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 ý 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 royalt