THERAVANCE INC Form 10-K February 27, 2015

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **FORM 10-K**

(Mark One)

ý 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

o 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. 000-30319

## THERAVANCE, INC.

(Exact name of registrant as specified in its charter)

Delaware

94-3265960

(State or other jurisdiction of incorporation or organization)

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

951 Gateway Boulevard, South San Francisco, California (Address of principal executive offices)

94080

(Zip Code)

Registrant's telephone number, including area code: 650-238-9600

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

## Title of Each Class Common Stock \$0.01 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 \( \times \) No o

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 o No ý

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 \(\xi\) No o

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

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. ý

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 ý

Accelerated filer o

Non-accelerated filer o

Smaller reporting company o

(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 o No ý

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of the registrant's Common Stock on The NASDAQ Global Market on June 30, 2014 was \$1,411,186,319. Shares of Common Stock held by each executive officer and director and stockholders known by the registrant to own 10% or more of the outstanding stock based on public filings and other information known to the registrant have been excluded since such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On February 12, 2015, there were 116,624,973 shares of the registrant's Common Stock 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 Stockholders, 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.

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#### **Special Note Regarding Forward-Looking Statements**

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, 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, without limitation, statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions, expectations, goals and objectives may be forward-looking statements. The words "anticipates," "believes," "could," "designed," "estimates," "expects," "goal," "intends," "may," "plans," "projects," "pursuing," "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. All written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

Important factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited to, risks related to: the disruption of operations during the transition period following the Spin-Off, including the diversion of managements' and employees' attention, disruption of relationships with collaborators and increased employee turnover, lower than expected future royalty revenue from respiratory products partnered with GSK, delays or difficulties in commencing or completing clinical studies, the potential that results from clinical or non-clinical studies indicate product candidates are unsafe or ineffective, dependence on third parties to conduct its clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with third parties to discover, develop and commercialize products and risks discussed below in "Risk Factors" in Item 1A of Part I, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of Part II 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 as of the date hereof and we do not assume any obligation to update any forward-looking statements on account of new information, future events or otherwise, except as required by law.

We encourage you to read Management's Discussion and Analysis of our Financial Condition and Results of Operations and our consolidated financial statements contained in this annual report on Form 10-K. We also encourage you to read Item 1A of Part I of this annual report on Form 10-K, entitled "Risk Factors," which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in Item 1A of this report, other unknown or unpredictable factors also could affect our results. Therefore, the information in this report should be read together with other reports and documents that we file with the Securities and Exchange Commission (SEC) from time to time, including on Form 10-Q and Form 8-K, which may supplement, modify, supersede or update those risk factors. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

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#### PART I

#### ITEM 1. BUSINESS

#### Overview

Theravance, Inc. ("Theravance", the "Company", the "Registrant" or "we" and other similar pronouns) is a royalty management company primarily focused on maximizing the potential value of the respiratory assets partnered with Glaxo Group Limited ("GSK"), including RELVAR®/BREO® ELLIPTA® (fluticasone furoate/ vilanterol, "FF/VI") and ANORO® ELLIPTA® (umeclidinium bromide/ vilanterol, "UMEC/VI"), with the intention of providing capital returns to stockholders. Under the Long-Acting Beta2 Agonist ("LABA") Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein collectively as the "GSK Agreements"), Theravance is eligible to receive the associated royalty revenues from RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and if approved and commercialized, VI monotherapy. Theravance is also entitled to 15% of any future payments made by GSK under its agreements originally entered into with us, and since assigned to Theravance Respiratory Company, LLC ("TRC"), relating to the combination FF/UMEC/VI and the Bifunctional Muscarinic Antagonist-Beta2 Agonist ("MABA") program. We do not manufacture or sell any of the products commercialized under the GSK Agreements, as it is the exclusive responsibility of GSK.

Our headquarters are located at 951 Gateway Boulevard, South San Francisco, California 94080. Theravance was incorporated in Delaware in November 1996 under the name Advanced Medicine, Inc. and began operations in May 1997. The Company changed its name to Theravance, Inc. in April 2002.

On June 1, 2014, we separated our biopharmaceutical research and drug development operations from our late-stage partnered respiratory assets by transferring our research and drug development operations into our then wholly-owned subsidiary, Theravance Biopharma, Inc. ("Theravance Biopharma"). We contributed \$393.0 million of cash, cash equivalents and marketable securities to Theravance Biopharma and all outstanding shares of Theravance Biopharma were then distributed to Theravance stockholders as a pro-rata dividend distribution on June 2, 2014 by issuing one ordinary share of Theravance Biopharma for every 3.5 shares held of our common stock to stockholders of record on May 15, 2014 (the "Spin-Off"). The Spin-Off resulted in Theravance Biopharma operating as an independent publicly-traded company. The results of operations for the former research and drug development operations conducted by us and by Theravance Biopharma until June 1, 2014 are included as part of this report as discontinued operations.

As a royalty management company, we have designed our company structure and organization to be focused on managing our respiratory assets with GSK, the commercial and developmental obligations associated with the GSK Agreements, intellectual property, licensing operations, and providing for certain essential reporting and management functions of a public company. As of December 31, 2014, we had ten employees. Our revenues consist of royalties and potential milestone payments, if any, from our respiratory partnership agreements with GSK.

#### **Our Strategy**

Our corporate strategy is focused on stockholder returns by:

- 1. Maximizing the potential value of our respiratory assets partnered with GSK;
- Providing capital returns to our stockholders through dividends or share repurchases;
- 3. Reducing our overall corporate cost of capital; and
- 4. Building a long term recurring revenue business.

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#### Our Relationship with GSK

#### LABA Collaboration

In November 2002, we entered into our LABA Collaboration Agreement with GSK to develop and commercialize once-daily LABA products for the treatment of chronic obstructive pulmonary disease ("COPD") and asthma. For the treatment of COPD, the collaboration has developed two combination products: (1) RELVAR®/BREO® ELLIPTA® (FF/VI) (BREO® ELLIPTA® is the proprietary name in the U.S. and Canada and RELVAR® ELLIPTA® is the proprietary name outside the U.S. and Canada), a once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF) and (2) ANORO® ELLIPTA® (UMEC/VI), a once-daily medicine combining a long-acting muscarinic antagonist ("LAMA"), umeclidinium bromide (UMEC), with a LABA, VI. Under the collaboration agreements between the parties, GSK and Theravance are exploring various paths to create triple therapy medications. For the treatment of asthma, RELVAR® ELLIPTA® is approved in multiple regions outside of North America and the collaboration is further developing FF/VI for the U.S. The FF/VI program is aimed at developing a once-daily combination LABA/ICS to succeed GSK's Advair ® /Seretide (salmeterol and fluticasone as a combination) franchise, which had reported 2014 sales of approximately \$7.0 billion, and to compete with Symbicort® (formoterol and budesonide as a combination), which had reported 2014 sales of approximately \$3.8 billion. ANORO® ELLIPTA®, which is also a combination product, is targeted as an alternative treatment option to Spiriva® (tiotropium), a once-daily, single-mechanism bronchodilator, which had reported 2013 sales of approximately \$4.7 billion.

As a result of the launch and approval of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® in the U.S., Japan and Europe, we were obligated to pay milestone fees to GSK totaling \$220.0 million, which we have paid in their entirety as of December 31, 2014. Although we have no further milestone payment obligations to GSK pursuant to the LABA Collaboration Agreement, we continue to have ongoing development and commercialization activities under the GSK Agreements that are expected to continue over the life of the agreements. The milestone fees paid to GSK were recognized as capitalized fees paid to a related party, which are being amortized over their estimated useful lives commencing upon the commercial launch of the product.

We are entitled to receive annual royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® as follows: 15% on the first \$3.0 billion of annual global net sales and 5% for all annual global net sales above \$3.0 billion. Sales of single-agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the LABA collaboration, such as ANORO ELLIPTA, royalties are upward tiering and range from 6.5% to 10%.

#### 2004 Strategic Alliance

In March 2004, we entered into the Strategic Alliance Agreement with GSK where GSK received an option to license exclusive development and commercialization rights to product candidates from certain of pre-Spin-Off our discovery programs on pre-determined terms and on an exclusive, worldwide basis. Upon GSK's decision to license a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. In addition, GSK is obligated to use diligent efforts to develop and commercialize product candidates from any program that it licenses. If the program is successfully advanced through development by GSK, we are entitled to receive clinical, regulatory and commercial milestone payments and royalties on any sales of medicines developed from the program. If GSK chooses not to license a program, we retain all rights to the program and may continue the program alone or with a third party. GSK has no further option rights on any of our research or development programs under the strategic alliance.

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In 2005, GSK licensed our MABA program for the treatment of COPD, and in October 2011, we and GSK expanded the MABA program by adding six additional Theravance-discovered preclinical MABA compounds (the "Additional MABAs"). GSK's development, commercialization, milestone and royalty obligations under the Strategic Alliance Agreement remain the same with respect to GSK961081 ('081), the lead compound in the MABA program. GSK is obligated to use diligent efforts to develop and commercialize at least one MABA within the MABA program, but may terminate progression of any or all Additional MABAs at any time and return them to us, at which point we may develop and commercialize such Additional MABAs alone or with a third party. Both GSK and we have agreed not to conduct any MABA clinical studies outside of the strategic alliance so long as GSK is in possession of the Additional MABAs. If a single-agent MABA medicine containing '081 is successfully developed and commercialized, GSK is required to pay royalties of 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 as a combination product, such as a '081/FF, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. For single-agent MABA medicines containing an Additional MABA, GSK is required to pay royalties of between 10% and 15% of annual global net sales up to \$3.5 billion, and 10% for all annual global net sales above \$3.5 billion. For combination products containing an Additional MABA, such as a MABA/ICS combination, the royalty rate is 50% 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 could be required to pay total contingent 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. If a MABA medicine containing an Additional MABA is successfully developed and commercialized in multiple regions of the world, GSK could be required to pay total contingent payments of up to \$129.0 million. As a result of the transactions effected by the Spin-Off, we are only entitled to receive 15% of any contingent payments and royalties payable by GSK from sales of FF/UMEC/VI (and MABA, and MABA/FF) while Theravance Biopharma receives 85% of those same payments.

