

Theravance Biopharma, Inc.  
Form 10-K  
March 13, 2015

Use these links to rapidly review the document

[Table of Contents](#)

[ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA](#)  
[PART IV](#)

[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, 2014

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**

---

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

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

### Title of Each Class

Ordinary Share \$0.00001 Par Value

### Name of Each Exchange On Which Registered

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, 2014 was \$565,284,301.

On February 28, 2015, there were 33,801,727 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 2015 Annual Meeting of Shareholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2014, 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.**

**2014 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>13</u>
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	<u>38</u>
<u>Item 2.</u>	<u>Properties</u>	<u>38</u>
<u>Item 3.</u>	<u>Legal Proceedings</u>	<u>38</u>
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	<u>38</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>39</u>
<u>Item 6.</u>	<u>Selected Financial Data</u>	<u>42</u>
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>44</u>
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>55</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>56</u>
<u>Item 9.</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	<u>96</u>
<u>Item 9A.</u>	<u>Controls and Procedures</u>	<u>96</u>
<u>Item 9B.</u>	<u>Other Information</u>	<u>97</u>
<b><u>PART III</u></b>		
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>97</u>
<u>Item 11.</u>	<u>Executive Compensation</u>	<u>97</u>
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>97</u>
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>97</u>
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	<u>97</u>
<b><u>PART IV</u></b>		
<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	<u>98</u>
<u>Signatures</u>		<u>99</u>
<u>Exhibits</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, and Section 21E of the Securities Exchange Act of 1934, as amended. 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," "anticipates," "believes," "could," "designed," "developed," "drive," "estimates," "expects," "goal," "intends," "may," "mission," "opportunities," "plans," "potential," "projects," "pursuing," "represents," "suggest," "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. 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.*

**PART I**

**ITEM 1. BUSINESS**

**Overview**

The mission of Theravance Biopharma, Inc. ("Theravance Biopharma", the "Company", or "we" and other similar pronouns) is to create value from a unique and diverse set of assets: an approved product; a development pipeline of mid- and late-stage assets; and a productive research platform designed for long-term growth.

Our pipeline of internally discovered product candidates includes potential best-in-class opportunities in underserved markets in the acute care setting, representing multiple opportunities for value creation. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the United States and Europe for certain difficult-to-treat infections. TD-4208 is an investigational long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease (COPD). Axelopran (TD-1211) is an investigational potential once-daily, oral treatment for opioid-induced constipation (OIC). Our earlier-stage clinical assets represent novel approaches for potentially treating diseases of the lung and gastrointestinal tract and infectious disease. In addition, we have an economic interest in future payments that may be made by GlaxoSmithKline plc ("GSK") pursuant to its agreements with Theravance, Inc. ("Theravance") relating to certain drug development programs, including the combination of fluticasone furoate, umeclidinium, and vilanterol (or the "Closed Triple").

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.

On June 1, 2014, Theravance 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

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

## Table of Contents

and marketable securities into its then wholly-owned subsidiary Theravance Biopharma. On June 2, 2014 Theravance 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 Theravance 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, Theravance operated the Biopharmaceutical Business.

The Spin-Off was effected pursuant to a Separation and Distribution Agreement between Theravance and Theravance Biopharma (the "Separation and Distribution Agreement"), which provides, among other things, for the principal corporate transactions required to effect the Spin-Off and certain other agreements governing Theravance's relationship with Theravance Biopharma after the Spin-Off.

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, Uglund 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.

## **2014 Highlights**

In 2014 we accomplished a number of key corporate goals. In June 2014, we announced the completion of the separation of the Biopharmaceutical Business from Theravance. We believe this transaction allows us to maximize the potential value of our discovery, development, and commercial assets, and creates a more efficient corporate structure. In addition, we achieved our objectives supporting the initial commercial plan for the reintroduction of VIBATIV to the U.S. market by building an experienced sales force targeting a small number of geographic territories, thus establishing a foundation for a commercial infrastructure focused on the acute care market. We announced positive top-line results from a Phase 2b dose-ranging study of TD-4208 for the treatment of COPD, followed by an end-of-Phase 2 meeting with the FDA in December 2014 to discuss the design of the Phase 3 registrational program. We also made meaningful advancements in our research and development pipeline which includes mid- and late-stage assets across three primary therapeutic areas: diseases of the lung and gastrointestinal tract and infectious disease.

## **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 three therapeutic areas: diseases of the lung and gastrointestinal tract and infectious disease and our commercial infrastructure is focused 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 Theravance and GSK, and which we refer to as the "GSK-Partnered Respiratory Programs". We have an economic interest in these programs

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

### Table of Contents

through our interest in Theravance Respiratory Company, LLC ("TRC"), a limited liability company managed by Theravance.

THERAPEUTIC AREA	COMMERCIAL	LATE-STAGE	MID-STAGE
Infectious Disease / Other	VIBATIV® (telavancin) cSSSI HABP/VABP	Telavancin (Bacteremia)	TD-6450 (HCV) TD-1792, TD-1607 (MRSA) TD-9855 (Fatigue)
Lung Disease		TD-4208 (COPD) Closed Triple (COPD)	MABA (COPD) MABA-ICS (COPD, Asthma)
Gastrointestinal Disease		Axelopran (OIC) Axelopran / Opioid FDC (OIC/Pain)	Velusetrag (GP) TD-8954 (ICU IV prokinetic)

Key: cSSSI: complicated skin and skin structure infections; COPD: chronic obstructive pulmonary disease; FDC: fixed-dose combination; GP: gastroparesis; HABP/VABP: hospital-acquired and ventilator-associated bacterial pneumonia; HCV: hepatitis C virus; ICU: intensive care unit; IV: intravenous; MABA: bifunctional muscarinic antagonist-beta<sub>2</sub> agonist; MRSA: methicillin-resistant *Staphylococcus aureus*; OIC: opioid-induced constipation

In the table above:

Denotes GSK-Partnered Respiratory Programs

"Late-stage" includes approved products and assets in Phase 3 development or Phase 3-ready

"Mid-stage" includes assets between Phase 1 and Phase 2b

### **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. and Canada for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria. VIBATIV is also approved in the U.S. 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 approved 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.

#### *Commercial Program Expansion*

In 2014, we implemented a phased launch strategy for VIBATIV in the U.S. that focused on a small number of targeted geographic territories across the country. We have since expanded our sales force and medical affairs presence to include additional territories in the U.S. with the goal of strengthening our commercial infrastructure comprised of experienced sales representatives and a significant medical information component focused on the acute care market.

#### *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.



Table of Contents

*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 multicenter, 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.

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

TD-4208 is an investigational, long-acting muscarinic antagonist (LAMA) in development for the treatment of COPD. We believe that TD-4208 may become a valuable addition to the COPD treatment regimen and that it represents a significant commercial opportunity. Our market research indicates approximately 9% of the treated COPD patients in the U.S. 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. TD-4208 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 TD-4208, 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 Registrational Study in COPD*

In December 2014, following the announcement of positive top-line results of our Phase 2b program, we conducted an end-of-Phase 2 meeting with the FDA to discuss the design of the Phase 3 registrational program. We are progressing TD-4208 into a Phase 3 registrational program that will include two replicate three-month efficacy studies and a single twelve-month safety study. Based on our discussion with the FDA, the studies will include approximately 2,200 patients. The studies will test two doses: 88 mcg and 175 mcg administered once-daily. We expect to initiate the Phase 3 program in 2015.

*Mylan Collaboration*

In January 2015, Mylan Inc., which is now a subsidiary of Mylan N.V. ("Mylan"), and we established a strategic collaboration for the development and, subject to FDA approval, commercialization of TD-4208. Partnering with a world leader in nebulized respiratory therapies enables us to expand the breadth of our TD-4208 development program and extend our commercial reach beyond the acute care setting where we currently market VIBATIV. Funding of the Phase 3 registrational program by Mylan strengthens our capital position and enhances our financial flexibility to advance other high-value pipeline assets alongside TD-4208.

Under the terms of the agreement, Mylan and we will co-develop nebulized TD-4208 for COPD and other respiratory diseases. We will lead the U.S. registrational development program and Mylan will be 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-US territory outright, Mylan does have a right of first negotiation with respect to the development and commercialization of nebulized TD-4208 in China.



Table of Contents

Under the agreement, Mylan will pay 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 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. 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 TD-4208 monotherapy and \$45.0 million for future potential combination products.

We retain worldwide rights to TD-4208 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 TD-4208 delivered other than via a nebulized inhalation product.

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

Axelopran is an investigational, once-daily, oral peripherally active mu opioid receptor antagonist for opioid-induced constipation (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 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.

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

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. Based on these results, we have agreed with Alfa Wassermann to advance velusetrag into a Phase 2b study. Pursuant to our agreement with Alfa Wassermann, the first Phase 2 study was, and the bulk of the Phase 2b study will be, funded by Alfa Wassermann.

Table of Contents

***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 Theravance) relating to the Closed Triple program and the 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%. In July 2014, Theravance and GSK announced the initiation of a large, global Phase 3 program for the Closed Triple in patients with COPD. In February 2015, Theravance and GSK announced the start of a second global Phase 3 study to evaluate the effects of the Closed Triple in patients with COPD.

*Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA)*

GSK961081 ('081) is an investigational, single-molecule bifunctional bronchodilator with both muscarinic antagonist and beta2 receptor agonist (MABA) activity that was discovered by us when we were part of Theravance. In August 2014, Theravance reported that preclinical Phase 3-enabling studies and a Phase 1 study with healthy volunteers of '081/FF are ongoing to explore its potential as a once-daily medicine delivered in GSK's ELLIPTA® inhaler.

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, Theravance assigned to TRC, a Delaware limited liability company formed and controlled by Theravance, 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 mid- and 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 three therapeutic areas – diseases of the lung and gastrointestinal tract and infectious disease – and we have established a commercial infrastructure focused 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 all 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**

Although we have limited in-house active pharmaceutical ingredient ("API") production capabilities, we rely primarily on a number of third parties, including contract manufacturing organizations and our collaborative partners, to produce our active pharmaceutical ingredient and drug product.

We believe that we have in-house expertise to manage a network of third-party manufacturers. 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 of VIBATIV drug product is unable or unwilling to perform, or if its performance does not meet regulatory requirements, including maintaining 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 could cause the price of our securities to fall.

Table of Contents

**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 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 that includes, among other things, the results of preclinical studies. If the FDA accepts the Investigational New Drug submission, clinical studies are usually conducted in three phases and under FDA oversight. These phases generally include the following:

**Phase 1.** The product candidate is introduced into 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, or NDA. The NDA also must contain extensive manufacturing information. NDAs for new chemical entities are subject to performance goals defined in the Prescription Drug User Fee Act ("PDUFA") which suggests a goal for FDA action within six months of the 60-day filing date for applications that are granted priority review and 10 months of the 60-day filing date for applications that receive standard review. For a product candidate no active ingredient of which has been previously approved by the FDA, the FDA must either refer the product candidate to an advisory committee for review or provide in the action letter on the application for the product candidate a summary of the reasons why the product candidate was not referred to an advisory committee prior to approval. In addition, under the 2009 Food and Drug Administration Amendments Act, the FDA has authority to require submission of a formal Risk Evaluation and Management Strategy ("REMS") to ensure safe use of the product. At the end of the review period, the FDA communicates an approval of the NDA or issues a complete response listing the application's deficiencies.

Once approved, the FDA may withdraw the product approval if compliance with pre- and 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 effect 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 institute criminal prosecution.

Table of Contents

If regulatory approval for a medicine is obtained, the clearance to market the product will be limited to those diseases and conditions for which the medicine is effective, as demonstrated through clinical studies and included 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 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 institute 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, 2014, we or one of our wholly-owned subsidiaries owned 385 issued United States patents and 1,362 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.

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.

Theravance entered into a License Agreement with Janssen Pharmaceutica ("Janssen") pursuant to which it licensed rights under certain patents owned by Janssen covering an excipient used in the formulation of telavancin. This license agreement was transferred to us as a result of the Spin-Off. We believe that the general and financial terms of the agreement with Janssen are ordinary course terms. Pursuant to the terms of this license agreement, we will be 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 mission is to create value from a diverse and unique set of assets: an approved product, a pipeline of mid- and late-stage assets, and a productive research platform designed for long-term growth. Our marketed product and our research and development programs target three therapeutic areas – infectious disease and diseases of the lung and gastrointestinal tract – and our commercial infrastructure is focused 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, a generic drug that is 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.; Zyvox® (linezolid) marketed by Pfizer; Teflaro® (ceftaroline) and Dalvance (dalbavancin) marketed by Actavis; and Orbactiv (oritavancin) marketed by The Medicines Company. To compete effectively with these medicines, and in particular with the

Table of Contents

relatively inexpensive generic option of vancomycin, we will need to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, VIBATIV is a suitable alternative to vancomycin and other existing or subsequently-developed anti-infective drugs in certain clinical situations.

*TD-4208 long-acting muscarinic antagonist (LAMA).* If successfully developed and approved as the first once-daily nebulized LAMA, TD-4208 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.

