

THERAVANCE INC  
Form 10-K  
February 26, 2013

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2012

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File No. 0-30319

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**THERAVANCE, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**94-3265960**  
(I.R.S. Employer  
Identification No.)

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

**94080**  
(Zip Code)

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

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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**

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

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

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

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

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

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

Large accelerated filer ☒

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a  
smaller reporting company)

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of the Common Stock on the Nasdaq Global Market on June 30, 2012 was \$940,773,069.

On February 14, 2013, there were 98,451,008 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 2013 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2012, are incorporated by reference into Part III of this Annual Report. Except as expressly incorporated by reference, the registrant's Proxy Statement shall not be deemed to be a part of this Annual Report on Form 10-K.

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**THERAVANCE, INC.**

**2012 Form 10-K Annual Report**

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**Special Note regarding Forward-Looking Statements**

*This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements involve substantial risks, uncertainties and assumptions. All statements in this Annual Report on Form 10-K, other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions, expectations and objectives could be forward-looking statements. The words "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. Factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited to, those discussed below in "Risk Factors" in Item 1A, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 and elsewhere in this Annual Report on Form 10-K. Our forward-looking statements in this Annual Report on Form 10-K are based on current expectations and we do not assume any obligation to update any forward-looking statements.*

**PART I**

**ITEM 1. BUSINESS**

**Overview**

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. We are focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain. Our key programs include: RELVAR or BREO (fluticasone furoate/vilanterol), ANORO (umeclidinium bromide/vilanterol) and MABA (Bifunctional Muscarinic Antagonist-Beta<sub>2</sub> Agonist), each partnered with GlaxoSmithKline plc (GSK), and our oral Peripheral Mu Opioid Receptor Antagonist program. By leveraging our proprietary insight of multivalency to drug discovery, we are pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need. Our headquarters are located at 901 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.

Our strategy focuses on the discovery, development and commercialization of medicines with superior efficacy, convenience, tolerability and/or safety. Our proprietary approach combines chemistry and biology to discover new product candidates using our expertise in multivalency. Multivalency refers to the simultaneous attachment of a single molecule to multiple binding sites on one or more biological targets. When compared to monovalency, whereby a molecule attaches to only one binding site, multivalency can significantly increase a compound's potency, duration of action and/or selectivity. Multivalent compounds generally consist of several individual small molecules, at least one of which is biologically active when bound to its target, joined by linking components. In addition, we believe that we can enhance the probability of successfully developing and commercializing medicines by identifying at least two structurally different product candidates, whenever practicable, in each therapeutic program.

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In total, our research and development expenses, including stock-based compensation expense, incurred for all of our therapeutic programs were \$117.9 million in 2012, \$103.6 million in 2011, and \$75.1 million in 2010.

**Our Programs**

Our drug discovery efforts are based on the principles of multivalency. Multivalency involves the simultaneous attachment of a single molecule to multiple binding sites on one or more biological targets. We have applied our expertise in multivalency to discover product candidates and lead compounds in a wide variety of therapeutic areas. We have conducted extensive research in both relevant laboratory and animal models to demonstrate that by applying the design principles of multivalency, we can achieve significantly stronger and more selective attachment of our compounds to a variety of intended biological targets. We believe that medicines that attach more strongly and selectively to their targets will be superior to many medicines by substantially improving potency, duration of action and/or safety.

Prior to entering into human clinical studies, a product candidate undergoes preclinical studies which include formulation development or safety testing in animal models. The table below summarizes the status of our most advanced product candidates for internal development or co-development.

The table below summarizes the status of our most advanced product candidates for internal development or co-development.

**Key:** **ADHD:** Attention Deficit Hyperactivity Disorder; **CNS:** Central Nervous System; **COPD:** Chronic Obstructive Pulmonary Disease; **FF:** Fluticasone Furoate; **GI:** Gastrointestinal; **LAMA:** Long-Acting Muscarinic Antagonist; **MABA:** Bifunctional Muscarinic Antagonist-Beta<sub>2</sub> Agonist; **UMEC:** Umeclidinium; **VI:** Vilanterol  
In the table above:

Development Status indicates the most advanced stage of development that has been completed or is in process.

Phase 1 indicates initial clinical safety testing in healthy volunteers, or studies directed toward understanding the mechanisms of action of the drug.

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Phase 2 indicates further clinical safety testing and preliminary efficacy testing in a limited patient population.

Phase 3 indicates evaluation of clinical efficacy and safety within an expanded patient population.

Filed indicates that a marketing application has been submitted to a regulatory authority and is under review.

We consider programs in which at least one compound has successfully completed a Phase 2a study showing efficacy and tolerability as having achieved Proof-of-Concept.

**Our Relationship with GlaxoSmithKline**

*LABA collaboration*

In November 2002, we entered into our long-acting beta<sub>2</sub> agonist (LABA) collaboration 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 is developing two combination products: (1) RELVAR or BREO (FF/VI), an investigational once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF) and (2) ANORO (UMEC/VI), a once-daily investigational medicine combining a long-acting muscarinic antagonist (LAMA), umeclidinium bromide (UMEC), with a LABA, VI. For the treatment of asthma, the collaboration is developing FF/VI. 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 2012 sales of approximately \$8.0 billion, and to compete with Symbicort® (formoterol and budesonide as a combination), which had reported 2012 sales of approximately \$3.2 billion. ANORO, 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 2011 sales of approximately \$4.2 billion.

In the event that a product containing VI is successfully developed and commercialized, we will be obligated to make milestone payments to GSK which could total as much as \$220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. Of these potential milestone payments, we estimate up to \$140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014. We are entitled to annual royalties from GSK of 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, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS combination product at the time that the first other LABA combination is launched, then the royalties described above for the LABA/ICS combination medicine would be applicable.

*2004 Strategic Alliance*

In March 2004, we entered into our strategic alliance with GSK. Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from certain of 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

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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.

In 2005, GSK licensed our bifunctional muscarinic antagonist-beta<sub>2</sub> agonist (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 remain the same with respect to '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, we are entitled to receive royalties from GSK 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 only as a combination product, such as a MABA/ICS, 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, we are entitled to receive royalties from GSK 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, 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, we could earn total milestone payments of up to \$125.0 million for a single-agent medicine and up to \$250.0 million for both a single-agent and a combination medicine. If a MABA medicine containing an Additional MABA is successfully developed and commercialized in multiple regions of the world, we could earn total milestone payments of up to \$129.0 million. GSK has no further option rights on any of our research or development programs under the strategic alliance.

#### *Purchases of Common Stock by GSK*

Prior to 2012 affiliates of GSK purchased an aggregate of 15,725,953 shares of our common stock. On May 16, 2012, we issued and Glaxo Group Limited, an affiliate of GSK, purchased 10,000,000 shares of our common stock at a price of \$21.2887 per share, for a total investment of \$212.9 million.

In addition, in 2012 Glaxo Group Limited purchased 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 GSK, GlaxoSmithKline LLC, Glaxo Group Limited and us (governance agreement), for a total investment of \$16.8 million as follows:

	<b>Through December 31, 2012</b>	
	<b>Common Stock</b>	<b>Aggregate</b>
	<b>Shares</b>	<b>Amounts</b>
	<b>Purchased</b>	<b>(in millions)</b>
<i>Purchase dates</i>		
February 14, 2012	88,468	\$ 1.6
August 3, 2012	316,334	\$ 8.9
November 2, 2012	280,348	\$ 6.3

As of February 14, 2013, GSK beneficially owned approximately 26.8% of our outstanding capital stock.

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**Program Highlights**

Respiratory Programs with GlaxoSmithKline plc (GSK)

*RELVAR or BREO (Fluticasone Furoate/Vilanterol, FF/VI)*

FF/VI is an investigational once-daily inhaled ICS/ LABA combination treatment, comprising fluticasone furoate (FF) and vilanterol (VI), for the maintenance treatment of patients with COPD and patients with asthma. FF/VI is administered by a new dry powder inhaler called ELLIPTA . RELVAR (FF/VI for the European Union (EU) and Japan), BREO (FF/VI for the United States (U.S.)), and ELLIPTA (for the EU, U.S. and Japan) are proposed brand names and use of these brand names has not yet been approved by any regulatory authority.

In September 2012, GSK and Theravance announced that the New Drug Application (NDA) for FF/VI for patients with COPD was accepted by the U.S. Food and Drug Administration (FDA), indicating that the application is sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act goal date was confirmed as May 12, 2013 and the FDA's Pulmonary-Allergy Drugs Advisory Committee is scheduled to discuss the NDA for BREO for COPD at a meeting on March 7, 2013. GSK and Theravance also reported that the Marketing Authorization Application for FF/VI for COPD and asthma was validated by the European Medicines Agency (EMA) and GSK also submitted a Japanese New Drug Application for FF/VI for patients with COPD and asthma in September 2012.

*ANORO (Umeclidinium Bromide/Vilanterol, UMEC/VI)*

UMEC/VI is a once-daily investigational medicine, combining a LAMA, UMEC, and a LABA, VI, for the maintenance treatment of patients with COPD. UMEC/VI is administered by the ELLIPTA dry powder inhaler.

In December 2012, GSK and Theravance announced the submission to the FDA of a NDA for UMEC/VI for patients with COPD and in February 2013, GSK and Theravance announced that the NDA was accepted by the FDA, indicating that the application is sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act goal date was confirmed as December 18, 2013. In January 2013, GSK and Theravance announced the submission of a regulatory application to the EMA for UMEC/VI for patients with COPD, which has now been validated for assessment by the EMA. Regulatory submissions for UMEC/VI are planned in other countries during the course of 2013.

*Inhaled Bifunctional Muscarinic Antagonist-Beta<sub>2</sub> Agonist (MABA)*

GSK961081 ('081) is an investigational, single molecule bifunctional bronchodilator with both muscarinic antagonist and beta<sub>2</sub> receptor agonist activities. Based on the results from the Phase 2b study, GSK and Theravance plan to advance '081 monotherapy into Phase 3 in 2013 and the '081/FF combination into Phase 3-enabling studies shortly.

Bacterial Infections Program

*VIBATIV® (telavancin)*

In November, 2012, Theravance announced a favorable outcome of the FDA's Anti-Infective Drugs Advisory Committee meeting on VIBATIV® (telavancin) for the treatment of nosocomial pneumonia (NP) due to susceptible isolates of Gram-positive microorganisms. Theravance remains in dialogue with the FDA on the NP indication and is working toward re-establishing consistent product supply.



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Central Nervous System (CNS)/Pain Program

*Oral Peripheral Mu Opioid Receptor Antagonist TD-1211*

TD-1211 is an investigational once-daily, orally administered, peripherally selective, multivalent inhibitor of the mu opioid receptor designed with a goal of alleviating gastrointestinal side effects of opioid therapy without affecting analgesia. In July 2012, Theravance announced positive topline results from the Phase 2b Study 0084, the key study in the Phase 2b program evaluating TD-1211 as potential treatment for chronic, non-cancer pain patients with opioid-induced constipation. The Phase 2b program consisted of three studies (0074, 0076 and 0084) designed to evaluate doses and dosing regimens for Phase 3. We are currently evaluating our Phase 3 strategy due to potentially evolving FDA requirements for this class of drug.

*Monoamine Reuptake Inhibitor TD-9855*

TD-9855 is an investigational norepinephrine and serotonin reuptake inhibitor for the treatment of central nervous system conditions such as Attention-Deficit/Hyperactivity Disorder (ADHD) and chronic pain. TD-9855 is being evaluated in an ongoing Phase 2 safety and efficacy study in adults with ADHD. In addition, we initiated a Phase 2 study with TD-9855 in patients with fibromyalgia in December 2012.

Theravance Respiratory Program

*Long-Acting Muscarinic Antagonist TD-4208*

In November 2011, we announced positive topline results from a Phase 2a single-dose COPD study of TD-4208, an investigational inhaled LAMA discovered by Theravance. In this study, TD-4208 met the primary endpoint by demonstrating a statistically significant mean change from baseline in peak forced expiratory volume in one second (FEV1) compared to placebo, and was generally well tolerated. In December 2012, we initiated a Phase 2b study to evaluate the safety and pharmacokinetics of multiple doses of TD-4208.

GI Motility Dysfunction Program

*Velusetrag*

Velusetrag, an oral, investigational medicine dosed once-daily, is a highly selective agonist with high intrinsic activity at the human 5-HT4 receptor. In October 2012, we entered into an exclusive development and commercialization agreement with Alfa Wassermann for velusetrag, our lead compound in the 5-HT4 program, covering the EU, Russia, China, Mexico and certain other countries. In January 2013, Theravance and Alfa Wassermann announced the initiation of a Phase 2 proof-of-concept study to evaluate the efficacy and safety of velusetrag for the treatment of patients with diabetic or idiopathic gastroparesis.

**Multivalency**

Our proprietary approach combines chemistry and biology to discover new product candidates using our expertise in multivalency. Multivalency refers to the simultaneous attachment of a single molecule to multiple binding sites on one or more biological targets. When compared to monovalency, whereby a molecule attaches to only one binding site, multivalency can significantly increase a compound's potency, duration of action and/or selectivity. Multivalent compounds generally consist of several individual small molecules, at least one of which is biologically active when bound to its target, joined by linking components.

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Our approach is based on an integration of the following insights:

many targets have multiple binding sites and/or exist in clusters with similar or different targets;

biological targets with multiple binding sites and/or those that exist in clusters lend themselves to multivalent drug design;

molecules that simultaneously attach to multiple binding sites can exhibit considerably greater potency, duration of action and/or selectivity than molecules that attach to only one binding site; and

greater potency, duration of action and/or selectivity provides the basis for superior therapeutic effects, including enhanced convenience, tolerability and/or safety compared to conventional drugs.

**Our Strategy**

Our objective is to discover, develop and commercialize new medicines with superior efficacy, convenience, tolerability and/or safety. The key elements of our strategy are to:

***Apply our expertise in multivalency to discover and develop superior medicines in areas of significant unmet medical need.*** We intend to continue to concentrate our efforts on discovering and developing product candidates where:

existing drugs have levels of efficacy, convenience, tolerability and/or safety that are insufficient to meet an important medical need;

we believe our expertise in multivalency can be applied to create superior product candidates that are more potent, longer acting and/or more selective than currently available medicines;

there are established animal models that can be used to provide us with evidence as to whether our product candidates have the potential to provide superior therapeutic benefits relative to current medicines; and

there is a relatively large commercial opportunity.

***Identify two structurally different product candidates in each therapeutic program whenever practicable.*** We believe that we can increase the likelihood of successfully bringing superior medicines to market by identifying, whenever practicable, two product candidates for development in each program. Our second product candidates are typically in a different structural class from the first product candidate. Applying this strategy can reduce our dependence on any one product candidate and provide us with the potential opportunity to commercialize two compounds in a given area.

***Partner with pharmaceutical companies.*** Our strategy is to seek collaborations with pharmaceutical companies to accelerate development and commercialization of our product candidates at the strategically appropriate time. The LABA collaboration and our strategic alliance with GSK are examples of these types of partnerships.

***Leverage the extensive experience of our people.*** We have an experienced senior management team with many years of experience discovering, developing and commercializing new medicines with companies such as Bristol-Myers Squibb Company, Gilead Sciences, Merck & Co. and Pfizer.

***Improve, expand and protect our technical capabilities.*** We have created a substantial body of know-how and trade secrets in the application of our multivalent approach to drug discovery. We believe this is a significant asset that distinguishes us from our competitors. We expect to continue to make substantial investments in drug discovery using multivalency and other technologies to maintain what we believe are our competitive advantages.



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**Manufacturing**

Though we have limited in-house active pharmaceutical ingredient (API) production capabilities, we rely primarily on a number of third parties, including contract manufacturing organizations and our collaborative partners, to produce our active pharmaceutical ingredient and drug product. Manufacturing of RELVAR or BREO (FF/VI) and ANORO (UMEC/VI) and for the MABA program is handled by GSK.

We believe that we have in-house expertise to manage a network of third party manufacturers. We believe that we will be able to continue to negotiate third-party manufacturing arrangements on commercially reasonable terms and that it will not be necessary for us to obtain internal manufacturing capacity in order to develop or commercialize our products. However, if we are unable to obtain contract manufacturing or obtain such manufacturing on commercially reasonable terms, or if manufacturing is interrupted at one of our suppliers, whether due to regulatory or other reasons, we may not be able to develop or commercialize our products as planned. Due to manufacturing issues at the previous single-source supplier of VIBATIV® drug product, VIBATIV® is currently subject to critical product shortages and we currently do not have sufficient finished drug product inventories to commercialize VIBATIV®. In May 2012, we entered into a Technology Transfer and Supply Agreement with Hospira Worldwide, Inc. (Hospira) for VIBATIV® drug product supply. We must obtain regulatory approval for VIBATIV® drug product manufactured at Hospira's facility before any such product may be sold, and this regulatory approval process could extend through mid-2013 or beyond.

**Government Regulation**

The development and commercialization of VIBATIV® and our product candidates and our ongoing research are subject to extensive regulation by governmental authorities in the United States and other countries. Before marketing in the United States, any medicine we develop must undergo rigorous preclinical studies and clinical studies and an extensive regulatory approval process implemented by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act. Outside the United States, our ability to market a product depends upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical studies, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, however, we will be permitted to commercialize our medicines only if the appropriate regulatory authority is satisfied that we have presented adequate evidence of the safety, quality and efficacy of our medicines.

Before commencing clinical studies in humans in the United States, we must submit to the FDA an Investigational New Drug application that includes, among other things, the results of preclinical studies. If the FDA accepts the Investigational New Drug submission, clinical studies are usually conducted in three phases and under FDA oversight. These phases generally include the following:

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

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

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

The results of product development, preclinical studies and clinical studies must be submitted to the FDA as part of a new drug application, or NDA. The NDA also must contain extensive

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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 8 months for applications that are granted priority review and 12 months 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 we obtain regulatory approval for a medicine, this 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 current Good Manufacturing Practice (cGMP) regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packaging of a medicine. The regulations are intended to make sure that a medicine is safe for use, and that it has the ingredients and strength it claims to have. Discovery of previously unknown problems with a medicine, manufacturer or facility may result in restrictions on the medicine or manufacturer, including costly recalls or withdrawal of the medicine from the market.

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

Outside the United States our ability to market our products will also depend on receiving marketing authorizations from the appropriate regulatory authorities. Risks similar to those associated with FDA approval described above exist with the regulatory approval processes in other countries.

**Patents and Proprietary Rights**

We will be able to protect our technology from unauthorized use by third parties only to the extent that our technology is covered by valid and enforceable patents or is effectively maintained as trade secrets. Our success in the future will depend in part on obtaining patent protection for our product candidates. Accordingly, patents and other proprietary rights are essential elements of our business. Our policy is to seek in the United States and selected foreign countries patent protection for novel technologies and compositions of matter that are commercially important to the development of our

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business. For proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery process that involve proprietary know-how and technology that is not covered by patent applications, we rely on trade secret protection and confidentiality agreements to protect our interests. We require all of our employees, consultants and advisors to enter into confidentiality agreements. Where it is necessary to share our proprietary information or data with outside parties, our policy is to make available only that information and data required to accomplish the desired purpose and only pursuant to a duty of confidentiality on the part of those parties.

As of December 31, 2012, we owned 329 issued United States patents and 1,110 granted foreign patents, as well as additional pending United States patent applications and foreign patent applications. The claims in these various patents and patent applications are directed to compositions of matter, including claims covering product candidates, lead compounds and key intermediates, pharmaceutical compositions, methods of use and processes for making our compounds along with methods of design, synthesis, selection and use relevant to multivalency in general and to our research and development programs in particular. In particular, we own the following U.S. patents which are listed in the *FDA Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) for telavancin: U.S. Patent No. 6,635,618 B2, expiring on September 22, 2021; U.S. Patent No. 6,858,584 B2, expiring on August 24, 2022; U.S. Patent No. 6,872,701 B2, expiring on June 5, 2021; U.S. Patent No. 7,008,923 B2, expiring on May 6, 2021; U.S. Patent No. 7,208,471 B2, expiring on May 1, 2021; U.S. Patent No. 7,351,691 B2, expiring on May 1, 2021; U.S. Patent No. 7,531,623 B2, expiring on January 1, 2027; U.S. Patent No. 7,544,364 B2, expiring on May 1, 2021; and U.S. Patent No. 7,700,550 B2, expiring on May 1, 2021. On October 15, 2010, we filed patent term extension (PTE) applications in the United States Patent and Trademark Office (USPTO) for U.S. Patent Nos. 6,635,618 B2; 6,872,701 B2; and 7,208,471 B2. These PTE applications are currently pending and if granted, we will be permitted to extend the term of one of these patents for the period determined by the USPTO.