#### Agreements Entered into with GSK in Connection with the Spin-Off

On March 3, 2014, in contemplation of the Spin-Off of Theravance Biopharma, we, Theravance Biopharma and GSK entered into a series of agreements clarifying how the companies would implement the Spin-Off and operate following the Spin-Off. We, Theravance Biopharma and GSK entered into a three-way master agreement providing for GSK's consent to the Spin-Off provided certain conditions were met. In addition, we and GSK also entered into amendments to the GSK Agreements, and Theravance Biopharma and GSK entered into a governance agreement, a registration rights agreement and an extension agreement. The three-way master agreement was effective on June 1, 2014 when we transferred our research and drug development operations to Theravance Biopharma. Pursuant to a three-way master agreement entered into by and among us, Theravance Biopharma and GSK in connection with the Spin-Off, we agreed to sell a certain number of Theravance Biopharma shares withheld from a taxable dividend of Theravance Biopharma shares to GSK. After such Theravance Biopharma shares were sent to the transfer agent, we agreed to purchase the Theravance Biopharma shares from the transfer agent, rather than have them sold on the open market, in order to satisfy tax withholdings. GSK had a right to purchase these shares of Theravance Biopharma from us, but this right expired unexercised. Accordingly, at December 31, 2014, we owned 436,802 ordinary shares of Theravance Biopharma.

The amendments to the GSK Agreements do not change the economics or royalty rates under the GSK Agreements, though the assignment of the Strategic Alliance Agreement and portions of the LABA Collaboration Agreement to TRC do change how the economics are allocated between Theravance Biopharma and us. The amendments to the GSK Agreements do provide that GSK's diligent efforts obligations regarding commercialization matters under both agreements will change

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upon regulatory approval in either the United States or the European Union (the "EU") of FF/UMEC/VI or a MABA in combination with FF. Upon such regulatory approval, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements 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. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we will retain our full interests upon the Spin-Off and also products in which we have retained only a portion of our interests following the Spin-Off, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements following the Spin-Off.

#### Purchases of Common Stock by GSK

Prior to 2014, affiliates of GSK purchased an aggregate of 29.9 million shares of our common stock. During 2014, GSK purchased 1.7 million shares of our common stock pursuant to its periodic "top-up" rights under our Amended and Restated Governance Agreement, dated as of June 4, 2004, as amended, among us, GSK and certain GSK affiliates, for an aggregate purchase price of \$38.1 million. As of February 12, 2015, GSK beneficially owned approximately 27.1% of our outstanding capital stock.

#### **Product Highlights**

- 1. In the fourth quarter 2014, sales for RELVAR®/BREO® ELLIPTA® by GSK were \$62.2 million compared to \$25.6 million in the previous quarter, an increase of approximately 142%, resulting in total sales of \$110.9 million in 2014.
- 2. In the fourth quarter 2014, sales for ANORO® ELLIPTA® by GSK were \$17.4 million compared to \$1.8 million in the previous quarter, a substantial increase resulting in total sales of \$27.4 million in 2014.
- 3.
  GSK announced that as of January 2015, U.S. Medicare Part D coverage has increased to 76 percent for BREO® ELLIPTA® and to 65 percent for ANORO® ELLIPTA®. In addition, as of January 2015, 64 percent are insured through commercial plans for BREO® ELLIPTA® and 78 percent for ANORO® ELLIPTA®.
- 4.

  A Phase 3 study evaluating the effectiveness of RELVAR®/BREO® ELLIPTA® compared to other COPD treatments, as measured by the primary endpoint of the mean annual rate of moderate and severe exacerbations, one of the Salford Lung Studies being conducted, completed enrollment of 2,800 patients.
- 5.
  GSK secured reimbursement for ANORO® ELLIPTA® via the Australian Pharmaceutical Benefits Scheme (PBS) as a long-term once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.

## Manufacturing

Manufacturing of RELVAR®/BREO® ELLIPTA® (FF/VI) and ANORO ELLIPTA (UMEC/VI) and for the MABA program is handled by GSK.

### **Government Regulation**

The development and commercialization of products and product candidates pursuant to the GSK Agreements 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.

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The requirements governing the conduct of clinical studies, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, the commercialization of medicines is permitted only if the appropriate regulatory authority is satisfied that our collaborative partner has presented adequate evidence of the safety, quality and efficacy of such medicines.

Before commencing clinical studies in humans in the United States, our collaborative partner 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 (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 ten 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.

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

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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 collaborative partner 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 the development and commercialization of products and product candidates. 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 collaborative partner's ability to market partnered 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 and our collaborative partner will be able to protect our partnered technology from unauthorized use by third parties only to the extent that such 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 us and our collaborative partner obtaining patent protection for our partnered products and product candidates. Accordingly, patents and other proprietary rights are essential elements 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 business 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 owned 37 issued United States patents and 192 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.

United States issued patents and foreign patents generally expire 20 years after filing. 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.

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#### Competition

We anticipate that any approved product from our LABA collaboration with GSK, including RELVAR®/BREO® ELLIPTA® (FF/VI) and ANORO® ELLIPTA® (UMEC/VI), will compete with a number of approved bronchodilator drugs and drug candidates under development that are designed to treat asthma and COPD. These include but are not limited to:

Advair®/Seretide (salmeterol and fluticasone as a combination) marketed by GSK,

Foradil®/Oxis® (formoterol) marketed by a number of companies,

Symbicort® (formoterol and budesonide as a combination) marketed by AstraZeneca,

Dulera® (formoterol and mometasone as a combination) marketed by Merck,

Spiriva® (tiotropium) marketed by Boehringer Ingelheim and Pfizer,

Striverdi® Respimat® (olodaterol) marketed by Boehringer Ingelheim,

Onbrez®/Arcapta® (indacaterol) marketed by Novartis,

Tudorza ® (aclidinium) marketed by Forest/Actavis and Seebri® (glycopyrronium) were also launched in 2012 (Seebri, ex-U.S.),

Incruse® (Umec) and Arnuity® (FF), recently launched in January 2015 by GSK in the U.S. (we are not entitled to any royalties from either product)

Indacaterol in combination with an ICS (mometasone), being developed by Novartis for markets outside the U.S.,

Indacaterol combined with a muscarinic antagonist glycopryyonium bromid (Ultibro®), developed by Novartis for the treatment of COPD,

Ultibro®, approved and launched in European in 2013 and currently under regulatory review in the U.S.,

Tiotropium combined with the long acting beta agonist olodaterol, being developed by Boehringer Ingelheim for the treatment of COPD and currently under regulatory review in the U.S.,

AirFluSal® (a branded generic containing salmeterol fluticasone), developed by the Sanoz division of Novartis and approved in Denmark in late 2013 with further EU approval expected in coming months; and

Duaklir® Genuair® (aclidinium bromide/formoterol fumarate), developed by AstaZeneca and approved in November 2014 in the EU as a maintenance bronchodilator treatment for COPD.

In addition, several firms are reported to be developing new formulations of salmeterol fluticasone and formoterol budesonide which may be marketed as generics or branded generics relative to the existing products from GSK and AstraZeneca, respectively. All of these efforts represent potential competition for any of our partnered products.

## **Employees**

After giving effect to the Spin-Off, as of December 31, 2014, we had ten employees. None of our employees are represented by a labor union. We consider our employee relations to be good.

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#### **Available Information**

Our Internet address is www.thrxinc.com. Our investor relations website is located at http://investor.thrxinc.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 and the Theravance logo are registered trademarks of Theravance, Inc. Trademarks, tradenames or service marks of other companies appearing in this report are the property of their respective owners.

#### ITEM 1A. RISK FACTORS

#### Risks Related to our Business

For the foreseeable future we will derive all of our royalty revenues from GSK and our future success depends on GSK's ability to successfully develop and commercialize the products in the respiratory programs partnered with GSK.

Pursuant to the GSK Agreements, GSK is responsible for the development and commercialization of products in the partnered respiratory programs. Through December 31, 2014, sales of both BREO® ELLIPTA® and ANORO® ELLIPTA® by GSK have been significantly below our expectations which resulted in a decline in our stock price. Although we may receive milestone payments from GSK if certain development milestones are achieved in our MABA program, we believe that royalty revenues from BREO® ELLIPTA® and ANORO® ELLIPTA® will represent the majority of our future revenues from GSK. The amount and timing of revenue from such royalties and milestones is unknown and highly uncertain. Our future success depends upon the performance by GSK of its commercial obligations under the GSK Agreements. We have no control over GSK's marketing and sales efforts, and GSK might not be successful, which would harm our business and cause the price of our securities to fall.