In addition, as the principles of multivalent medicine design become more widely known and appreciated based on patent and scientific publications and regulatory filings, we expect the field to become highly competitive. Pharmaceutical companies, biotechnology companies and academic and research institutions may seek to develop product candidates based upon the principles underlying our multivalent technologies.

**Employees**

As of December 31, 2014, we had 287 employees, of which 187 were engaged primarily in research and development activities. Some of our employees continue to provide services to Theravance pursuant to agreements between our companies. None of our employees are represented by a labor union. We consider our employee relations to be good.

**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.

**ITEM 1A. RISK FACTORS**

**RISKS RELATING TO THE COMPANY**

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

First as Theravance, Inc. ("Theravance"), 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, 2014, 2013 and 2012, we recognized losses of \$237.0 million, \$156.3 million and \$9.6 million, respectively, which are reflected in the Shareholders' Equity and Parent Company Deficit 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

Table of Contents

to VIBATIV® (telavancin). In particular, to the extent we advance our product candidates into and through later stage clinical studies without a partner, such as axelopran (TD-1211) in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation, we will incur substantial expenses. We are also making additional investments in telavancin, our approved antibiotic. 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, we have increased, and may continue to increase, the number of 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. 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; and

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

Other than potential revenues from VIBATIV, our only approved medicine, and potential contingent 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 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 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 additional funding sooner in the form of public or private equity offerings, debt financings or additional collaborations and licensing arrangements. For example, if we chose to progress axelopran (TD-1211) in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation 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



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

### Table of Contents

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, we have increased, and may continue to increase, the number of sales representatives and medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV.

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 and research and development programs;

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;

our facilities expenses, which will vary depending on the time and terms of any facility lease or sublease we may enter into;

potential litigation and other contingencies; and

the regulatory approval process for our product candidates.

We may seek to raise additional capital or obtain future funding through public or private equity offerings, debt financings or additional collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions may make it very difficult for us to seek financing from the capital markets. We may be required to relinquish rights to our technologies or product candidates, 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 preclinical and clinical studies as opposed to conducting them concomitantly in order to conserve resources, or delay, reduce or eliminate one or more of our research or development programs and reduce overall overhead expenses. If we are unable to raise additional capital or obtain future funding in sufficient amounts or on terms acceptable to us, we may have to make reductions in our workforce and may be prevented from continuing our discovery

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

and development 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

Table of Contents

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) TD-4208 in February 2015, Mylan made a \$30 million equity investment in us by purchasing 1,585,790 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. 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 commercialize products or technologies that we would otherwise seek to commercialize ourselves or on terms that are less attractive than they might otherwise be, any of which could materially harm our business.

In addition, the terms of debt securities may also 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.

***We do not control TRC and, in particular, have no control over or access to non-public information about the respiratory programs that Theravance partnered with GSK and assigned to TRC in connection with the Spin-Off (the "GSK-Partnered Respiratory Programs").***

Theravance 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"). These other drug programs include 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. Theravance controls TRC and, except for certain limited consent rights, we have no right to participate in the business and affairs of TRC. Theravance 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.

Table of Contents

***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 Theravance. 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

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

***Without a commercialization partner for VIBATIV in the U.S. we will bear the full cost of developing the capability to market, sell and distribute the product.***

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 to Theravance by Astellas Pharma Inc. ("Astellas"), Theravance's 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, Theravance announced the reintroduction of VIBATIV to the U.S. market with the commencement of shipments into the wholesaler channel and we have increased, and may continue to increase, our small sales force and medical affairs presence 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,

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

### Table of Contents

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 development of telavancin.

If we are not successful in building an internal sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability, 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.

***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. 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 (for example, as Theravance experienced when TD-9855 did not meet the primary efficacy endpoints in the Phase 2 study in adult patients with Attention-Deficit/Hyperactivity Disorder);

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;

our 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;

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

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.

Table of Contents

***If our product candidates that we develop on our own or with collaborative partners 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 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 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.

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

Frequently, product candidates that have shown promising results in early preclinical or clinical studies have subsequently suffered significant setbacks or failed in later 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 have increased uncertainty regarding the approvability of new drugs. In addition, over the past decade, the FDA has implemented additional requirements for approval of new drugs, including advisory committee meetings for new chemical 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.

Theravance's previous VIBATIV commercialization partner failed to maintain a reliable source of drug product supply which resulted in critical product shortages and, eventually, suspension of

Table of Contents

commercialization for well over a year. In May 2012, Theravance entered into an agreement with Hospira Worldwide, Inc. ("Hospira") to supply VIBATIV drug product. 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 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, in February 2015 it was announced that Pfizer plans to acquire Hospira later this year 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 for or related to the proposed 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 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.



Table of Contents

***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 number of 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 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 make it more difficult to market VIBATIV. 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 contract manufacturers' 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 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.

***VIBATIV may not be accepted by physicians, patients, third party payors, or the medical community in general.***

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, a relatively inexpensive generic drug that is 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. If we are unable to demonstrate to physicians that, based on

Table of Contents

experience, clinical data, side-effect profiles and other factors, VIBATIV for the treatment of complicated skin and skin structure infections (cSSSI) and HABP/VABP caused by susceptible Gram-positive bacteria in adult patients is a suitable alternative to vancomycin and other antibacterial drugs in certain clinical situations, we may never generate meaningful revenue from VIBATIV which could cause the price of our securities to fall. The degree of market acceptance of VIBATIV depends on a number of factors, including, but not limited to:

the demonstration of the clinical efficacy and safety of VIBATIV;

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

potential negative perceptions of physicians related to product shortages and regional supply outages that halted commercialization of VIBATIV, stemming from the manufacturing issues at the previous drug product supplier;

potential negative perceptions of physicians related to the European Commission's previous suspension of marketing authorization for VIBATIV (which suspension was lifted in March 2014) because the prior VIBATIV commercialization partner's single-source VIBATIV drug product supplier did not meet the cGMP requirements for the manufacture of VIBATIV;

any adverse developments or perceived adverse developments with respect to whether Pfizer's planned acquisition of Hospira later this year will 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 reimbursement policies of government and third party payors; and

the market price of VIBATIV relative to competing therapies.

***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.***

In October 2012, Theravance entered into 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, and Theravance 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 on an exclusive, worldwide basis. In March 2013, Theravance entered into 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, Theravance granted to these parties certain rights regarding the use of its patents and technology with respect to the compounds in our development programs, including development and marketing rights. In September 2013, Merck terminated its research collaboration and license agreement with Theravance. 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, and if it decides not to progress the licensed program, we may not be able to develop or commercialize the program on our own. In January 2015, we entered into a collaboration agreement with Mylan for the development and commercialization of a nebulized formulation of our LAMA TD-4208. Under the terms of the agreement, we and Mylan will co-develop nebulized TD-4208 for COPD and other respiratory diseases.

Table of Contents

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 to Theravance in January 2012 with its VIBATIV agreement and as Merck did to Theravance 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 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 Theravance, a strategic partner of TRC and a significant shareholder of us, it may take actions that in certain cases are materially harmful to both our business and to our other shareholders.***

Based on our review of publicly available filings as of February 17, 2015, GSK beneficially owned approximately 24.5% of our outstanding ordinary shares. GSK is also a strategic partner to Theravance with rights and obligations under the GSK Agreements that may cause GSK's interests to differ from the interests of us and our other shareholders. In particular, upon the regulatory approval of the Closed Triple or a MABA/ICS in either the U.S. or the European Union, GSK's diligent efforts obligations under the GSK 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 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 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 Theravance and TRC. For example, GSK could promote its own respiratory products and/or delay or terminate the development or commercialization of the respiratory programs covered by the GSK Agreements. Also, given the potential future royalty payments GSK may be obligated to pay under the GSK Agreements, GSK may seek to acquire us or acquire our interests in TRC in order to effectively reduce those payment obligations, 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 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 Theravance's post-Spin-Off operations as violating or allowing it to terminate the GSK Agreements, including by violating the confidentiality provisions of those agreements or the master agreement between GSK, Theravance 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 Agreements, the master agreement and

Table of Contents

applicable law, there can be no assurance that we or Theravance 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 Theravance 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 Theravance's partnered products and other GSK respiratory products, disputes over public statements, and similar matters. In general, any uncertainty about the respiratory programs partnered with GSK, the enforceability of the GSK Agreements or the relationship/partnership between Theravance 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, Theravance and GSK entered into a number of agreements that may significantly restrict our business and affairs. In particular, we, Theravance 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, Transition Services Agreement, Employee Matters Agreement and Tax Matters Agreement 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. The Master Agreement also limits the periods of time that Theravance employees may provide services to us pursuant to the transition services agreement between Theravance and us. 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 Theravance under the GSK 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.***

Theravance's 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 were assigned to us in connection with the Spin-Off. Also, through our interest in TRC we may participate economically in Theravance's collaborations with GSK with respect to the GSK-Partnered Respiratory Programs. In addition, in January 2015 we entered into a collaboration agreement with Mylan for the development and commercialization of a nebulized formulation of TD-4208, our LAMA compound. Additional collaborations will 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, TD-9855 for fatigue/pain, and TD-6450 for hepatitis C, or for a territory that is not covered by existing collaborations, and to commercialize these product

Table of Contents

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 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 and development 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 our collaborative partners will compete with existing or future market-leading medicines.

Many of our potential competitors have substantially greater financial, technical and personnel resources than we have. In addition, many of these competitors have significantly greater commercial

Table of Contents

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 and retain qualified 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.

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, a relatively inexpensive generic drug that is manufactured by a number of companies, and a number of existing antibacterial drugs marketed by major and other pharmaceutical companies. 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.

As the principles of multivalency become more widely known, we expect to face increasing competition from companies and other organizations that pursue the same or similar approaches. Novel therapies, such as gene therapy or effective vaccines for infectious diseases, may emerge that will make both conventional and multivalent medicine discovery efforts obsolete or less competitive.

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

Certain of our directors and all of our executive officers hold shares of Theravance'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 Theravance 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 Theravance and for us. For example, potential or actual conflicts could arise relating to: our relationship with Theravance, including Theravance's and our respective rights and obligations under agreements entered into in connection with the Spin-Off; Theravance's management of TRC, particularly given that we and Theravance have different economic interests in TRC; and corporate opportunities that may be available to both companies in the future. Although we and Theravance have implemented policies and procedures to identify and properly address such potential and actual conflicts of interest, there can be no assurance that such conflicts of interest will not harm our business, prospects and financial condition and result in the diversion of corporate opportunities to Theravance.

Table of Contents

***If we lose key management or scientific personnel, or if we fail to retain our key employees, our ability to discover and develop our product candidates 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 market new medicines.

The Spin-Off represented a significant organizational change and our employees may have 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 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.***

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. 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, or inadvertent disclosure of confidential or proprietary information, 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

Table of Contents

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. We plan to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be 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 2014 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 and we have been subject to public company reporting obligations for at least twelve calendar months as of the end of the fiscal year, (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.

***We and our shareholders may not realize the potential benefits from the Spin-Off.***

On June 2, 2014, the Spin-Off of the Company from Theravance was completed via a pro rata dividend distribution to Theravance stockholders of record of one of our ordinary shares for every three and one half shares of Theravance common stock outstanding on the May 15, 2014 record date. We and our shareholders may not realize the potential benefits that we expected from our Spin-Off from Theravance. By separating from Theravance, 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 Theravance. In addition, we have incurred and will continue to incur significant costs, including those described elsewhere herein, which may exceed our estimates. As a separate company, we will not receive potential royalty revenue derived from certain of Theravance's late-stage partnered respiratory assets (the "Royalty Business").



Table of Contents

*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 Theravance as part of its broader corporate organization rather than as a stand-alone company, and our business was able to leverage Theravance's financial resources and creditworthiness;

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

our cost of capital will likely be higher than Theravance's cost of capital prior to the Spin-Off; and

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

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.

As a result of the Spin-Off, 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" or an "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.

To comply with these requirements, we anticipate that we may need to upgrade our systems, including information technology, implement additional financial and management controls, reporting systems and procedures and hire additional legal, accounting and/or finance staff. If we are unable to upgrade our financial and management controls, reporting systems, information technology and procedures in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies could be impaired. In addition, if in the future we are unable to conclude that our internal control over financial reporting is effective (or if the auditors are unable to express an opinion on the effectiveness of our internal controls), we could lose investor confidence in the accuracy and completeness of our financial reports.

Our management will be 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

Table of Contents

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 Theravance, we did not operate as a stand-alone company without 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 will not be able to rely upon the revenues, capital resources and cash flows of the Royalty Business remaining with Theravance. In addition, we will need certain transition services from Theravance to be able to operate our business and we will be required to deliver a significant number of services to Theravance during a transition period.

***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. Because Theravance Biopharma is incorporated under Cayman Islands law, it should be a non-U.S. corporation under this general rule. Section 7874 of the Internal Revenue Code of 1986, as amended (the "Code"), however, 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 Theravance constituted "substantially all" of the properties of Theravance (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 Theravance did constitute "substantially all" of the properties of Theravance. 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.