United States issued patents and foreign patents generally expire 20 years after filing. The patent rights relating to telavancin owned by us currently consist of United States patents that expire between 2019 and 2027, additional pending United States patent applications and counterpart patents and patent applications in a number of jurisdictions, including Europe. Nevertheless, issued patents can be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products and threaten our ability to commercialize our product candidates. Our patent position, similar to other companies in our industry, is generally uncertain and involves complex legal and factual questions. To maintain our proprietary position we will need to obtain effective claims and enforce these claims once granted. It is possible that, before any of our products can be commercialized, any related patent may expire or remain in force only for a short period following commercialization, thereby reducing any advantage of the patent. Also, we do not know whether any of our patent applications will result in any issued patents or, if issued, whether the scope of the issued claims will be sufficient to protect our proprietary position.

We have entered into a License Agreement with Janssen Pharmaceutica (Janssen) pursuant to which we have licensed rights under certain patents owned by Janssen covering an excipient used in the formulation of telavancin. We believe that the general and financial terms of the agreement with Janssen are ordinary course terms. Pursuant to the terms of this license agreement, we are obligated to pay royalties and milestone payments to Janssen based on any commercial sales of telavancin. The license is terminable by us upon prior written notice to Janssen or upon an uncured breach or a liquidation event of one of the parties.

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**Competition**

Our objective is to discover, develop and commercialize new medicines with superior efficacy, convenience, tolerability and/or safety. We expect that any medicines that we commercialize with our collaborative partners or on our own will compete with existing and future market-leading medicines.

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

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

attract qualified scientific, product development and commercial personnel;

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

obtain required regulatory approvals; and

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

*LABA Collaboration with GSK.* We anticipate that, if approved, any product from our LABA collaboration with GSK, including RELVAR or BREO (FF/VI) and ANORO (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, and Spiriva® (tiotropium) marketed by Boehringer-Ingelheim and Pfizer. Onbrez®/Arcapta® (indacaterol) is marketed in multiple international markets by Novartis and was launched in the United States in 2012. For markets outside of the United States, Novartis is developing indacaterol in combination with an ICS (mometasone). In addition, indacaterol combined with a muscarinic antagonist is being developed by Novartis and a European regulatory submission was made in 2012. Boehringer-Ingelheim is developing a combination product with tiotropium and the long-acting beta agonist olodaterol for the treatment of 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 product from our LABA collaboration.

*VIBATIV® (telavancin).* VIBATIV® competes with vancomycin, a generic drug that is manufactured by a variety of companies, as well as other drugs marketed to treat complicated skin and skin structure infections caused by Gram-positive bacteria. Currently marketed products include but are not limited to Cubicin® (daptomycin) marketed by Cubist Pharmaceuticals, Zyvox® (linezolid) and Tygacil® (tigecycline) both marketed by Pfizer, and Teflaro® (ceftaroline) marketed by Forest Laboratories. To compete effectively with these medicines, and in particular with the relatively inexpensive generic option of vancomycin, we will need to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, VIBATIV® is preferable to vancomycin and other existing or subsequently-developed anti-infective drugs in certain clinical situations.

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

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**Employees**

As of December 31, 2012, we had 226 employees, of which 174 were engaged primarily in research and development activities. None of our employees are represented by a labor union. We consider our employee relations to be good.

**Available Information**

Our Internet address is [www.theravance.com](http://www.theravance.com). Our investor relations website is located at <http://ir.theravance.com>. We make available free of charge on our investor relations website under "SEC Filings" our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, our directors' and officers' Section 16 Reports and any amendments to those reports as soon as reasonably practicable after filing or furnishing such materials to the U.S. Securities and Exchange Commission (SEC). The information found on our website is not part of this or any other report that we file with or furnish to the SEC. Theravance 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**

In addition to the other information in this Annual Report on Form 10-K, the following risk factors should be considered carefully in evaluating our business and us.

**Risks Related to our Business**

*If FF/VI receives an unfavorable outcome at the FDA's Pulmonary-Allergy Drugs Advisory Committee in March 2013, the FDA does not approve FF/VI on the May 12, 2013 PDUFA date or regulatory authorities determine that the Phase 3 programs for FF/VI in asthma and/or chronic obstructive pulmonary disease (COPD) do not demonstrate adequate safety and efficacy, the continued development of FF/VI may be significantly delayed, it may not be approved by 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.*

During the first quarter of 2012, we announced the completion of, and reported certain top-line data from, the Phase 3 registrational program for FF/VI in COPD and asthma. In July 2012, GSK submitted regulatory applications for FF/VI (proposed brand name RELVAR ) in Europe for both COPD and asthma, and for FF/VI (proposed brand name BREO ) in the U.S. for COPD and both submissions have been accepted for review. In September 2012, GSK announced that it was commencing an additional Phase 3 study to complete the U.S. asthma filing package. The Phase 3b program for FF/VI in COPD commenced in February 2011. Any adverse developments or results or perceived adverse developments or results with respect to the FF/VI regulatory submissions, the asthma Phase 3 study or the Phase 3b program will significantly harm our business and could cause the price of our securities to 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 the FDA and/or other regulatory authorities may determine that additional clinical studies are required;

inability to gain, or delay in gaining, regulatory approval for the new ELLIPTA investigational dry powder inhaler used in these programs;

safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs. For example, GSK is investigating seven cases of fatal pneumonia in the Phase 3 FF/VI COPD program, six of which were at a dose that is higher than the dose being pursued for approval and a majority of which occurred at one clinical site;



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safety, efficacy or other concerns arising from clinical or non-clinical studies with umeclidinium bromide/vilanterol (proposed brand name ANORO ) (UMEC/VI) having to do with the LABA VI, which is also a component of FF/VI;

regulatory authorities determining that the Phase 3 program in asthma or COPD raises safety concerns or does not demonstrate adequate efficacy;

any unfavorable announcements made, or comments emanating from, the FDA's Pulmonary-Allergy Drugs Advisory Committee meeting in March 2013; or

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 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, on March 10 and 11, 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 United States for FF/VI and increase the overall risk for FF/VI for the treatment of asthma in the United States.

***If regulatory authorities determine that the Phase 3 program for UMEC/VI for the treatment of COPD does not demonstrate adequate safety and efficacy, or the FDA does not approve UMEC/VI on the December 18, 2013 PDUFA date, continued development of UMEC/VI will be significantly delayed or terminated, our business will be harmed, and the price of our securities could fall.***

The Phase 3 program for UMEC/VI with the combination of a LAMA umeclidinium bromide (UMEC), and a LABA, VI, for the treatment of COPD commenced in February 2011. In July 2012, GSK and we reported top-line results from four pivotal studies in this Phase 3 program and in August 2012, GSK and we announced the completion of this Phase 3 program and reported certain top-line data from the remaining studies in the registrational program. GSK submitted regulatory applications for UMEC/VI (proposed brand name ANORO ) for the treatment of COPD in December 2012 in the United States and in January 2013 in Europe and both submissions have been accepted for review. GSK plans to make regulatory submissions in other countries during the course of 2013. Any adverse developments or results or perceived adverse developments or results with respect to these regulatory submissions or the UMEC/VI program will significantly harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

the FDA and/or other regulatory authorities determining that additional clinical studies are required with respect to the Phase 3 program in COPD;

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inability to gain, or delay in gaining, regulatory approval for the new ELLIPTA<sup>®</sup> investigational dry powder inhaler used in the program;

safety, efficacy or other concerns arising from clinical or non-clinical studies in this program;

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

regulatory authorities determining that the Phase 3 program in COPD raises safety concerns or does not demonstrate adequate efficacy; or

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

***If the MABA program for the treatment of COPD does not demonstrate safety and efficacy, the MABA program will be significantly delayed or terminated, our business will be harmed, and the price of our securities could fall.***

The lead compound, GSK961081 ('081), in the bifunctional muscarinic antagonist-beta<sub>2</sub> agonist (MABA) program with GSK has completed a Phase 2b study, a Phase 1 study in combination with fluticasone propionate (FP), an inhaled corticosteroid (ICS), and a number of Phase 3-enabling non-clinical studies. Based on the results from the Phase 2b study, GSK and Theravance plan to advance '081 monotherapy into Phase 3 in 2013 and the '081/FF combination into Phase 3-enabling studies shortly. Any adverse developments or results or perceived adverse developments or results with respect to these studies will harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

the FDA and/or other regulatory authorities determining that any of these studies do not demonstrate adequate safety or efficacy, or that additional non-clinical or clinical studies are required with respect to the MABA program;

inability to gain, or delay in gaining, regulatory approval for the investigational dry powder inhaler used in the program;

safety, efficacy or other concerns arising from clinical or non-clinical studies in this program; or

any change in FDA policy or guidance regarding the use of MABAs to treat COPD.

***If VIBATIV<sup>®</sup> is not approved for nosocomial pneumonia (NP) in the United States or is approved but is subject to restrictive labeling, the commercialization of VIBATIV<sup>®</sup> in the United States may continue to be adversely affected and the price of our securities could fall.***

Our first NDA, for VIBATIV<sup>®</sup> (telavancin) for the treatment of complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria in adult patients, was approved by the FDA in September 2009. In January 2009, we submitted a second telavancin NDA to the FDA for the NP indication based on data from our two Phase 3 studies referred to as the ATTAIN studies. These studies were conducted in accordance with the then current draft FDA guidelines and met their primary efficacy endpoint of clinical cure. During the fourth quarter of 2010 the FDA issued new draft guidance for antibacterial clinical trial design for the treatment of NP with a focus on mortality as the primary efficacy endpoint. In late 2010, we received a Complete Response Letter from the FDA indicating that the ATTAIN studies do not meet the new draft guidance and that additional clinical studies will be required for approval. While we do not plan to conduct additional clinical studies for NP, we have continued to engage with the FDA concerning the NP NDA. In late November 2012, the FDA's Anti-Infective Drugs Advisory Committee discussed the NP NDA for VIBATIV<sup>®</sup> and voted 6 (yes) and 9 (no) that the results of the totality of the data presented provided substantial evidence of the safety and effectiveness of VIBATIV<sup>®</sup> for NP and voted 13 (yes) and 2 (no) that the

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results provided substantial evidence of the safety and effectiveness of VIBATIV® for the treatment of NP when other alternatives are not suitable. The NP NDA remains under review by the FDA. Any adverse developments or perceived adverse developments with respect to our NP NDA could adversely affect the prospects of VIBATIV® and could cause the price of our securities to fall. Lack of FDA approval for use of VIBATIV® to treat NP has adversely affected and may continue to adversely affect commercialization of this medicine in the United States.

***Our collaboration agreement for VIBATIV® was terminated in early 2012, VIBATIV® was returned to us, and if we cannot locate a suitable commercialization partner we will need to develop the capability to market, sell and distribute the product.***

Generally, our strategy is to engage pharmaceutical or other healthcare companies with an existing sales and marketing organization and distribution system to market, sell and distribute our products. We may not be able to establish these sales and distribution relationships on acceptable terms, or at all. For any of our product candidates that receive regulatory approval in the future and are not covered by our current agreements with GSK or another partner, we will need a partner in order to commercialize such products unless we establish independent sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure. VIBATIV® was returned to us by Astellas in January 2012, and if we cannot locate a suitable commercialization partner in the United States for this product, we intend to reintroduce it in the United States ourselves. At present, we have no sales or distribution personnel and a limited number of marketing personnel. The risks of commercializing VIBATIV® in the United States without a partner include:

significant costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability, which costs and expenses are likely to exceed any product revenue from VIBATIV® for several years;

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

the unproven ability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products; and

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

If we are not able to partner VIBATIV® with a third party with marketing, sales and distribution capabilities and if we are not successful in recruiting sales and marketing personnel or in building an internal sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability, we will have difficulty commercializing VIBATIV®, which would adversely affect our business and financial condition and which could cause the price of our securities to fall.

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

Each of our product candidates must undergo extensive non-clinical and clinical studies as a condition to regulatory approval. Non-clinical and clinical studies are expensive, take many years to complete and study results may lead to delays in further studies or decisions to terminate programs. For example, we had planned to commence the Phase 2b study in our MABA program with GSK in 2009, but the program was delayed until late 2010.

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The commencement and completion of clinical studies for our product candidates may be delayed and programs may be terminated due to many factors, including, but not limited to:

lack of effectiveness of product candidates during clinical studies;

adverse events, safety issues or side effects relating to the product candidates or their formulation into medicines;

inability to raise additional capital in sufficient amounts to continue our development programs, which are very expensive;

the need to sequence clinical studies as opposed to conducting them concomitantly in order to conserve resources;

our inability to enter into partnering arrangements relating to the development and commercialization of our programs and product candidates;

our inability or the inability of our collaborators or licensees to manufacture or obtain from third parties materials sufficient for use in non-clinical and clinical studies;

governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;

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

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

difficulty in maintaining contact with patients after treatment, resulting in incomplete data;

varying regulatory requirements or interpretations of data among the FDA and foreign regulatory authorities; and

a regional disturbance where we or our collaborative partners are enrolling patients in clinical trials, such as a pandemic, terrorist activities or war, political unrest or a natural disaster.

***If our product candidates that we develop on our own or through collaborative partners are not approved by regulatory authorities, including the FDA, we will be unable to commercialize them.***

The FDA must approve any new medicine before it can be marketed and sold in the United States. We must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. We will not obtain this approval for a product candidate unless and until the FDA approves a NDA. The processes by which regulatory approvals are obtained from the FDA to market and sell a new product are complex, require a number of years and involve the expenditure of substantial resources. In order to market our medicines in foreign jurisdictions, we must obtain separate regulatory approvals in each country. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Conversely, failure to obtain approval in one or more jurisdictions may make approval in other jurisdictions more difficult.



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

Frequently, product candidates that have shown promising results in early preclinical or clinical studies have subsequently suffered significant setbacks or failed in later clinical or non-clinical studies. In addition, clinical and non-clinical studies of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates. If these studies are substantially delayed or fail to prove the safety and effectiveness of our product candidates in development, we may not receive regulatory approval of any of these product candidates and our business and financial condition will be materially harmed and the price of our securities may fall.

***If any product candidates, in particular those in any respiratory program with GSK, are determined to be unsafe or ineffective in humans, our business will be adversely affected and the price of our securities could fall.***

Although our first product, VIBATIV®, is approved in the U.S. and Canada, none of our other product candidates have been approved by regulatory authorities. We are uncertain whether any of our other product candidates and our collaborative partners' product candidates will prove effective and safe in humans or meet applicable regulatory standards. In addition, our approach to applying our expertise in multivalency to drug discovery may not result in the creation of successful medicines. The risk of failure for our product candidates is high. For example, in late 2005, we discontinued our overactive bladder program based upon the results of our Phase 1 studies with compound TD-6301, and GSK discontinued development of TD-5742, the first LAMA compound licensed from us, after completing a single-dose Phase 1 study. In addition, although we believe the results of our Phase 2b program with TD-1211, our investigational mu-opioid antagonist, support progression into Phase 3 development, the FDA appears to be exploring whether there is evidence of a potential cardiovascular class effect related to opioid withdrawal associated with mu-opioid antagonists. Accordingly, we are currently evaluating our Phase 3 strategy due to the potentially evolving FDA requirements in this area. The data supporting our drug discovery and development programs is derived solely from laboratory experiments, non-clinical studies and clinical studies. A number of other compounds remain in the lead identification, lead optimization, preclinical testing or early clinical testing stages.

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 an increasingly 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 (REMS) at the FDA's discretion. These laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's review and approval of our and our collaborative partner's product candidates.

***There currently is no reliable manufacturer for VIBATIV® drug product supply and our business will be harmed if a reliable alternate source of VIBATIV® drug product is not qualified and engaged on a timely basis; we also rely on a single source of supply for a number of our product candidates, and our business will be harmed if any of these other single-source manufacturers are not able to satisfy demand and alternative sources are not available***

During the fourth quarter of 2011, the third party manufacturer of VIBATIV® drug product notified the FDA of an ongoing investigation related to its production equipment and processes. The

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notification included all products manufactured at the third party manufacturer's facility which remain within expiry, including batches of manufactured but unreleased VIBATIV®. In November 2011, Astellas (our former VIBATIV® collaboration partner) voluntarily placed a hold on distribution of VIBATIV® to wholesalers, and cancelled pending orders for VIBATIV® with this manufacturer. VIBATIV® drug product previously manufactured by this manufacturer will not become available for sale in the U.S. unless and until the batches are released. Similarly, our purchase orders for this inventory cannot be fulfilled unless and until the batches are released. In August 2011 the third party manufacturer of VIBATIV® drug product announced its intention to transition out of the contract manufacturing services business over the next several years, and in January 2013 it announced that it has voluntarily entered into a consent decree with the FDA that relates to current Good Manufacturing Practice (cGMP) requirements. Attached to the consent decree is a list of specified drugs that the third party manufacturer is permitted to continue to manufacture and distribute. VIBATIV® currently is not included on this list and therefore it is unlikely that we will be able to use the previously manufactured drug product for commercial supply. Additional VIBATIV® drug product will need to be manufactured to meet U.S. demand as well as demand from the E.U. and Canada. In May 2012 the European Commission suspended marketing authorization for VIBATIV® because the single-source VIBATIV® drug product supplier at that time did not meet cGMP requirements for the manufacture of VIBATIV®. No VIBATIV® drug product intended to meet E.U. specifications has as yet been manufactured.

If the VIBATIV® drug product manufactured by this third party manufacturer is not released in the near future, the commercialization of VIBATIV® in the U.S. will continue to be adversely affected, and if supplemental or alternative commercial manufacture of VIBATIV® drug product cannot be arranged on a timely basis, the commercial introduction of VIBATIV® in the E.U. and Canada will be further delayed. In each such case, our business will be harmed and the price of our securities could fall. In May 2012, we entered into a Technology Transfer and Supply Agreement with Hospira and technology transfer activities are in process. We must obtain regulatory approval for VIBATIV® drug product manufactured at Hospira's facility before any such product may be sold, and this regulatory approval process could extend through mid-2013 and beyond.

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

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

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Our manufacturing strategy presents the following additional risks:

because of the complex nature of our compounds, our manufacturers may not be able to successfully manufacture our APIs and/or drug products in a cost effective and/or timely manner and changing manufacturers for our APIs or drug products could involve lengthy technology transfer, validation and regulatory qualification activities for the new manufacturer. For example, we are in the process of transitioning to a new drug product manufacturer for VIBATIV®, and delays in technology transfer, validation and regulatory qualification activities could be encountered;

the processes required to manufacture certain of our APIs and drug products are specialized and available only from a limited number of third-party manufacturers;

some of the manufacturing processes for our APIs and drug products have not been scaled to quantities needed for continued clinical studies or commercial sales, and delays in scale-up to commercial quantities could delay clinical studies, regulatory submissions and commercialization of our product candidates; and

because some of the third-party manufacturers are located outside of the U.S., there may be difficulties in importing our APIs and drug products or their components into the U.S. as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging.

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

Even if we receive regulatory approval for our product candidates, this approval may include limitations on the indicated uses for which we can market our medicines or the patient population that may utilize our medicines, which may limit the market for our medicines or put us at a competitive disadvantage relative to alternative therapies. For example, VIBATIV®'s U.S. labeling for cSSSI contains a boxed warning regarding the risks of use of VIBATIV® during pregnancy. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. In addition, the VIBATIV® labeling that was approved for the E.U. in 2011 specifies that VIBATIV® should be used only in situations where it is known or suspected that other alternatives are not suitable. These restrictions could make it more difficult to market VIBATIV®. In May 2012 the European Commission suspended marketing authorization for VIBATIV® because the single-source VIBATIV® drug product supplier at that time did not meet the cGMP requirements for the manufacture of VIBATIV®. With VIBATIV® approved in certain countries, we are subject to continuing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of promotion and marketing.