The amount of royalties and milestone payments, if any, we receive will depend on many factors, including the following:

the competitive landscape for approved products and developing therapies that compete with our partnered products, including other products owned by GSK (such as Advair®) but which are not partnered with us and pricing pressure in the respiratory markets targeted by our partnered products;

the ability of patients to be able to afford our partnered products or obtain health care coverage that covers our partnered products;

acceptance of, and ongoing satisfaction with, our partnered products by the medical community, patients receiving therapy and third party payors;

a satisfactory efficacy and safety profile as demonstrated in a broad patient population;

the size of the market for our partnered products;

the extent and effectiveness of the sales and marketing and distribution support GSK provides our partnered products;

safety concerns in the marketplace for respiratory therapies in general and with our partnered products in particular;

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regulatory developments relating to the manufacture or continued use of our partnered products;

decisions as to the timing of product launches, pricing and discounts;

GSK's ability to expand the indications for which our partnered products can be marketed;

GSK's ability to successfully achieve development milestones with respect to our partnered MABA program;

GSK's ability to obtain regulatory approval of our partnered products in additional countries; or

the unfavorable outcome of any potential litigation relating to our partnered products.

Reductions on pricing and reimbursement from governments, payors, or other healthcare cost containment initiatives such as restrictions on use, may negatively impact royalties generated under the GSK Agreements.

The continuing efforts of governments, pharmaceutical benefit management organizations (PBMs), insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care has adversely affected the price, market access, and total revenues of BREO® ELLIPTA® and ANORO® ELLIPTA® and may continue to adversely affect them in the future.

The Patient Protection and Affordable Care Act and other potential legislative or regulatory action regarding healthcare and insurance matters, along with the trend toward managed healthcare in the U.S., could adversely influence the purchase of healthcare products and reduce demand and prices for our partnered products. This could harm GSK's ability to market our partnered products and significantly reduce future revenues. For example, when GSK launched BREO® ELLIPTA® for the treatment of COPD in the U.S. in October 2013, GSK experienced significant challenges gaining coverage at some of the largest PBMs, healthcare payors, and providers and lower overall prices that expected. Recent actions by U.S. PBMs in particular have increased discount levels for respiratory products resulting in lower net sales pricing realized for products in our collaboration. Further, if the ongoing Phase 3b studies with FF/VI do not show improved outcomes relative to the standard of care, obtaining payor coverage for RELVAR®/BREO® ELLIPTA® could become more difficult 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 will continue and may increase. This may make it difficult for GSK to sell our partnered products a price acceptable to us or GSK or to generate revenues in-line with our analysts' expectations, which may cause the price of our securities to fall.

If the commercialization of RELVAR®/BREO® ELLIPTA® or ANORO® ELLIPTA® in the countries in which they have received regulatory approval encounters any delays or adverse developments, or perceived delays or adverse developments, or if sales or payor coverage do not meet investor or our expectations, our business will be harmed, and the price of our securities could fall.

Under our agreements with our collaborative partner GSK, GSK has full responsibility for commercialization of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®. GSK has launched RELVAR®/BREO® ELLIPTA® in a number of countries including the United States (U.S.), Canada, Japan, the United Kingdom, and Germany among others. The commercial launch of both products has been below our expectations primarily due to lower overall pricing levels in the U.S. and a longer timeframes to obtain payor coverage. For example, GSK recently stated that it has experienced more restrictive formulary access and lower net pricing in the U.S. respiratory market than it expected, which may indicate broader weakness in the respiratory markets targeted by RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®. As a result, a number of analysts have adjusted their sales forecasts downward from previous projections. Any further delays or adverse developments or perceived

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additional delays or adverse developments with respect to the commercialization of RELVAR®/ BREO® ELLIPTA® and ANORO® ELLIPTA® including if sales or payor coverage do not meet investor or our expectations, will significantly harm our business and the price of our securities could fall.

If the U.S. Food and Drug Administration ("FDA") does not approve the supplemental New Drug Application ("SNDA") for a fixed dose combination of FF/VI as a once-daily treatment for asthma in patients aged 12 years and older, or if the PDUFA date is extended, or if the approval contains restrictions or limitations on usage, our business will be significantly harmed, and the price of our securities could fall.

In June 2014, we and GSK announced the submission of a sNDA to the FDA for a fixed dose combination of FF/VI as a once-daily treatment for asthma in patients aged 12 years and older. The FDA determined the action target date under the Prescription Drug User Fee Act (PDUFA-V) to be April 30, 2015 and recently the FDA announced that on March 19, 2015, the FDA's Pulmonary-Allergy Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee will discuss the sNDA. Any adverse developments, results or delays or perceived adverse developments, results or delays with respect to the asthma sNDA, the Pulmonary-Allergy Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee meeting, or the FF/VI Phase 3 program will significantly harm our business and could cause the market price of our securities to decline. Examples of such adverse developments include, but are not limited to:

not every study, nor every dose in every study, in the Phase 3 asthma program for FF/VI achieved its primary endpoint and regulatory authorities may determine that additional clinical studies are required;

safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs, other studies of FF/VI, or previous studies with other LABAs; and

any change in FDA policy or guidance regarding the use of LABAs to treat asthma.

On February 18, 2010, the FDA announced that LABAs should not be used alone in the treatment of asthma and it will require manufacturers to include this warning in the product labels of these drugs, along with taking other steps to reduce the overall use of these medicines. The FDA now requires that the product labels for LABA medicines reflect, among other things, that the use of LABAs is contraindicated without the use of an asthma controller medication such as an inhaled corticosteroid, that LABAs should only be used long-term in patients whose asthma cannot be adequately controlled on asthma controller medications, and that LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. In addition, in March 2010, the FDA held an Advisory Committee to discuss the design of medical research studies (known as "clinical trial design") to evaluate serious asthma outcomes (such as hospitalizations, a procedure using a breathing tube known as intubation, or death) with the use of LABAs in the treatment of asthma in adults, adolescents, and children. Further, in April 2011, the FDA announced that to further evaluate the safety of LABAs, it is requiring the manufacturers of currently marketed LABAs to conduct additional randomized, double-blind, controlled clinical trials comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone. Results from these post-marketing studies are expected in 2017. It is unknown at this time what, if any, effect these or future FDA actions will have on the prospects for FF/VI. The current uncertainty regarding the FDA's position on LABAs for the treatment of asthma and the lack of consensus expressed at the March 2010 Advisory Committee may result in the FDA requiring additional asthma clinical trials in the U.S. for FF/VI and increase the overall risk of FF/VI for the treatment of asthma in the U.S. We cannot predict the extent to which new FDA policy or guidance might significantly impede the discovery, development, production and marketing of FF/VI. Any adverse change in FDA

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policy or guidance regarding the use of LABAs to treat asthma may significantly harm our business and the price of our securities could fall.

Any adverse developments to the regulatory status of either RELVAR®/BREO® ELLIPTA® or ANORO® ELLIPTA® in the countries in which they have received regulatory approval including labeling restrictions, safety findings, or any other limitation to usage, will harm our business and may cause the price of our securities to fall.

Although RELVAR®/BREO® ELLIPTA® or ANORO® ELLIPTA® are approved and marketed in a number of countries, it is possible that adverse changes to the regulatory status of these products could occur in the event new safety issues are identified, treatment guidelines are changed, or new studies fail to demonstrate product benefits. A number of notable pharmaceutical products have experienced adverse developments during commercialization that have resulted in the product being withdrawn, approved uses being limited, or new warnings being included. In the event that any adverse regulatory change were to occur to any of our products, our business will be harmed and the price of our securities will fall.

Any adverse developments or results or perceived adverse developments or results with respect to the ongoing Phase 3 programs for FF/VI in asthma or COPD, for UMEC/VI in COPD, or any future studies will significantly harm our business and the price of our securities could fall, and if regulatory authorities in those countries in which approval has not yet been granted determine that the Phase 3 programs for FF/VI in asthma or COPD or the Phase 3 programs for UMEC/VI for COPD do not demonstrate adequate safety and efficacy, the continued development of FF/VI or UMEC/VI or both may be significantly delayed, they may not be approved by these regulatory authorities, and even if approved it may be subject to restrictive labeling, any of which will harm our business, and the price of our securities could fall.

Although we have announced the completion of, and reported certain top-line data from, the Phase 3 registrational program for FF/VI in COPD and asthma, additional studies of FF/VI are underway. The Phase 3b program for FF/VI in COPD commenced in February 2011. Any adverse developments or perceived adverse developments with respect to the asthma sNDA, the COPD Phase 3b program or any future studies in these programs will significantly harm our business and the price of our securities could fall.

Although the FDA, the European Medicines Agency, the Japanese Ministry of Health, Labour and Welfare and Health Canada have approved ANORO® ELLIPTA®, it has not yet been approved in other countries. Any adverse developments or results or perceived adverse developments or results with respect to other pending or future regulatory submissions for the FF/VI program or the UMEC/VI program will significantly harm our business and the price of our securities could fall. Examples of such adverse developments include, but are not limited to:

not every study, nor every dose in every study, in the Phase 3 programs for FF/VI achieved its primary endpoint and regulatory authorities may determine that additional clinical studies are required;

safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs having to do with the LABA VI, which is a component of FF/VI and UMEC/VI;

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

regulatory authorities determining that the Phase 3 programs in asthma or in COPD raise safety concerns or do not demonstrate adequate efficacy; or

any change in FDA policy or guidance regarding the use of LABAs to treat asthma or the use of LABAs combined with a LAMA to treat COPD.

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RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® face substantial competition for their intended uses in the targeted markets from products discovered, developed, launched and commercialized both by GSK and by other pharmaceutical companies, which could cause the royalties payable to us pursuant to the LABA Collaboration Agreement to be less than expected, which in turn would harm our business and the price of our securities could fall.

