaxo Group Limited, dated November 14, 2002(1)		
10.23	Strategic Alliance Agreement by and between Innoviva, Inc. and Glaxo Group Limited, dated March 30, 2004(2)		
10.24	Amendment to Strategic Alliance Agreement by and between Innoviva, Inc. and Glaxo Group Limited, dated October 3, 2011(3)		
10.25	Collaboration Agreement Amendment by and between Innoviva, Inc. and Glaxo Group Limited dated, March 3, 2014(4)		
10.26	Strategic Alliance Agreement Amendment by and between Innoviva, Inc. and Glaxo Group Limited dated, March 3, 2014(4)		
10.27	Master Agreement by and between Innoviva, Inc., Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014(4)		
10.28	Extension Agreement by and between the Company and Glaxo Group Limited, dated March 3, 2014	10-12B	April 8, 2014
10.29	Governance Agreement by and between Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014	10-12B	April 8, 2014
10.30+	Amended Offer Letter with Rick E Winningham dated August 6, 2014	10-Q	Sept. 30, 2014
10.31+	Offer Letter with Frank Pasqualone May 12, 2014	10-Q	Aug. 14, 2014

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

### Table of Contents

Exhibit Number	Description	Incorporated by Reference Form	Filing Date/Period End Date
10.32+	Offer Letter with Brett K. Haumann dated May 12, 2014	10-Q	Aug. 14, 2014
10.33+	Offer Letter with Renee D. Gala dated May 12, 2014	10-Q	Sept. 30, 2014
10.34+	Offer Letter with Junning Lee dated August 20, 2014	10-Q	Sept. 30, 2014
10.35+	Offer Letter with Brad Shafer dated August 20, 2014	10-Q	Sept. 30, 2014
10.36+	Offer Letter with Leonard Blum dated September 15, 2014	10-Q	Sept. 30, 2014
10.37+	Offer Letter with Mathai Mammen dated September 15, 2014	10-Q	Sept. 30, 2014
10.38+	Forms of Equity Award Amendment	10-12B	May 7, 2014
10.39+	Form of TFIO Cash Award Amendment	10-12B	May 7, 2014
10.40+	Consulting Agreement with Jeff Jonker, effective as of November 14, 2014	10-K	March 13, 2015
10.41*	Development and Commercialization Agreement by and between Theravance Biopharma R&D, Inc. and Mylan Ireland Limited, dated January 30, 2015	8-K/A	April 24, 2015
10.42	Ordinary Share Purchase Agreement by and between Theravance Biopharma, Inc. and Mylan Inc., dated January 30, 2015	8-K/A	April 24, 2015
10.43	Letter Agreement by and between Theravance Biopharma, Inc. and Glaxo Group Limited, dated September 11, 2015, including the form of Ordinary Share Purchase Agreement and Schedule as attached thereto	8-K	Sept. 11, 2015
10.44	Ordinary Share Purchase Agreement by and between Theravance Biopharma, Inc. and Glaxo Group Limited, dated October 7, 2015	8-K	Oct. 13, 2015
10.45	Ordinary Share Purchase Agreement by and among Theravance Biopharma, Inc. and the funds managed by Woodford Investment Management LLP named therein, dated as of October 26, 2015	8-K	Oct. 26, 2015
10.46+	Form of Acknowledgment for Irish Non-Employee Directors		
10.47+	Irish Addendum to the 2013 Equity Incentive Plan		
10.48+	Irish Addendum to the 2014 New Employee Equity Incentive Plan		
10.49+	UK and Irish Addendums to the 2013 Employee Share Purchase Plan		
21.1	Subsidiaries of Theravance Biopharma, Inc.		
23.1	Consent of Independent Registered Public Accounting Firm		
24.1	Power of Attorney (see signature page to this Annual Report on Form 10-K)		
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934		

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-K

### Table of Contents

Exhibit Number	Description	Incorporated by Reference Filing Form	Date/Period End Date
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934		
32	Certifications Pursuant to 18 U.S.C. Section 1350		
101	The following materials from Registrant's Annual Report on Form 10-K for the year ended December 31, 2015, 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 and Parent Company Deficit, (v) Consolidated Statements of Cash Flows, and (vi) Notes to Consolidated Financial Statements.		
<hr/>			
+	Management contract or compensatory plan or arrangement required to be filed pursuant to Item 15(b) of Form 10-K.		
*	Confidential treatment has been requested for certain portions which are omitted in the copy of the exhibit electronically filed with the Securities and Exchange Commission. The omitted information has been filed separately with the Securities and Exchange Commission pursuant to Theravance Biopharma, Inc.'s application for 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 8, 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.		

---