In addition, the manufacturing, labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for the approved product remain subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with an approved product in the U.S. or overseas or at contract manufacturers' facilities, a regulatory authority may impose restrictions on the product, the contract manufacturers or on us, including requiring us to reformulate the product, conduct additional clinical studies, change the labeling of the product, withdraw the product from the market or require the contract manufacturer to implement changes to its facilities. For example, during the fourth quarter of 2011, the third party manufacturer of VIBATIV® drug product notified the FDA of an ongoing investigation related to its production equipment and processes. The notification included all products manufactured at the third party manufacturer's facility which remain within expiry, including batches of manufactured but unreleased VIBATIV®. Astellas (our former VIBATIV® collaboration partner) subsequently placed a voluntary hold on distribution of VIBATIV® to wholesalers and cancelled pending orders for VIBATIV® with this manufacturer. With this supply



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interruption and the termination of our VIBATIV® collaboration agreement with Astellas, commercialization of VIBATIV® has essentially stopped, we have experienced a significant drop in the sales of the product and the reputation of VIBATIV® in the marketplace will likely suffer.

We are also subject to regulation by regional, national, state and local agencies, including the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies with respect to VIBATIV®, as well as governmental authorities in those foreign countries in which any of our product candidates are approved for commercialization. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including non-clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. If we or any third parties that provide these services for us are unable to comply, we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business. Any failure to maintain regulatory approval will limit our ability to commercialize our product candidates, which would materially and adversely affect our business and financial condition, which may cause the price of our securities to fall.

***We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future.***

We have been engaged in discovering and developing compounds and product candidates since mid-1997. Our first approved product, VIBATIV®, was launched by our former partner Astellas in the U.S. in November 2009, and to date we have received only modest revenues from VIBATIV® sales. We may never generate sufficient revenue from the sale of medicines or royalties on sales by our partners to achieve profitability. As of December 31, 2012, we had an accumulated deficit of approximately \$1.3 billion.

We expect to incur substantial expenses as we continue our drug discovery and development efforts, particularly to the extent we advance our product candidates into and through clinical studies, which are very expensive. For example, TD-9855 in our MARIN program is in Phase 2 studies for both attention-deficit/hyperactivity disorder (ADHD) and fibromyalgia, and our LAMA compound TD-4208 commenced a Phase 2b study in December 2012. Also, in July 2012, we announced positive results from the key study in our Phase 2b program with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation. Though we seek to partner this program, we may choose to progress TD-1211 into Phase 3 studies by ourselves, which would increase our operating expenses substantially. Furthermore, should we decide to commercialize VIBATIV® in the United States without a partner, we will incur significant costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities. As a result, we expect to continue to incur substantial losses for the foreseeable future. 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 and our ability to raise capital and continue operations.

***If we fail to obtain the capital necessary to fund our operations, we may be unable to develop our product candidates or commercialize VIBATIV® and we could be forced to share our rights to commercialize our product candidates with third parties on terms that may not be favorable to us.***

We need large amounts of capital to support our research and development efforts. If we are unable to secure capital to fund our operations we will not be able to continue our discovery and development efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to our medicines to a greater extent than we currently intend. Based on our

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current operating plans, milestone and royalty forecasts and spending assumptions, we believe that our cash and cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next twelve months. If our current operating plans, milestone and royalty forecasts or spending assumptions change, we may seek additional funding sooner in the form of public or private equity offerings or debt financings. For example, if we chose to conduct Phase 3 studies with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation by ourselves our capital needs would increase substantially. In addition, we initiated two Phase 2 studies with TD-9855 in the MARIN program and a Phase 2b study with our LAMA compound, TD-4208. We also intend to invest in other assets in our pipeline, including programs in earlier-stage clinical development and late-stage discovery. Further, in 2012, we issued purchase orders to Astellas for the purchase of VIBATIV® active pharmaceutical ingredient and other raw materials of up to \$7.7 million, and as of December 31, 2012 we had purchased \$5.8 million pursuant to these orders and the remaining active pharmaceutical ingredient and other raw materials will not be purchased. Also in 2012, we issued purchase orders to Astellas for the purchase of VIBATIV® finished goods inventory of up to \$4.2 million, and as of December 31, 2012 this finished goods inventory remained subject to release. In addition, under our LABA collaboration with GSK, in the event that a product containing vilanterol (VI), which is the LABA product candidate in FF/VI and UMEC/VI and which was discovered by GSK, is approved and launched in multiple regions of the world as both a single-agent and a combination product or two different combination products, we will be obligated to pay GSK milestone payments that could total as much as \$220.0 million and we will not be entitled to receive any further milestone payments from GSK. Of these potential milestone payments, we estimate up to \$140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014. Future financing to meet our capital needs may not be available in sufficient amounts or on terms acceptable to us, if at all. Even if we are able to raise additional capital, such financing may result in significant dilution to existing security holders. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to make reductions in our workforce and may be prevented from continuing our discovery and development efforts and exploiting other corporate opportunities. This could harm our business, prospects and financial condition and cause the price of our securities to fall.

***VIBATIV® may not be accepted by physicians, patients, third party payors, or the medical community in general, and this risk is aggravated by the current critical product shortages and regional supply outages and the suspension of marketing authorization in the European Union.***

The commercial success of VIBATIV® depends upon its acceptance by physicians, patients, third party payors and the medical community in general. We cannot be sure that VIBATIV® will be accepted by these parties. VIBATIV® competes with vancomycin, a relatively inexpensive generic drug that is manufactured by a variety of companies, and a number of existing antibacterials manufactured and marketed by major pharmaceutical companies and others, and may compete against new antibacterials that are not yet on the market. Even if the medical community accepts that VIBATIV® is safe and efficacious for its indicated use, physicians may restrict the use of VIBATIV® due to the current product shortages stemming from the manufacturing issues at the previous drug product supplier, the January 2012 termination of our VIBATIV® collaboration agreement with Astellas, or otherwise. If we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, VIBATIV® is preferable to vancomycin and other antibacterial drugs, we may never generate meaningful revenue from VIBATIV® which could cause the price of our securities to fall. The degree of market acceptance of VIBATIV® depends on a number of factors, including, but not limited to:

the demonstration of the clinical efficacy and safety of VIBATIV®;

the experiences of physicians, patients and payors with the use of VIBATIV® in the U.S.;

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potential negative perceptions of physicians related to our inability to obtain FDA approval of our NP NDA, the product shortages and regional supply outages stemming from the manufacturing issues at the previous drug product supplier or the termination of our VIBATIV® collaboration agreement with Astellas in January 2012;

potential negative perceptions of physicians related to the European Commission's suspension of marketing authorization for VIBATIV® because the previous single-source VIBATIV® drug product supplier did not meet the cGMP requirements for the manufacture of VIBATIV®;

the advantages and disadvantages of VIBATIV® compared to alternative therapies;

our ability to educate the medical community about the safety and effectiveness of VIBATIV®;

the reimbursement policies of government and third party payors; and

the market price of VIBATIV® relative to competing therapies.

***If our partners do not satisfy their obligations under our agreements with them, or if they terminate our partnerships with them, as Astellas did with our VIBATIV® collaboration agreement in January 2012, we may not be able to develop or commercialize our partnered product candidates as planned.***

We entered into our LABA collaboration agreement with GSK in November 2002, our strategic alliance agreement with GSK in March 2004, and our VIBATIV® collaboration agreement with Astellas in November 2005. In October 2012, we entered into an exclusive development and commercialization agreement with Alfa Wassermann for velusetrag, our lead compound in the 5-HT<sub>4</sub> program, covering the EU, Russia, China, Mexico and certain other countries, and we entered into a research collaboration and license agreement with Merck to discover, develop and commercialize novel small molecule therapeutics for the treatment of cardiovascular disease on an exclusive, worldwide basis. In connection with these agreements, we have granted to these parties certain rights regarding the use of our patents and technology with respect to compounds in our development programs, including development and marketing rights. Under our GSK agreements, GSK has full responsibility for development and commercialization of FF/VI, UMEC/VI and any product candidates in the MABA program. Any future milestone payments or royalties to us from these programs will depend on the extent to which GSK advances the product candidate through development and, if approved, commercialization. Astellas terminated the VIBATIV® agreement in January 2012. The Merck and Alfa Wassermann agreements provide us with research and development funding, respectively, for the programs under license, and if either partner decides not to progress the licensed program, we may not be able to develop or commercialize the program on our own.

Our partners might not fulfill all of their obligations under these agreements, and, in certain circumstances, they may terminate our partnership with them, as Astellas did in January 2012. In either event, we may be unable to assume the development and commercialization of the product candidates covered by the agreements or enter into alternative arrangements with a third party to develop and commercialize such product candidates. If a partner elected to promote its own products and product candidates in preference to those licensed from us, future payments to us could be reduced and our business and financial condition would be materially and adversely affected. Accordingly, our ability to receive any revenue from the product candidates covered by these agreements is dependent on the efforts of the partner. We could also become involved in disputes with a partner, which could lead to delays in or termination of our development and commercialization programs and time-consuming and expensive litigation or arbitration.

If a partner terminates or breaches its agreements with us, or otherwise fails to complete its obligations in a timely manner, the chances of successfully developing or commercializing product candidates under the collaboration could be materially and adversely affected. For example, Astellas terminated the VIBATIV® collaboration agreement in January 2012, and due to the termination,

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current product shortages, regional supply outages and suspension of marketing authorization in the European Union stemming from the manufacturing issues at the previous third party VIBATIV® drug product supplier, the commercialization of VIBATIV® in the U.S. has essentially stopped and the commercial introduction of VIBATIV® in the E.U. and Canada has been delayed.

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

We have active collaborations with GSK for FF/VI, UMEC/VI and the MABA program, with Alfa Wassermann for velusetrag, with Merck for novel small molecule therapeutics for the treatment of cardiovascular disease, and with R-Pharm CJSC for telavancin and TD-1792, our investigational antibiotic. Additional collaborations will be needed to fund later-stage development of our product candidates that have not been licensed to a collaborator or for territory that is not covered by the collaboration, and to commercialize these product candidates if approved by the necessary regulatory authorities. Each of velusetrag, our lead compound in the 5-HT4 program, TD-1792, our investigational antibiotic and TD-4208, our LAMA compound, has successfully completed a Phase 2 proof-of-concept study, and in July 2012 we reported positive results from a Phase 2b study with TD-1211, the lead compound in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation. In addition, in connection with the expansion of the MABA program under the strategic alliance with GSK in October 2011, GSK relinquished its right to option our MARIN and ARNI programs. Also, we now have full rights to VIBATIV® as a result of the termination of our collaboration agreement with Astellas in January 2012. We currently intend to seek additional third parties with which to pursue collaboration arrangements for the development and commercialization of our development programs and for the future commercialization of VIBATIV®. Collaborations with third parties regarding these programs or our other programs may require us to relinquish material rights, including revenue from commercialization of our medicines, on terms that are less attractive than our current arrangements or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We face significant competition in seeking third-party collaborators, especially in the current uncertain economy, which is driving many biotechnology and biopharmaceutical companies to seek to sell or license their assets. We may be unable to find third parties to pursue product collaborations on a timely basis or on acceptable terms. Furthermore, for any collaboration, we may not be able to control the amount of time and resources that our partners devote to our product candidates and our partners may choose to pursue alternative products. Our inability to successfully collaborate with third parties would increase our development costs and would limit the likelihood of successful commercialization of our product candidates which may cause the price of our securities to fall.

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

We depend on independent clinical investigators, contract research organizations and other third-party service providers in the conduct of our non-clinical and clinical studies for our product candidates. We rely heavily on these parties for execution of our non-clinical and clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that our clinical studies are conducted in accordance with good clinical practices (GCPs) and other regulations as required by the FDA and foreign regulatory authorities, and the applicable protocol. Failure by these parties to comply with applicable regulations, GCPs and protocols in conducting studies of our product candidates can result in a delay in our development programs or non-approval of our product candidates by regulatory authorities.

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

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

Our ability to succeed in the future depends on our ability to demonstrate and maintain a competitive advantage with respect to our approach to the discovery and development of medicines. Our objective is to discover, develop and commercialize new small molecule medicines with superior efficacy, convenience, tolerability and/or safety. We expect that any medicines that we commercialize with our collaborative partners will compete with existing or future market-leading medicines.

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

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

attract and retain qualified personnel;

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

obtain required regulatory approvals; and

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

Established pharmaceutical companies may invest heavily to quickly discover and develop or in-license novel compounds that could make our product candidates obsolete. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing medicines before we do. Other companies are engaged in the discovery of medicines that would compete with the product candidates that we are developing.

Any new medicine that competes with a generic or proprietary market leading medicine must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to overcome severe price competition and be commercially successful. VIBATIV® must demonstrate these advantages, as it competes with vancomycin, a relatively inexpensive generic drug that is manufactured by a number of companies, and a number of existing antibacterial drugs marketed by major and other pharmaceutical companies. If we are not able to compete effectively against our current and future competitors, our business will not grow, our financial condition and operations will suffer and the price of our securities could fall.

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

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

We are highly dependent on principal members of our management team and scientific staff 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 development and commercialization activities, which may cause the price of our securities to fall.

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

Although we have security measures in place, our internal computer systems and those of our CROs and other service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any material system failure, accident or security breach could result in a material disruption to our business. For example, the loss of clinical trial data from completed or ongoing clinical trials of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If a disruption or security breach results in a loss of or damage to our data or regulatory applications, or inadvertent disclosure of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed and the price of our securities could fall.

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

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

**Risks Related to our Alliance with GSK**

***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 14, 2013, GSK beneficially owned approximately 26.8% of our outstanding capital stock, and GSK has the right to acquire stock from us to maintain its percentage ownership of our capital stock. 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.

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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.

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 14, 2013, GSK beneficially owned approximately 26.8% 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 our stockholder rights plan, 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 of directors 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 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





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were made to a single buyer or group of buyers, could contribute to a transfer of control of our company to a third party.

**Risks Related to Legal and Regulatory Uncertainty**

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

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of December 31, 2012, we owned 329 issued United States patents and 1,110 granted foreign patents, as well as additional pending United States and foreign patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be invalidated or be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by our patents with respect to a product candidate is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, the product candidate. Further, if we encounter delays in our clinical trials or in obtaining regulatory approval of our product candidates, the patent lives of the related product candidates would be reduced.

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

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

Our commercial success depends in part on us and our partners not infringing the patents and proprietary rights of third parties. Third parties may assert that we or our partners are using their proprietary rights without authorization. There are third party patents that may cover materials or methods for treatment related to our product candidates. At present, we are not aware of any patent claims with merit that would adversely and materially affect our ability to develop our product candidates, but nevertheless the possibility of third party allegations cannot be ruled out. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Furthermore, parties making claims against us or our partners may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would

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involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. In addition, in the future we could be required to initiate litigation to enforce our proprietary rights against infringement by third parties. Prosecution of these claims to enforce our rights against others would involve substantial litigation expenses and divert substantial employee resources from our business. If we fail to effectively enforce our proprietary rights against others, our business will be harmed, which may cause the price of our securities to fall.

***If the efforts of our partner, GSK, to protect the proprietary nature of the intellectual property related to the assets in the LABA collaboration, including FF/VI and UMEC/VI, are not adequate, the future commercialization of any medicines resulting from the LABA collaboration could be delayed or prevented, which would materially harm our business and could cause the price of our securities to fall.***

The risks identified in the two preceding risk factors also apply to the intellectual property protection efforts of our partner, GSK. To the extent the intellectual property protection of any of the assets in the LABA collaboration are successfully challenged or encounter problems with the United States Patent and Trademark Office or other comparable agencies throughout the world, the future commercialization of these potential medicines could be delayed or prevented. Any challenge to the intellectual property protection of a late-stage development asset arising from the LABA collaboration could harm our business and cause the price of our securities to fall.

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

The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical products. Side effects of, or manufacturing defects in, products that we or our partners develop or commercialize could result in the deterioration of a patient's condition, injury or even death. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits tends to increase. Claims may be brought by individuals seeking relief for themselves or by individuals or groups seeking to represent a class. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the applicable products.

Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities. In addition, inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercial production and sale of our products, which could adversely affect our business. Product liability claims could also harm our reputation, which may adversely affect our and our partners' ability to commercialize our products successfully, which could cause the price of our securities to fall.

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

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect one or more of the following:

our or our collaborators' ability to set a price we believe is fair for our products, if approved;

our ability to generate revenues and achieve profitability; and

the availability of capital.

The Patient Protection and Affordable Care Act and other potential legislative or regulatory action regarding healthcare and insurance matters, along with the trend toward managed healthcare in the United States, could influence the purchase of healthcare products and reduce demand and prices for our products, if approved. This could harm our or our collaborators' ability to market our potential medicines and generate revenues. Cost containment measures that health care payors and providers are instituting and the effect of the Patient Protection and Affordable Care Act and further agency regulations that are likely to emerge in connection with the passage of this act could significantly reduce potential revenues from the sale of any product candidates approved in the future. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures at the state and federal level, as well as internationally, will continue and may increase, which may make it difficult for us to sell our potential medicines that may be approved in the future at a price acceptable to us or our collaborators, which may cause the price of our securities to fall.

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may incur significant additional costs to comply with these and other applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, which could cause the price of our securities to fall.

**Risks 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. 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

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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 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 (for example, the negative investor reaction to the topline results from the Phase 3 registrational programs for FF/VI announced in early 2012);

any adverse developments or results or perceived adverse developments or results with respect to the development of UMEC/VI with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for UMEC/VI, or 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 MABA program with GSK, including, without limitation, any further delays encountered in commencing the single-agent Phase 3 program, any difficulties or delays encountered with regard to the regulatory path for '081, such as the '081/FF Phase 3-enabling studies planned for 2013 or any indication from non-clinical studies of '081 that the compound is not safe or efficacious;

any further adverse developments with respect to the commercialization of VIBATIV®, including, without limitation, the uncertainties surrounding drug product manufacture and supply, difficulties that may be encountered by Hospira in technology transfer activities and how, when and where VIBATIV® will be commercialized;

any further adverse developments or perceived adverse developments with respect to our telavancin NP NDA, including, without limitation, adverse developments or perceived adverse developments with regard to the label for VIBATIV® if it is approved for NP;

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 and equity vesting activity;

any announcements of developments with, or comments by, the FDA or other regulatory authorities with respect to products we or our partners have under development or have commercialized;

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 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;



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any adverse developments or perceived adverse developments with respect to our relationship with any of our research, development or commercialization partners other than GSK, including, without limitation, disagreements that may arise between us and any of those partners;

any adverse developments or perceived adverse developments with respect to our partnering efforts with VIBATIV®, our 5-HT<sub>4</sub> receptor agonist, Peripheral Mu Opioid Receptor Antagonist, MARIN and ARNI programs, TD-1792 or TD-4208;

announcements regarding GSK generally;

announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;

developments concerning any collaboration we undertake with companies other than GSK;

publicity regarding actual or potential study results or the outcome of regulatory review relating to products under development by us, our partners or our competitors;

regulatory developments in the United States and foreign countries;

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 34.7% of our outstanding capital stock as of February 14, 2013 based on our review of publicly available filings); and

potential sales or purchases of our capital stock by GSK.

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

As of February 14, 2013, GSK beneficially owned approximately 26.8% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 5.6% of our outstanding capital stock. Based on our review of publicly available filings as of February 14, 2013, our three largest stockholders other than GSK collectively owned approximately 34.7% 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.

***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:

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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 of directors or for proposing matters that can be acted on by stockholders at meetings.

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In addition, our board of directors 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**

None.

**ITEM 2. PROPERTIES**

Our headquarters consist of 130,000 square feet of office and laboratory space leased in two buildings in South San Francisco, CA. The lease expires in May 2020 and we may extend the terms for two additional five-year periods. The current annual rental expense under these leases is approximately \$5.7 million. As security for performance of certain obligations under the facility operating leases for our headquarters, we were required to have a financial institution issue letters of credit in the aggregate of approximately \$0.8 million, which we have collateralized with the financial institution by an equal amount of restricted cash.

**ITEM 3. LEGAL PROCEEDINGS**

We are not a party to any material legal proceedings.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.