GSK has responsibility for obtaining regulatory approval, launching and commercializing RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® for their intended uses in the targeted markets around the world. While these products have received regulatory approval and been launched and commercialized in the U.S. and certain other targeted markets, the products face substantial competition from existing products previously developed and commercialized both by GSK and by other competing pharmaceutical companies and can expect to face additional competition from new products that are discovered, developed and commercialized by the same pharmaceutical companies and other competitors going forward. For example, sales of Advair®, GSK's approved medicine for both COPD and asthma, continue to be significantly greater than sales of RELVAR®/BREO® ELLIPTA®, and GSK has indicated publicly that it intends to continue commercializing Advair®.

Many of the pharmaceutical companies competing in respiratory markets are international in scope with substantial financial, technical and personnel resources that permit them to discover, develop, obtain regulatory approval and commercialize new products in a highly efficient and low cost manner at competitive prices to consumers. In addition, many of these competitors have substantial commercial infrastructures that facilitate commercializing their products in a highly efficient and low cost manner at competitive prices to consumers. The market for products developed for treatment of COPD and asthma continues to experience significant innovation and reduced cost in bringing products to market over time. There can be no assurance that RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® will not be replaced by new products that are deemed more effective at lower cost to consumers. The ability of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® to succeed and achieve the anticipated level of sales depends on the commercial and development performance of GSK to achieve and maintain a competitive advantage over other products with the same intended use in the targeted markets.

If sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® are less than anticipated because of existing or future competition in the markets in which they are commercialized, including competition from existing and new products that are perceived as lower cost or more effective, our royalty payments will be less than anticipated, which in turn would harm our business and the price of our securities could fall.

We and GSK are developing UMEC/VI/FF (LAMA/LABA/ICS) and MABA/FF as potential triple combination treatments for COPD and, potentially, asthma. As a result of the Spin-Off, most of our economic rights in these programs were assigned to Theravance Biopharma, Inc. If these programs are successful and GSK and the respiratory market in general views triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, our business could be harmed, and the price of our securities could fall.

Under our LABA Collaboration Agreement with GSK, we and GSK are exploring various paths to create triple therapy respiratory medications. The use of triple therapy is supported by the GOLD ("Global initiative for chronic Obstructive Lung Disease") guidelines in high-risk patients with severe COPD and a high risk of exacerbations. One potential triple therapy path is the combination of UMEC/VI (two separate bronchodilators) and FF (an inhaled corticosteroid), to be administered via the ELLIPTA® dry powder inhaler, referred to as UMEC/VI/FF or the "closed triple." Prior to the Spin-Off, we were entitled to receive 100% of any royalties payable under the GSK Agreements arising from sales of UMEC/VI/FF (as well as MABA and MABA/FF) if such products were successfully developed, approved and commercialized. In July 2014, we and GSK announced the initiation of a

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large, global Phase 3 study for the closed triple in patients with COPD. If this Phase 3 study (or any other closed triple Phase 3 studies that may be initiated in the future) is successful, GSK and the respiratory market in general may view this triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®. In such event the commercialization of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® could be adversely affected, which in turn could result in lower royalties to us. Furthermore, if the closed triple (or MABA /FF) receives regulatory approval in either the U.S. or the EU, GSK's diligent efforts obligations regarding 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. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a small portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements in the future. As a result of the transactions effected by the Spin-Off, however, we are now only entitled to receive 15% of any contingent payments and royalties payable by GSK from sales of FF/UMEC/VI (and MABA, and MABA/FF) while Theravance Biopharma receives 85% of those same payments.

We have ongoing discussions with the SEC staff about the way we present and account for the different payments made and received under the LABA Collaboration Agreement in our current and historic financial statements. In the event the SEC staff disagrees with our accounting we may be required to restate prior financial statements which could, among other potential adverse effects, result in us incurring substantial costs, affect our ability to timely file our periodic reports, divert the attention of our management and employees and cause our stock price to decline.

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of these financial statements requires us to interpret accounting principles and guidance and make estimates and judgments 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. For instance, pursuant to GAAP, we are required to present and characterize the different payments made and received under the LABA Collaboration Agreement. Our most critical accounting estimates are described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of this Annual Report on Form 10-K. Our interpretations, estimates and judgments 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 the preparation of our financial statements. GAAP presentation is subject to interpretation by the United States Securities and Exchange Commission ("SEC"), the Financial Accounting Standards Board ("FASB") and various other bodies formed to interpret and create appropriate accounting principles and guidance. In the event that one of these bodies disagrees with our accounting recognition, measurement or disclosure or any of our accounting interpretations, estimates or assumptions, it may have a significant effect on our reported results and may retroactively affect previously reported results.

The SEC routinely reviews the periodic filings of public companies. For instance, we received in April 2014 a comment letter from the staff of the SEC in connection with a routine review of our Annual Report on Form 10-K for the year ended December 31, 2013 relating to our amortization of intangible assets and recognition of amortization charges associated with the LABA Collaboration Agreement. We responded to the comment letter in May 2014 and the SEC did not inquire further regarding the matters raised in the comment letter. More recently, the SEC inquired regarding our historical and current recognition of the up-front and milestone payments received from GSK pursuant to the LABA Collaboration Agreement between 2002 and 2006, and the milestone fees paid by us to GSK in 2013 and 2014. We are currently engaged in discussions with the SEC staff regarding our

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recognition of the payments made and received under the LABA Collaboration Agreement. While we believe that our historical accounting related to the LABA Collaboration Agreement is appropriate and in accordance with U.S. generally accepted accounting principles, the SEC reserves the right to make further inquiries regarding our accounting treatment regarding the payments made and received under the LABA Collaboration Agreement. If the SEC disagrees with our accounting treatment, we may be required to restate our financial statements for prior periods. The need to restate our financial results could, among other potential adverse effects, result in us incurring substantial costs, affect our ability to timely file our periodic reports until such restatement is completed, divert the attention of our management and employees from managing our business, result in material changes to our historical and future financial results, result in investors losing confidence in our operating results, and cause our stock price to decline.

In addition, a restatement could also subject us to securities class action litigation. Defending against such potential litigation relating to a restatement of our financial statements would be expensive and would require significant attention and resources of our management. Moreover, our insurance to cover our obligations with respect to the ultimate resolution of any such litigation may be inadequate. As a result of these factors, any such potential litigation could have a material adverse effect on our financial results and cause our stock price to decline.

We were relying significantly upon Theravance Biopharma for a variety of services following the Spin-Off during which time we established our own separate administrative infrastructure, systems and controls to enable us to function as an independent public company and, if the new administrative infrastructure, systems and controls do not perform as expected, our business will be harmed and the price of our securities could fall.

Under the terms of a transition services agreement entered into between us and Theravance Biopharma, Theravance Biopharma has provided us with a variety of administrative services following the Spin-Off, including (i) record keeping support, (ii) finance, tax and accounting support to assist us in a secondary capacity to our own personnel, (iii) legal support, (iv) human resources support and (v) facilities support to the extent we continue to occupy separate space at our current South San Francisco, California facilities. We relied on Theravance Biopharma for execution of these administrative activities through a transition period extending into early 2015, which is a period when Theravance Biopharma personnel were highly focused on supporting its own new public company operations. We are in the process of establishing our own stand-alone capabilities, controls and systems including finance, tax, accounting, human resources, and IT systems, among others that are properly suited to our new post-spin business operations and to support our ongoing operations as an independent public company. If our new administrative infrastructure should cause us to be unable to comply with the accounting and legal standards required of publicly traded companies, our business and our reputation will be harmed, and the price of our securities could fall.

On June 2, 2014, we completed the separation of our businesses into two independent, publicly traded companies by separating our late-stage partnered respiratory assets from our biopharmaceutical operations; the lengthy, complicated process to separate the two businesses has diverted the attention of our management and employees, and has increased our professional services expenses in 2014 and will continue to do so in early 2015.

On April 25, 2013, we announced our intention to separate our businesses into two independent, publicly traded companies. On August 1, 2013, the company to be spun-off, Theravance Biopharma, filed a preliminary Form 10 with the SEC, and subsequent amendments throughout 2013 and the spring of 2014. The Spin-Off was completed on June 2, 2014. Theravance continues to be responsible for all development and commercial activities under the GSK Agreements. Theravance is eligible to receive the associated royalty revenues from FF/VI (RELVAR®/BREO® ELLIPTA®), UMEC/VI (ANORO®

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ELLIPTA®) and potentially VI monotherapy and 15% of the aggregate potential royalty revenues payable to Theravance Respiratory Company, LLC from UMEC/VI/FF, MABA, and MABA/FF and other products that may be developed under the GSK Agreements. Theravance Biopharma is now a separate and independent publicly traded biopharmaceutical company focusing on the discovery, development and commercialization of small-molecule medicines in areas of significant unmet medical need.

In conjunction with the Spin-Off of Theravance Biopharma, on March 3, 2014, we, Theravance Biopharma and GSK entered into a series of agreements clarifying how the companies would implement the separation and operate following the Spin-Off. We, Theravance Biopharma and GSK entered into a three-way master agreement providing for GSK's consent to the Spin-Off provided certain conditions were met. We and GSK also entered into amendments of the GSK Agreements. The master agreement and the other agreements are all currently effective.

The amendments to the GSK Agreements do not change the royalty rates or other economic terms. The amendments do provide that GSK's diligent efforts obligations regarding commercialization matters under both agreements will change upon regulatory approval in either the U.S. or the EU of UMEC/VI/FF or a MABA combined with FF. Upon such regulatory approval, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements 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. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a small portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements in the future.

The process of planning for and effecting the business separation demanded a significant amount of time and effort from our management and certain employees, continued to do so in 2014 and will continue to do so until early 2015. The diversion of our management's and employees' attention to the business separation process and the post-separation transition has disrupted and may continue to disrupt our operations and may adversely impact our relationship with GSK and increase employee turnover.