Table of Contents

***We believe that our company (and one of our subsidiaries) is a passive foreign investment company, or "PFIC," for 2014, which may have adverse U.S. federal income tax consequences to U.S. holders.***

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 is a PFIC for the 2014 taxable year and may continue to be a PFIC in subsequent years. In addition, we believe that one of our company's wholly-owned subsidiaries, Theravance Biopharma R&D, Inc. is also a PFIC for the 2014 taxable year. 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 wish to file an election 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. U.S. holders of our ordinary shares should consult their tax advisers regarding the potential PFIC, QEF and mark-to-market treatment of their interests in our ordinary shares, as well as the application of the PFIC rules with respect to their indirect interests in Theravance Biopharma R&D, Inc.

***If we are required to indemnify Theravance, or if we are not able to collect on indemnification rights from Theravance, our business prospects and financial condition may be harmed.***

We agreed to indemnify Theravance 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 Theravance stockholders in connection with the Spin-Off and (iii) any breach by us of certain agreements entered into with Theravance 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, Theravance agreed to indemnify us from and after the Spin-Off with respect to (i) all debts, liabilities and obligations retained by Theravance 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 Theravance 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 Theravance's ability to satisfy these indemnities, if called upon to do so, will depend upon our and Theravance's future financial strength. If we are required to indemnify Theravance, or if we are not able to collect on indemnification rights from Theravance, 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, 2014, we or one of our wholly-owned subsidiaries owned 385 issued United States patents and 1,362 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, and threaten our ability to commercialize, the product candidate. 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 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 of 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. 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. 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.

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.

Table of Contents

***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 a price we believe is fair for our products, if approved;

our ability to generate revenues and achieve profitability; and

the availability of capital.

The Patient Protection and Affordable Care Act and other potential legislative or regulatory actions 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 products, if approved. This could harm our or our collaborators' ability to market our 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 and further agency regulations that are likely to emerge in connection with the passage of this act could significantly reduce potential revenues from the sale of 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 our 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 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.

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

### Table of Contents

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 Theravance, 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 Theravance. Additionally, the stock market from time to time has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. Also, the trading price of shares of newly public companies distributed in spin-off transactions, as our shares have been distributed, can often be very volatile and subject to sharp declines, particularly shortly following the Spin-Off. 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 planned acquisition of Hospira later this year will lead to changes in Hospira's operations which may adversely impact our single source of supply for VIBATIV drug product;

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;

any adverse developments or agreements or perceived adverse developments or agreements with respect to the relationship of Theravance 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;

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

loss of key personnel;

relative illiquidity in the public market for our ordinary shares related to the concentration of ownership;

developments or disputes as to patent or other proprietary rights;



Table of Contents

approval or introduction of competing products and technologies;

results of clinical trials;

failures or unexpected delays in timelines for our potential products in development, including the obtaining of regulatory approvals;

delays in manufacturing adversely affecting clinical or commercial operations;

fluctuations in our operating results;

market reaction to announcements by other biotechnology or pharmaceutical companies;

initiation, termination or modification of agreements with our collaborators or disputes or disagreements with collaborators;

litigation or the threat of litigation;

public concern as to the safety of 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.

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

Based on our review of publicly available filings as of February 17, 2015, GSK beneficially owned approximately 24.5% of our outstanding ordinary shares and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 3.2% of our outstanding ordinary shares. Based on our review of publicly available filings as of February 17, 2015, our two largest shareholders other than GSK collectively owned approximately 23.9% 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;

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

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.

Table of Contents

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, 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

Table of Contents

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 consist of 150,000 square feet of office and laboratory space leased in two buildings in South San Francisco, CA. The lease expires in May 2020 and we may extend the terms for two additional five-year periods. We believe our current space is sufficient for our needs. The current annual rental expense under these leases is \$6.6 million. As security for performance of certain obligations under the facility operating leases for our principal physical properties we are required to have a financial institution issue letters of credit in the aggregate of approximately \$0.8 million, which we have collateralized with the financial institution by an equal amount of restricted cash.

**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>2014</b>		
Fourth Quarter	\$ 24.06	\$ 13.11
Third Quarter	\$ 34.07	\$ 23.01
Second Quarter	\$ 35.67	\$ 14.75

As of February 28, 2015, there were 126 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, 2014:

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)
Equity compensation plans approved by security holders	3,857,626	\$ 25.00	1,570,945(1)
Equity compensation plans not approved by security holders	104,800	\$ 14.90	645,200
<b>Total</b>	<b>3,962,426</b>	<b>\$ 24.73</b>	<b>2,216,145</b>

(1)

Includes 857,142 ordinary shares available under our Employee Stock Purchase Plan.

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"). Under the 2013 EIP and 2013 ESPP, we are authorized to issue 5,428,571 ordinary shares and 857,142 ordinary shares. 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



Table of Contents

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, 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.

Additional information regarding share-based compensation is included in Note 1, "Description of Operations and Summary of Significant Accounting Policies," and Note 6, "Share-Based Compensation," to the consolidated financial statements appearing in this Annual Report on Form 10-K.

*Share Performance Graph*

The graph set forth below compares the cumulative total shareholder return on our ordinary shares for the period commencing on June 3, 2014, the date on which our ordinary shares began trading on The NASDAQ Global Market, through December 31, 2014, 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 \$100.00 on June 3, 2014 in each of (1) our ordinary shares, (2) the NASDAQ Composite Index, (3) the NASDAQ

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

### Table of Contents

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. Information used in the graph was obtained from Research Data Group, Inc., a source believed to be reliable, but we are not responsible for any errors or omissions in such information.

Notwithstanding anything to the contrary set forth in any of our previous or future filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, 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 United States Securities and Exchange Commission 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

#### **COMPARISON OF 7 MONTH CUMULATIVE TOTAL RETURN\***

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

---

\*

\$100 invested on 6/3/14 in stock or 5/31/14 in index, including reinvestment of dividends. Fiscal year ending December 31.

\*

\$100 invested on June 3, 2014 in stock or index, including 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, 2014, which have been derived from our (i) audited consolidated financial statements as of December 31, 2014, and 2013 and for the years ended December 31, 2014, 2013 and 2012, which are included in this Annual Report, (ii) audited combined financial statements as of December 31, 2012 and 2011 and for the year ended December 31, 2011, which are not included in this Annual Report, and (iii) unaudited combined financial statements as of December 31, 2010 and for the year ended December 31, 2010, 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,				
	2014	2013	2012	2011	2010
	(In thousands, except per share data)				
<b>CONSOLIDATED STATEMENTS OF OPERATIONS DATA</b>					
Product sales	\$ 4,418	\$	\$	\$	\$
Revenue from collaborative arrangements(1)	7,270	226	130,145	14,854	14,397
Costs and expenses:					
Cost of goods sold(2)	4,058				
Research and development	168,522	120,579	113,995	98,850	70,819
Selling, general and administrative	71,647	35,931	25,725	25,339	23,321
Total costs and expenses(3)	244,227	156,510	139,720	124,189	94,140
Loss from operations	(232,539)	(156,284)	(9,575)	(109,335)	(79,743)
Interest and other income	1,865				
Provision for income taxes	6,364				
Net loss	\$ (237,038)	\$ (156,284)	\$ (9,575)	\$ (109,335)	\$ (79,743)
Basic and diluted net loss per share	\$ (7.46)	\$ (4.92)	\$ (0.30)	\$ (3.44)	\$ (2.51)
Shares used to compute basic and diluted net loss per share(4)	31,755	31,741	31,741	31,741	31,741

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

Table of Contents

	As of December 31,				
	2014	2013	2012	2011	2010
	(In thousands)				
<b>CONSOLIDATED BALANCE SHEETS DATA</b>					
Cash, cash equivalents and marketable securities(5)	\$ 306,010	\$	\$	\$	\$
Working capital	234,114	(22,747)	(11,837)	(33,565)	(21,584)
Total assets	337,771	25,177	20,962	13,821	16,901
Long-term liabilities(6)	6,728	5,359	5,280	118,664	129,462
Accumulated deficit	(139,337)				
Parent company deficit		(17,035)	(6,990)	(140,724)	(139,538)
Total shareholders' equity and parent company deficit	\$ 289,787	\$ (17,035)	\$ (6,990)	\$ (140,724)	\$ (139,538)

(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) In 2014, cost of goods sold includes a charge of \$2.9 million for the write-down of VIBATIV inventory due to the dating of the product. We continue to hold this inventory for sale as of December 31, 2014.

(3) The following table discloses the allocation of shared-based compensation expense included in total operating expenses:

	Year Ended December 31,				
	2014	2013	2012	2011	2010
	(In thousands)				
Research and development	\$ 21,191	\$ 15,444	\$ 13,192	\$ 12,696	\$ 10,093
Selling, general and administrative	22,043	7,032	8,131	8,767	7,515
Total share-based compensation	\$ 43,234	\$ 22,476	\$ 21,323	\$ 21,463	\$ 17,608

(4) Prior to the Spin-Off in June 2014, we operated as part of Theravance 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 Theravance stockholders in connection with the Spin-Off, less the number of ordinary shares subject to forfeiture, were outstanding from the beginning of all periods presented.

(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:

Year Ended December 31,				
2014	2013	2012	2011	2010
(In thousands)				

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

Deferred revenue	\$	712	\$	585	\$	206	\$	112,843	\$	125,819
------------------	----	-----	----	-----	----	-----	----	---------	----	---------

43

---

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 of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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**

Our mission is to create value from a unique and diverse set of assets: an approved product; a development pipeline of mid- and late-stage assets; and a productive research platform designed for long-term growth.

Our pipeline of internally discovered product candidates includes potential best-in-class opportunities in underserved markets in the acute care setting, representing multiple opportunities for value creation. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the United States and Europe for certain difficult-to-treat infections. TD-4208 is an investigational long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for COPD. Axelopran (TD-1211) is an investigational potential once-daily, oral treatment for opioid-induced constipation (OIC). Our earlier-stage clinical assets represent novel approaches for potentially treating diseases of the lung and gastrointestinal tract and infectious disease. In addition, we have an economic interest in future payments that may be made by GlaxoSmithKline plc ("GSK") pursuant to its agreements with Theravance, Inc. ("Theravance") relating to certain drug programs, including the combination of fluticasone furoate, umeclidinium, and vilanterol (or the "Closed Triple").

In 2014, our net loss was \$237.0 million, an increase of \$80.7 million from \$156.3 million in 2013. Our research and development expenses were \$168.5 million in 2014, an increase of \$47.9 million from \$120.6 million in 2013, primarily due to external costs for progression of our key clinical programs. Our selling, general and administrative expenses were \$71.6 million in 2014, an increase of \$35.7 million from \$35.9 million in 2013, primarily due to VIBATIV commercialization and achievement of performance conditions under special long-term retention and incentive awards granted to certain employees in 2011. Cash, cash equivalents, and marketable securities, excluding restricted cash, totaled \$306.0 million on December 31, 2014, primarily reflecting the contribution of \$393.0 million from Theravance in connection with the Spin-Off (as defined below) less cash used in operations.

**The Separation of Theravance Biopharma from Theravance**

On June 1, 2014, Theravance 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 Theravance made a pro rata dividend distribution to its stockholders of record on May 15, 2014

Table of Contents

of one ordinary share of Theravance Biopharma for every three and one half shares of Theravance 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, Theravance operated the Biopharmaceutical Business.

The Spin-Off was effected pursuant to a Separation and Distribution Agreement between Theravance and Theravance Biopharma (the "Separation and Distribution Agreement"), which provides, among other things, for the principal corporate transactions required to effect the Spin-Off and certain other agreements governing Theravance's relationship with Theravance Biopharma after the Spin-Off.

**Basis of Presentation**

For the periods prior to June 2, 2014, the consolidated financial statements have been prepared using Theravance's historical cost basis of the assets, liabilities, revenues, and expenses of the various activities that comprise the Biopharmaceutical Business as a component of Theravance and reflect the results of operations, financial condition and cash flows of the Biopharmaceutical Business as a component of Theravance. The statements of operations include expense allocations for general corporate overhead functions historically shared with Theravance, 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 Theravance were allocated to Theravance Biopharma based on the relative percentages, as compared to Theravance's other businesses, of headcount or square footage usage.

The costs historically allocated to us by Theravance 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. and Canada for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria. VIBATIV is also approved in the U.S. 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 approved 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.

*Commercial Program Expansion*

In 2014, we implemented a phased launch strategy for VIBATIV in the U.S. that focused on a small number of targeted geographic territories across the country. We have since expanded our sales force and medical affairs presence to include additional territories in the U.S. with the goal of strengthening our commercial infrastructure comprised of experienced sales representatives and a significant medical information component focused on the acute care market.

Table of Contents

*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.

*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 multicenter, 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.