Table of Contents**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

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:

<b>Calendar Quarter</b>	<b>High</b>	<b>Low</b>
<b>2012</b>		
Fourth Quarter	\$ 26.90	\$ 20.12
Third Quarter	\$ 31.69	\$ 23.81
Second Quarter	\$ 23.42	\$ 17.61
First Quarter	\$ 20.50	\$ 16.39
<b>2011</b>		
Fourth Quarter	\$ 23.91	\$ 19.02
Third Quarter	\$ 24.87	\$ 16.89
Second Quarter	\$ 28.70	\$ 21.18
First Quarter	\$ 25.78	\$ 20.98

As of February 14, 2013, there were 174 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.

On November 7, 2012, we completed the sale of 280,348 shares of our common stock to an affiliate of GSK at a price of \$22.35 per share, resulting in aggregate gross proceeds of approximately \$6.3 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.

*Dividend Policy*

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

Table of Contents*Equity Compensation Plans*

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2012:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	7,002,982(1)	\$ 20.72(3)	5,446,945(4)
Equity compensation plans not approved by security holders	357,028(2)	\$ 13.55(3)	
<b>Total</b>	<b>7,360,010(1)(2)</b>	<b>\$ 20.30(3)</b>	<b>5,446,945(4)</b>

- 
- (1) Includes 5,765,183 shares issuable upon exercise of outstanding options and 1,237,799 shares issuable upon vesting of outstanding restricted stock units and restricted stock awards.
- (2) Includes 354,903 shares issuable upon exercise of outstanding options and 2,125 shares issuable upon vesting of outstanding restricted stock units.
- (3) Does not take into account outstanding restricted stock units as these awards have no exercise price.
- (4) Includes 423,575 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 available 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. While a maximum of 12,667,411 shares could be added to the 2012 Plan from the Prior Plans, since this assumes that all the awards outstanding on December 31, 2011 will be forfeited, repurchased, cash settled or terminated, the actual number to be added to the 2012 Plan share reserve may be less. Upon adoption of the 2012 Plan, we reserved 6,500,000 shares of common stock for issuance under the 2012 Plan. No additional awards have been or will be made after May 15, 2012 under the 2004 Plan. Stock options and 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 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 stock appreciation rights ("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 features of

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the 2012 Plan are outlined in Note 1, "Description of Operations and Summary of Significant Accounting Policies-Fair Value of Stock-Based Compensation Awards," and Note 8, "Stock-Based Compensation," in the Notes to Consolidated Financial Statements below in Part II, Item 8, "Financial Statements and Supplementary Data" of 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, 2007 and ending on December 31, 2012, with the cumulative total return of (i) the Nasdaq Composite Index and (ii) the NYSE Arca Biotechnology Index, over the same period. This graph assumes the investment of \$100.00 on December 31, 2007 in each of (1) our common stock, (2) the Nasdaq Composite Index and (3) the NYSE Arca Biotechnology Index, and assumes the reinvestment of dividends, if any, although dividends have never been declared on our common stock.

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 United States Securities and Exchange Commission and shall not be deemed incorporated by reference into any of those prior filings or into any future filings made by us under those statutes.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***

Among Theravance, Inc., the NASDAQ Composite Index, and  
the NYSE Arca Biotechnology Index

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\*

\$100 invested on 12/31/07 in stock or index, including reinvestment of dividends.

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The following tables reflect selected consolidated summary financial data for each of the last five fiscal years and are derived from our audited consolidated financial statements. This data 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 financial data for the years ended December 31, 2012, 2011 and 2010 are derived from, and are qualified by reference to, the audited consolidated financial statements that are included in this Form 10-K. The financial data for the years ended December 31, 2009 and 2008 are derived from audited, consolidated financial statements which are not included in this Form 10-K.

	Year Ended December 31,					
	2012	2011	2010	2009	2008	
	(in thousands, except per share data)					
<b>CONSOLIDATED STATEMENT OF OPERATIONS DATA:</b>						
Revenue	\$ 135,758	\$ 24,512	\$ 24,223	\$ 24,374	\$ 23,096	
Operating expenses:						
Research and development	117,898	103,568	75,070	77,524	82,020	
General and administrative	30,859	30,681	27,476	27,066	28,861	
Restructuring charges				1,145	5,419	
Total operating expenses(1)	148,757	134,249	102,546	105,735	116,300	
Loss from operations	(12,999)	(109,737)	(78,323)	(81,361)	(93,204)	
Interest and other income	460	415	505	2,111	5,242	
Interest expense	(6,003)	(6,022)	(6,044)	(6,052)	(5,681)	
Net loss	\$ (18,542)	\$ (115,344)	\$ (83,862)	\$ (85,302)	\$ (93,643)	
Basic and diluted net loss per share	\$ (0.20)	\$ (1.41)	\$ (1.16)	\$ (1.35)	\$ (1.53)	
Shares used in computing basic and diluted net loss per share(2)(3)(4)(5)	90,909	82,051	72,070	63,027	61,390	

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	As of December 31,				
	2012	2011	2010	2009	2008
<b>CONSOLIDATED BALANCE SHEET DATA:</b>					
Cash, cash equivalents and marketable securities	\$ 343,683	\$ 240,915	\$ 309,634	\$ 155,390	\$ 200,605
Working capital	231,167	199,267	276,300	123,096	166,006
Total assets	368,582	258,782	331,202	181,393	236,156
Long-term liabilities(6)	183,588	300,338	313,568	331,441	327,150
Accumulated deficit	(1,334,502)	(1,315,960)	(1,200,616)	(1,116,754)	(1,031,452)
Total stockholders' equity (net capital deficiency)	155,028	(87,052)	(22,420)	(188,994)	(134,949)

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

	Year Ended December 31,				
(in thousands)	2012	2011	2010	2009	2008
Research and development	\$ 13,667	\$ 13,422	\$ 10,322	\$ 11,542	\$ 10,264
General and administrative	10,116	11,494	8,687	8,458	7,755
Total stock-based compensation	\$ 23,783	\$ 24,916	\$ 19,009	\$ 20,000	\$ 18,019

- (2) In March 2010, we completed a public offering of 8,625,000 shares of common stock. The financing raised proceeds, net of issuance costs, of \$93.5 million.
- (3) In November 2010, we completed a private placement of 5,750,000 shares of common stock to Glaxo Group Limited, an affiliate of GSK. The financing raised proceeds, net of issuance costs, of \$129.2 million.
- (4) During 2011, Glaxo Group Limited, an affiliate of GSK, purchased a total of 574,454 shares of common stock pursuant to its rights under our governance agreement with GSK dated June 4, 2004, as amended. The purchases resulted in net cash proceeds of \$13.6 million.
- (5) In May 2012, we completed a private placement of 10,000,000 shares of common stock to Glaxo Group Limited, an affiliate of GSK. The financing raised proceeds, net of issuance costs, of \$212.5 million. Also, during 2012, Glaxo Group Limited, an affiliate of GSK, purchased a total of 685,150 shares of common stock pursuant to its rights under our governance agreement with GSK dated June 4, 2004, as amended. The purchases resulted in net cash proceeds of \$16.8 million.
- (6) Long-term liabilities include the long-term portion of deferred revenue as follows:

(in thousands)	2012	2011	2010	2009	2008
Deferred revenue	\$ 6,014	\$ 122,017	\$ 137,425	\$ 157,426	\$ 152,771

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

*Management's Discussion and Analysis (MD&A) is intended to facilitate an understanding of our business and results of operations. You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes included in Item 8, "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K. The information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, our operating expenses, and future payments under our collaboration agreements, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements are based upon current expectations that involve risks and uncertainties. You should review the section entitled "Risk Factors" in Item 1A of Part I above for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. See the section entitled "Special Note regarding Forward Looking Statements" above for more information.*

**Executive Summary**

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. We are focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain. Our key programs include: RELVAR or BREO (fluticasone furoate/vilanterol), ANORO (umeclidinium bromide/vilanterol) and MABA (Bifunctional Muscarinic Antagonist-Beta<sub>2</sub> Agonist), each partnered with GlaxoSmithKline plc (GSK), and our oral Peripheral Mu Opioid Receptor Antagonist program. By leveraging our proprietary insight of multivalency to drug discovery, we are pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need.

In 2012, our net loss was \$18.5 million, a decrease of 84% from \$115.3 million in 2011. Net income in 2012 reflects the recognition of deferred revenue of \$125.8 million from our global collaboration arrangement with Astellas Pharma Inc. (Astellas) for the development and commercialization of VIBATIV®. This recognition resulted from Astellas' January 6, 2012 termination of our agreement with them. In 2012, our research and development expenses were \$117.9 million, an increase of 14% from \$103.6 million 2011. Cash, cash equivalents, short-term investments, and long-term marketable securities totaled \$343.7 million at December 31, 2012, an increase of \$102.8 million from December 31, 2011. The increase was primarily due to net proceeds of \$229.3 million received from our private placements of common stock to an affiliate of GSK and net proceeds of \$7.1 million received from employee stock transactions, partially offset by cash used in operations of \$128.0 million.

In 2012, our total operating expenses were \$148.8 million. We anticipate total operating expenses for 2013 to increase relative to 2012.

**Recent Developments**

On January 24, 2013, we completed an underwritten public offering of \$287.5 million aggregate principal amount of unsecured 2.125% convertible subordinated notes due 2023. The financing raised proceeds, net of issuance costs, of approximately \$244.4 million. The notes are convertible into shares of our common stock at an initial conversion rate of 35.9903 shares per \$1,000 principal amount of the

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notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately \$27.79 per share.

In connection with the offering of the notes, we entered into privately-negotiated capped call option transactions. The capped call option transaction is an integrated instrument consisting of a call option purchased by us with a strike price equal to the conversion price of \$27.79 per share for the underlying number of shares and a cap price of \$38.00 per share. The cap component is economically equivalent to a call option sold by us for the underlying number of shares with a strike price of \$38.00 per share. As an integrated instrument, the settlement of the capped call coincides with the due date of the convertible debt. At settlement, we will receive from our hedge counterparty a number of our common shares that will range from zero, if the stock price is below \$27.79 per share, to a maximum of 2,779,659 shares, if the stock price is above \$38.00 per share. However, if the market price of our common stock, as measured under the terms of the capped call transactions, exceeds \$38.00 per share, there is no incremental anti-dilutive benefit from the capped call. The aggregate cost of the capped call options was \$36.8 million.

**Program Highlights**

Respiratory Programs with GlaxoSmithKline plc (GSK)

*RELVAR or BREO (Fluticasone Furoate/Vilanterol, FF/VI)*

FF/VI is an investigational once-daily ICS/ LABA combination treatment, comprising fluticasone furoate (FF) and vilanterol (VI), for the maintenance treatment of patients with COPD and patients with asthma. FF/VI is administered by a new dry powder inhaler called ELLIPTA . RELVAR (FF/VI for the European Union (EU) and Japan), BREO (FF/VI for the United States (U.S.)), and ELLIPTA (for the EU, U.S. and Japan) are proposed brand names and use of these brand names has not yet been approved by any regulatory authority.

In September 2012, GSK and Theravance announced that the NDA for FF/VI for patients with COPD was accepted by the FDA, indicating that the application is sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act goal date was confirmed as May 12, 2013 and the FDA's Pulmonary-Allergy Drugs Advisory Committee is scheduled to discuss the NDA for BREO for COPD at a meeting on March 7, 2013. GSK and Theravance also reported that the Marketing Authorization Application for FF/VI for COPD and asthma was validated by the EMA and GSK also submitted a Japanese New Drug Application for FF/VI for patients with COPD and asthma in September 2012.

*ANORO (Umeclidinium Bromide/Vilanterol, UMEC/VI)*

UMEC/VI is a once-daily investigational medicine, combining a LAMA, UMEC, and a LABA, VI, for the maintenance treatment of patients with COPD. UMEC/VI is administered by the ELLIPTA dry powder inhaler.

In December 2012, GSK and Theravance announced the submission to the FDA of a NDA for UMEC/VI for patients with COPD and in February 2013, GSK and Theravance announced that the NDA was accepted by the FDA, indicating that the application is sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act goal date was confirmed as December 18, 2013. In January 2013, GSK and Theravance announced the submission of a regulatory application to the EMA for UMEC/VI for patients with COPD, which has now been validated for assessment by the EMA. Regulatory submissions for UMEC/VI are planned in other countries during the course of 2013.

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*Inhaled Bifunctional Muscarinic Antagonist-Beta<sub>2</sub> Agonist (MABA)*

GSK961081 ('081) is an investigational, single molecule bifunctional bronchodilator with both muscarinic antagonist and beta<sub>2</sub> receptor agonist activities. Based on the results from the Phase 2b study, GSK and Theravance plan to advance '081 monotherapy into Phase 3 in 2013 and the '081/FF combination into Phase 3-enabling studies shortly.

Bacterial Infections Program

*VIBATIV® (telavancin)*

In November, 2012, Theravance announced a favorable outcome of the FDA's Anti-Infective Drugs Advisory Committee meeting on VIBATIV® (telavancin) for the treatment of NP due to susceptible isolates of Gram-positive microorganisms. Theravance remains in dialogue with the FDA on the NP indication and is working toward re-establishing consistent product supply.

Central Nervous System (CNS)/Pain Program

*Oral Peripheral Mu Opioid Receptor Antagonist TD-1211*

TD-1211 is an investigational once-daily, orally administered, peripherally selective, multivalent inhibitor of the mu opioid receptor designed with a goal of alleviating gastrointestinal side effects of opioid therapy without affecting analgesia. In July 2012, Theravance announced positive topline results from the Phase 2b Study 0084, the key study in the Phase 2b program evaluating TD-1211 as potential treatment for chronic, non-cancer pain patients with opioid-induced constipation. The Phase 2b program consisted of three studies (0074, 0076 and 0084) designed to evaluate doses and dosing regimens for Phase 3. We are currently evaluating our Phase 3 strategy due to potentially evolving FDA requirements for this class of drug.

*Monoamine Reuptake Inhibitor TD-9855*

TD-9855 is an investigational norepinephrine and serotonin reuptake inhibitor for the treatment of central nervous system conditions such as ADHD and chronic pain. TD-9855 is being evaluated in an ongoing Phase 2 safety and efficacy study in adults with ADHD. In addition, we initiated a Phase 2 study with TD-9855 in patients with fibromyalgia in December 2012.

Theravance Respiratory Program

*Long-Acting Muscarinic Antagonist TD-4208*

In November 2011, we announced positive topline results from a Phase 2a single-dose COPD study of TD-4208, an investigational inhaled LAMA discovered by Theravance. In this study, TD-4208 met the primary endpoint by demonstrating a statistically significant mean change from baseline in peak forced expiratory volume in one second (FEV1) compared to placebo, and was generally well tolerated. In December 2012, we initiated a Phase 2b study to evaluate the safety and pharmacokinetics of multiple doses of TD-4208.

GI Motility Dysfunction Program

*Velusetrag*

Velusetrag, an oral, investigational medicine dosed once-daily, is a highly selective agonist with high intrinsic activity at the human 5-HT<sub>4</sub> receptor. In October 2012, we entered into an exclusive development and commercialization agreement with Alfa Wassermann for velusetrag, our lead compound in the 5-HT<sub>4</sub> program, covering the EU, Russia, China, Mexico and certain other countries. In January 2013, Theravance and Alfa Wassermann announced the initiation of a Phase 2 proof-of-concept study to evaluate the efficacy and safety of velusetrag for the treatment of patients with diabetic or idiopathic gastroparesis.



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**Critical Accounting Policies and Estimates**

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenue and expenses during the reporting periods. We periodically evaluate our material estimates and judgments based on the terms of underlying agreements, the expected course of development, historical experience and other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1, "Description of Operations and Summary of Significant Accounting Policies," in the Notes to our consolidated financial statements contained in Part II, Item 8, "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K, we believe that the following accounting policies relating to revenue recognition, preclinical study and clinical study expenses, stock-based compensation charges and inventories require us to make significant estimates, assumptions and judgments.

***Revenue Recognition***

Our revenues are related primarily to our collaboration arrangements (see Collaboration Arrangements section below). Our arrangements provide for various types of payments to us, including non-refundable upfront fees, milestone and other contingent payments and royalty payments.

Beginning in January 1, 2011, we account for new multiple element arrangements, such as license and development agreements in which a customer may purchase several deliverables, in accordance with Financial Accounting Standards Board (FASB) Subtopic ASC 605-25, "Multiple Element Arrangements". For new or materially amended multiple element arrangements, at the inception of the arrangement each deliverable within a multiple deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. We allocate revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, we determine the selling price for each deliverable using vendor-specific objective evidence (VSOE) of selling price, if it exists, or third-party evidence (TPE) of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, we use best estimated selling price for that deliverable. Revenue allocated to each element is then recognized based on when the basic four revenue recognition criteria are met for each element.

For multiple-element arrangements entered into prior to January 1, 2011, we determined the deliverables under our collaboration agreements which did not meet the criteria required to be considered separate accounting units for the purposes of revenue recognition. As a result, we recognized revenue from non-refundable, upfront fees and development milestone payments ratably over the term of our performance under the agreements. These upfront or milestone payments received, pending recognition as revenue, are recorded as deferred revenue and are classified as a short-term or long-term liability on our consolidated balance sheet and amortized over the estimated period of performance. We periodically review the estimated performance periods of our contracts based on the progress of our programs.

Where a portion of non-refundable upfront fees or other payments received are allocated to continuing performance obligations under the terms of a collaboration agreement, they are recorded as deferred revenue and recognized as revenue or as an accrued liability and recognized as a reduction of

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research and development expenses ratably over the term of our estimated performance period under the agreement. We determine the estimated performance periods and they are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated performance period, and therefore revenue recognized, would occur on a prospective basis in the period that the change was made.

Under certain collaboration arrangements, we have been reimbursed for a portion of our research and development expenses. These reimbursements have been reflected as a reduction of research and development expense in our consolidated statements of operation, as we do not consider performing research and development services to be a part of our ongoing and central operations. Therefore, the reimbursement of research and developmental services and any amounts allocated to our research and development services are recorded as a reduction of research and development expense.

Amounts deferred under a collaboration agreement in which the performance obligations are terminated will result in an immediate recognition of any remaining deferred revenue and accrued liability in the period that termination occurred, provided that all performance obligations have been satisfied.

Beginning in 2011, we account for milestones in accordance with FASB Subtopic ASC 605-28 "Revenue Recognition Milestone Method". We recognize revenue from milestone payments when (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) we do not have ongoing performance obligations related to the achievement of the milestone. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment (a) is commensurate with either our performance to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from our performance to achieve the milestone, (b) relates solely to past performance, and (c) is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement. See Note 3, "Collaboration Arrangements," in the Notes to the Consolidated Financial Statements below in part II, Item 8, "Financial Statements and Supplementary Data" on this Annual Report on Form 10-K, for analysis of each milestone event deemed to be substantive or non-substantive.

In accordance with ASC Subtopic 808-10, "Collaborative Arrangement," and pursuant to our agreement with Astellas, we recognized as revenue the net impact of transactions with Astellas related to VIBATIV® inventories including revenue specifically attributable to any sales, and cost of inventories either transferred or expensed as unrealizable.

We recognize royalty revenue on licensee net sales in the period in which the royalties are earned.

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

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

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

We use the Black-Scholes-Merton option pricing model to estimate the fair value of options granted under our equity incentive plans and rights to acquire stock granted under our employee stock purchase plan (ESPP). The Black-Scholes-Merton option valuation model requires the use of assumptions, including the expected term of the award and the expected stock price volatility. We used the "simplified" method as described in Staff Accounting Bulletin No. 107, "Share-Based Payment", for the expected option term because the usage of our historical option exercise data is limited due to post-IPO exercise restrictions. Beginning April 1, 2011, we use our historical volatility to estimate expected stock price volatility. Prior to April 1, 2011, we used peer company price volatility to estimate expected stock price volatility due to our limited historical common stock price volatility since our initial public offering in 2004.

Restricted Stock Units (RSUs) and Restricted Stock Awards (RSAs) are measured based on the fair market values of the underlying stock on the dates of grant.

Stock-based compensation expense was calculated based on awards ultimately expected to vest and was reduced for estimated forfeitures at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differed from those estimates. We estimated annual forfeiture rates for stock options, RSUs and RSAs based on our historical forfeiture experience.