We cannot assure you that we will not undertake additional restructuring activities, that the business separation will succeed in meeting our objectives and increasing stockholder value, or that the actual results will not differ materially from the results that we anticipate.

We have incurred and will continue to incur significant expenditures for professional services in connection with the business separation and our post-separation operations, including financial advisory, accounting and legal fees.

Under the terms of a separation and distribution agreement entered into between us and Theravance Biopharma, Theravance Biopharma will indemnify us from (i) all debts, liabilities and obligations transferred to Theravance Biopharma in connection with the Spin-Off (including its 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 in its information statement filed with the SEC, resulting in a misleading statement and (iii) any breach by it of certain agreements entered into between the parties in connection with the Spin-Off. Theravance Biopharma's ability to satisfy these indemnities, if called upon to do so, will depend upon its future financial strength and if we are not able to collect on indemnification rights from Theravance Biopharma, our financial condition may be harmed.

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We may not be able to utilize all of our net operating loss carryforwards.

We have net operating loss carryforwards and other significant U.S. tax attributes that we believe could offset otherwise taxable income in the U.S. As a part of the overall Spin-Off transaction, the transfer of certain assets by us to Theravance Biopharma and our distribution of Theravance Biopharma ordinary shares resulted in taxable transfers pursuant to applicable provisions of the Internal Revenue Code of 1986, as amended (the "Code") and Treasury Regulations. The taxable gain recognized by us attributable to the transfer of certain assets to Theravance Biopharma will generally equal the excess of the fair market value of each asset transferred over our adjusted tax basis in such asset. Although we will not recognize any gain with respect to the cash we transferred to Theravance Biopharma, we may recognize substantial gain based on the fair market value of the other assets (other than cash) transferred to Theravance Biopharma. The determination of the fair market value of these assets is subjective and could be subject to adjustments or future challenge by the Internal Revenue Service ("IRS"), which could result in an increase in the amount of gain realized by us as a result of the transfer. Our U.S. federal income tax resulting from any gain recognized upon the transfer of our assets to Theravance Biopharma (including any increased U.S. federal income tax that may result from a subsequent determination of higher fair market values for the transferred assets), may be reduced by our net operating loss carryforward. The net operating loss carryforwards available in any year to offset our net taxable income will be reduced following a more than 50% change in ownership during any period of 36 consecutive months (an "ownership change") as determined under the Internal Revenue Code of 1986 (the "Code"). As of December 31, 2014, we have conducted an analysis to determine whether an ownership change had occurred since inception through December 31, 2014, and concluded that we had undergone two ownership changes in prior years. We have approximately \$1.4 billion of net operating loss carryforward available during 2014. We currently expect our net operating losses to be fully available to offset current year net taxable income after taking into account the taxable nature of the Spin-Off. With respect to our remaining net operating losses of approximately \$1.2 billion as of December 31, 2014, there may be certain annual limitations for utilization based on the above-described ownership change provisions. In addition, we may not be able to have sufficient future taxable income prior to their expiration because net operating losses have carryforward periods. Future changes in federal and state tax laws pertaining to net operating loss carryforwards may also cause limitations or restrictions from us claiming such net operating losses. If the net operating loss carryforwards become unavailable to us or are fully utilized, our future taxable income will not be shielded from federal and state income taxation absent certain U.S. federal and state tax credits, and the funds otherwise available for general corporate purposes would be reduced.

Our stockholders who received ordinary shares of Theravance Biopharma in the Spin-Off and/or dividends we paid during 2014 could incur significant U.S. federal income tax liabilities as a result of the distributions.

The Theravance Biopharma ordinary shares received by our stockholders in the Spin-Off and dividends we paid during 2014, are expected to be taxable to stockholders. An amount equal to the fair market value of Theravance Biopharma ordinary shares received (including any fractional shares deemed to be received) on the distribution date, and/or the dividends we paid in 2014, will be treated as a taxable dividend to the extent of each Theravance stockholder's ratable share of any current and accumulated earnings and profits of Theravance, measured as of the end of 2014, with the excess treated as a non-taxable return of capital to the extent of such stockholder's tax basis in our common stock and any remaining excess treated as a capital gain. Accordingly, Theravance stockholders who received ordinary shares of Theravance Biopharma in the Spin-Off and/or dividends during 2014 could incur significant U.S. federal income tax liabilities as a result of the distribution. We periodically update Form 8937 Report of Organizational Actions Affecting Basis of Securities, which we post on our website, in order to provide investors with relevant information associated with the distributions.

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The Spin-Off resulted in substantial changes in our Board, management, and employees. If we fail to hire and effectively integrate new executive officers into our organization, the future development and commercialization of our product candidates may suffer, harming future regulatory approvals, sales of our product candidates or our results of operations.

Since the Spin-Off, substantially all of our directors and senior management team has changed. Our current board and management team has only been working together for a relatively short period of time. In addition, Rick E Winningham resigned as our president and chief executive officer effective as of August 15, 2014 and as chairman of our Board and as a director effective as of October 30, 2014. We have appointed Michael W. Aguiar as our chief executive officer and as a member of our Board and appointed Eric d'Esparbes as our chief financial officer. We expect to continue to expand our management team in the future. Our future performance will depend significantly on our ability to successfully integrate our new directors into our Board and our new chief executive officer, chief financial officer and other recently and subsequently hired executive officers into our management team, and on those individuals' ability to develop and maintain an effective working relationship. Our failure to integrate recently and subsequently appointed directors and executive officers, including our new chief executive officer and chief financial officer, with other members of management could result in inefficiencies in the conduct of our business, which can adversely affect our results of operations.

If any product candidates in any respiratory program partnered with GSK are not approved by regulatory authorities or are determined to be unsafe or ineffective in humans, our business will be adversely affected and the price of our securities could fall.

The FDA must approve any new medicine before it can be marketed and sold in the U.S. Our partner GSK must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that the product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. GSK will not obtain this approval for a partnered product candidate unless and until the FDA approves a 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 medicines in foreign countries, separate regulatory approvals must be obtained 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 country may make approval in other countries more difficult.

Clinical studies involving product candidates partnered with GSK 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 product candidates in development partnered with GSK, GSK may not receive regulatory approval for such product candidates and our business and financial condition will be materially harmed and the price of our securities may fall.

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Several well-publicized Complete Response letters issued by the FDA and safety-related product withdrawals, suspensions, post-approval labeling revisions to include boxed warnings and changes in approved indications over the last several years, as well as growing public and governmental scrutiny of safety issues, have created a conservative regulatory environment. The implementation of new laws and regulations and revisions to FDA clinical trial design guidance have increased uncertainty regarding the approvability of a new drug. Further, there are 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 any product candidates in any respiratory program partnered with GSK.

Even if product candidates in any respiratory program partnered with GSK receive regulatory approval, as is the case with RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, commercialization of such products may be adversely affected by regulatory actions and oversight.

Even if GSK receives regulatory approval for product candidates in any respiratory program partnered with GSK, this approval may include limitations on the indicated uses for which GSK can market the medicines or the patient population that may utilize the medicines, which may limit the market for the medicines or put GSK at a competitive disadvantage relative to alternative therapies. These restrictions make it more difficult to market the approved products.

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 or GSK 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 GSK, including requiring it 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. GSK is 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 as well as governmental authorities in those foreign countries in which any of the product candidates in any respiratory program partnered with GSK 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. Any failure to maintain regulatory approval will limit GSK's ability to commercialize the product candidates in any respiratory program partnered with GSK, which would materially and adversely affect our business and financial condition and which may cause the price of our securities to fall.

We have incurred operating losses in each year since our inception and will continue to incur losses until royalties from the sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® exceed total expenses, including interest expenses, and our revenues and operating results will likely fluctuate in future periods.

From mid-1997 until the Spin-Off, we were engaged in discovering and developing compounds and product candidates and we never generated sufficient revenue from the sale of medicines or royalties on sales by our partners to achieve sustained profitability. As of December 31, 2014, we had an accumulated deficit of approximately \$1.7 billion. Although we expect to have a substantial reduction in our expenses in future periods as a result of the Spin-Off, we will continue to incur losses until royalties from the sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® exceed total expenses, including interest expenses, and our revenues and operating results will likely fluctuate from

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period to period. We are uncertain when or if we will be able to achieve or sustain profitability. Failure to become and remain profitable would adversely affect the price of our securities, our ability to return capital to stockholders and continue operations.

We may not be successful in our efforts to expand our portfolio of royalty generating products.

In the future, we may choose to acquire rights to one or more additional royalty generating products. However, we may be unable to license or acquire rights to suitable royalty generating products for a number of reasons. In particular, the licensing and acquisition of pharmaceutical product rights is a competitive area. Several more established companies are also pursuing strategies to license or acquire rights to royalty generating products. These established companies may have a competitive advantage over us. Other factors that may prevent us from licensing or otherwise acquiring rights to suitable royalty generating products include the following:

we may be unable to license or acquire the rights on terms that would allow us to make an appropriate return from the product;

companies that perceive us to be their competitors may be unwilling to assign or license their product rights to us; or

we may be unable to identify suitable royalty generating products.

If we are unable to acquire or license rights to suitable royalty generating product candidates, our business may suffer.

We have a significant amount of debt including Convertible Subordinated Notes and Fixed Rate Royalty notes that are senior in capital structure and cash flow, respectively, to our common stockholders. Satisfying the obligations relating to our debt could adversely affect the amount or timing of distributions to our stockholders.