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

TD-4208 is an investigational, long-acting muscarinic antagonist (LAMA) in development for the treatment of COPD. We believe that TD-4208 may become a valuable addition to the COPD treatment regimen and that it represents a significant commercial opportunity. Our market research indicates approximately 9% of the treated COPD patients in the U.S. 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. TD-4208 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 TD-4208, 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 Registrational Study in COPD*

In December 2014, following the announcement of positive top-line results of our Phase 2b program, we conducted an end-of-Phase 2 meeting with the FDA to discuss the design of the Phase 3 registrational program. We are progressing TD-4208 into a Phase 3 registrational program that will include two replicate three-month efficacy studies and a single twelve-month safety study. Based on our discussion with the FDA, the studies will include approximately 2,200 patients. The studies will test two doses: 88 mcg and 175 mcg administered once-daily. We expect to initiate the Phase 3 program in 2015.

*Mylan Collaboration*

In January 2015, Mylan Inc., which is now a subsidiary of Mylan N.V. ("Mylan"), and we established a strategic collaboration for the development and, subject to FDA approval, commercialization of TD-4208. Partnering with a world leader in nebulized respiratory therapies enables us to expand the breadth of our TD-4208 development program and extend our commercial reach beyond the acute care setting where we currently market VIBATIV. Funding of the Phase 3 registrational program by Mylan strengthens our capital position and enhances our financial flexibility to advance other high-value pipeline assets alongside TD-4208.

Under the terms of the agreement, Mylan and we will co-develop nebulized TD-4208 for COPD and other respiratory diseases. We will lead the U.S. registrational development program and Mylan will be 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

Table of Contents

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-US territory outright, Mylan does have a right of first negotiation with respect to the development and commercialization of nebulized TD-4208 in China.

Under the agreement, Mylan will pay 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 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. 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 TD-4208 monotherapy and \$45.0 million for future potential combination products.

We retain worldwide rights to TD-4208 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 TD-4208 delivered other than via a nebulized inhalation product.

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

Axelopran is an investigational, once-daily, oral peripherally active mu opioid receptor antagonist for opioid-induced constipation (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 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.

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

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



Table of Contents

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. Based on these results, we have agreed with Alfa Wassermann to advance velusetrag into a Phase 2b study. Pursuant to our agreement with Alfa Wassermann, the first Phase 2 study was, and the bulk of the Phase 2b study will be, funded by Alfa Wassermann.

**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.

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 Theravance'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

Table of Contents

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.

***Inventories***

Inventories consist of raw materials, work-in-process and finished goods related to the production of VIBATIV. Raw materials include VIBATIV active pharmaceutical ingredient (API) and other raw materials. Work-in-process and finished goods include third-party manufacturing costs and labor and indirect costs 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 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 validation batches. We analyze 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. 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 2014, we recognized a charge of \$2.9 million to write-down inventory to net realizable value. Refer to Note 4, "Inventories," to the consolidated financial statements appearing in this Annual Report on Form 10-K for further information. As of December 31, 2014, the carrying value of our inventory is \$12.5 million. In order to realize the value of our recorded inventory, we will be dependent upon continued increases in the sales volumes of VIBATIV.

***Income Taxes***

The provision for income taxes in 2014 is a result of operating in multiple jurisdictions and generating taxable income in our U.S. operations, although we incur operating losses on a consolidated basis.

We recognize income taxes under the asset and liability method. This approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. 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.

Realization of deferred tax assets requires us to make estimates regarding the timing and amount of future taxable income. 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.

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 and expertise in federal and state income tax laws, regulations and strategies. Our filings, including the positions taken therein, will be subject to audit by various taxing authorities. While we believe we have provided adequately for our income tax liabilities in our consolidated financial statements, adverse determinations by these taxing authorities could have a material adverse effect on the consolidated financial condition, results of operations or cash flows.

For periods prior to June 2, 2014, our operations have been included in Theravance's consolidated U.S. federal and state income tax returns. Our effective tax rate in future years are expected to vary from Theravance's historical effective tax rates and will depend on our future operations, profitability, legal structure and related tax elections. The historical net operating loss and research and development tax credit carryforwards generated by us prior to the Spin-Off remained with Theravance. Tax attributes generated by us following the Spin-Off remain with us.

Table of Contents**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,			2014		2013	
	2014	2013	2012	\$	%	\$	%
Product sales	\$ 4,418	\$	\$	\$ 4,418	NM	\$	
Revenue from collaborative arrangements	7,270	226	130,145	7,044	NM	(129,919)	NM
<b>Total revenue</b>	<b>\$ 11,688</b>	<b>\$ 226</b>	<b>\$ 130,145</b>	<b>\$ 11,462</b>	<b>NM</b>	<b>\$ (129,919)</b>	<b>NM</b>

---

NM: Not Meaningful

Commencing in 2014, we recognized revenue from sales of VIBATIV. 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 R-Pharm collaborative arrangement of \$2.1 million. Recognition of both resulted from the completion of the technical transfer of the license in 2014.

Revenue from collaborative arrangements decreased in 2013 from 2012 primarily due to the accelerated recognition of deferred revenue of \$125.8 million resulting from the termination of the collaboration arrangement with Astellas in 2012 and the recognition of the upfront payment of \$4.4 million in 2012 under the collaboration arrangement with Merck, which was terminated in 2013.

***Cost of Goods Sold***

In 2014 cost of goods sold was \$4.1 million, which resulted from recognizing revenue from product sales of VIBATIV and includes a charge of \$2.9 million for the write-down of VIBATIV inventory due to the dating of the product. We continue to hold this inventory for sale as of December 31, 2014. There was no cost of goods sold for the years ended December 31, 2013 and 2012.

***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, 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.



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

### Table of Contents

The following table summarizes our R&D expenses incurred during the periods presented:

(In thousands)	Year Ended December 31,			Change			
	2014	2013	2012	2014			2013
	\$	\$	\$	\$	%	\$	%
Employee-related	\$ 57,427	\$ 36,917	\$ 36,391	\$ 20,510	56%	\$ 526	1%
Share-based compensation	21,191	15,444	13,192	5,747	37	2,252	17
External-related	62,975	45,926	42,980	17,049	37	2,946	7
Facilities, depreciation and other allocated	26,929	22,292	21,432	4,637	21	860	4
	\$ 168,522	\$ 120,579	\$ 113,995	\$ 47,943	40	\$ 6,584	6

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 in our LAMA program with TD-4208 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 in our LAMA program with TD-4208 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.

R&D expenses increased in 2013 compared to 2012 primarily due to higher external costs of \$2.9 million and an increase of \$2.3 million in share-based compensation expense. The key Phase 2 clinical trials we were conducting in 2012 were our Phase 2b program in our opioid-induced constipation program with TD-1211 and one Phase 2 study in our MARIN program with TD-9855.

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 \$1.9 million, \$6.5 million and \$0.9 million for 2014, 2013 and 2012.

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

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

(In thousands)	Year Ended December 31,			Change			
	2014	2013	2012	2014			2013
	\$	\$	\$	\$	%	\$	%
Selling, general and administrative	\$ 71,647	\$ 35,931	\$ 25,725	\$ 35,716	99%	\$ 10,206	40%

Selling, general and administrative expenses increased in 2014 compared to 2013 primarily due to costs associated with VIBATIV commercialization activities and incremental share-based compensation expense, including incentive awards.

Selling, general and administration expenses increased in 2013 compared to 2012 primarily due to an increase in external legal and accounting fees in connection with the separation strategy, selling costs resulting from our reintroduction of VIBATIV into the U.S. wholesaler channel in August 2013 and employee-related expenses.

Selling, general and administrative expenses include share-based compensation expenses of \$22.0 million, \$7.0 million and \$8.1 million in 2014, 2013 and 2012.

Table of Contents

***Interest and Other Income***

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 Theravance of \$1.6 million. There was no interest and other income in 2013 and 2012.

***Provision for Income Taxes***

The 2014, provision for income taxes of \$6.4 million resulted from operating in multiple jurisdictions and generating taxable income in our U.S. operations, although we incurred operating losses on a consolidated basis. There was no provision for income taxes in 2013 and 2012.

At December 31, 2014, we had no net operating loss carryforwards for federal income taxes and no federal research and development tax credit carryforwards. We had state operating loss carryforwards of \$3.2 million expiring in 2034 and state research and development credit carryforwards of \$1.5 million to be carried forward indefinitely. We had unrecognized tax benefits of \$1.1 million as of December 31, 2014. Our unrecognized tax benefits would reduce our effective income tax rate if recognized, due to the valuation allowance that currently offsets our deferred tax assets.

**Liquidity and Capital Resources**

***Liquidity***

At the closing of the Spin-Off, Theravance provided to us cash, cash equivalents and marketable securities of \$393.0 million. In addition, Theravance was obligated to fund all current liabilities, with the exception of deferred rent, deferred revenue, accrued vacation and accrued discretionary cash bonuses that were incurred by us through the Spin-Off date in accordance with the Separation and Distribution Agreement between the two companies. For ease of administration and in connection with the assignment of certain rights and obligations under the Separation and Distribution Agreement, certain current liabilities, which were transferred to us on the Spin-Off date, were paid by us and reimbursed by Theravance. As such, Theravance provided us with an additional \$17.0 million in July 2014 to reimburse us for these liabilities that were incurred before the Spin-Off and transferred to us on the Spin-Off date.

In 2011, Theravance granted special long-term retention and incentive cash bonus awards to certain employees. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and continued employment. In May 2014, Theravance's Compensation Committee determined that the requisite performance conditions for the first tranche of the awards were achieved and, as a result, \$9.5 million was paid by Theravance.

In May 2014, Theravance'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 cash awards. The maximum amount payable by us under these modified cash bonus awards is \$10.4 million. The remaining tranches of the cash awards were forfeited.

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, such as axelpran (TD-1211) in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation, we will incur substantial expenses. We are also making additional investments in telavancin, our approved antibiotic. In February 2015, we announced initiation of a

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

### Table of Contents

Phase 3 registrational study for bacteremia and initiation of a patient registry study. In addition, we have increased, and may continue to increase, the number of 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, 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. Furthermore, if in our view favorable financing opportunities arise, we may seek additional funding at any time. However, future financing may not be available in amounts or on terms acceptable to us, if at all. This could leave us without adequate financial resources to fund our operations as presently conducted.

### *Cash Flows*

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

(In thousands)	Year ended December 31,			Change	
	2014	2013	2012	2014	2013
Net cash used in operating activities	\$ (175,155)	\$ (120,959)	\$ (119,107)	\$ (54,196)	\$ (1,852)
Net cash used in investing activities	(106,251)	(2,634)	(2,430)	(103,617)	(204)
Net cash provided by financing activities	370,621	123,593	121,537	247,028	2,056

Net cash used in our operating activities was \$175.2 million, \$121.0 million and \$119.1 million for 2014, 2013 and 2012. Operating activities in 2014 include an increase in costs related to progression of clinical studies in our key clinical programs and costs related to VIBATIV commercialization.

Net cash used in investing activities was \$106.3 million, \$2.6 million and \$2.4 million for 2014, 2013 and 2012. Investing activities in 2014 include \$103.3 million in purchases of available-for-sale securities, net of maturities. Investing activities include capital expenditures for property acquisitions.

Net cash provided by financing activities was \$370.6 million, \$123.6 million and \$121.5 million for 2014, 2013 and 2012. In 2014, \$277.5 million of cash and cash equivalents were contributed to us from Theravance as a result of the Spin-Off.

### *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 Theravance (the "GSK Agreements"). We have determined TRC to be a variable interest entity that is not consolidated in our financial statements. See Note 10, "Contractual Agreements with Theravance, 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

Table of Contents

publicly available information about those drug candidates as we do not have access to confidential information regarding their progression or status.

***Commitments and Contingencies***

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, shareholder suits and tax matters, as such, we are unable to estimate the potential exposure related to these indemnification agreements. We have not recognized any liabilities relating to these agreements as of December 31, 2014.

In 2011, Theravance granted special long-term retention and incentive restricted stock awards to members of senior management and special long-term retention and incentive cash bonus awards to certain employees. 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, Theravance'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 and cash awards. The share-based compensation expense of \$6.9 million associated with a portion of these awards after the modification is expected to be recognized by us during the 12-month service period commencing in June 2014.

During the fourth quarter of 2014, we determined that it was probable that the performance conditions associated with the remaining 417,000 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 Theravance on June 2, 2014 of one ordinary share of Theravance Biopharma for every three and one half shares of Theravance common stock. As a result, \$1.4 million of the total share-based compensation expense of \$9.5 million related to these remaining RSAs and the pro rata dividend was recognized by us in 2014. The RSAs and pro rata dividend remain subject to a twelve-month service period, which commenced in February 2015.

**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, 2014. 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)	Years				
	Total	Within 1	Over 1 to 3	Over 3 to 5	After 5
Facility operating leases(1)	\$ 33,391	\$ 5,770	\$ 12,064	\$ 12,799	\$ 2,758
Purchase obligations	78,023	51,712	26,063	242	6
<b>Total</b>	<b>\$ 111,414</b>	<b>\$ 57,482</b>	<b>\$ 38,127</b>	<b>\$ 13,041</b>	<b>\$ 2,764</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.