The estimated fair value of stock options, RSUs and RSAs is expensed on a straight-line basis over the expected term of the grant and the estimated fair value of performance-contingent RSUs and RSAs is expensed using an accelerated method over the term of the award once we determine that it is probable that those performance milestones will be achieved. Compensation expense for RSUs and RSAs that contain performance conditions is based on the grant date fair value of the award. Compensation expense is recorded over the requisite service period based on management's best estimate as to whether it is probable that the shares awarded are expected to vest. We assess the probability of the performance indicators being met on a continuous basis.

In 2011, we granted special long-term retention and incentive restricted stock awards (RSAs) to members of senior management. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and continued employment. The maximum potential expense associated with the RSAs is \$31.9 million, which would be recognized in increments based on achievement of the performance conditions. As of December 31, 2012, we determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense has been recognized. If sufficient performance conditions are achieved in 2013, then we would recognize up to \$15.6 million in stock-based compensation expense associated with these RSAs in 2013.

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

We have not recognized, and we do not expect to recognize in the near future, any tax benefit related to employee stock-based compensation expense as a result of the full valuation allowance on our deferred tax assets including deferred tax assets related to our net operating loss carryforwards.

See Note 8, "Stock-Based Compensation," in the Notes to Consolidated Financial Statements in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K, for more information.

***Inventories***

Inventories are stated at the lower of cost or market value. Inventories include VIBATIV® active pharmaceutical ingredient and other raw materials of \$5.7 million and work-in-process of \$1.8 million

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at December 31, 2012. Work-in-process consists of third party manufacturing costs and associated labor costs relating to our personnel directly involved in the production process. Due to manufacturing issues at the previous single-source supplier of VIBATIV® drug product, VIBATIV® is currently subject to critical product shortages and we currently do not have sufficient finished drug product inventories to commercialize VIBATIV®. We are in the process of re-establishing drug product supply with a new third-party manufacturer, Hospira. We must obtain regulatory approval for VIBATIV® drug product manufactured at Hospira's facility before any such product may be sold. These inventories are capitalized based upon management's judgment of the likely achievement of this regulatory licensure. If information becomes available that suggests the inventories may not be realizable, we may be required to expense a portion or all of the previously capitalized inventories.

## **Collaboration Arrangements**

### **GSK**

#### *LABA collaboration*

In November 2002, we entered into our long-acting beta<sub>2</sub> agonist (LABA) collaboration 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 is developing two combination products: (1) RELVAR or BREO (FF/VI), an investigational once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF) and (2) ANORO (UMEC/VI), a once-daily investigational medicine combining a long-acting muscarinic antagonist (LAMA), umeclidinium bromide (UMEC), with a LABA, VI. For the treatment of asthma, the collaboration is developing FF/VI. 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 2012 sales of approximately \$8.0 billion, and to compete with Symbicort® (formoterol and budesonide as a combination), which had reported 2012 sales of approximately \$3.2 billion. ANORO, 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 2011 sales of approximately \$4.2 billion.

In the event that a product containing VI is successfully developed and commercialized, we will be obligated to make milestone payments to GSK which could total as much as \$220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. Of these potential milestone payments, we estimate up to \$140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014. We are entitled to receive annual royalties from GSK of 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, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS combination product at the time that the first other LABA combination is launched, then the royalties described above for the LABA/ICS combination medicine would be applicable.

#### *2004 Strategic Alliance*

In March 2004, we entered into our strategic alliance with GSK. Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from certain of 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,

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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.

In 2005, GSK licensed our bifunctional muscarinic antagonist-beta<sub>2</sub> agonist (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 remain the same with respect to '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, we are entitled to receive royalties from GSK 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 only as a combination product, such as a MABA/ICS, 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, we are entitled to receive royalties from GSK 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, 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, we could earn total milestone payments of up to \$125.0 million for a single-agent medicine and up to \$250.0 million for both a single-agent and a combination medicine. If a MABA medicine containing an Additional MABA is successfully developed and commercialized in multiple regions of the world, we could earn total milestone payments of up to \$129.0 million. GSK has no further option rights on any of our research or development programs under the strategic alliance.

*Purchases of Common Stock under our Governance Agreement and Common Stock Purchase Agreement with GSK*

On May 16, 2012, we issued and Glaxo Group Limited, an affiliate of GSK, purchased 10,000,000 shares of our common stock at a price of \$21.2887 per share, for a total investment of \$212.9 million.

In addition, Glaxo Group Limited purchased shares of our common stock pursuant to its periodic "top-up" rights under our governance agreement with GSK dated June 4, 2004, as amended, as follows:

	<b>Through December 31, 2012</b>	
	<b>Common Stock Shares Purchased</b>	<b>Aggregate Amounts (in millions)</b>
<i>Purchase dates</i>		
February 14, 2012	88,468	\$ 1.6
August 3, 2012	316,334	\$ 8.9
November 2, 2012	280,348	\$ 6.3

Table of Contents*GSK Contingent Payments and Revenue*

The potential future contingent payments related to the MABA program of \$102.0 million are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to GSK's performance of future development, manufacturing and commercialization activities for product candidates after licensing the program.

Revenue recognized from GSK under the LABA collaboration and strategic alliance agreements was as follows:

(in millions)	Year Ended December 31,		
	2012	2011	2010
LABA collaboration(1)	\$ 3.6	\$ 4.7	\$ 5.1
Strategic alliance agreement		1.9	2.7
Strategic alliance MABA program license(2)	2.0	3.1	2.0
Total revenue	\$ 5.6	\$ 9.7	\$ 9.8

(1) We revised the estimated performance period for the LABA program based on its progress in the fourth quarter of 2011, resulting in an increase to net loss of \$0.4 million for the year ended December 31, 2011. We do not expect that the revision will have a material impact on future revenue recognized under this program.

(2) We revised the estimated performance period for the MABA program based on its progress as follows: (i) in the fourth quarter of 2010, resulting in an increase to net loss of \$1.0 million for the year ended December 31, 2010; (ii) in the fourth quarter of 2011, resulting in an increase to net loss of \$0.2 million for the year ended December 31, 2011; and (iii) in the fourth quarter of 2012, resulting in an increase to net loss of \$0.1 million for the year ended December 31, 2012. We do not expect that the revision will have a material impact on future revenue recognized under this program

Under the GSK collaboration arrangements, we are reimbursed for research and development expenses. These reimbursements have been reflected as a reduction of research and development expense of \$0.2 million for the year ended December 31, 2012, and \$0.4 million for each of the years ended December 31, 2011 and 2010.

***Merck****Research Collaboration and License Agreement with Merck*

In October 2012, we signed a collaboration agreement with Merck, known as MSD outside the United States and Canada, to discover, develop and commercialize novel small molecule therapeutics directed towards a target being investigated for the treatment of hypertension and heart failure. In exchange for granting Merck a worldwide, exclusive license to our therapeutic candidates, we received a \$5.0 million upfront payment in November 2012. Also, we will receive funding for research and be eligible for potential future contingent payments totaling up to \$148.0 million for the first indication and royalties on worldwide annual net sales of any products derived from the collaboration. The contingent payments are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to Merck's performance of future development and commercialization activities. The initial research term is twelve months, with optional extensions by mutual agreement, and Merck can terminate the agreement at any time.

The \$5.0 million upfront payment received in November 2012 was allocated to the three units of accounting based on the relative selling price method as follows: \$4.4 million to the license, \$0.4 million

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to the research services and \$0.2 million to the committee participation. We recognized revenue from the license in 2012 as the technical transfer activities were complete and the associated unit of accounting was deemed delivered. The amount allocated to the committee participation was deferred and will be recognized as revenue over the estimated performance period. The amount allocated to the research services was deferred and will be recognized as a reduction to research and development expense as the underlying services are performed, as the nature of the research services is more appropriately characterized as research and development expense, consistent with the research reimbursements being received. Revenue recognized from Merck under the collaboration agreement was \$4.4 million in 2012. Deferred research services of \$0.4 million were included in other accrued liabilities at December 31, 2012. Amounts associated with deferred committee participation of \$19,000 were included in deferred revenue, current and \$0.2 million were included in deferred revenue, non-current at December 31, 2012.

We recognized \$0.8 million in research reimbursement due from Merck as a reduction of research and development expense in 2012, which receivable was included in receivables from collaboration partners at December 31, 2012.

***Alfa Wassermann***

*Development and Commercialization Agreement with Alfa Wassermann*

In October 2012, we entered into a development and commercialization agreement with Alfa Wassermann società per azioni (S.p.A.) for velusetrag (or TD-5108), our investigational 5-HT<sub>4</sub> agonist in development for gastrointestinal motility disorders. Under the agreement, we will collaborate in the execution of a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis. Alfa Wassermann has an exclusive option to develop and commercialize velusetrag in the European Union, Russia, China, Mexico and certain other countries, while we retain full rights to velusetrag in the US, Canada, Japan and certain other countries. We are entitled to receive funding for the Phase 2a study and a subsequent Phase 2b study if the parties agree to proceed. If Alfa Wassermann exercises its license option at the completion of the Phase 2 program, then we are entitled to receive a \$10.0 million option fee. If velusetrag is successfully developed and commercialized, we are entitled to receive potential future contingent payments totaling up to \$53.5 million, and royalties on net sales by Alfa Wassermann ranging from the low teens to 20%. The contingent payments are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to Alfa Wassermann's performance of future development and commercialization activities. At December 31, 2012, Alfa Wassermann's option right had not been exercised. The option right could be exercised within the next two years. We recognized \$0.2 million in research reimbursement due from Alfa Wassermann as a reduction of research and development expense in 2012, which receivable was included in receivables from collaboration partners at December 31, 2012.

***R-Pharm CJSC***

*Development and Commercialization Agreement with R-Pharm CJSC*

In October 2012, we entered into two separate development and commercialization agreements with R-Pharm CJSC (R-Pharm). The first was for TD-1792, our investigational glycopeptide-cephalosporin heterodimer antibiotic for the treatment of resistant Gram-positive infections, and the second was for telavancin. In exchange for granting R-Pharm exclusive development and commercialization rights in Russia, Ukraine, other member countries of the Commonwealth of Independent States, and Georgia under both agreements, we received \$1.1 million in license and maintenance fees in November 2012. Also, we are eligible to receive an additional \$1.0 million in near-term licensing fees, potential future contingent payments totaling up to \$10.0 million, and royalties

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on net sales by R-Pharm of 15% from TD-1792 and 25% from telavancin. The contingent payments are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to R-Pharm's performance of future development and commercialization activities.

The amounts received in license and maintenance fees of \$1.1 million are included in deferred revenue, current at December 31, 2012, as the completion of the technical transfer to R-Pharm was not completed. The technical transfer is expected to be completed during the first quarter of 2013.

**Astellas***License, Development and Commercialization Agreement with Astellas*

In November 2005, we entered into a global collaboration arrangement with Astellas for the development and commercialization of VIBATIV®. On January 6, 2012, Astellas exercised its right to terminate this agreement. The rights previously granted to Astellas ceased upon termination of the agreement and Astellas stopped all promotional sales efforts. Pursuant to the terms of the agreement, Astellas is entitled to a ten-year, 2% royalty on future net sales of VIBATIV®. We continue to evaluate global commercialization alternatives for VIBATIV® either with partners or alone, and we intend to reintroduce VIBATIV® in the U.S. later in 2013 provided we can assure a reasonable source of VIBATIV® drug product.

In 2012, we issued purchase orders to Astellas for the purchase of VIBATIV® active pharmaceutical ingredient and other raw materials of up to \$7.7 million, and as of December 31, 2012 we had purchased \$5.8 million pursuant to these orders. The remaining active pharmaceutical ingredient and other raw materials will not be purchased. Also in 2012, we issued purchase orders to Astellas for the purchase of VIBATIV® finished goods inventories of up to \$4.2 million, and as of December 31, 2012 these finished goods inventories remained subject to release.

In addition, beginning July 1, 2012, we were responsible to fund governmental rebate and governmental chargeback claims for Astellas-labeled product sales. As a result of the termination of the VIBATIV® collaboration agreement, we recognized \$31,000 in governmental rebate and governmental chargeback claims in 2012.

Through January 6, 2012, we had received \$191.0 million in upfront license, milestone payments and other fees from Astellas. We previously recorded these payments as deferred revenue and amortized them ratably over our estimated performance period (development and commercialization period). As a result of the termination of the VIBATIV® collaboration agreement, the development and commercialization period ended on January 6, 2012. As such, we recognized into revenue \$125.8 million of deferred revenue related to Astellas in the first quarter of 2012, and we are no longer eligible to receive any further milestone payments from Astellas.

Net revenue recognized under this collaboration agreement was as follows:

(in millions)	Year Ended December 31,		
	2012	2011	2010
Recognition of deferred revenue	\$ 125.8	\$	\$
Amortization of deferred revenue		13.0	13.0
Royalties from net sales of VIBATIV®		2.4	1.1
Proceeds from VIBATIV® delivered to Astellas		1.2	2.0
Cost of VIBATIV® delivered to Astellas		(1.2)	(0.9)
Cost of unrealizable VIBATIV® inventories		(0.5)	(0.8)
Astellas-labeled product sales allowance		*	
Total net revenue	\$ 125.8	\$ 14.9	\$ 14.4

\*

Allowance is less than \$50,000.



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Under the Astellas collaboration arrangement, we were reimbursed for a portion of our research and development expenses. These reimbursements have been reflected as a reduction of research and development expense of \$0.4 million for the year ended December 31, 2011 and \$0.3 million for the year ended December 31, 2010.

**Results of Operations****Revenue**

Revenue, as compared to the prior years, was as follows:

(in millions, except percentages)	Year Ended December 31,			Change 2012/2011		Change 2011/2010	
	2012	2011	2010	\$	%	\$	%
Revenue	\$ 135.8	\$ 24.5	\$ 24.2	\$ 111.3	454%	\$ 0.3	1%

We recognized revenue from the amortization of upfront license fees and milestone payments related to our GSK LABA collaboration and strategic alliance agreements, our Merck collaboration, and our Astellas telavancin collaboration, which was terminated on January 6, 2012. In addition, we recognized revenue related to our Astellas telavancin collaboration from royalties from net sales of VIBATIV® and from the impact of VIBATIV® inventories transfers or dispositions.

Revenue increased 454% to \$135.8 million in 2012 from 2011. The increase in 2012 reflects the accelerated recognition of deferred revenue of \$125.8 million from our global collaboration arrangement with Astellas for the development and commercialization of VIBATIV® in the first quarter of 2012. This accelerated recognition was the result of the termination of the Astellas agreement on January 6, 2012. Also, we recognized \$4.4 million from our collaboration arrangement with Merck.

Revenue increased 1% to \$24.5 million in 2011 compared to 2010. This increase was due primarily to an (i) increase in royalty revenue of \$1.3 million from higher net sales of VIBATIV®, (ii) an increase in revenue related to our GSK MABA program of \$1.1 million reflecting primarily the Additional MABA upfront license fee, and (iii) a decrease in expense of \$0.3 million related to VIBATIV® inventories that was no longer realizable. These increases in 2011 were partially offset by (i) a decrease in revenue related to our GSK strategic alliance agreement of \$0.8 million resulting from the deferred revenue being fully amortized in the third quarter of 2011, (ii) a decrease in net proceeds of \$1.1 million in 2011, compared to 2010, related to the delivery of VIBATIV® to Astellas, and (iii) a decrease in revenue of \$0.4 million in 2011, compared to 2010, resulting from a change in the estimated performance period related to our GSK LABA collaboration.

A portion of our upfront fees and certain contingent payments received from our collaboration arrangements have been deferred and are being amortized ratably into revenue or research and development expense over the estimated performance period. Future revenue will include the ongoing amortization of upfront and contingent payments earned. We periodically review and, if necessary, revise the estimated periods of our performance pursuant to these contracts.

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### Research & Development

Research and development (R&D) expenses, as compared to the prior years, were as follows:

(in millions, except percentages)	Year Ended December 31,			Change 2012/2011		Change 2011/2010	
	2012	2011	2010	\$	%	\$	%
Employee-related	\$ 37.4	\$ 35.6	\$ 30.4	\$ 1.8	5%	\$ 5.2	17%
External research and development	43.1	30.8	12.2	12.3	40%	18.6	152%
Stock-based compensation	13.7	13.4	10.3	0.3	2%	3.1	30%
Facilities, depreciation and other allocated	23.7	23.8	22.2	(0.1)	*	1.6	7%
<b>Total research and development expenses</b>	<b>\$ 117.9</b>	<b>\$ 103.6</b>	<b>\$ 75.1</b>	<b>\$ 14.3</b>	<b>14%</b>	<b>\$ 28.5</b>	<b>38%</b>

\*

Change is less than 1%.

R&D expenses increased 14% to \$117.9 million in 2012 from 2011. This increase was primarily due to increases in outside services costs related to our Phase 2 studies in our program for opioid-induced constipation with TD-1211 and in our MARIN program with TD-9855, higher employee-related expenses and costs related to VIBATIV® advisory committee activities.

R&D expenses increased 38% to \$103.6 million in 2011 from 2010, due primarily to our program for opioid-induced constipation with TD-1211 and our MARIN program with TD-9855, laboratory supplies, and higher employee related expenses in 2011.

We have not provided program costs in detail because we do not track, and have not tracked, all of the individual components (specifically the internal cost components) of our research and development expenses on a program basis. We do not have the systems and processes in place to accurately capture these costs on a program basis.

### General & Administrative

General and administrative (G&A) expenses, as compared to the prior years, were as follows:

(in millions, except percentages)	Year Ended December 31,			Change 2012/2011		Change 2011/2010	
	2012	2011	2010	\$	%	\$	%
General and administrative	\$ 30.9	\$ 30.7	\$ 27.5	\$ 0.2	1%	\$ 3.2	12%

G&A expenses remained relatively flat in 2012, compared to 2011. An increase in consulting services costs, as well as higher facility-related costs, were partially offset by a decrease in employee-related expenses that was driven by lower stock-based compensation expense. Stock-based compensation expense was \$10.1 million in 2012, compared to \$11.5 million in 2011.

G&A expenses increased 12% to \$30.7 million in 2011 from 2010, due primarily to higher employee related and external expenses offset by lower facilities related costs.

### Interest and other income

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

(in millions, except percentages)	Year Ended December 31,			Change 2012/2011		Change 2011/2010	
	2012	2011	2010	\$	%	\$	%
Interest and other income	\$ 0.5	\$ 0.4	\$ 0.5	\$ 0.1	25%	\$ (0.1)	(20)%

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Interest and other income increased 25% to \$0.5 million in 2012 from 2011, primarily due to an increase in our in cash, cash equivalents and marketable securities balances, primarily due to \$229.3 million, net of issuance costs, received from the sales of our common stock to an affiliate of GSK in 2012.

Interest and other income decreased 20% to \$0.4 million in 2011 from 2010, primarily due to a trend of lower prevailing rates of interest income earned on our investments.

**Interest expense**

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

(in millions, except percentages)	Year Ended December 31,			Change 2012/2011		Change 2011/2010	
	2012	2011	2010	\$	%	\$	%
Interest expense	\$ 6.0	\$ 6.0	\$ 6.0	\$	%	\$	%

Interest expense is primarily comprised of interest expense and amortization of debt issuance costs from our convertible subordinated notes issued in January 2008. Interest expense will increase in 2013 relative to 2012, as a result of issuing \$287.5 million aggregate principal amount of unsecured 2.125% convertible subordinated notes due 2023.

**Income Taxes**

At December 31, 2012, we had net operating loss carryforwards for federal income taxes of \$1,221.4 million and federal research and development tax credit carryforwards of \$43.2 million. We recorded a valuation allowance to offset in full the benefit related to our deferred tax assets because realization of these benefits is uncertain.

We had unrecognized tax benefits of \$52.5 million as of December 31, 2012 and \$46.9 million as of December 31, 2011. If we eventually are able to recognize these uncertain positions, most of the \$52.5 million of the unrecognized benefit would reduce our effective tax rate, except for excess tax benefits related to stock-based payments.