As of December 31, 2014 we had approximately \$725.6 million in total long-term liabilities outstanding, comprised primarily of \$255.1 million in principal that remains outstanding under our 2.125% Convertible Subordinated Notes due 2023 (the "2023 Notes") and \$470.5 million in principal that remains outstanding under our 9% Fixed Rate Royalty term notes due 2029 (the "2029 Notes" and with the 2023 Notes, the "Notes"). The 2023 Notes are unsecured debt and are not redeemable by us prior to the maturity date. Holders of the Notes may require us to purchase all or any portion of their Notes at 100% of their principal amount, plus any unpaid interest, upon a fundamental change. A fundamental change is generally defined to include a merger involving us, an acquisition of a majority of our outstanding common stock, and the change of a majority of our board without the approval of the board. In addition, to the extent we pursue and complete a monetization transaction, the structure of such transaction may qualify as a fundamental change under the Notes, which could trigger the put rights of the holders of the Notes, in which case we would be required to use a portion of the net proceeds from such transaction to repurchase any Notes put to us. Our 2029 Notes have rights to 40% of all royalty payments received from GSK related to RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA®, and VI monotherapy until the notes are paid in full.

Satisfying the obligations of this debt could adversely affect the amount or timing of any distributions to our stockholders. We may choose to satisfy repurchase, or refinance this debt through public or private equity or debt financings if we deem such financings available on favorable terms. If any or all of the Convertible Subordinated Notes are not converted into shares of our common stock before the maturity date, we will have to pay the holders the full aggregate principal amount of the Notes then outstanding. If the Fixed Rate Royalty are not refinanced or paid in full, then they will receive 40% of all future economics associated with RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA®, and VI monotherapy, until the notes are paid in full. Any of the above payments could have a material adverse effect on our cash position. If we fail to satisfy these obligations, it may result

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in a default under the indenture, which could result in a default under certain of our other debt instruments, if any. Any such default would harm our business and the price of our securities could fall.

If we lose key management personnel, or if we fail to retain our key employees, our ability to manage our business will be impaired.

Following the Spin-Off, we have a much smaller management team and very few employees. We are highly dependent on principal members of our management team and a small group of key employees to operate our business. Our company is located in northern California, which is 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 remains 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 business operations, which may cause the price of our securities to fall.

We rely and will continue to rely on outsourcing arrangements for many of our activities, including financial reporting and accounting and human resources.

We currently have only ten full-time employees and, as a result, we rely, and expect to continue to rely, on outsourcing arrangements for a significant portion of our activities, including financial reporting and accounting and human resources, as well as for certain functions as a public company through the end of the first quarter of 2015. We may have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner.

As we continue to develop our business, our mix of assets and our sources of income may require that we register with the SEC as an "investment company" in accordance with the Investment Company Act of 1940.

We have not been and have no current intention to register as an "investment company" under the Investment Company Act of 1940, or the 40 Act, because we believe the nature of our assets and the sources of our income currently exclude us from the definition of an investment company pursuant to Sections (3)(a)(1)(A), (3)(a)(1)(C) under the 40 Act and Rule 270.3a-1 of Title 17 of the Code of Federal Regulations. Accordingly, we are not currently subject to the provisions of the 40 Act, such as compliance with the 40 Act's registration and reporting requirements, capital structure requirements, affiliate transaction restrictions, conflict of interest rules, requirements for disinterested directors, and other substantive provisions. Generally, to avoid being a company that is an "investment company" under the 40 Act, it must both: (a) not be or hold itself out as being engaged primarily in the business of investing, reinvesting or trading in securities, and (b) either (i) not be engaged or propose to engage in the business of investing in securities or own or propose to acquire investment securities having a value exceeding 40% of the value of its total assets (exclusive of U.S. government securities and cash items) on an unconsolidated basis or (ii) not have more than 45% of the value of its total assets (exclusive of Government securities and cash items) consist of or more than 45% of its net income after taxes (for the last four fiscal quarters combined) be derived from securities. In addition, we would not be an "investment company" if an exception, exemption, or safe harbor under the 40 Act applies.

We monitor our assets and income for compliance with the tests under the 40 Act and seek to conduct our business activities to ensure that we do not fall within its definitions of "investment company." If we were to become an "investment company" and be subject to the strictures of the 40 Act, the restrictions imposed by the 40 Act would likely require changes in the way we do business and add significant administrative burdens to our operations. In order to ensure that we do not fall within the 40 Act, we may need to take various actions which we might otherwise not pursue. These actions may include restructuring the Company and/or modifying our mixture of assets and income.

Specifically, our mixture of debt vs. royalty assets is important to our classification as an "investment company" or not. In this regard, while we currently believe that none of the definitions of

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"investment company" apply to us, we may in the future rely on an exception under the 40 Act provided by Section 3(c)(5)(A). To qualify for Section 3(c)(5)(A), as interpreted by the staff of the SEC, we would be required to have at least 55% of our total assets in "notes, drafts, acceptances, open accounts receivable, and other obligations representing part or all of the sales price of merchandise, insurance, and services" (or Qualifying Assets). In a no-action letter issued to Royalty Pharma on August 13, 2010, the staff stated that royalty interests are Qualifying Assets under this exception. If the SEC or its staff in the future adopts a contrary interpretation or otherwise restricts the conclusions in the staff's no-action letter such that our royalty interests are no longer Qualifying Assets for purposes of Section 3(c)(5)(A), we could be required to register under the 40 Act.

The rules and interpretations of the SEC and the courts, relating to the definition of "investment company" are highly complex in numerous respects. While we currently intend to conduct our operations so that we will not be deemed an investment company, we can give no assurances that we will not determine it to be in the Company's and our stockholders' interest to register as an "investment company", not be deemed an "investment company" and not be required to register under the 40 Act.

#### Risks Related to our Alliance with GSK

Because all our current and projected revenues are derived from products under the GSK Agreements, disputes with GSK could harm our business and cause the price of our securities to fall.

All of our current and projected revenues are derived from products under the GSK Agreements. Any action or inaction by either GSK or us that results in a material dispute, allegation of breach, litigation, arbitration, or significant disagreement between the 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 our partnered products and other GSK respiratory products, disputes over public statements, and similar matters. In addition, while we obtained GSK's consent to the Spin-Off as structured, GSK could decide to challenge various aspects of our post-Spin-Off operation of Theravance Respiratory Company, LLC ("TRC"), the limited liability company jointly owned by us and Theravance Biopharma as violating or allowing it to terminate the GSK Agreements. Although we believe our operation of TRC fully complies with the GSK Agreements and applicable law, there can be no assurance that we would 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 market or investor uncertainty about the respiratory programs partnered with GSK or the enforceability of the GSK Agreements could result in significant reduction in the market price of our securities and other material harm to our business.

Because GSK is a strategic partner as well as a significant stockholder, it may take actions that in certain cases are materially harmful to both our business or to our other stockholders.

Although GSK beneficially owns approximately 27.1% of our outstanding capital stock as of February 12, 2015, it is also a strategic partner with rights and obligations under the GSK Agreements that cause its interests to differ from the interests of us and our other stockholders. In particular, GSK has a substantial respiratory product portfolio in addition to the partnered products that are 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 us. For example, GSK could promote its non-GSK/THRX respiratory products, delay or terminate the development or commercialization of the respiratory programs covered by the GSK Agreements, or take other actions, such as making public statements, that have a negative effect on our stock price. In this regard and by way of example, sales of Advair®, GSK's approved medicine for both COPD and asthma, continue to be significantly greater than sales of RELVAR®/BREO® ELLIPTA®, and GSK has

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indicated publicly that it intends to continue commercializing Advair®. Also, given the potential future royalty payments GSK may be obligated to pay under the GSK Agreements, GSK may seek to acquire us to reduce those payment obligations. 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 stockholders. In addition, upon regulatory approval of UMEC/VI/FF or a MABA/ICS in either the U.S. or the EU, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements 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. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the products covered by the GSK Agreements in the future.

GSK has also indicated to us that it believes its consent may be required before we can engage in certain royalty monetization transactions with third parties, which may inhibit our ability to engage in these transactions.

In the course of our discussions with GSK concerning the Spin-Off of Theravance Biopharma, GSK indicated to us that it believes that its consent may be required before we can engage in certain transactions designed to monetize the future value of royalties that may be payable to us from GSK under the GSK Agreements. GSK has informed us that it believes that there may be certain covenants included in these types of transactions that might violate certain provisions of the GSK Agreements. Although we believe that we can structure royalty monetization transactions in a manner that fully complies with the requirements of the GSK Agreements without GSK's consent, a third party in a proposed monetization transaction may nonetheless insist that we obtain GSK's consent for the transaction or re-structure the transaction on less favorable terms. We have obtained GSK's agreement that (i) we may grant certain pre-agreed covenants in connection with monetization of our interests in RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and vilanterol monotherapy and portions of our interests in TRC, and (ii) it will not unreasonably withhold its consent to our requests to grant other covenants, provided, among other conditions, that in each case, the covenants are not granted in favor of pharmaceutical or biotechnology company with a product either being developed or commercialized for the treatment of respiratory disease. If we seek GSK's consent to grant covenants other than pre-agreed covenants, we may not be able to obtain GSK's consent on reasonable terms, or at all. If we proceed with a royalty monetization transaction that is not otherwise covered by the GSK Agreement without GSK's consent, GSK could request that its consent be obtained or seek to enjoin or otherwise challenge the transaction as violating or allowing it to terminate the GSK Agreements. Regardless of the merit of any claims by GSK, we would incur significant cost and diversion of resources in defending against GSK's claims or asserting our own claims and GSK may seek concessions from us in order to provide its consent. Any uncertainty about whether or when we could engage in a royalty monetization transaction, the potential impact on the enforceability of the GSK Agreements or the loss of potential royalties from the respiratory programs partnered with GSK, could impair our ability to pursue a return of capital strategy for our stockholders ahead of our receipt of significant royalties from GSK, result in significant reduction in the market price of our securities and cause other material harm to our business.