#### **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, 2014, a hypothetical 100 basis point increase in interest rates would result in a \$1.4 million decline in the fair market value of the portfolio. Such losses would only be realized if we sold the investments prior to maturity. A hypothetical decrease in market interest rates by 10% would not have a material impact to our interest income from our investment portfolio.

Table of Contents

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

<u>Consolidated Balance Sheets as of December 31, 2014 and 2013</u>	<u>57</u>
<u>Consolidated Statements of Operations for each of the three years in the period ended December 31, 2014</u>	<u>58</u>
<u>Consolidated Statements of Comprehensive Loss for each of the three years in the period ended December 31, 2014</u>	<u>59</u>
<u>Consolidated Statements of Shareholders' Equity and Parent Company Deficit for each of the three years in the period ended December 31, 2014</u>	<u>60</u>
<u>Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2014</u>	<u>61</u>
<u>Notes to Consolidated Financial Statements</u>	<u>62</u>
<u>Supplementary Financial Data (unaudited)</u>	<u>94</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>95</u>

Table of Contents**THERAVANCE BIOPHARMA, INC.****Consolidated Balance Sheets****(In thousands, except per share data)**

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
		<b>(Note 1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 89,215	\$
Short-term marketable securities	165,396	
Accounts receivable, net of allowances of \$87 and \$89 at December 31, 2014 and 2013	289	199
Receivables from collaborative arrangements	1,840	934
Prepaid and other current assets	6,084	2,567
Inventories	12,546	10,406
<b>Total current assets</b>	<b>275,370</b>	<b>14,106</b>
Marketable securities	51,399	
Restricted cash	833	833
Property and equipment, net	9,663	10,238
Other assets	506	
<b>Total assets</b>	<b>\$ 337,771</b>	<b>\$ 25,177</b>
<b>Liabilities:</b>		
Current liabilities:		
Accounts payable	\$ 9,921	\$ 6,940
Accrued personnel-related expenses	18,156	9,870
Accrued clinical and development expenses	7,871	9,714
Other accrued liabilities	5,219	2,122
Deferred revenue	89	8,207
<b>Total current liabilities</b>	<b>41,256</b>	<b>36,853</b>
Deferred rent	5,150	4,774
Other long-term liabilities	1,578	585
Commitments and contingencies (Note 2, 6 and 8)		
<b>Shareholders' Equity and Parent Company Deficit (Note 1):</b>		
Preferred shares, \$0.00001 par value: 230 shares authorized, no shares issued or outstanding at December 31, 2014; no shares authorized, issued or outstanding at December 31, 2013		
Ordinary shares, \$0.00001 par value: 200,000 shares authorized at December 31, 2014; 32,221 shares issued and outstanding at December 31, 2014; no shares authorized, issued or outstanding at December 31, 2013		
Additional paid-in capital	429,206	
Accumulated other comprehensive loss	(82)	
Accumulated deficit	(139,337)	
Parent company deficit		(17,035)
<b>Total shareholders' equity and parent company deficit</b>	<b>289,787</b>	<b>(17,035)</b>
<b>Total liabilities, shareholders' equity and parent company deficit</b>	<b>\$ 337,771</b>	<b>\$ 25,177</b>

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,		
	2014	2013 (Note 1)	2012 (Note 1)
<b>Revenue:</b>			
Product sales	\$ 4,418	\$	\$
Revenue from collaborative arrangements	7,270	226	130,145
<b>Total revenue</b>	<b>11,688</b>	<b>226</b>	<b>130,145</b>
<b>Costs and expenses:</b>			
Cost of goods sold	4,058		
Research and development	168,522	120,579	113,995
Selling, general and administrative	71,647	35,931	25,725
<b>Total costs and expenses</b>	<b>244,227</b>	<b>156,510</b>	<b>139,720</b>
Loss from operations	(232,539)	(156,284)	(9,575)
Interest and other income	1,865		
Loss before income taxes	(230,674)	(156,284)	(9,575)
Provision for income taxes	6,364		
<b>Net loss</b>	<b>\$ (237,038)</b>	<b>\$ (156,284)</b>	<b>\$ (9,575)</b>
<b>Net loss per share:</b>			
Basic and diluted net loss per share	\$ (7.46)	\$ (4.92)	\$ (0.30)
<b>Shares used to compute basic and diluted net loss per share</b>	<b>31,755</b>	<b>31,741</b>	<b>31,741</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>2014</b>	<b>2013</b>	<b>2012</b>
		<b>(Note 1)</b>	<b>(Note 1)</b>
Net loss	\$ (237,038)	\$ (156,284)	\$ (9,575)
Other comprehensive loss:			
Net unrealized loss on marketable securities	(173)		
Comprehensive loss	\$ (237,211)	\$ (156,284)	\$ (9,575)

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	Parent	Total
	Shares	Amount	Paid-In	Other	Company	Shareholders'
			Capital	Income	Deficit	Equity and
				(Loss)	Deficit	Parent
						Company
						Deficit
Balances at December 31, 2011						
(Note 1)		\$	\$	\$	\$	\$
Net loss						
Employee share-based						
compensation expense						
Net transfers from parent						
Balances at December 31, 2012						
(Note 1)						
Net loss						
Employee share-based						
compensation expense						
Net transfers from parent						
Balances at December 31, 2013						
(Note 1)						
Contribution of net assets from						
Theravance, Inc.	32,260,105		402,787	91	(402,878)	
Cash contribution from						
Theravance, 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			282			282
compensation						
Net unrealized loss on marketable				(173)		(173)
securities						
Net loss					(139,337)	(97,701)
Balances at December 31, 2014	32,221,083	\$	\$ 429,206	\$ (82)	\$ (139,337)	\$ 289,787

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>2014</b>	<b>2013</b>	<b>2012</b>
		<b>(Note 1)</b>	<b>(Note 1)</b>
<b>Operating activities</b>			
Net loss	\$ (237,038)	\$ (156,284)	\$ (9,575)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	2,662	2,653	3,251
Amortization of premium on marketable securities	612		
Share-based compensation	43,234	22,476	21,323
Charge to write-down inventory to net realizable value	2,887		
Excess tax benefit of share-based compensation	(282)		
Other non-cash items		20	196
Changes in operating assets and liabilities:			
Accounts receivable	(90)	(199)	
Receivables from collaborative arrangements	(906)	7	(617)
Receivable from Theravance, Inc.	14,635		
Prepaid and other current assets	(2,878)	19	(388)
Inventories	(6,628)	(3,101)	(4,822)
Other assets	(211)		
Accounts payable	3,917	2,113	(1,532)
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	11,680	4,170	(1,702)
Deferred rent	376	(300)	(747)
Deferred revenue	(7,991)	7,467	(124,494)
Other long-term liabilities	866		
 Net cash used in operating activities	 (175,155)	 (120,959)	 (119,107)
<b>Investing activities</b>			
Changes in restricted cash	(833)		60
Purchases of property and equipment	(3,107)	(2,734)	(2,590)
Purchases of marketable securities	(168,893)		
Maturities of marketable securities	65,564		
Sale of short-term investments and marketable securities	878		
Payments received on notes receivable, net of issuances	140	100	100
 Net cash used in investing activities	 (106,251)	 (2,634)	 (2,430)
<b>Financing activities</b>			
Cash and cash equivalents contributed from Theravance, Inc. (Note 9)	277,541		
Excess tax benefit of share-based compensation	282		
Repurchase of shares to satisfy tax withholding	(178)		
Payments on notes payable and capital leases			(69)
Transfers from Theravance, Inc.	92,976	123,593	121,606
 Net cash provided by financing activities	 370,621	 123,593	 121,537
 <b>Net increase in cash and cash equivalents</b>	 <b>89,215</b>		
<b>Cash and cash equivalents at beginning of period</b>			



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

<b>Cash and cash equivalents at end of period</b>	\$	89,215	\$	\$
---	----	--------	----	----

**Supplemental disclosure of cash flow information**

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

**Supplemental disclosure of noncash information**

Contribution of net assets, excluding cash and cash equivalents, from Theravance, Inc. (Note 9)	\$	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*

The mission of Theravance Biopharma, Inc. ("Theravance Biopharma", the "Company", or "we" and other similar pronouns) is to create value from a unique and diverse set of assets: an approved product; a development pipeline of mid- and late-stage assets; and a productive research platform designed for long-term growth.

Our pipeline of internally discovered product candidates includes potential best-in-class opportunities in underserved markets in the acute care setting, representing multiple opportunities for value creation. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the United States and Europe for certain difficult-to-treat infections. TD-4208 is an investigational long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease (COPD). Axelopran (TD-1211) is an investigational potential once-daily, oral treatment for opioid-induced constipation (OIC). Our earlier-stage clinical assets represent novel approaches for potentially treating diseases of the lung and gastrointestinal tract and infectious disease. In addition, we have an economic interest in future payments that may be made by GlaxoSmithKline plc ("GSK") pursuant to its agreements with Theravance, Inc. ("Theravance") relating to certain drug development programs, including the combination of fluticasone furoate, umeclidinium, and vilanterol (or the "Closed Triple").

On June 1, 2014, Theravance 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 Theravance 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 Theravance 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, Theravance operated the Biopharmaceutical Business.

The Spin-Off was effected pursuant to a Separation and Distribution Agreement between Theravance and Theravance Biopharma (the "Separation and Distribution Agreement"), which provides, among other things, for the principal corporate transactions required to effect the Spin-Off and certain other agreements governing Theravance's relationship with Theravance Biopharma after the Spin-Off. These agreements are discussed further in Note 10, "Contractual Agreements with Theravance, Inc."

*Basis of Presentation*

The consolidated financial statements have been prepared using Theravance's historical cost basis of the assets and liabilities of the various activities that comprised the Biopharmaceutical Business of Theravance and reflect the consolidated results of operations, financial condition and cash flows of Theravance Biopharma as a wholly-owned subsidiary of Theravance prior to the Spin-Off. The various assets, liabilities, revenues and expenses associated with Theravance 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 10, "Contractual Agreements with Theravance, Inc.". Changes in parent company deficit represent Theravance's net investment in

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

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

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

Theravance Biopharma, after giving effect to Theravance Biopharma's net loss, parent company expense allocations, and net cash transfers to and from Theravance.

For purposes of preparing the consolidated financial statements, the Biopharmaceutical Business was derived from Theravance'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 Theravance'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 Theravance'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 Theravance 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 Theravance until June 2, 2014, no separate cash accounts for the Biopharmaceutical Business were historically maintained prior to the Spin-Off and, therefore, Theravance 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, Theravance contributed to Theravance Biopharma cash, cash equivalents and marketable securities of \$393.0 million.

We describe the Biopharmaceutical Business transferred to us by Theravance 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.

***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

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

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

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

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. Revenues are generated primarily from our collaborative arrangements with Astellas Pharma Inc. ("Astellas") (which agreement terminated in January 2012), located in Japan, Merck (which agreement terminated in December 2013), located in the United States, Clinigen Group plc ("Clinigen") located in England, R-Pharm CSJC ("R-Pharm") located in Russia and Alfa Wassermann S.p.A. ("Alfa Wassermann") located in Italy.

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, 2014, 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 (deficit). 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 income. 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.

***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 Theravance, 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.

***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

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

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. Work-in-process includes third-party manufacturing and associated labor costs relating to our personnel directly involved 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 validation batches.

We analyze 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 or for inventory quantities in excess of expected requirements. 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 2014, we recognized a charge of \$2.9 million to write-down inventory to net realizable value. Refer to Note 4, "Inventories," for further information.

***Property and Equipment***

Property, equipment and leasehold improvements are stated at cost 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. Capitalized software costs are 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.

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

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

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

***Bonus Accruals***

We have short-term bonus programs for eligible employees. Bonuses are determined based on various criteria, including the achievement of corporate, departmental and individual goals. Bonus accruals are estimated based on various factors, including target bonus percentages per level of employee and probability of achieving the goals upon which bonuses are based. We periodically review the progress made towards the goals under the bonus programs.

***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 1.5 years of the leases exceeded our actual cash rent payments. Also included in deferred rent are lease incentives of \$1.4 million as of December 31, 2014, 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 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. 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

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

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

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

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 Theravance'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 our customers, generally 2% of the sales price, as an incentive for prompt payment. We expect our customers to comply with the prompt payment terms to earn the cash discount. We account for cash 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. 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 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. Additionally, we have granted more expansive return rights to our distributors following our product launch of VIBATIV. 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, 2014 and 2013, there was no allowance for doubtful accounts as we have not had any write-offs historically.

*Collaborative Arrangements and Multiple-Element Arrangements*

Revenue from nonrefundable, 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.



Table of Contents

**THERAVANCE BIOPHARMA, INC.**

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

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

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 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.

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

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

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

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 Costs***

Research and development costs are expensed in the period that services are rendered or goods are received. Research and development costs 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 costs reimbursed under our collaborative arrangements.