Utilization of net operating loss and tax credit carryforwards may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. We conducted an analysis through 2011 to determine whether an ownership change had occurred since inception. The analysis indicated that two ownership changes occurred in prior years. However, notwithstanding the applicable annual limitations, we estimate that no portion of the net operating loss or credit carryforwards will expire before becoming available to reduce federal and state income tax liabilities. Annual limitations may result in expiration of net operating loss and tax credit carryforwards before some or all of such amounts have been utilized.

**Liquidity and Capital Resources**

**Liquidity**

Since our inception, we have financed our operations primarily through private placements and public offerings of equity and debt securities and payments received under corporate collaboration arrangements. As of December 31, 2012, we had \$343.7 million in cash, cash equivalents and marketable securities, excluding \$0.8 million in restricted cash that was pledged as collateral for certain of our leases. On May 16, 2012, we issued and Glaxo Group Limited, an affiliate of GSK, purchased 10,000,000 shares of our common stock at a price of \$21.2887 per share, for net proceeds to us of \$212.5 million. Also during 2012, Glaxo Group Limited purchased an aggregate of 685,150 shares of our common stock for an aggregate purchase price of \$16.8 million pursuant to its rights under our governance agreement with GSK dated June 4, 2004, as amended.

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On January 24, 2013, we completed an underwritten public offering of \$287.5 million aggregate principal amount of unsecured 2.125% convertible subordinated notes due 2023. The financing raised proceeds, net of issuance costs, of approximately \$244.4 million. In connection with the offering of the notes, we entered into privately-negotiated capped call option transactions with an aggregate cost of \$36.8 million.

We expect to incur substantial expenses as we continue our drug discovery and development efforts, particularly to the extent we advance our product candidates into and through clinical studies, which are very expensive. For example, TD-9855 in our MARIN program is in Phase 2 studies for both attention-deficit/hyperactivity disorder (ADHD) and fibromyalgia, and our LAMA compound TD-4208 commenced a Phase 2b study in December 2012. Also, in July 2012, we announced positive results from the key study in our Phase 2b program with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation. Though we seek to partner this program, we may choose to progress TD-1211 into Phase 3 studies by ourselves, which would increase our operating expenses substantially. In addition, provided we can assure a reasonable source of VIBATIV® drug product, we intend to reintroduce VIBATIV® in the U.S. later in 2013, which will involve outside services costs associated with manufacturing and distribution capabilities. Furthermore, should we decide to commercialize VIBATIV® in the United States without a partner, we will incur significant costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure. We also intend to invest in other assets in our pipeline, including programs in earlier-stage clinical development and late-stage discovery. In addition, pursuant to our LABA collaboration with GSK (see the section entitled "GSK LABA Collaboration" above), we will be obligated to make milestone payments to GSK which could total as much as \$220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. Of these potential milestone payments, we estimate up to \$140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014.

In 2012, we issued purchase orders to Astellas for the purchase of VIBATIV® active pharmaceutical ingredient and other raw materials of up to \$7.7 million, and as of December 31, 2012 we had purchased \$5.8 million pursuant to these orders. The remaining active pharmaceutical ingredient and other raw materials will not be purchased. Also in 2012, we issued purchase orders to Astellas for the purchase of VIBATIV® finished goods inventories of up to \$4.2 million, and as of December 31, 2012 these finished goods inventories remained subject to release.

In 2011, we granted special long-term retention and incentive cash bonus awards to certain employees. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and continued employment. As of December 31, 2012, we determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense has been recognized. If sufficient performance conditions are achieved in 2013, then we would recognize up to \$18.7 million related to cash bonus expense in 2013.

*Adequacy of cash resources to meet future needs*

We believe that our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next twelve months based upon current operating plans, milestone and royalty forecasts and spending assumptions. If our current operating plans, milestone and royalty forecasts or spending assumptions change, we may require additional funding sooner in the form of public or private equity offerings or debt financings. Furthermore, if in our view favorable financing opportunities arise, we may seek additional funding at any time. However, future financing may not be available in amounts or on terms acceptable to us, if at all. This could leave us without adequate financial resources to fund our operations as currently planned. In addition, we regularly

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explore debt restructuring and/or reduction alternatives, including through tender offers, redemptions, repurchases or otherwise, all consistent with the terms of our debt agreements.

### *Cash Flows*

	Year Ended December 31,			Change 2012/2011	Change 2011/2010
(in millions)	2012	2011	2010	\$	\$
Net cash used in operating activities	\$ (128.0)	\$ (88.3)	\$ (75.1)	\$ (39.7)	\$ (13.2)
Net cash provided by (used in) investing activities	\$ (58.3)	\$ (55.8)	\$ (40.3)	\$ (2.5)	\$ (15.5)
Net cash provided by financing activities	\$ 236.3	\$ 25.6	\$ 231.2	\$ 210.7	\$ (205.6)
<u>Cash Flows from Operating Activities</u>					

Cash used in operations increased \$39.7 million in 2012, compared to 2011, primarily due to higher uses of cash for operating liabilities resulting from an increase in R&D activity and purchase of inventories.

Cash used in operations increased in 2011, compared to 2010, due primarily to higher uses of cash for operating liabilities.

### Cash Flows from Investing Activities

Cash used in investing activities remained relatively flat in 2012, compared to 2011.

Cash used in investing activities increased in 2011, compared to 2010, primarily resulting from higher cash balances being invested in short-term investments during 2011, compared to 2010.

### Cash Flows from Financing Activities

Cash provided by financing activities increased \$210.7 million in 2012, compared to 2011, primarily due to net proceeds received from our private placements of common stock with an affiliate of GSK of \$229.3 million in 2012, compared to \$13.6 million in 2011.

Cash provided by financing activities decreased in 2011, compared to 2010, primarily due to net proceeds of \$129.2 million received from our private placement of common stock with an affiliate of GSK in November 2010, net proceeds of \$93.5 million received from our public offering of common stock that closed in March 2010 and \$2.7 million in Qualifying Therapeutic Discovery Project Grants received from the National Institute of Health in December 2010. This decrease was partially offset by proceeds of \$13.6 million received from sales of our common stock to an affiliate of GSK throughout 2011, an increase in proceeds of \$3.7 million resulting from the exercises of employee stock options in 2011, a \$3.0 million milestone payment received from GSK for the initiation of a Phase 1 combination study in the MABA program in August 2011 and \$1.0 million upfront license fee received from GSK for the Additional MABAs in October 2011.

### *Off-Balance Sheet Arrangements*

We lease various real properties under an operating lease that generally requires us to pay taxes, insurance, maintenance, and minimum lease payments. This lease has options to renew.

We have not entered into any off-balance sheet financial arrangements and have not established any structured finance or special purpose entities. We have not guaranteed any debts or commitments of other entities or entered into any options on non-financial assets.

Table of Contents**Commitments and Contingencies**

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, shareholder suits and tax matters, as such, we are unable to estimate the potential exposure related to these indemnification agreements. We have not recognized any liabilities relating to these agreements as of December 31, 2012.

In 2011, we granted special long-term retention and incentive RSAs to members of senior management and special long-term retention and incentive cash bonus awards to certain employees. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and continued employment. The maximum potential expense associated with this program is \$31.9 million related to stock-based compensation expense and \$38.2 million related to cash bonus expense, which would be recognized in increments based on achievement of the performance conditions. As of December 31, 2012, we determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense has been recognized. If sufficient performance conditions are achieved in 2013, then we would recognize up to \$15.6 million in stock-based compensation expense associated with these RSAs and \$18.7 million related to cash bonus expense in 2013.

**Contractual Obligations and Commercial Commitments**

In the table below, we set forth our enforceable and legally binding obligations and future commitments, as well as obligations related to all contracts that we are likely to continue, regardless of the fact that they were cancelable as of December 31, 2012. Some of the figures that we include in this table are based on management's estimate and assumptions about these obligations, including their duration, the possibility of renewal, anticipated actions by third parties, and other factors. Because these estimates and assumptions are necessarily subjective, the obligations we will actually pay in future periods may vary from those reflected in the table.

(in millions)	Total	Less than 1 year	1 - 3 years	4 - 5 years	After 5 years
Convertible subordinated notes due 2015(1)	\$ 183.1	\$ 5.2	\$ 177.9	\$	\$
Convertible subordinated notes due 2023(2)	348.4	5.7	12.2	12.2	318.3
Facility operating leases(3)	38.9	5.0	9.9	10.5	13.5
Purchase obligations(4)	2.5	1.8	0.7		
<b>Total</b>	<b>\$ 572.9</b>	<b>\$ 17.7</b>	<b>\$ 200.7</b>	<b>\$ 22.7</b>	<b>\$ 331.8</b>

(1)

In January 2008, we completed an underwritten public offering of \$172.5 million aggregate principal amount of unsecured convertible subordinated notes that will mature on January 15, 2015. The financing raised proceeds, net of issuance costs, of \$166.7 million which is being used for general corporate purposes. The notes bear interest at the rate of 3.0% per year that is payable semi-annually in arrears in cash on January 15 and July 15 of each year, beginning on July 15, 2008. The notes are convertible, at the option of the holder, into shares of our common stock at an initial conversion rate of 38.6548 shares per \$1,000 principal amount of the notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately \$25.87 per share.

(2)

In January 2013, we completed an underwritten public offering of \$287.5 million aggregate principal amount of unsecured 2.125% convertible subordinated notes due 2023, which includes the full exercise of the underwriters' over-allotment option for \$37.5 million aggregate principal amount. The financing raised proceeds, net of issuance costs, of approximately \$244.4 million. The

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notes are convertible into shares of our common stock at an initial conversion rate of 35.9903 shares per \$1,000 principal amount of the notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately \$27.79 per share.

- (3) As security for performance of certain obligations under the operating leases for our headquarters, we have issued letters of credit in the aggregate of approximately \$0.8 million, collateralized by an equal amount of restricted cash.
- (4) On January 6, 2012, Astellas exercised its right to terminate our collaboration agreement for VIBATIV®. Pursuant to an outstanding purchase order with Astellas, we may purchase up to \$4.2 million of VIBATIV® finished goods inventories from Astellas in 2013. These inventories remain subject to release. As such, we have not included any amounts under this purchase agreement in the Contractual Obligations and Commercial Commitments table.

Pursuant to our LABA collaboration with GSK (see "GSK LABA Collaboration" above), we will be obligated to make milestone payments to GSK which could total as much as \$220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. Of these potential milestone payments, we estimate up to \$140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014. We have not recognized any liabilities relating to this agreement as of December 31, 2012.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to market risk, including changes to interest rates which are confined to our cash, cash equivalents, restricted cash and marketable securities. We have invested primarily in money market funds, federal agency notes, corporate debt securities and U.S. treasury notes. To reduce the volatility relating to these exposures, we have put investment and risk management policies and procedures in place. The securities in our investment portfolio are not leveraged, are classified as available-for-sale and, due to their very short-term nature, are subject to minimal interest rate risk. We currently do not engage in hedging activities. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have any significant negative impact on the realized value of our investment portfolio. Our outstanding note payable has a fixed interest rate and therefore, we have no exposure to interest rate fluctuations.

Most of our transactions are conducted in U.S. dollars, although we do conduct some preclinical activities and manufacture some active pharmaceutical ingredients with vendors located outside the United States. Some of these expenses are paid in U.S. dollars, and some are paid in the local foreign currency. If the exchange rates undergo a change of 10%, we do not believe that it would have a material impact on our results of operations or cash flows.

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

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[Table of Contents](#)**THERAVANCE, INC.****Consolidated Balance Sheets****(in thousands, except per share data)**

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 94,849	\$ 44,778
Short-term investments	153,640	196,137
Receivables from collaboration partners (including amounts from a related party of \$123 at December 31, 2012 and \$223 at December 31, 2011)	1,064	223
Notes receivable, current	100	100
Prepaid and other current assets	3,966	3,525
Inventories	7,514	
<b>Total current assets</b>	<b>261,133</b>	<b>244,763</b>
Long-term marketable securities	95,194	
Restricted cash	833	893
Property and equipment, net	9,154	10,372
Notes receivable, non-current	140	240
Other assets, non-current	2,128	2,514
<b>Total assets</b>	<b>\$ 368,582</b>	<b>\$ 258,782</b>
<b>Liabilities and stockholders' equity (net capital deficiency)</b>		
Current liabilities:		
Accounts payable	\$ 5,377	\$ 5,813
Accrued personnel-related expenses	9,002	9,643
Accrued clinical and development expenses	6,550	6,956
Accrued interest on convertible subordinated notes	2,372	2,372
Other accrued liabilities	2,072	1,946
Note payable and capital lease, current		69
Deferred revenue, current	4,593	18,697
<b>Total current liabilities</b>	<b>29,966</b>	<b>45,496</b>
Convertible subordinated notes	172,500	172,500
Deferred rent	5,074	5,821
Deferred revenue, non-current	6,014	122,017
Commitments and contingencies (Notes 3, 8 and 10)		
Stockholders' equity (net capital deficiency):		
Preferred stock, \$0.01 par value, 230 shares authorized, no shares issued and outstanding		
Common stock, \$0.01 par value; authorized: 200,000 shares; outstanding: 98,379 at December 31, 2012 and 85,543 at December 31, 2011	984	855
Class A common stock, \$0.01 par value, 30,000 shares authorized, no shares issued and outstanding		
Additional paid-in capital	1,488,447	1,228,037
Accumulated other comprehensive income	99	16
Accumulated deficit	(1,334,502)	(1,315,960)
<b>Total stockholders' equity (net capital deficiency)</b>	<b>155,028</b>	<b>(87,052)</b>
<b>Total liabilities and stockholders' equity (net capital deficiency)</b>	<b>\$ 368,582</b>	<b>\$ 258,782</b>

See accompanying notes to consolidated financial statements.

Table of Contents**THERAVANCE, INC.****Consolidated Statements of Operations****(in thousands, except per share data)**

	<b>Year Ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
Revenue (including amounts from a related party of \$5,613 in 2012, \$9,658 in 2011, and \$9,826 in 2010)	\$ 135,758	\$ 24,512	\$ 24,223
Operating expenses:			
Research and development	117,898	103,568	75,070
General and administrative	30,859	30,681	27,476
Total operating expenses	148,757	134,249	102,546
Loss from operations	(12,999)	(109,737)	(78,323)
Interest and other income	460	415	505
Interest expense	(6,003)	(6,022)	(6,044)
Net loss	\$ (18,542)	\$ (115,344)	\$ (83,862)
Basic and diluted net loss per share	\$ (0.20)	\$ (1.41)	\$ (1.16)
Shares used in computing basic and diluted net loss per share	90,909	82,051	72,070

See accompanying notes to consolidated financial statements.

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**THERAVANCE, INC.**

**Consolidated Statements of Comprehensive Loss**

(in thousands)

	Year Ended December 31,		
	2012	2011	2010
Net loss	\$ (18,542)	\$ (115,344)	\$ (83,862)
Other comprehensive income (loss):			
Net unrealized gain (loss) on available-for-sale securities, net of tax	83	(17)	(2)
Comprehensive loss	\$ (18,459)	\$ (115,361)	\$ (83,864)

See accompanying notes to consolidated financial statements.

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## THERAVANCE, INC.

## Consolidated Statements of Stockholders' Equity (Net Capital Deficiency)

(in thousands)

	Common Stock		Class A Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Net Capital Deficiency)
	Shares	Amount	Shares	Amount				
<i>Balance at December 31, 2009</i>	54,830	\$ 549	9,402	\$ 94	\$ 927,082	\$ 35	\$ (1,116,754)	\$ (188,994)
Exercise of stock options, and issuance of common stock in settlement of restricted stock units, stock awards and purchase plan	1,745	17			8,744			8,761
Issuance of common stock for cash in secondary stock offering, net of expenses of \$5.7 million	8,625	86			93,392			93,478
Issuance of common stock in private placement to a related party, net of expenses of \$0.2 million	5,750	58			129,132			129,190
Stock-based compensation					19,009			19,009
Net loss							(83,862)	(83,862)
Net unrealized loss on marketable securities						(2)		(2)
<i>Balance at December 31, 2010</i>	70,950	710	9,402	94	1,177,359	33	(1,200,616)	(22,420)
Exercise of stock options, and Issuance of common stock in settlement of restricted stock units, stock awards and purchase plan	4,617	46			12,149			12,195
Issuance of common stock in private placements to a related party	574	5			13,613			13,618
Conversion of Class A common stock (Note 3)	9,402	94	(9,402)	(94)				
Stock-based compensation					24,916			24,916
Net loss							(115,344)	(115,344)
Net unrealized loss on marketable securities						(17)		(17)
<i>Balance at December 31, 2011</i>	85,543	855			1,228,037	16	(1,315,960)	(87,052)
Exercise of stock options, and issuance of common stock in settlement of restricted stock units, stock awards and purchase plan	2,151	22			7,059			7,081
Issuance of common stock in private placement to a related party, net of expenses of \$0.4 million	10,685	107			229,189			229,296
Stock-based compensation					24,162			24,162
Net loss							(18,542)	(18,542)
Net unrealized gain on marketable securities						83		83
<i>Balance at December 31, 2012</i>	98,379	\$ 984		\$	\$ 1,488,447	\$ 99	\$ (1,334,502)	\$ 155,028

See accompanying notes to consolidated financial statements.

[Table of Contents](#)**THERAVANCE, INC.****Consolidated Statements of Cash Flows****(in thousands)**

	<b>Year Ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
<b>Cash flows from operating activities</b>			
Net loss	\$ (18,542)	\$ (115,344)	\$ (83,862)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	7,326	7,583	6,336
(Gain) loss on sales of available-for-sale securities	(9)	2	(3)
Stock-based compensation	23,783	24,916	19,009
Loss on disposal of equipment	196		33
Forgiveness of notes receivable		16	8
Changes in operating assets and liabilities:			
Receivables from collaboration partners	(841)	(29)	81
Prepaid and other current assets	(441)	2,288	652
Inventories	(4,822)		
Other assets, non-current	(441)		
Accounts payable	(1,480)	3,310	(236)
Accrued personnel-related expenses and other accrued liabilities	(1,829)	5,124	3,321
Deferred rent	(747)	2,429	1,446
Deferred revenue	(130,107)	(18,633)	(21,801)
Other long-term liabilities			(128)
<b>Net cash used in operating activities</b>	<b>(127,954)</b>	<b>(88,338)</b>	<b>(75,144)</b>
<b>Cash flows from investing activities</b>			
Purchases of property and equipment	(2,590)	(3,628)	(861)
Purchases of short-term investments and marketable securities	(330,484)	(301,563)	(183,899)
Maturities of short-term investments and marketable securities	224,902	231,476	131,855
Sales of short-term investments and marketable securities	49,729	17,321	12,024
Sale of equipment			12
Release of restricted cash	60		417
Issuance of notes receivable	(140)	(140)	
Payments received on notes receivable	240	715	140
<b>Net cash used in investing activities</b>	<b>(58,283)</b>	<b>(55,819)</b>	<b>(40,312)</b>
<b>Cash flows from financing activities</b>			
Payments on note payable and capital leases	(69)	(206)	(184)
Proceeds from issuances of common stock, net	236,377	25,808	231,429
<b>Net cash provided by financing activities</b>	<b>236,308</b>	<b>25,602</b>	<b>231,245</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>50,071</b>	<b>(118,555)</b>	<b>115,789</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>44,778</b>	<b>163,333</b>	<b>47,544</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 94,849</b>	<b>\$ 44,778</b>	<b>\$ 163,333</b>
<b>Supplemental Disclosure of Cash Flow Information</b>			
Cash paid for interest	\$ 5,177	\$ 5,195	\$ 5,217

See accompanying notes to consolidated financial statements.

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**THERAVANCE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

*Description of Operations*

Theravance, Inc. (the Company or Theravance) is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain.

*Principles of Consolidation*

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

*Use of Management's Estimates*

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

*Segment Reporting*

The Company has determined that it operates in a single segment which is the discovery (research), development and commercialization of human therapeutics. Revenues are generated primarily from the Company's collaboration arrangements with GlaxoSmithKline plc (GSK), located in the United Kingdom, Astellas Pharma Inc. (Astellas) (through January 6, 2012), located in Japan, and Merck located in the United States. All long-lived assets, which were comprised of property and equipment, are maintained in the United States.

*Cash and Cash Equivalents*

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

Under certain lease agreements and letters of credit, the Company has pledged cash and cash equivalents as collateral. Restricted cash related to such agreements was \$0.8 million as of December 31, 2012 and \$0.9 million as of December 31, 2011.