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GSK's ownership of a significant percentage of our stock and its ability to acquire additional shares of our stock may create conflicts of interest, and may inhibit our management's ability to continue to operate our business in the manner in which it is currently being operated.

As of February 12, 2015, GSK beneficially owned approximately 27.1% of our outstanding capital stock, and GSK has the right to acquire stock from us to maintain its percentage ownership of our capital stock in certain circumstances. GSK could have substantial influence in the election of our directors, delay or prevent a transaction in which stockholders might receive a premium over the prevailing market price for their shares and have significant control over certain changes in our business.

In addition, GSK may make an offer to our stockholders to acquire outstanding voting stock that would bring GSK's percentage ownership of our voting stock to no greater than 60%, provided that:

the offer includes no condition as to financing;

the offer is approved by a majority of our independent directors;

the offer includes a condition that the holders of a majority of the shares of the voting stock not owned by GSK accept the offer by tendering their shares in the offer; and

the shares purchased will be subject to the same provisions of the governance agreement as are the shares of voting stock currently held by GSK.

If pursuant to the provision described above GSK's ownership of us is greater than 50.1%, then GSK is allowed to make an offer to our stockholders to acquire outstanding voting stock that would bring GSK's percentage ownership of our voting stock to 100%, provided that;

the offer includes no condition as to financing;

the offer is approved by a majority of our independent directors; and

the offer includes a condition that the holders of a majority of the shares of the voting stock not owned by GSK accept the offer by tendering their shares in the offer.

The procedures governing GSK offers to ours stockholders to acquire outstanding voting stock set forth in the preceding two paragraphs are applicable until the termination of the governance agreement on September 1, 2015 and thereafter the foregoing restrictions will not apply.

Further, pursuant to our Certificate of Incorporation, we renounce our interest in and waive any claim that a corporate or business opportunity taken by GSK constitutes a corporate opportunity of ours unless such corporate or business opportunity is expressly offered to one of our directors who is a director, officer or employee of GSK, primarily in his or her capacity as one of our directors.

GSK's significant ownership position and its rights under the governance agreement may deter or prevent efforts by other companies to acquire us, which could prevent our stockholders from realizing a control premium.

As of February 12, 2015, GSK beneficially owned approximately 27.1% of our outstanding capital stock. GSK may vote at its sole discretion on any proposal to effect a change of control of us or for us to issue equity securities to one or more parties that would result in that party or parties beneficially owning more than 20% of our outstanding capital stock. Our governance agreement with GSK requires us to exempt GSK from any stockholder rights plan we may adopt in the future, affords GSK certain rights to offer to acquire us in the event third parties seek to acquire our stock and contains other provisions that could deter or prevent another company from seeking to acquire us.

For example, GSK may offer to acquire 100% of our outstanding stock from stockholders in certain circumstances, such as if we are faced with a hostile acquisition offer or if our Board acts in a manner to facilitate a change in control of us with a party other than GSK. As a result of GSK's significant ownership and its rights under the governance agreement, other companies may be less

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inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares.

GSK could sell or transfer a substantial number of shares of our common stock, which could depress the price of our securities or result in a change in control of our company.

Under our governance agreement with GSK, GSK could previously sell or transfer our common stock only pursuant to a public offering registered under the Securities Act or pursuant to Rule 144 of the Securities Act. GSK no longer has contractual restrictions on its ability to sell or transfer our common stock on the open market, in privately negotiated transactions or otherwise, and these sales or transfers could create substantial declines in the price of our securities or, if these sales or transfers were made to a single buyer or group of buyers, could contribute to a transfer of control of our company to a third party. Sales by GSK of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock.

#### Risks Related to Legal and Regulatory Uncertainty

If the efforts of our partner, GSK, to protect the proprietary nature of the intellectual property related to products in any respiratory program partnered with GSK are not adequate, the future commercialization of any such product could be delayed, limited or prevented, which would materially harm our business and the price of our securities could fall.

To the extent the intellectual property protection of products in any respiratory program partnered with GSK are successfully challenged or encounter problems with the U.S. Patent and Trademark Office or other comparable agencies throughout the world, the commercialization of these products could be delayed, limited or prevented. Any challenge to the intellectual property protection of a late-stage development asset or approved product arising from any respiratory program partnered with GSK could harm our business and cause the price of our securities to fall.

Our commercial success depends in part on products in any respiratory program partnered with GSK not infringing the patents and proprietary rights of third parties. Third parties may assert that these products are using their proprietary rights without authorization. In addition, third parties may obtain patents in the future and claim that use of GSK's technologies infringes upon these patents. Furthermore, parties making claims against GSK may obtain injunctive or other equitable relief, which could effectively block GSK's ability to further develop or commercialize one or more of the product candidates or products in any respiratory program partnered with GSK.

In the event of a successful claim of infringement against GSK, it 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, GSK may need to obtain licenses from third parties to advance its research or allow commercialization of the products. GSK may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, GSK would be unable to further develop and commercialize one or more of the products, which could harm our business significantly. In addition, in the future GSK could be required to initiate litigation to enforce its proprietary rights against infringement by third parties. Prosecution of these claims to enforce its rights against others would involve substantial litigation expenses. If GSK fails to effectively enforce its proprietary rights related to our partnered respiratory programs against others, our business will be harmed, and the price of our securities could fall.

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#### Risks Related to Ownership of our Common Stock

The price of our securities has been extremely volatile and may continue to be so, and purchasers of our securities could incur substantial losses.

The price of our securities has been extremely volatile and may continue to be so. Between January 1, 2014 and December 31, 2014, the high and low sales prices of our common stock as reported on The NASDAQ Global Market varied between \$12.90 and \$40.49 per share. The stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the companies' operating performance, in particular during the last several years. The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our securities:

any adverse developments or results or perceived adverse developments or results with respect to the commercialization of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® with GSK, including, without limitation, if payor coverage is lower than anticipated or if sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® are less than anticipated because of pricing pressure in the respiratory markets targeted by our partnered products or existing or future competition in the markets in which they are commercialized, including competition from existing and new products that are perceived as lower cost or more effective, and our royalty payments are less than anticipated;

any positive developments or results or perceived positive developments or results with respect to the development of UMEC/VI/FF with GSK, including, without limitation if the new Phase 3 study (or any other closed triple Phase 3 studies that may be initiated in the future) is successful and GSK and the respiratory market in general view this triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®;

any adverse developments or results or perceived adverse developments or results with respect to the on-going development of FF/VI with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for FF/VI or any indication from clinical or non-clinical studies, including the large Phase 3b program, that FF/VI is not safe or efficacious or does not sufficiently differentiate itself from alternative therapies;

any adverse developments or results or perceived adverse developments or results with respect to the on-going development of UMEC/VI with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for UMEC/VI, any indication from clinical or non-clinical studies that UMEC/VI is not safe or efficacious;

any adverse developments or results or perceived adverse developments or results with respect to the sNDA submitted to the FDA for a fixed dose combination of FF/VI as a once-daily treatment for asthma in patients aged 12 years and older;

any adverse developments or perceived adverse developments in the field of LABAs, including any change in FDA policy or guidance (such as the pronouncement in February 2010 warning that LABAs should not be used alone in the treatment of asthma and related labeling requirements, the impact of the March 2010 FDA Advisory Committee discussing LABA clinical trial design to evaluate serious asthma outcomes or the FDA's April 2011 announcement that manufacturers of currently marketed LABAs conduct additional clinical studies comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone);

GSK's decisions whether or not to purchase, on a quarterly basis, sufficient shares of our common stock to maintain its ownership percentage taking into account our preceding quarter's option exercise, equity vesting and debt conversion activity;

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the occurrence of a fundamental change triggering a put right of the holders of the Notes or our inability, or perceived inability, to satisfy the obligations under the Notes when they become due;

our incurrence of expenses in any particular quarter that are different than market expectations;

the extent to which GSK advances (or does not advance) FF/VI, UMEC/VI, UMEC/VI/FF, VI monotherapy and the MABA program through development into commercialization in all indications in all major markets;

any adverse developments or perceived adverse developments with respect to our relationship with GSK, including, without limitation, disagreements that may arise between us and GSK;

announcements regarding GSK generally;

announcements of patent issuances or denials, technological innovations or new commercial products by GSK;

publicity regarding actual or potential study results or the outcome of regulatory review relating to products under development by GSK;

regulatory developments in the U.S. and foreign countries;

economic and other external factors beyond our control;

sales of stock by us or by our stockholders, including sales by certain of our employees and directors whether or not pursuant to selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934;

relative illiquidity in the public market for our common stock (our three largest stockholders other than GSK collectively owned approximately 38.2% of our outstanding capital stock as of February 12, 2015 based on our review of publicly available filings);

any adverse developments or perceived adverse developments with respect to the business separation; and

potential sales or purchases of our capital stock by GSK.