***Preclinical Study and Clinical Study Expenses***

A substantial portion of our preclinical studies and all of our clinical studies have been performed by third-party contract research organizations ("CROs"). Some CROs bill monthly for services performed, while others bill based upon milestones achieved. We review the activities performed under the significant contracts each quarter. For preclinical studies, the significant factors used in estimating accruals include the percentage of work completed to date and contract milestones achieved. For clinical study expenses, the significant factors used in estimating accruals include the number of patients enrolled and percentage of work completed to date. Vendor confirmations are obtained for contracts with longer duration when necessary to validate our estimate of expenses. Our estimates are highly dependent upon the timeliness and accuracy of the data provided by our CROs regarding the status of each program and total program spending and adjustments are made when deemed necessary.

***Advertising Expenses***

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses were \$1.1 million, \$1.4 million and none in 2014, 2013 and 2012.

***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 described in Staff Accounting Bulletin No. 107, "Share-Based Payment," for

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

the expected option term since our share 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 share started trading on June 3, 2014 after the Spin-Off.

Share-based compensation expense was calculated based on awards ultimately expected to vest and was reduced for estimated forfeitures at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differed 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, 2014, 2013 and 2012, 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 Theravance 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 Theravance stockholders in connection with the Spin-Off, less the number of ordinary shares subject to forfeiture, were outstanding from the beginning of all periods presented.

***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,		
	2014	2013	2012
Share issuances under equity incentive plan and ESPP	3,475		
Forfeitable shares	424		
	3,899		

***Other Income, net***

Other income includes \$1.6 million related to transition services rendered to Theravance. Refer to Note 10, "Contractual Agreements with Theravance, Inc." for further information on transition services.

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

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

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

***Income Taxes***

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

Our unrecognized tax benefits would reduce our effective income tax rate if recognized. We do not anticipate the total amount of unrecognized income tax benefits relating to uncertain tax positions existing at December 31, 2014 will significantly increase or decrease in the next 12 months.

We assess all material positions taken in any income tax return, 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 25.8% of our shares outstanding as of December 31, 2014.

Robert V. Gunderson, Jr. is a director of the Company. We have engaged Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, of which Mr. Gunderson is a partner, as our primary legal counsel. Fees incurred in the ordinary course of business were \$1.1 million in 2014, \$1.4 million in 2013 and \$0.4 million in 2012.

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

In May 2014, the FASB issued Accounting Standards Update 2014-09, *Revenue from Contracts with Customers* ("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. This guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2016, at which time we may adopt the new standard under the full retrospective method or the modified retrospective method. Early adoption is not permitted. 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,		
	2014	2013	2012
Clinigen	\$ 5,011	\$	\$
R-Pharm	2,259		
Astellas			125,788
Merck		226	4,357
Total revenue from collaborative arrangements	\$ 7,270	\$ 226	\$ 130,145

*Alfa Wassermann**Development and Collaboration Arrangement*

In October 2012, Theravance entered into a development and collaboration arrangement with Alfa Wassermann for velusetrag under which the parties agreed to collaborate in the execution of a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis (a medical condition consisting of a paresis (partial paralysis) of the stomach, resulting in food remaining in the stomach for a longer time than normal). Alfa Wassermann has an exclusive option to develop and commercialize velusetrag in the European Union, Russia, China, Mexico and certain other countries, while Theravance retains full rights to velusetrag in the United States, Canada, Japan and certain other countries. Theravance is entitled to receive funding for the Phase 2a study and most of the Phase 2b study. If Alfa Wassermann exercises its license option at the completion of the Phase 2 program, then Theravance is entitled to receive a \$10.0 million option fee. If velusetrag is successfully developed and commercialized, Theravance is entitled to receive potential future contingent payments totaling up to \$53.5 million, and royalties on net sales by Alfa Wassermann ranging from the low teens to 20%.

This agreement was assigned to us in the Spin-Off, and we will be eligible to receive any potential future option fee, contingent payments and royalties on net sales.

*Clinigen**Commercialization Agreement*

In March 2013, Theravance entered into a commercialization agreement (the "Clinigen Commercialization Agreement") with Clinigen to commercialize VIBATIV for the treatment of hospital acquired nosocomial pneumonia, including ventilator-associated pneumonia, known or suspected to be caused by methicillin resistant *Staphylococcus aureus* (MRSA) when other alternatives are not suitable. Under the agreement, Theravance granted Clinigen exclusive commercialization rights in the European Union and certain other European countries, including Switzerland and Norway. Theravance received a \$5.0 million upfront payment in March 2013. This agreement was assigned to us in the Spin-Off, and we are now eligible to receive tiered royalty payments on net sales of VIBATIV in these countries, ranging from 20% to 30%. We are responsible, either directly or through our vendors or contractors, for supplying at Clinigen's expense both API and finished drug product for Clinigen's

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

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

**2. Collaborative Arrangements (Continued)**

commercialization activities. The agreement has a term of at least 15 years, with an option to extend exercisable by Clinigen. However, Clinigen may terminate the agreement at any time after it has initiated commercialization upon 12 months' advance notice.

Under the Clinigen Commercialization Agreement, the significant deliverables were determined to be the license, committee participation and manufacturing supply. Theravance determined that the license represents a separate unit of accounting as the license, which includes rights to Theravance's underlying technologies for VIBATIV, has standalone value because the rights conveyed permit Clinigen to perform all efforts necessary to use Theravance's technologies to bring the compound through commercialization and based the best estimate of selling price for the license based on potential future cash flows under the arrangement over the estimated commercialization period. Theravance determined the best estimate of selling price for the manufacturing supply based on a fully burdened cost to purchase and transfer the underlying API and finished goods from Theravance's third party contract manufacturer. The license and supply obligations under the Clinigen Commercialization Agreement are now our obligations.

The \$5.0 million upfront payment received by Theravance was recognized by us as revenue in the third quarter of 2014 due to the completion of technical transfer for the underlying license. Amounts received under a future separate supply agreement for API, which will be manufactured by our third party contract manufacturers, will be recognized as revenue to the extent of future API and finished goods inventory sales.

***R-Pharm***

*Development and Commercialization Agreements with R-Pharm*

In October 2012, Theravance entered into two development and commercialization agreements with R-Pharm: one to develop and commercialize VIBATIV (the "VIBATIV Development and Commercialization Agreement") and the other to develop and commercialize TD-1792 (the "TD-1792 Development and Commercialization Agreement"), one of Theravance's investigational glycopeptide-cephalosporin heterodimer antibiotics for the treatment of Gram-positive infections. Under each agreement, Theravance granted R-Pharm exclusive development and commercialization rights in Russia, Ukraine, other member countries of the Commonwealth of Independent States, and Georgia. Theravance received \$1.1 million in upfront payments for each agreement. These agreements were transferred to us as a result of the Spin-Off. We are now eligible to receive potential future contingent payments totaling up to \$10.0 million for both agreements and royalties on net sales by R-Pharm of 15% from TD-1792 and 25% from VIBATIV. 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.

*TD-1792*

Under the TD-1792 Development and Commercialization 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, either directly or through Theravance's contract manufacturer. Theravance determined that the license represents a separate unit of accounting as the license, which includes rights to Theravance's underlying technologies for TD-1792, has standalone value because the rights conveyed permit R-Pharm to perform all efforts necessary to use Theravance's

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

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

**2. Collaborative Arrangements (Continued)**

technologies to bring the compounds through development and, upon regulatory approval, commercialization. Also, Theravance determined that the committee participation represents a separate unit of accounting as R-Pharm could negotiate for and/or acquire these services from other third parties, and Theravance based the best estimate of selling price on the nature and timing of the services to be performed. In March 2013, Theravance entered into a supply agreement for TD-1792 API under which Theravance sold its existing API to R-Pharm. Upon execution of this supply agreement, Theravance determined that the supply agreement represents a separate unit of accounting under the development and commercialization arrangement and based the best estimate of selling price for the supply agreement on its fully burdened cost to manufacture the API.

The \$1.1 million upfront payment received for the TD-1792 agreement was allocated to two units of accounting based on the relative selling price method as follows: \$0.9 million to the license and \$0.1 million to the committee participation. 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 for the underlying license. The amount allocated to committee participation was deferred and is being recognized as revenue over the estimated performance period.

Amounts to be received under the supply agreement described above will be recognized by us as revenue to the extent R-Pharm purchases API from us.

*VIBATIV*

Under the VIBATIV Development and Commercialization 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. Theravance determined that the license represents a separate unit of accounting as the license, which includes rights to Theravance's underlying technologies for VIBATIV, has standalone value because the rights conveyed permit R-Pharm to perform all efforts necessary to use Theravance's technologies to bring the compounds through development and, upon regulatory approval, commercialization and Theravance based the best estimate of selling price for the license based on potential future cash flows under the arrangement over the estimated performance period. Theravance determined that the committee participation represents a separate unit of accounting as R-Pharm could negotiate for and/or acquire these services from other third parties and Theravance 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 VIBATIV agreement was allocated to two units of accounting based on the relative selling price method as follows: \$1.0 million to the license and \$33,000 to the committee participation. 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.

***Former Collaboration Arrangement with Astellas***

*License, Development and Commercialization Agreement*

In November 2005, Theravance entered into a global collaboration arrangement with Astellas for the license, development and commercialization of VIBATIV. Under this agreement, Astellas paid

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

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

**2. Collaborative Arrangements (Continued)**

Theravance non-refundable cash payments totaling \$191.0 million. In January 2012, Astellas exercised its right to terminate the collaboration agreement. The rights previously granted to Astellas ceased upon termination of the agreement and Astellas stopped all promotional sales efforts. As such, \$125.8 million of deferred revenue related to Astellas was recognized in the first quarter of 2012, and no further milestone payments remain from Astellas. This agreement was assigned to us in the Spin-Off, and we are now obligated to pay Astellas royalties on future net sales of VIBATIV. Pursuant to the terms of the agreement, Astellas is entitled to a ten-year, 2% royalty on future net sales of VIBATIV.

***Former Collaboration Arrangement with Merck***

*Research Collaboration and License Agreement*

In October 2012, Theravance entered into a research collaboration and license agreement (the "Research Collaboration and License Agreement") with Merck, known as MSD outside the United States and Canada, to discover, develop and commercialize novel small molecule therapeutics directed towards a target being investigated for the treatment of hypertension and heart failure. Under the agreement, Theravance granted Merck a worldwide, exclusive license to Theravance's therapeutic candidates. Theravance received a \$5.0 million upfront payment in November 2012. Also, Theravance received funding for research and was eligible for potential future contingent payments totaling up to \$148.0 million for the first indication and royalties on worldwide annual net sales of any products derived from the collaboration. The initial research term was twelve months, with optional extensions by mutual agreement. Merck had the right to terminate the agreement at any time, and provided Theravance with notice of termination in September 2013. The agreement was terminated in December 2013.

Under the Research Collaboration and License Agreement, the significant deliverables were determined to be the license, research services and committee participation. Theravance determined that the license represents a separate unit of accounting because the license has standalone value. The license, which included rights to Theravance's underlying technologies for its therapeutic candidates, permitted Merck to perform all efforts necessary to use Theravance's technologies to bring a therapeutic candidate through development and upon regulatory approval, commercialization. Theravance based the best estimate of selling price on potential future cash flows under the arrangement over the estimated development period. Theravance determined that the research services represent a separate unit of accounting and based the best estimate of selling price on the nature and timing of the services to be performed. Theravance determined that the committee participation represents a separate unit of accounting as Merck could negotiate for and/or acquire these services from other third parties and Theravance based the best estimate of selling price on the nature and timing of the services to be performed.

The \$5.0 million upfront payment received by Theravance in November 2012 was allocated to the three units of accounting based on the relative selling price method as follows: \$4.4 million to the license, \$0.4 million to the research services and \$0.2 million to the committee participation. Theravance recognized revenue of \$4.4 million from the license in 2012 as the technical transfer activities were complete and the associated unit of accounting was deemed delivered. The amount of the upfront payment allocated to the research services was deferred and is being recognized as a reduction of research and development expense as the underlying services are performed, since the



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

nature of the research services is more appropriately characterized as research and development expense consistent with the research reimbursements being received. The amount of the upfront payment allocated to the committee participation was deferred and recognized as revenue over the estimated performance period.

The amounts under this agreement were assigned to us in the Spin-Off.

***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,		
	2014	2013	2012
Alfa Wassermann	\$ 1,764	\$ 1,500	\$ 185
Merck		4,937	756
Other	120	86	
Total reduction to R&D expense	\$ 1,884	\$ 6,523	\$ 941

**3. 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,	
	2014	2013
Cash equivalents	\$ 69,866	\$
Short-term marketable securities	165,396	
Marketable securities	51,399	
Restricted cash	833	833
Total	\$ 287,494	\$ 833

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. Available-for-Sale Securities and Fair Value Measurements (Continued)**

The estimated fair value of available-for-sales 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. Available-for-sale securities are summarized below:

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

(In thousands)		December 31, 2013			
		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	Level 1	\$ 833	\$	\$	\$ 833

At December 31, 2014, all of the available-for-sale securities had contractual maturities within two years and the average duration of marketable securities was approximately eight months. 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, 2014 were temporary in nature. All marketable securities with unrealized losses at December 31, 2014 have been in a loss position for less than twelve months. There were no transfers between Level 1 and Level 2 during the periods presented.