*Marketable Securities*

The Company's management determines the appropriate classification of its marketable securities, which consist of debt securities, at the time of purchase and reevaluates such designation at each balance sheet date. All of the marketable securities are classified as available-for-sale and carried at estimated fair values and reported in cash equivalents, short-term investments or long-term marketable securities. Unrealized gains and losses on available-for-sale securities are reported in the consolidated statements of comprehensive loss. Interest, amortization of purchase premiums and discounts, and realized gains and losses on sales of securities are included in interest and other income. The cost of securities sold is based on the specific identification method.



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**THERAVANCE, INC.**

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

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

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

*Fair Value of Financial Instruments*

Financial instruments include cash equivalents, marketable securities, related party receivables, accounts payable, accrued liabilities and convertible subordinated notes. Marketable securities are carried at estimated fair value. The carrying value of cash equivalents, receivables from related party, accounts payable and accrued liabilities approximate their estimated fair value due to the relatively short nature of these instruments. Convertible subordinated notes are described in Note 7.

*Concentration of Credit Risks*

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

*Notes Receivable*

The Company provided loans to certain employees to assist them primarily with the purchase of a primary residence, which collateralizes the resulting loans. There was no interest receivable related to the loans as of December 31, 2012 and December 31, 2011. The outstanding loans have maturity dates ranging from January 2013 through May 2014.

*Inventories*

Inventories are stated at the lower of cost or market value. Inventories include VIBATIV® active pharmaceutical ingredient and other raw materials of \$5.7 million and work-in-process of \$1.8 million at December 31, 2012. Work-in-process consists of third party manufacturing and associated labor costs relating to the Company's personnel directly involved in the production process. VIBATIV® is a U.S. Food and Drug Administration (FDA) approved drug. If information becomes available that suggests the inventories may not be realizable, the Company may be required to expense a portion or all of the previously capitalized inventories.

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

Property, equipment and leasehold improvements are stated at cost and depreciated using the straight-line method as follows:

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

The Company capitalizes certain costs related to direct material and service costs for software obtained for internal use. Capitalized software costs are depreciated over 3 years.

*Impairment of Long-Lived Assets*

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

*Bonus Accruals*

The Company has short-term bonus programs for eligible employees. Bonuses are determined based on various criteria, including the achievement of corporate, departmental and individual goals. Bonus accruals are estimated based on various factors, including target bonus percentages per level of employee and probability of achieving the goals upon which bonuses are based. The Company's management periodically reviews the progress made towards the goals under the bonus programs. As bonus accruals are dependent upon management's judgments of the likelihood of achieving the various goals, it is possible for bonus expense to vary significantly in future periods if changes occur in those management estimates.

In 2011, the Company granted special long-term retention and incentive cash bonus awards to certain employees. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and continued employment. As of December 31, 2012, the Company's management determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense has been recognized.

*Deferred Rent*

Deferred rent consists of the difference between cash payments and the recognition of rent expense on a straight-line basis for the buildings the Company occupies. Rent expense is being recognized ratably over the life of the leases. Because the Company's facility operating leases provide for rent increases over the terms of the leases, average annual rent expense during the first 1.5 years of the leases exceeded the Company's actual cash rent payments. Also included in deferred rent are lease

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**THERAVANCE, INC.**

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

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

incentives of \$2.6 million as of December 31, 2012, which is being recognized ratably over the life of the leases.

*Revenue Recognition*

The Company's revenues are related primarily to its collaboration arrangements. The Company's arrangements provide for various types of payments to the Company, including non-refundable upfront fees, milestone and other contingent payments and royalty payments.

Beginning in January 1, 2011, the Company accounts for new multiple element arrangements, such as license and development agreements in which a customer may purchase several deliverables, in accordance with Financial Accounting Standards Board (FASB) Subtopic ASC 605-25, "Multiple Element Arrangements". For new or materially amended multiple element arrangements, at the inception of the arrangement each deliverable within a multiple deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in the Company's control. The Company allocates revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, the Company's management determines the selling price for each deliverable using vendor-specific objective evidence (VSOE) of selling price, if it exists, or third-party evidence (TPE) of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, the Company uses best estimated selling price for that deliverable. Revenue allocated to each element is then recognized based on when the basic four revenue recognition criteria are met for each element.

For multiple-element arrangements entered into prior to January 1, 2011, the Company's management determined the deliverables under its collaboration agreements which did not meet the criteria to be considered for separate accounting units for the purposes of revenue recognition. As a result, the Company recognized revenue from non-refundable, upfront fees and development milestone payments ratably over the term of its performance under the agreements. These upfront or milestone payments received, pending recognition as revenue, are recorded as deferred revenue and are classified as a short-term or long-term liability on the Company's consolidated balance sheet and amortized over the estimated period of performance. The Company periodically reviews the estimated performance periods of its contracts based on the progress of its programs.

Where a portion of non-refundable upfront fees or other payments received are allocated to continuing performance obligations under the terms of a collaboration agreement, they are recorded as deferred revenue and recognized as revenue or as an accrued liability and recognized as a reduction of research and development expenses ratably over the term of its estimated performance period under the agreement. The Company's management determines the estimated performance periods and they are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated performance period and therefore revenue recognized would occur on a prospective basis in the period that the change was made.

Under certain collaboration arrangements, the Company has been reimbursed for a portion of its research and development expenses. These reimbursements have been reflected as a reduction of research and development expense in the Company's consolidated statements of operation, as the

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**THERAVANCE, INC.**

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

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

Company does not consider performing research and development services to be a part of its ongoing and central operations. Therefore, the reimbursement of research and developmental services and any amounts allocated to the Company's research and development services are recorded as a reduction of research and development expense.

Amounts deferred under a collaboration agreement in which the performance obligations are terminated will result in an immediate recognition of any remaining deferred revenue and accrued liability in the period that termination occurred, provided that all performance obligations have been satisfied.

Beginning in 2011, the Company accounts for milestones in accordance with FASB Subtopic ASC 605-28 "Revenue Recognition-Milestone Method". The Company recognizes revenue from milestone payments when (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) the Company does not have ongoing performance obligations related to the achievement of the milestone. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment (a) is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (b) relates solely to past performance, and (c) is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement. See Note 3, "Collaboration Arrangements," for analysis of each milestone event deemed to be substantive or non-substantive.

In accordance with ASC Subtopic 808-10, "Collaborative Arrangement," and pursuant to the Company's agreement with Astellas, the Company recognized as revenue the net impact of transactions with Astellas related to VIBATIV® inventories including revenue specifically attributable to any sales, and cost of inventories either transferred or expensed as unrealizable.

The Company recognizes royalty revenue on licensee net sales in the period in which the royalties are earned.

*Research and Development Costs*

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

*Preclinical Study and Clinical Study Expenses*

A substantial portion of the Company's preclinical studies and all of its clinical studies have been performed by third-party contract research organizations (CROs). Some CROs bill monthly for services performed, while others bill based upon milestones achieved. The Company reviews the activities performed under the significant contracts each quarter. For preclinical studies, the significant factors used in estimating accruals include the percentage of work completed to date and contract milestones achieved. For clinical study expenses, the significant factors used in estimating accruals include the number of patients enrolled and percentage of work completed to date. Vendor confirmations are

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**THERAVANCE, INC.**

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

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

obtained for contracts with longer duration when necessary to validate the Company's estimate of expenses. The Company's estimates are highly dependent upon the timeliness and accuracy of the data provided by its CROs regarding the status of each program and total program spending and adjustments are made when deemed necessary.

*Fair Value of Stock-Based Compensation Awards*

The Company uses the Black-Scholes-Merton option pricing model to estimate the fair value of options granted under its equity incentive plans and rights to acquire stock granted under its employee stock purchase plan (ESPP). The Black-Scholes-Merton option valuation model requires the use of assumptions, including the expected term of the award and the expected stock price volatility. The Company used the "simplified" method as described in Staff Accounting Bulletin No. 107, "Share-Based Payment", for the expected option term because the usage of its historical option exercise data is limited due to post-IPO exercise restrictions. Beginning April 1, 2011, the Company used its historical volatility to estimate expected stock price volatility. Prior to April 1, 2011, the Company used peer company price volatility to estimate expected stock price volatility due to the Company's limited historical common stock price volatility since its initial public offering in 2004.

Restricted Stock Units (RSUs) and Restricted Stock Awards (RSAs) are measured based on the fair market values of the underlying stock on the dates of grant.

Stock-based compensation expense was calculated based on awards ultimately expected to vest and was reduced for estimated forfeitures at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differed from those estimates. The Company's estimated annual forfeiture rates for stock options, RSUs and RSAs are based on its historical forfeiture experience.

The estimated fair value of stock options, RSUs and RSAs is expensed on a straight-line basis over the expected term of the grant and the estimated fair value of performance-contingent RSUs and RSAs is expensed using an accelerated method over the term of the award once the Company's management has determined that it is probable that performance milestones will be achieved. Compensation expense for RSUs and RSAs that contain performance conditions is based on the grant date fair value of the award. Compensation expense is recorded over the requisite service period based on management's best estimate as to whether it is probable that the shares awarded are expected to vest. The Company's management assesses the probability of the performance milestones being met on a continuous basis.

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

The Company has not recognized, and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation expense as a result of the full valuation allowance on the Company's deferred tax assets including deferred tax assets related to its net operating loss carryforwards.

*Income Taxes*

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax basis of assets and liabilities and are measured using enacted tax rates and laws that

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**THERAVANCE, INC.**

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

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

will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

None of the Company's currently unrecognized tax benefits would affect its effective income tax rate if recognized, due to the valuation allowance that currently offsets the Company's deferred tax assets. The Company does not anticipate the total amount of unrecognized income tax benefits relating to tax positions existing at December 31, 2012 will significantly increase or decrease in the next 12 months.

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

The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

*Foreign Currency*

The Company uses the U.S. dollar as the functional currency for its foreign subsidiary. Monetary and non-monetary assets and liabilities are remeasured into U.S. dollars at the applicable period end exchange rate. Operating expenses are remeasured at average exchange rates in effect during each period, except for those expenses related to non-monetary assets which are remeasured at historical exchange rates. Gains or losses from remeasurement of foreign currency financial statements into U.S. dollars are included in the condensed consolidated statements of operations and were insignificant for all periods presented, as was the effect of exchange rate changes on cash and cash equivalents.

*Comprehensive Loss*

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) consists of changes in unrealized gains and losses on the Company's available-for-sale securities, net of tax.

*Related Parties*

Transactions with GSK are described in Note 3, "Collaboration Arrangements".

Robert V. Gunderson, Jr. is a director of the Company. The Company has engaged Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, of which Mr. Gunderson is a partner, as its primary legal counsel. Fees incurred in the ordinary course of business were \$1.2 million in 2012, \$0.3 million in 2011, and \$0.7 million in 2010.

Table of Contents**THERAVANCE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Net Loss per Share**

Basic net loss per share (basic EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding during the period, less unvested RSAs subject to forfeiture. Diluted net loss per share (diluted EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding during the period, less unvested RSAs subject to forfeiture, plus dilutive potential common shares. Diluted EPS is identical to basic EPS for all periods presented since potential common shares are excluded from the calculation, as their effect is anti-dilutive.

*Weighted-Average Shares Outstanding*

The following table sets forth the computation of basic and diluted net loss and the weighted-average number of shares used in computing basic and diluted net loss per share:

(in thousands, except for per share data)	Year Ended December 31,		
	2012	2011	2010
<b>Basic and diluted:</b>			
Net loss	\$ (18,542)	\$ (115,344)	\$ (83,862)
Weighted-average shares of common stock outstanding	93,410	84,493	72,103
Less: unvested RSAs	(2,501)	(2,442)	(33)
Weighted-average shares used in computing basic and diluted net loss per common share	90,909	82,051	72,070
Basic and diluted net loss per share	\$ (0.20)	\$ (1.41)	\$ (1.16)

*Anti-dilutive Securities*

Securities that were not included in the computation of diluted EPS because their effect would have been anti-dilutive were as follows:

(in thousands)	Year Ended December 31,		
	2012	2011	2010
Shares issuable under Equity Incentive Plans and ESPP	5,367	5,464	6,636
Shares issuable upon the conversion of convertible subordinated notes	6,668	6,668	6,668
Total anti-dilutive securities	12,035	12,132	13,304

**3. Collaboration Arrangements****GSK***LABA collaboration*

In November 2002, the Company entered into its long-acting beta<sub>2</sub> agonist (LABA) collaboration 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 is developing two combination products: (1) RELVAR or BREO (FF/VI), an investigational

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**THERAVANCE, INC.**

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

**3. Collaboration Arrangements (Continued)**

once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF) and (2) ANORO (UMEC/VI), a once-daily investigational medicine combining a long-acting muscarinic antagonist (LAMA), umeclidinium bromide (UMEC), with a LABA, VI. For the treatment of asthma, the collaboration is developing FF/VI.

In the event that a product containing VI is successfully developed and commercialized, the Company will be obligated to make milestone payments to GSK which could total as much as \$220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. Of these potential milestone payments, the Company estimates up to \$140.0 million could be payable during 2013 and all the milestone payments could be payable by the end of 2014. The Company is entitled to receive annual royalties from GSK of 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, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS combination product at the time that the first other LABA combination is launched, then the royalties described above for the LABA/ICS combination medicine would be applicable.

*2004 Strategic Alliance*

In March 2004, the Company entered into its strategic alliance with GSK. Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from certain of the Company's 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, the Company is 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, the Company retains all rights to the program and may continue the program alone or with a third party.

In 2005, GSK licensed the Company's bifunctional muscarinic antagonist-beta<sub>2</sub> agonist (MABA) program for the treatment of COPD, and in October 2011, the Company 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 remain the same with respect to '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 the Company, at which point the Company may develop and commercialize such Additional MABAs alone or with a third party. Both GSK and the Company 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, the Company is entitled to receive royalties from GSK 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 only as a combination product, such as a



Table of Contents**THERAVANCE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. Collaboration Arrangements (Continued)**

MABA/ICS, 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, the Company is entitled to receive royalties from GSK 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, 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, the Company could earn total milestone payments of up to \$125.0 million for a single-agent medicine and up to \$250.0 million for both a single-agent and a combination medicine. If a MABA medicine containing an Additional MABA is successfully developed and commercialized in multiple regions of the world, the Company could earn total milestone payments of up to \$129.0 million. GSK has no further option rights on any of the Company's research or development programs under the strategic alliance.

*Purchases of Common Stock under the Company's Governance Agreement and Common Stock Purchase Agreements with GSK; GSK Conversion of the Company's Class A Common Stock*

On May 16, 2012, the Company issued and Glaxo Group Limited, an affiliate of GSK, purchased 10,000,000 shares of the Company's common stock at a price of \$21.2887 per share, for a total investment of \$212.9 million.

In addition, Glaxo Group Limited purchased shares of the Company's common stock pursuant to its periodic "top-up" rights under the Company's governance agreement with GSK dated June 4, 2004, as amended, as follows:

	<b>Through December 31, 2012</b>	
	<b>Common Stock Shares Purchased</b>	<b>Aggregate Amounts (in thousands)</b>
<i>Purchase dates</i>		
February 18, 2011	152,278	\$ 3,609
May 3, 2011	261,299	\$ 6,689
August 2, 2011	102,466	\$ 2,020
November 1, 2011	58,411	\$ 1,298
February 14, 2012	88,468	\$ 1,603
August 3, 2012	316,334	\$ 8,924
November 2, 2012	280,348	\$ 6,266

In July 2011, GSK converted all of the shares of the Company's Class A common stock held by its affiliates into 9,401,499 shares of the Company's common stock on a one share-for-one share basis in accordance with the terms of the Company's restated certificate of incorporation.

*GSK Contingent Payments and Revenue*

The potential future contingent payments related to the MABA program of \$102.0 million are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to GSK's performance of future development, manufacturing and commercialization activities for product candidates after licensing the program.

Table of Contents**THERAVANCE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. Collaboration Arrangements (Continued)**

Revenue recognized from GSK under the LABA collaboration and strategic alliance agreements was as follows:

(in thousands)	Year Ended December 31,		
	2012	2011	2010
LABA collaboration(1)	\$ 3,629	\$ 4,718	\$ 5,081
Strategic alliance agreement		1,858	2,738
Strategic alliance MABA program license(2)	1,984	3,082	2,007
Total revenue	\$ 5,613	\$ 9,658	\$ 9,826

(1) The Company revised the estimated performance period for the LABA program based on its progress in the fourth quarter of 2011, resulting in an increase to net loss of \$0.4 million for the year ended December 31, 2011. The Company does not expect that the revision will have a material impact on future revenue recognized under this program.

(2) The Company revised the estimated performance period for the MABA program based on its progress as follows: (i) in the first quarter of 2010, resulting in an increase to net loss of \$1.0 million for the year ended December 31, 2010; (ii) in the fourth quarter of 2011, resulting in an increase to net loss of \$0.2 million for the year ended December 31, 2011; and (iii) in the fourth quarter of 2012, resulting in an increase to net loss of \$0.1 million for the year ended December 31, 2012. The Company does not expect that the revision will have a material impact on future revenue recognized under this program.

Under the GSK collaboration arrangements, the Company is reimbursed for research and development expenses. These reimbursements have been reflected as a reduction of research and development expense of \$0.2 million for the year ended December 31, 2012, and \$0.4 million for each of the years ended December 31, 2011 and 2010.

***Merck******Research Collaboration and License Agreement with Merck***

In October 2012, the Company signed a collaboration agreement with Merck, known as MSD outside the United States and Canada, to discover, develop and commercialize novel small molecule therapeutics directed towards a target being investigated for the treatment of hypertension and heart failure. In exchange for granting Merck a worldwide, exclusive license to the Company's therapeutic candidates, the Company received a \$5.0 million upfront payment in November 2012. Also, the Company will receive funding for research and be eligible for potential future contingent payments totaling up to \$148.0 million for the first indication and royalties on worldwide annual net sales of any products derived from the collaboration. The contingent payments are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to Merck's performance of future development and commercialization activities. The initial research term is twelve months, with optional extensions by mutual agreement, and Merck can terminate the agreement at any time.

The Company identified all of the deliverables at the inception of the agreement. The significant deliverables were determined to be the license, research services and committee participation. The

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**THERAVANCE, INC.**

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

**3. Collaboration Arrangements (Continued)**

Company's management determined that the license represents a separate unit of accounting as the license, which includes rights to the underlying technologies for the Company's therapeutic candidates, has standalone value because the rights conveyed permit Merck to perform all efforts necessary to use the Company's technologies to bring a therapeutic candidate through development, commercialization and begin selling the drug upon regulatory approval. Also, the Company's management determined that the research services and committee participation each represent individual units of accounting. The Company's management determined the best estimate of selling price for the license based on potential future cash flows under the arrangement over the estimated development period. The Company's management determined the best estimate of selling price of the research services and committee participation based on the nature and timing of the services to be performed.

The \$5.0 million upfront payment received in November 2012 was allocated to the three units of accounting based on the relative selling price method as follows: \$4.4 million to the license, \$0.4 million to the research services and \$0.2 million to the committee participation. The Company recognized revenue from the license in 2012 as the technical transfer activities were complete and the associated unit of accounting was deemed delivered. The amount allocated to the committee participation was deferred and will be recognized as revenue over the estimated performance period. The amount allocated to the research services was deferred and will be recognized as an offset to research and development expense as the underlying services are performed, as the nature of the research services is more appropriately characterized as research and development expense, consistent with the research reimbursements being received. Revenue recognized from Merck under the collaboration agreement was \$4.4 million in 2012. Deferred research services of \$0.4 million were included in other accrued liabilities at December 31, 2012. Amounts associated with deferred committee participation of \$19,000 were included in deferred revenue, current and \$0.2 million were included in deferred revenue, non-current at December 31, 2012.

The Company recognized \$0.8 million in research reimbursement due from Merck as a reduction of research and development expense in 2012, which receivable was included in receivables from collaboration partners at December 31, 2012.