#### We may be unable to or elect not to continue returning capital to our stockholders

We have a corporate goal of returning capital to stockholders and have paid quarterly dividends during the 3<sup>rd</sup> and 4<sup>th</sup> quarters of 2014. The payment of, or continuation of, capital returns to stockholders is at the discretion of our board of directors and is dependent upon our financial condition, results of operations, capital requirements, general business conditions, tax treatment of capital returns, potential future contractual restrictions contained in credit agreements and other agreements and other factors deemed relevant by our board of directors. Future capital returns may also be affected by, among other factors: our views on potential future capital requirements for investments in acquisitions and our working capital and debt maintenance requirements; legal risks; stock repurchase programs; changes in federal and state income tax laws or corporate laws; and changes to our business model. Our capital returns may change from time to time, and we cannot provide assurance that we will continue to provide any particular amounts. A reduction or suspension in our capital returns programs could have a negative effect on our stock price.

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

As of February 12, 2015, GSK beneficially owned approximately 27.1% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 0.9% of our outstanding capital stock. Based on our review of publicly available filings as of February 12, 2015, our three largest stockholders other than GSK collectively owned approximately 38.2% of our outstanding capital stock. These stockholders could control the outcome of actions taken by us that require stockholder approval, including a transaction in which stockholders might receive a premium over the prevailing market price for their shares.

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Anti-takeover provisions in our charter and bylaws, in our rights agreement and in Delaware law could prevent or delay a change in control of our company.

Provisions of our Certificate of Incorporation and Bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include:

requiring supermajority stockholder voting to effect certain amendments to our Certificate of Incorporation and Bylaws;

restricting the ability of stockholders to call special meetings of stockholders;

prohibiting stockholder action by written consent; and

establishing advance notice requirements for nominations for election to the Board or for proposing matters that can be acted on by stockholders at meetings.

In addition, our Board has adopted a rights agreement that may prevent or delay a change in control of us. Further, some provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

#### ITEM 1B. UNRESOLVED STAFF COMMENTS

During the first quarter of 2015, the SEC staff has inquired regarding our historical and current recognition of the up-front and milestone payments received from GSK pursuant to the LABA Collaboration Agreement between 2002 and 2006, and the milestone fees paid by us to GSK in 2013 and 2014. We are currently engaged in discussions with the SEC staff regarding our recognition of the payments made and received under the LABA Collaboration Agreement. While we believe that our accounting related to the LABA Collaboration Agreement is appropriate and in accordance with U.S. generally accepted accounting principles, the SEC staff reserves the right to make further inquiries regarding our accounting treatment of the payments made and received under the LABA Collaboration Agreement. If the SEC staff disagrees with our accounting treatment, we may be required to restate our financial statements for prior periods.

#### ITEM 2. PROPERTIES

Our former headquarters consisted of 150,000 square feet of office and laboratory space leased in two buildings located in South San Francisco, California. Pursuant to the Assignment and Assumption of Lease agreement between us and Theravance Biopharma, we assigned and Theravance Biopharma assumed all of the rights and obligations under the existing lease agreements for these two buildings. We also entered into a Sublease Agreement with Theravance Biopharma to sublease 4,847 square feet of space in Building 951, which expires in May 2020. Management believes that this facility is suitable and adequate to meet the company's anticipated near-term needs. We anticipate that following the expiration of the sublease, additional or alternative space will be available at commercially reasonable terms. We do not own or lease any other properties.

#### ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

#### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

#### PART II

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

Price Range of Common Stock

Our common stock has been traded on The NASDAQ Global Market under the symbol "THRX" since October 5, 2004. The following table sets forth the high and low closing prices of our common stock on a per share basis for the periods indicated and as reported on The NASDAQ Global Market. On June 2, 2014, we completed the Spin-Off, in which each of our stockholders received one ordinary share of Theravance Biopharma for every 3.5 shares of our common stock. The closing price of Theravance Biopharma shares on the first day of regular trading was \$23.51, which represents an adjustment of \$6.72. The stock prices below have not been adjusted for the impact of the Spin-Off.

Calendar Quarter		High	Low			
2014						
Fourth Quarter	\$	18.64	\$	12.90		
Third Quarter	\$	30.40	\$	17.09		
Second Quarter	\$	31.33	\$	23.10		
First Quarter	\$	40.49	\$	30.17		
2013						
Fourth Quarter	\$	41.53	\$	33.74		
Third Quarter	\$	42.64	\$	35.82		
Second Quarter	\$	41.87	\$	22.53		
First Quarter	\$	24.84	\$	20.16		
Holders						

As of February 12, 2015, there were 141 stockholders of record of our common stock. As many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

#### Recent Sales of Unregistered Securities

In November 2014, we completed the sale of 832,456 shares of our common stock to an affiliate of GSK at a price of \$15.36 per share, resulting in aggregate gross proceeds of approximately \$12.8 million before deducting transaction expenses. Neither we nor the affiliate of GSK engaged any investment advisors with respect to the sale and no finders' fees were paid or will be paid to any party in connection with the sale. We issued and sold the shares in reliance upon an exemption from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended.

#### Dividends

During the third and fourth quarters of 2014, we paid aggregate cash dividends of \$57.0 million to our stockholders. On February 20, 2015, our board of directors declared a \$0.25 per share dividend for the first quarter of 2015 for a total of approximately \$29.2 million. The payment of, or continuation of, capital returns to stockholders is at the discretion of our board of directors and is dependent upon our financial condition, results of operations, capital requirements, general business conditions, tax treatment of capital returns, potential future contractual restrictions contained in credit agreements and other agreements and other factors deemed relevant by our board of directors.

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On June 2, 2014, we completed the Spin-Off, in which each of our stockholders received one ordinary share of Theravance Biopharma for every 3.5 shares of our common stock.

#### 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	exer	nted-average cise price of nding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))			
	(a)		<b>(b)</b>	(c)			
Equity compensation plans approved by security holders	6,097,875(1)	\$	22.68(3)	3,320,959(4)			
Equity compensation plans not approved by security holders	99,500(2)	\$	10.67(3)				
Total	6,197,375(1)(2	()\$	22.46(3)	3,320,959(4)			

- (1) Includes 5,322,719 shares issuable upon exercise of outstanding options and 775,156 shares issuable upon vesting of outstanding restricted stock units and restricted stock awards.
- (2) Includes 99,500 shares issuable upon exercise of outstanding options and no outstanding restricted stock units.
- (3)

  Does not take into account outstanding restricted stock units as these awards have no exercise price.
- (4) Includes 284,139 shares of common stock available under our Employee Stock Purchase Plan.

In May 2012, we adopted the 2012 Equity Incentive Plan ("2012 Plan"). The number of shares of our common stock originally reserved for issuance under the 2012 Plan is equal to 6,500,000 shares plus up to 12,667,411 additional shares that may be added to the 2012 Plan in connection with the forfeiture, repurchase, cash settlement or termination of awards outstanding under the 2004 Equity Incentive Plan ("2004 Plan"), the 2008 New Employee Equity Incentive Plan, the 1997 Stock Plan and the Long-Term Stock Option Plan (collectively, the "Prior Plans") as of December 31, 2011. In connection with the Spin-Off, outstanding stock options and other awards, along with the number of shares remaining available for future stock options and other awards, were adjusted pursuant to the anti-dilution provisions of the 2012 Plan and Prior Plans. An additional 1,373,201 shares were added to the 2012 Plan share reserve as a result of the anti-dilution adjustment of the outstanding stock options and other awards granted under the 2012 Plan and the shares remaining available for future grant under the 2012 Plan. The additional 993,130 shares added to the Prior Plans as a result of the anti-dilution provisions are included in the 12,667,411 additional shares that may be added to the 2012 Plan.

While a maximum of 12,667,411 shares could be added to the 2012 Plan from the Prior Plans, this assumes that all the awards outstanding on December 31, 2011 will be forfeited, repurchased, cash settled or terminated. Therefore, the actual number that may be added to the 2012 Plan share reserve will likely be lower. No additional awards were made after May 15, 2012 under the 2004 Plan. Stock options and stock appreciation rights ("SARs") will reduce the 2012 Plan reserve by one share for every share granted, and stock awards other than options and SARs granted will reduce the 2012 Plan share reserve by 1.45 shares for every share granted. The 2012 Plan share reserve was also reduced by

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the number of stock awards granted under the 2004 Plan on or after January 1, 2012, using the same ratios described.

The 2012 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, stock unit awards and SARs to our employees, non-employee directors and consultants. Stock options may be 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. 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 be forfeited at the end of three months or the expiration of the option, whichever is earlier. Additional information regarding stock-based compensation is included in Note 1, "Description of Operations and Summary of Significant Accounting Policies," and Note 6, "Stock-Based Compensation," to the consolidated financial statements appearing in this Annual Report on Form 10-K.

#### Stock Performance Graph

The graph set forth below compares the cumulative total stockholder return on our common stock for the period commencing on December 31, 2009 and ending on 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 December 31, 2009 in each of (1) our common stock, (2) the Nasdaq Composite Index, (3) the NASDAQ Pharmaceutical Index and (4) the NASDAQ Biotechnology Index, and assumes the reinvestment of dividends.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock. 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 Stock Performance Graph section shall not be deemed filed with the SEC and shall not be deemed incorporated by reference into any of those prior filings or into any future filings made by us under those statutes.

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## COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\*

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

\$100 invested on December 31, 2009 in stock or index, including reinvestment of dividends.

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#### 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 historical results are not necessarily indicative of the results to be expected in any future period.

	Year ended December 31,									
		2014		2013		2012		2011		2010
	(In thousands, except per share data)									
CONSOLIDATED STATEMENTS OF OPERATIONS DATA										
Net revenue	\$	8,433	\$	4,532	\$	5,613	\$	9,658	\$	9,827
Operating expenses:										
Research and development		7,498		9,038		8,153		8,560		7,959
General and administrative		34,864		24,289		22,606		22,382		19,745
Total operating expenses(1)		42,362		33,327		30,759		30,942		27,704