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 2013 and 2012.

**4. Inventories**

Inventories are as follows:

(In thousands)	December 31,	
	2014	2013
Raw materials	\$ 6,830	\$ 5,138
Work-in-process	145	360
Finished goods	5,571	4,908
Total inventories	\$ 12,546	\$ 10,406



Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. Inventories (Continued)**

In 2014, we recorded within costs of goods sold on the consolidated statement of operations a charge of \$2.9 million for the write-down of VIBATIV inventory due to the dating of the product. We continue to hold this inventory for sale as of December 31, 2014.

**5. Property and Equipment**

Property and equipment consists of the following:

(In thousands)	December 31,	
	2014	2013
Computer equipment	\$ 3,152	\$ 3,084
Software	5,435	5,391
Furniture and fixtures	3,897	3,890
Laboratory equipment	33,790	31,910
Leasehold improvements	17,857	17,769
Subtotal	64,131	62,044
Less: accumulated depreciation	(54,468)	(51,806)
Property and equipment, net	\$ 9,663	\$ 10,238

For the years ended December 31, 2014, 2013 and 2012, depreciation expense for property and equipment was \$2.7 million, \$2.7 million and \$3.3 million. The change in accumulated depreciation is net of asset retirements.

**6. 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"). Under the 2013 EIP and 2013 ESPP, we are authorized to issue 5,428,571 ordinary shares and 857,142 ordinary shares. 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

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

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

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

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, 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.

***Theravance's Equity Plans***

Many of our employees have in the past received Theravance stock-based compensation awards, and, therefore, the following disclosures include information regarding share-based compensation expense allocated to Theravance Biopharma that related to Theravance 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, Theravance 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) Theravance employees who became our employees, and (2) members of the board of directors of Theravance 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 Theravance 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.

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

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

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

The 2012 Equity Incentive Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, stock unit awards and SARs to employees, non-employee directors and consultants. Stock options were granted with an exercise price not less than the fair market value of the common stock on the grant date. Stock options granted to employees generally have a maximum term of 10 years and vest over a four year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three years. However, Theravance 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, Theravance 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 Theravance common stock outstanding on the record date. Theravance'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 Theravance's outstanding stock options were adjusted and the number of shares underlying Theravance'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 Theravance 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 Theravance 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 now in service with us. The incremental expense recognized in 2014 was not material.

*Theravance Performance-Contingent Restricted Stock Awards*

Over the past three years, the Compensation Committee of Theravance's board of directors ("Theravance'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 timeframe from 2011 through December 31, 2016 and require continued employment.

In May 2014, Theravance'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.

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

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

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

In May 2014, Theravance'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 awards. Share-based compensation expense of \$6.9 million associated with this portion of the awards after the modification is expected to be recognized by us during the twelve-month service period commencing in June 2014.

During the fourth quarter of 2014, we determined that it was probable that the performance conditions associated with the vesting of the remaining 417,000 RSAs outstanding under these awards would be achieved. In addition, the remaining RSAs outstanding under these awards were entitled to the pro rata dividend distribution made by Theravance on June 2, 2014 of one ordinary share of Theravance Biopharma for every three and one half shares of Theravance common stock. As a result, \$1.4 million of the total share-based compensation expense of \$9.5 million related to these remaining RSAs and the pro rata dividend was recognized by us in 2014. The RSAs and pro rata dividend remain subject to a twelve-month service period, which commenced in February 2015.

***Director Compensation Program***

Each member of our board of directors who is not an employee is paid an annual retainer as well as a fee for each board and committee meeting attended. In addition, the chairpersons of the various committees of our board of directors and lead independent director of our board of directors receive a fixed annual retainer.

Each of our non-employee directors is also compensated with periodic automatic grants of equity awards under a program implemented under our 2013 EIP. These grants are non-discretionary, and only our non-employee directors are eligible to receive these automatic grants.

Under our automatic grant program, each individual who first becomes a non-employee director will, on the date such individual joins our board, automatically be granted a one-time nonstatutory share option grant covering 12,000 ordinary shares. These initial option grants vest monthly over the director's first two years of service. In addition, on the date of joining our board of directors, a new non-employee director will also receive the standard annual equity award (if joining on the date of our annual meeting of shareholders) or a pro-rated annual equity award (if joining on any other date), as described below. The pro-ration will be based upon the number of months of service the new board member will provide during the 12-month period ending on the one-year anniversary of the most recent annual meeting of shareholders.

Annually, upon his or her re-election to our board at the annual meeting of shareholders, each non-employee director automatically will be granted restricted share units ("RSUs") covering 6,000 ordinary shares. This standard annual RSU grant will vest in full on the earlier of the one-year anniversary of the date of grant or the next annual meeting of shareholders.

In connection with the Spin-Off and in contrast to our automatic grant program, however, each of our non-employee directors that was serving as a member of our board of directors at the time of the Spin-Off, as well as each of our non-employee directors that became a member of our board of directors in connection with the Spin-Off, received the initial option grant described above (with vesting occurring monthly over the director's first three years of service, rather than two years) as well as an

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. Share-Based Compensation (Continued)**

annual equity award provided in the form of an option covering 12,000 of our ordinary shares that vests monthly over the twelve month period following the date of grant.

**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,		
	2014	2013	2012
Research and development	\$ 21,191	\$ 15,444	\$ 13,192
Selling, general and administrative	22,043	7,032	8,131
<b>Total share-based compensation expense</b>	<b>\$ 43,234</b>	<b>\$ 22,476</b>	<b>\$ 21,323</b>

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

(In thousands)	Year Ended December 31,		
	2014	2013	2012
Transferred from parent	\$ 17,043	\$ 22,476	\$ 21,323
Theravance equity:			
Options	4,378		
RSUs	3,169		
RSAs	3,796		
Performance RSAs	4,490		
Theravance Biopharma equity:			
Options	9,404		
ESPP	954		
<b>Total share-based compensation expense</b>	<b>\$ 43,234</b>	<b>\$ 22,476</b>	<b>\$ 21,323</b>

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

As of December 31, 2014, 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
Theravance equity:		
Options	\$ 15,957	2.8
RSUs	7,092	1.9
RSAs	12,160	1.8
Performance RSAs	12,216	1.4
Theravance Biopharma equity:		
Options	49,479	3.3



\$ 96,904

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. Share-Based Compensation (Continued)***Compensation Awards*

The following table summarizes equity award activity under the 2013 EIP and 2014 NEEIP, and related information since the Company began trading on the NASDAQ Global Market on June 3, 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
Balance at December 31, 2014	3,962,426	\$ 24.73

As of December 31, 2014, the aggregate intrinsic value of the options outstanding and the aggregate intrinsic value of the options exercisable was not material. The total estimated fair value of options vested was \$1.0 million in 2014.

*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, 2014
<b>Options Under the 2013 EIP and 2014 NEEIP</b>	
Risk-free interest rate	1.7% - 2.0%
Expected term (in years)	5 - 6
Volatility	64% - 70%
Dividend yield	
Weighted-average estimated fair value	\$15.55
<b>2013 ESPP</b>	
Risk-free interest rate	0% - 0.7%
Expected term (in years)	0.6 - 2.2
Volatility	58% - 66%
Dividend yield	
Weighted-average estimated fair value	\$10.95

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. Share-Based Compensation (Continued)**

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

	Year Ended December 31,		
	2014	2013	2012
<b><i>Options under the 2012 Equity Incentive Plan</i></b>			
Risk-free interest rate	1.6% - 2.1%	0.7% - 2.0%	0.7% - 1.2%
Expected term (in years)	5 - 6	5 - 6	5 - 6
Volatility	52% - 61%	58% - 60%	55% - 60%
Dividend yield			
Weighted-average estimated fair value	\$16.14	\$19.96	\$11.50
<b><i>Employee stock purchase plan issuances</i></b>			
Risk-free interest rate		0.1% - 0.3%	0.1% - 0.3%
Expected term (in years)		0.5 - 2	0.5 - 2
Volatility		56% - 61%	51% - 64%
Dividend yield			
Weighted-average estimated fair value	\$	\$16.44	\$8.07

**7. 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 Theravance and began operations subsequent to the Spin-Off with wholly-owned subsidiaries in the Cayman Islands, U.S. and United Kingdom. The provision for income taxes in 2014 is a result of operating in multiple jurisdictions and generating taxable income in our U.S. operations, although we incur operating losses on a consolidated basis.

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. Income Taxes (Continued)**

The components of the provision for income taxes are as follows:

(In thousands)	2014	December 31,		2012
	2013			
Income (loss) before provision for income taxes:				
Cayman Islands	\$ (235,306)	\$		\$
Other	4,632	(156,284)		(9,575)
Total	\$ (230,674)	\$ (156,284)		\$ (9,575)
Provision for income taxes				
Current				
Cayman Islands				
United States	6,223			
United Kingdom	141			
Subtotal	6,364			
Deferred				
Cayman Islands				
United States				
United Kingdom				
Subtotal				
Total	6,364			
Effective tax rate	(2.76)%	0%		0%

The provision for income taxes of \$6.4 million for the year ended December 31, 2014 is primarily due to timing differences between the book and tax treatment of certain income and expenses. As the realization of our deferred tax assets is uncertain, we currently record a full valuation allowance against all deferred tax assets. Therefore, any timing differences between book and tax treatment of certain income and expenses will be reflected as current tax expense.

No provision for income taxes has been recognized on undistributed earnings of our foreign subsidiaries because we consider such earning 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, 2014, it is not practicable to determine the amount of the income tax liability related to the undistributed earnings due to a variety of factors.

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. 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,	
	2014	2013
Deferred tax assets:		
Net operating loss carryforwards	\$ 181	\$ 140,851
Deferred revenues		3,016
Capitalized research and development expenditures		202
Research and development tax credit carryforwards	821	11,019
Fixed assets and acquired intangibles	8,088	3,820
Deferred compensation	7,489	18,837
Accruals	2,563	4,944
Other	29	
Subtotal	19,171	182,689
Valuation allowance	(18,787)	(182,689)
Total deferred tax assets	384	
Deferred tax liabilities:		
Prepaid	(384)	
Total deferred tax liabilities	(384)	
Net deferred tax assets/liabilities	\$	\$

The deferred income taxes corresponding to the period ending December 31, 2013 are carve-out balances and are representative of amounts assuming the business began in 2011. However, upon separation from Theravance, the balances corresponding to net operating losses and research credits were not transferred. As such, the changes in such balances do not reflect the utilization of such amounts.

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. Income Taxes (Continued)**

The differences between the Cayman Islands and the U.S. federal statutory income tax rate and our effective tax rate are as follows:

	Year Ended December 31,		
	2014	2013	2012
Provision at statutory income tax rate	0%	34.00%	34.00%
Foreign rate differential	(0.99)		
State income taxes, net of federal benefit			(0.04)
Share-based compensation		0.31	(2.63)
Non-deductible executive compensation		(0.06)	(10.09)
United States federal and state research tax credits	1.00	2.87	
Meals & entertainment		(0.04)	(0.60)
Change in valuation allowance	(2.42)	(35.89)	(20.68)
Other	(0.35)	(1.19)	0.04
Effective tax rate	(2.76)%	%	%

Realization of deferred tax assets is dependent upon future taxable income in the respective jurisdiction, 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, 2014 increased by \$5.8 million from the \$13.0 million valuation allowance established as of the June 2, 2014 Spin-Off date. 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, 2014, we had no federal net operating loss carryforwards and no federal research and development tax credit carryforwards. We had state net operating loss carryforwards of \$3.2 million expiring in 2034 and state research and development credit carryforwards of \$1.5 million to be carried forward indefinitely.

The net operating loss deferred tax asset balances as of December 31, 2014 does 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. As of December 31, 2014, the amount of accrued tax expense related to interest or penalties was not material.

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. Income Taxes (Continued)***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 decrease 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

If we eventually are able to recognize these uncertain positions, the \$1.1 million of the unrecognized benefit would reduce the effective tax rate. We currently have a full valuation allowance against our deferred tax assets, which would impact the timing of the effective tax rate benefit should any of these uncertain positions be favorably settled in the future. We do not believe it is reasonably possible that our unrecognized tax benefits will significantly change within the next twelve months.

We are subject to taxation in the United Kingdom, United States, and various state jurisdictions. The tax years 2013 and forward remain open to examination in the U.S. while the tax years 2012 and forward remain open to examination in the United Kingdom.

**8. 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. Future minimum lease payments under this lease, exclusive of executory costs, at December 31, 2014, were as follows:

**(In thousands)**

Years ending December 31:	
2015	\$ 5,770
2016	5,943
2017	6,121
2018	6,305
2019	6,494
Thereafter	2,758
Total	\$ 33,391

Expenses and income associated with operating leases were as follows:

	<b>Year Ended December 31,</b>		
<b>(In thousands)</b>	<b>2014</b>	<b>2013</b>	<b>2012</b>
Rent expense	\$ 6,616	\$ 5,763	\$ 5,469
Sublease income, net	\$	\$	\$ (160)





Table of Contents

**THERAVANCE BIOPHARMA, INC.**

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

**8. Commitments and Contingencies (Continued)**

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

In 2011, Theravance granted special long-term retention and incentive cash bonus awards to certain employees. The awards had dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and continued employment.

In May 2014, Theravance's Compensation Committee determined that the requisite performance conditions for the first tranche of the awards were achieved and, as a result, we recognized cash bonus expense of \$9.5 million during the nine months ended September 30, 2014. In May 2014, the total cash bonus of \$9.5 million for the first tranche was paid.

In May 2014, Theravance'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 a 12-month service-based vesting for a portion of the cash awards. The maximum amount payable by us under these modified cash bonus awards is \$10.4 million. The remaining tranches of the cash awards were forfeited.

***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, 2014.

**9. Spin-Off from Theravance, Inc.**

On June 1, 2014, Theravance 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. Theravance 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, Theravance 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 Theravance common stock outstanding on the record date. The Spin-Off resulted in Theravance Biopharma operating as an independent, publicly traded company.

On June 1, 2014, we entered into the Separation and Distribution Agreement with Theravance that set forth the terms and conditions of our separation from Theravance. In addition, we entered into other definitive agreements in connection with the Spin-Off, including (1) a Transition Services Agreement, (2) a Tax Matters Agreement, (3) an Employee Matters Agreement, and (4) the Theravance Respiratory Company, LLC Limited Liability Company Agreement. See Note 10, "Contractual Agreements with Theravance, Inc.," for further discussion.

Table of Contents**THERAVANCE BIOPHARMA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****9. Spin-Off from Theravance, Inc. (Continued)**

The net book value of the net assets that were transferred to us in connection with the Spin-Off is 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>

**10. Contractual Agreements with Theravance, Inc.***Separation and Distribution Agreement*

In connection with the Spin-Off, on June 1, 2014, Theravance 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 Theravance, and Theravance will indemnify us from and after the Spin-Off with respect to all debts, liabilities and obligations transferred to Theravance 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 Employee Matters Agreement and the Tax Matters Agreement.

*Transition Services Agreement*

On June 2, 2014, we also entered into a Transition Services Agreement with Theravance pursuant to which Theravance and we will provide each other with a variety of administrative services, including financial, tax, accounting, information technology, legal and human resources services, for a period of time of up to two years following the Spin-Off. Certain services were terminated as of February 28, 2015, and we expect the remaining services will end on or before May 31, 2015. In connection with the services performed under the Transition Services Agreement, each party shall pay a monthly fee to the

**THERAVANCE BIOPHARMA, INC.**

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

**10. Contractual Agreements with Theravance, Inc. (Continued)**

performing party. For the year ended December 31, 2014, we billed Theravance \$1.6 million, and Theravance billed us \$0.5 million under the Transition Services Agreement. As of December 31, 2014, we had a receivable from Theravance of \$1.1 million.

***Tax Matters Agreement***

On June 2, 2014, we also entered into a Tax Matters Agreement with Theravance that governs Theravance'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 Theravance'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 Theravance's Biopharmaceutical Business to us, the distribution of our ordinary shares and the other separation transactions and (iii) otherwise attributable to Theravance, will be borne solely by Theravance. 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 Theravance, which governs the employee benefit obligations of Theravance 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 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 Theravance's equity compensation programs in connection with the Spin-Off.

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

Prior to the Spin-Off, Theravance assigned to Theravance Respiratory Company, LLC ("TRC"), a Delaware limited liability company formed by Theravance, 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 Theravance that governs the operation of TRC. Under the TRC LLC Agreement, Theravance 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

Table of Contents

**THERAVANCE BIOPHARMA, INC.**

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

**10. Contractual Agreements with Theravance, Inc. (Continued)**

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.

**11. Subsequent Events**

In January 2015, Mylan Inc., which is now a subsidiary of Mylan N.V. ("Mylan"), and we established a strategic collaboration for the development and, subject to FDA approval, commercialization of TD-4208. Partnering with a world leader in nebulized respiratory therapies enables us to expand the breadth of our TD-4208 development program and extend our commercial reach beyond the acute care setting where we currently market VIBATIV. Funding of the Phase 3 registrational program by Mylan strengthens our capital position and enhances our financial flexibility to advance other high-value pipeline assets alongside TD-4208.

Under the terms of the agreement, Mylan and we will co-develop nebulized TD-4208 for COPD and other respiratory diseases. We will lead the U.S. registrational development program and Mylan will be 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-US territory outright, Mylan does have a right of first negotiation with respect to the development and commercialization of nebulized TD-4208 in China.

Under the agreement, Mylan will pay 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 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. 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 TD-4208 monotherapy and \$45.0 million for future potential combination products.

We retain worldwide rights to TD-4208 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 TD-4208 delivered other than via a nebulized inhalation product.

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 period ended December 31, 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 Theravance 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 Theravance stockholders in connection with the Spin-Off, less the number of ordinary shares subject to forfeiture, were outstanding from the beginning of all periods presented.

	For the Quarters Ended			
	March 31	June 30	September 30	December 31
<b>2014</b>				
Total revenue(1)	\$ 945	\$ 2,974	\$ 6,336	\$ 1,433
Costs and 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)
<b>2013</b>				
Total revenue	\$ 22	\$ 5	\$ 24	\$ 175
Operating expenses	32,196	38,957	41,102	44,255
Loss from operations	(32,174)	(38,952)	(41,078)	(44,080)
Net loss	(32,174)	(38,952)	(41,078)	(44,080)
Basic and diluted net loss per share	\$ (1.01)	\$ (1.23)	\$ (1.29)	\$ (1.39)

- (1) 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 2014, 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, 2014 and 2013, 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, 2014. 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, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

San Jose, California  
March 13, 2015

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, 2014, 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 Securities Exchange Act of 1934 (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*

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

*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 fiscal quarter of the year ended December 31, 2014 which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

**ITEM 9B. OTHER INFORMATION**

None.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

For the information required by this Item, see "Questions and Answers About Procedural Matters", "Election of Directors", "Nominees", "Audit Committee", "Meetings of the Board of Directors", "Code of Conduct", "Executive Officers" 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.



Table of Contents

**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, 2014 and 2013</u>	<u>57</u>
<u>Consolidated Statements of Operations for each of the three years in the period ended December 31, 2014</u>	<u>58</u>
<u>Consolidated Statements of Comprehensive Loss for each of the three years in the period ended December 31, 2014</u>	<u>59</u>
<u>Consolidated Statements of Shareholders' Equity and Parent Company Deficit for each of the three years in the period ended December 31, 2014</u>	<u>60</u>
<u>Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2014</u>	<u>61</u>
<u>Notes to Consolidated Financial Statements</u>	<u>62</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>95</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 13, 2015
<u>/s/ HENRIETTA H. FORE</u> Henrietta H. Fore	Director	March 13, 2015
<u>/s/ BURTON G. MALKIEL, PH.D.</u> Burton G. Malkiel, Ph.D.	Director	March 13, 2015
<u>/s/ DEAN J. MITCHELL</u> Dean J. Mitchell	Director	March 13, 2015
<u>/s/ PETER S. RINGROSE, PH.D.</u> Peter S. Ringrose, Ph.D.	Director	March 13, 2015
<u>/s/ GEORGE M. WHITESIDES, PH.D.</u> George M. Whitesides, Ph.D.	Director	March 13, 2015
<u>/s/ WILLIAM D. YOUNG</u> William D. Young	Director	March 13, 2015

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

### Table of Contents

#### Exhibits

Exhibit Number	Description	Incorporated by Reference	
		Form	Filing Date/Period End Date
2.1	Separation and Distribution Agreement by and between Theravance Biopharma, Inc. and Theravance, 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
10.1	Transition Services Agreement by and between Theravance Biopharma, Inc. and Theravance, Inc., dated June 2, 2014.	8-K	June 3, 2014
10.2	Tax Matters Agreement by and between Theravance Biopharma, Inc. and Theravance, Inc., dated June 2, 2014.	8-K	June 3, 2014
10.3	Employee Matters Agreement by and between Theravance Biopharma, Inc. and Theravance, Inc., dated June 1, 2014.	8-K	June 3, 2014
10.4+	2013 Equity Incentive Plan and form of award agreement thereunder	S-8	Aug. 18, 2014
10.5+	UK Addendum to the 2013 Equity Incentive Plan	10-K	Aug. 14, 2014
10.6+	2014 New Employee Equity Incentive Plan and form of option agreement thereunder	S-8	Nov. 14, 2014
10.8+	Theravance Biopharma, Inc. 2013 Employee Share Purchase Plan, as amended.	S-8	Aug. 18, 2014
10.8+	Theravance Biopharma, Inc. Change in Control Severance Plan	10-12B	April 8, 2014
10.9+	Theravance Biopharma, Inc. Cash Bonus Program	10-12B	Nov. 22, 2013
10.10+	Form of Indemnity Agreement	10-12B	April 30, 2014
10.11	Amended and Restated Lease Agreement, 951 Gateway Boulevard, between Theravance, Inc. and HMS Gateway Office L.P., dated January 1, 2001	10-12B	Aug. 8, 2013
10.12	First Amendment to Lease for 951 Gateway Boulevard effective as of June 1, 2010 between Theravance, Inc. and ARE-901/951 Gateway Boulevard, LLC	10-12B	Aug. 8, 2013
10.13	Lease Agreement, 901 Gateway Boulevard, between Theravance, Inc. and HMS Gateway Office L.P., dated January 1, 2001	10-12B	Aug. 8, 2013
10.14	First Amendment to Lease for 901 Gateway Boulevard effective as of June 1, 2010 between Theravance, 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	Form	Incorporated by Reference
			Filing Date/Period End Date
10.15	Consent to Assignment by and among ARE-901/951 Gateway Boulevard, LLC, Theravance, Inc. and Theravance Biopharma, Inc. and Assignment and Assumption of Lease for 901 Gateway Blvd.	10-Q	Aug. 14, 2014
10.16	Consent to Assignment by and among ARE-901/951 Gateway Boulevard, LLC, Theravance, Inc. and Theravance Biopharma, Inc. and Assignment and Assumption of Lease for 951 Gateway Blvd.	10-Q	Aug. 14, 2014
10.17	Theravance Respiratory Company, LLC Limited Liability Company Agreement, dated May 31, 2014.	8-K	June 3, 2014
10.18*	Technology Transfer and Supply Agreement, dated as of May 22, 2012 between Theravance, Inc. and Hospira Worldwide, Inc.	10-12B	May 7, 2014
10.19*	Commercialization Agreement between Theravance, Inc. and Clinigen Group plc, dated March 8, 2013	10-12B	May 7, 2014
10.20	License Agreement with Janssen Pharmaceutica, dated as of May 14, 2002	10-Q	Aug. 14, 2014
10.21	Collaboration Agreement between Theravance, Inc. and Glaxo Group Limited, dated November 14, 2002(1)		
10.22	Strategic Alliance Agreement by and between Theravance, Inc. and Glaxo Group Limited, dated March 30, 2004(2)		
10.23	Amendment to Strategic Alliance Agreement by and between Theravance, Inc. and Glaxo Group Limited, dated October 3, 2011(3)		
10.24	Collaboration Agreement Amendment by and between Theravance, Inc. and Glaxo Group Limited dated, March 3, 2014(4)		
10.25	Strategic Alliance Agreement Amendment by and between Theravance, Inc. and Glaxo Group Limited dated, March 3, 2014(4)		
10.26	Master Agreement by and between Theravance, Inc., Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014(4)		
10.27	Extension Agreement by and between the Company and Glaxo Group Limited, dated March 3, 2014	10-12B	April 8, 2014
10.28	Governance Agreement by and between Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014	10-12B	April 8, 2014
10.29+	Amended Offer Letter with Rick E Winningham dated August 6, 2014	10-Q	Sept. 30, 2014
10.30+	Offer Letter with Frank Pasqualone May 12, 2014	10-Q	Aug. 14, 2014
10.31+	Offer Letter with Brett K. Haumann dated May 12, 2014	10-Q	Aug. 14, 2014
10.32+	Offer Letter with Renee D. Gala dated May 12, 2014	10-Q	Sept. 30, 2014

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

### Table of Contents

Exhibit Number	Description	Form	Incorporated by Reference Filing Date/Period End Date
10.33+	Offer Letter with Junning Lee dated August 20, 2014	10-Q	Sept. 30, 2014
10.34+	Offer Letter with Brad Shafer dated August 20, 2014	10-Q	Sept. 30, 2014
10.35+	Offer Letter with Leonard Blum dated September 15, 2014	10-Q	Sept. 30, 2014
10.36+	Offer Letter with Mathai Mammen dated September 15, 2014	10-Q	Sept. 30, 2014
10.37+	Forms of Equity Award Amendment	10-12B	May 7, 2014
10.38+	Form of TFIO Cash Award Amendment	10-12B	May 7, 2014
10.39+	Consulting Agreement with Jeff Jonker, effective as of November 14, 2014		
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		
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, 2014, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Income, (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 Theravance, 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 Theravance, 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 Theravance, 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 Theravance, Inc., filed with the Commission on March 6, 2014.

---