***Alfa Wassermann***

***Development and Commercialization Agreement with Alfa Wassermann***

In October 2012, the Company entered into a development and commercialization agreement with Alfa Wassermann società per azioni (S.p.A.) for velusetrag (or TD-5108), the Company's investigational 5-HT4 agonist in development for gastrointestinal motility disorders. Under the agreement, the companies will collaborate in the execution of a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis. Alfa Wassermann has an exclusive option to develop and commercialize velusetrag in the European Union, Russia, China, Mexico and certain other countries, while the Company retains full rights to velusetrag in the US, Canada, Japan and certain other countries. In October 2012, the Company entered into a development and commercialization agreement with Alfa Wassermann società per azioni (S.p.A.) for velusetrag (or TD-5108), the Company's investigational 5-HT4 agonist in development for gastrointestinal motility disorders. Under the agreement, the Company will collaborate in the execution of a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis. Alfa Wassermann has an exclusive option to develop and commercialize velusetrag in the

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**THERAVANCE, INC.**

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

**3. Collaboration Arrangements (Continued)**

European Union, Russia, China, Mexico and certain other countries, while the Company retains full rights to velusetrag in the US, Canada, Japan and certain other countries. The Company is entitled to receive funding for the Phase 2a study and a subsequent Phase 2b study if the parties agree to proceed. If Alfa Wassermann exercises its license option at the completion of the Phase 2 program, then the Company is entitled to receive a \$10.0 million option fee. If velusetrag is successfully developed and commercialized, the Company is entitled to receive potential future contingent payments totaling up to \$53.5 million, and royalties on net sales by Alfa Wassermann ranging from the low teens to 20%. The contingent payments are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to Alfa Wassermann's performance of future development and commercialization activities. At December 31, 2012, Alfa Wassermann's option right had not been exercised. The option right could be exercised within the next two years. The Company recognized \$0.2 million in research reimbursement due from Alfa Wassermann as a reduction of research and development expense in 2012, which receivable was included in receivables from collaboration partners at December 31, 2012.

***R-Pharm CJSC***

***Development and Commercialization Agreement with R-Pharm CJSC***

In October 2012, the Company entered into two separate development and commercialization agreements with R-Pharm CJSC (R-Pharm). The first was for TD-1792, the Company's investigational glycopeptide-cephalosporin heterodimer antibiotic for the treatment of resistant Gram-positive infections, and the second was for telavancin. In exchange for granting R-Pharm exclusive development and commercialization rights in Russia, Ukraine, other member countries of the Commonwealth of Independent States, and Georgia under both agreements, the Company received \$1.1 million in license and maintenance fees in November 2012. Also, the Company is eligible to receive an additional \$1.0 million in near-term licensing fees, potential future contingent payments totaling up to \$10.0 million and royalties on net sales by R-pharm of 15% from TD-1792 and 25% from telavancin. The contingent payments are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to R-Pharm's performance of future development and commercialization activities.

The Company identified all of the deliverables at the inception of the agreements. The significant deliverables were determined to be the licenses and committee participation for each agreement. The Company's management determined that the licenses represent a separate unit of accounting as the licenses, which include rights to the Company's underlying technologies for TD-1792 and telavancin, have standalone value because the rights conveyed permit R-Pharm to use the Company's technologies to bring the compounds through development, commercialization and begin selling the drugs upon regulatory approval. Also, the Company's management determined that the committee participation represents a separate unit of accounting under each agreement. The amounts received in license and maintenance fees of \$1.1 million are included in deferred revenue, current at December 31, 2012, as the completion of the technical transfer to R-Pharm was not completed. The technical transfer is expected to be completed during the first quarter of 2013.

Table of Contents**THERAVANCE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. Collaboration Arrangements (Continued)***Astellas**License, Development and Commercialization Agreement with Astellas*

In November 2005, the Company entered into a global collaboration arrangement with Astellas for the development and commercialization of VIBATIV®. On January 6, 2012, Astellas exercised its right to terminate this agreement. The rights previously granted to Astellas ceased upon termination of the agreement and Astellas stopped all promotional sales efforts. Pursuant to the terms of the agreement, Astellas is entitled to a ten-year, 2% royalty on future net sales of VIBATIV®. The Company continues to evaluate global commercialization alternatives for VIBATIV® either with partners or alone, and the Company intends to reintroduce VIBATIV® in the U.S. later in 2013 provided the Company can assure a reasonable source of VIBATIV® drug product.

In 2012, the Company issued purchase orders to Astellas for the purchase of VIBATIV® active pharmaceutical ingredient and other raw materials of up to \$7.7 million, and as of December 31, 2012 the Company had purchased \$5.8 million pursuant to these orders. The remaining active pharmaceutical ingredient and other raw materials will not be purchased. Also in 2012, the Company issued purchase orders to Astellas for the purchase of VIBATIV® finished goods inventories of up to \$4.2 million, and as of December 31, 2012 these finished goods inventories remained subject to release.

In addition, beginning July 1, 2012, the Company was responsible to fund governmental rebate and governmental chargeback claims for Astellas-labeled product sales. As a result of the termination of the VIBATIV® collaboration agreement, the Company recognized \$31,000 in governmental rebate and governmental chargeback claims in 2012.

Through January 6, 2012, the Company had received \$191.0 million in upfront license, contingent payments and other fees from Astellas. The Company previously recorded these payments as deferred revenue and amortized them ratably over its estimated performance period (development and commercialization period). As a result of the termination of the VIBATIV® collaboration agreement, the development and commercialization period ended on January 6, 2012. As such, the Company recognized into revenue \$125.8 million of deferred revenue related to Astellas in the first quarter of 2012, and the Company is no longer eligible to receive any further contingent payments from Astellas.

Net revenue recognized under this collaboration agreement was as follows:

(in thousands)	Year Ended December 31,		
	2012	2011	2010
Recognition of deferred revenue	\$ 125,819	\$	\$
Amortization of deferred revenue		12,975	12,975
Royalties from net sales of VIBATIV®		2,422	1,123
Proceeds from VIBATIV® delivered to Astellas		1,171	2,058
Cost of VIBATIV® delivered to Astellas		(1,177)	(938)
Cost of unrealizable VIBATIV® inventories		(537)	(821)
Astellas-labeled product sales allowance	(31)		
Total net revenue	\$ 125,788	\$ 14,854	\$ 14,397

Under the Astellas collaboration arrangement, the Company was reimbursed for a portion of the Company's research and development expenses. These reimbursements have been reflected as a

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## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 3. Collaboration Arrangements (Continued)

reduction of research and development expense of \$0.4 million for the year ended December 31, 2011 and \$0.3 million for the year ended December 31, 2010.

## 4. Marketable Securities

The following table is a summary of available-for-sale debt securities and money market funds recorded in cash equivalents or marketable securities in the Company's Consolidated Balance Sheets. Estimated fair values of available-for-sale securities are generally based on prices obtained from commercial pricing services:

(in thousands)	Amortized Cost	December 31, 2012		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
U.S. government securities	\$ 27,197	\$ 10	\$ (2)	\$ 27,205
U.S. government agencies	115,397	85	(16)	115,466
U.S. corporate notes	91,544	32	(10)	91,566
U.S. commercial paper	23,082			23,082
Money market funds	78,646			78,646
Total	\$ 335,866	\$ 127	\$ (28)	\$ 335,965

(in thousands)	Amortized Cost	December 31, 2011		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
U.S. government securities	\$ 66,150	\$ 24	\$ (17)	\$ 66,174
U.S. government agencies	93,183	9	(17)	93,175
U.S. corporate notes	2,707		(2)	2,705
U.S. commercial paper	34,973	3		34,976
Money market funds	38,721			38,721
Total	\$ 235,734	\$ 36	\$ (19)	\$ 235,751

The following table summarizes the classification of the available-for-sale debt securities on the Company's condensed consolidated balance sheets:

(in thousands)	December 31, 2012	December 31, 2011
Cash and cash equivalents	\$ 86,298	\$ 38,721
Short-term investments	153,640	196,137
Long-term marketable securities	95,194	
Restricted cash	833	893
Total	\$ 335,965	\$ 235,751

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

The following table provides the net realized gains (losses) on marketable securities for the periods presented:

(in thousands)	Year Ended December 31,		
	2012	2011	2010
Realized gains	\$ 9	\$	\$ 3
Realized losses		(2)	
Net realized gains (losses)	\$ 9	\$ (2)	\$ 3

The Company realized no gains or losses in 2012 and 2011 that were previously classified as unrealized gains and losses in accumulated other comprehensive income at December 31, 2011 and 2010, respectively.

The following table provides the breakdown of the marketable securities with unrealized losses at December 31, 2012:

(in thousands)	In loss position for less than 12 months		In loss position for more than 12 months		Total	
	Estimated		Estimated		Estimated	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government securities	\$ 7,002	\$ (2)	\$	\$	\$ 7,002	\$ (2)
U.S. government agencies	10,499	(16)			10,499	(16)
U.S. corporate notes	34,693	(10)			34,693	(10)
Total	\$ 52,194	\$ (28)	\$	\$	\$ 52,194	\$ (28)

At December 31, 2012, all of the available-for-sale debt securities had contractual maturities within twenty-four months and the average duration of marketable securities was approximately 9 months. The Company does not intend to sell the investments which are in an unrealized loss position and it is unlikely that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. The Company has determined that the gross unrealized losses on its marketable securities at December 31, 2012 were temporary in nature.

**5. Fair Value Measurements**

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

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

*Level 1 Inputs* Quoted prices for identical instruments in active markets.

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## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 5. Fair Value Measurements (Continued)

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

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

The estimated fair values of the Company's financial assets were as follows:

Types of Instruments (in thousands)	Estimated Fair Value Measurements at Reporting Date Using:			
	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs	Total
	Level 1	Level 2	Level 3	
<i>Assets at December 31, 2012:</i>				
U.S. government securities	\$ 27,205	\$	\$	\$ 27,205
U.S. government agency securities	56,969	58,497		115,466
U.S. corporate notes	40,472	51,094		91,566
U.S. commercial paper		23,082		23,082
Money market funds	78,646			78,646
Total assets measured at estimated fair value	\$ 203,292	\$ 132,673	\$	\$ 335,965
<i>Liabilities at December 31, 2012:</i>				
Convertible subordinated notes	\$	\$ 194,050	\$	\$ 194,050

Types of Instruments (in thousands)	Estimated Fair Value Measurements at Reporting Date Using:			
	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs	Total
	Level 1	Level 2	Level 3	
<i>Assets at December 31, 2011:</i>				
U.S. government securities	\$ 66,174	\$	\$	\$ 66,174
U.S. government agency securities	55,901	37,274		93,175
U.S. corporate notes	2,705			2,705
U.S. commercial paper		34,976		34,976
Money market funds	38,721			38,721
Total assets measured at estimated fair value	\$ 163,501	\$ 72,250	\$	\$ 235,751
<i>Liabilities at December 31, 2011:</i>				
Convertible subordinated notes	\$	\$ 189,588	\$	\$ 189,588

At December 31, 2012, there were no transfers from Level 1 to Level 2 or from Level 2 to Level 1 in comparison to December 31, 2011.





Table of Contents**THERAVANCE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. Property and Equipment**

Property and equipment consists of the following:

(in thousands)	December 31,	
	2012	2011
Computer equipment	\$ 3,027	\$ 3,158
Software	5,073	4,628
Furniture and fixtures	3,829	3,821
Laboratory equipment	29,229	28,894
Leasehold improvements	17,416	17,263
	58,574	57,764
Less accumulated depreciation and amortization	(49,420)	(47,392)
Property and equipment, net	\$ 9,154	\$ 10,372

Depreciation expense was \$3.3 million in 2012, \$3.8 million in 2011 and \$3.9 million in 2010. The change in accumulated depreciation is net of asset retirements. In 2012, the Company recognized a write-off of \$0.2 million related to assets that could no longer be used in operations.

**7. Long-Term Obligations**

Long-term obligations are as follows:

(in thousands)	December 31,	
	2012	2011
Convertible subordinated notes	\$ 172,500	\$ 172,500
<i>Convertible Subordinated Notes Due 2015</i>		

In January 2008, the Company closed an underwritten public offering of \$172.5 million aggregate principal amount of unsecured convertible subordinated notes which will mature on January 15, 2015. The financing raised proceeds, net of issuance costs, of \$166.7 million. The notes bear interest at the rate of 3.0% per year, that is payable semi-annually in arrears in cash on January 15 and July 15 of each year, beginning on July 15, 2008.

The notes are convertible, at the option of the holder, into shares of the Company's common stock at an initial conversion rate of 38.6548 shares per \$1,000 principal amount of the notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately \$25.87 per share. The debt issuance costs, which are included in other long-term assets, are being amortized on a straight-line basis over the life of the notes. Unamortized debt issuance costs totaled \$1.7 million as of December 31, 2012. Amortization expense was \$0.8 million in 2012, 2011 and 2010.

Holders of the notes will be able to require the Company to repurchase some or all of their notes upon the occurrence of a fundamental change (as defined) at 100% of the principal amount of the notes being repurchased plus accrued and unpaid interest. The Company may not redeem the notes prior to January 15, 2012. On or after January 15, 2012 and prior to the maturity date, the Company, upon notice of redemption, may redeem for cash all or part of the notes if the last reported sale price of its common stock has been greater than or equal to 130% of the conversion price then in effect for

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**THERAVANCE, INC.**

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

**7. Long-Term Obligations (Continued)**

at least 20 trading days during any 30 consecutive trading day period prior to the date on which it provides notice of redemption. The redemption price will equal 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest up to but excluding the redemption date.

**8. Stock-Based Compensation**

*Equity Incentive Plans*

In May 2012, the Company adopted the 2012 Equity Incentive Plan (2012 Plan). The number of shares of the Company's common stock available 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. While a maximum of 12,667,411 shares could be added to the 2012 Plan from the Prior Plans, since this assumes that all the awards outstanding on December 31, 2011 will be forfeited, repurchased, cash settled or terminated, the actual number to be added to the 2012 Plan share reserve may be less. The Company reserved 6,500,000 shares of common stock for issuance under the 2012 Plan. No additional awards have been or will be made after May 15, 2012 under the 2004 Plan. Stock options and 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 the number of stock awards granted under the 2004 Plan on or after January 1, 2012, using the same ratios described. As of December 31, 2012, approximately 5,023,370 shares remained available for issuance under the 2012 Plan.

The 2012 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, stock unit awards and stock appreciation rights ("SARs") to employees, non-employee directors and consultants of the Company. 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. The Company may grant options with different vesting terms from time to time. Unless an employee's termination of service is due to disability or death, upon termination of service, any unexercised vested options will be forfeited at the end of three months or the expiration of the option, whichever is earlier.

*Employee Stock Purchase Plan*

Under the 2004 Employee Stock Purchase Plan (ESPP), the Company's non-officer employees may purchase common stock through payroll deductions at a price equal to 85 percent of the lower of the fair market value of the stock at the beginning of the offering period or at the end of each applicable purchase period. The ESPP provides for consecutive and overlapping offering periods of 24 months in duration, with each offering period composed of four consecutive six-month purchase periods. The purchase periods end on either May 15<sup>th</sup> or November 15<sup>th</sup>. ESPP contributions are limited to a maximum of 15 percent of an employee's eligible compensation.

The Company's ESPP plan also includes a feature that provides for a new offering period to begin when the fair market value of the Company's common stock on any purchase date during an offering

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**THERAVANCE, INC.**

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

**8. Stock-Based Compensation (Continued)**

period falls below the fair market value of the Company's common stock on the first day of such offering period. This feature is called a reset. The Company had resets for new twenty-four month offering periods starting on May 16, 2008, November 16, 2008, May 16, 2010, November 16, 2011, May 16, 2012 and November 16, 2012. The Company applied modification accounting to determine the incremental fair value associated with the ESPP resets and recognized the related incremental stock-based compensation expense.

As of December 31, 2012, a total of 2,025,000 shares of common stock were approved and authorized for issuance under the ESPP. Through December 31, 2012, the Company had issued 1,601,425 shares under the ESPP at an average price of \$10.75 per share. As of December 31, 2012, total shares remaining available for issuance under the ESPP were 423,575.

*Performance-Contingent Restricted Stock Awards*

In 2012, the Compensation Committee of the Company's Board of Directors approved the grant of 44,500 performance-contingent RSAs to senior management. These awards have dual triggers of vesting based upon the achievement of one of three possible performance goals by December 31, 2013, as well as a requirement for continued employment through early 2016. As of December 31, 2012, one of the performance goals had been deemed achieved and time-based vesting commenced with respect to these awards. As a result, compensation expense of \$0.4 million was recognized in 2012, and the remaining unrecognized expense will be recognized over the remaining vesting period using the graded vesting expense attribution method.

In 2011, the Compensation Committee of the Company's Board of Directors approved the grant of 1,290,000 performance-contingent RSAs to senior management. These awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011-2016 and continued employment, both of which must be satisfied in order for the RSAs to vest. Expense associated with these RSAs would be recognized, if at all, during these years depending on the probability of meeting the performance conditions. The maximum potential expense associated with the RSAs could be up to approximately \$31.9 million (allocated as \$6.3 million for research and development expense and \$25.6 million for general and administrative expense) if all of the performance conditions are achieved on time. As of December 31, 2012, the Company had determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense has been recognized. As the RSAs are dependent upon the achievement of certain performance conditions, the expense associated with the RSAs may vary significantly from period to period.

In 2011, the Compensation Committee of the Company's Board of Directors approved the grant of a 25,000 performance-contingent RSA to a non-executive officer that has dual triggers of vesting based upon the achievement of a performance condition over a timeframe from 2012-2013 and continued employment through 2014, both of which must be satisfied in order for the award to vest in full. The maximum potential expense associated with this award is approximately \$475,000, which would be recognized in increments based on the achievement of the performance condition. As of December 31, 2012, the Company had determined that the achievement of the requisite performance condition was not probable and, as a result, no compensation expense has been recognized. As the vesting of the RSAs is contingent upon the achievement of the performance condition, the expense associated with the RSA may vary significantly from period to period.

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**THERAVANCE, INC.**

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

**8. Stock-Based Compensation (Continued)**

*Performance-Contingent Restricted Stock Units*

In 2010, the Compensation Committee of the Company's Board of Directors approved the grant of 210,000 performance-contingent RSUs to senior management. These awards have dual triggers of vesting based upon the successful achievement of certain corporate operating milestones during 2010 and 2011, as well as a requirement for continued employment through early 2014. As of February 11, 2011, both performance milestones had been deemed achieved, and time-based vesting commenced with respect to all of the performance-contingent RSU shares. As a result, compensation expense was \$0.3 million in 2012 and \$ 1.3 million in 2011, and the remaining unrecognized expense will be recognized over the remaining vesting period using the graded vesting expense attribution method.

*Director Compensation Program*

Non-employee directors of the Company receive compensation for services provided as a director. Each member of the Company's Board who is not an employee receives an annual retainer as well as a fee for each board and committee meeting attended. Commencing on April 27, 2011, chairpersons of the various committees of the Board, the Audit Committee, the Compensation Committee, Nominating/Corporate Governance Committee and the Science and Technology Advisory Committee receives a fixed retainer. The lead independent director also receives a fixed retainer.

Each of the Company's independent directors receives periodic automatic grants of equity awards under a program implemented under the 2004 Plan. These grants are non-discretionary. Only independent directors of the Company or affiliates of such directors are eligible to receive automatic grants under the 2004 Plan. Under the program, as amended in July 2010, each individual who first becomes an independent director will, on the date such individual joins the Board, automatically be granted (i) a one-time grant of RSUs covering 6,000 shares of the Company's common stock and (ii) a one-time nonstatutory stock option grant covering 6,000 shares of the Company's common stock.

These initial equity grants vest monthly over the director's first two years of service. In addition, on the date of joining the Board, the new director will also receive the standard annual equity awards (if joining on the date of the Company's Annual Meeting of Stockholders) or pro-rated annual equity awards (if joining on any other date). The pro-ration is based upon the number of months of service the new board member will provide during the 12-month period ending on the one-year anniversary of the most recent annual meeting of stockholders. Annually, upon his or her re-election to the Board at the Annual Meeting of Stockholders, each independent director is automatically granted both an RSU covering 6,000 shares of the Company's common stock and a nonstatutory stock option covering 6,000 shares of the Company's common stock. These standard annual equity awards vest monthly over the twelve month period of service following the date of grant. In addition, all automatic equity awards vest in full if the Company is subject to a change in control or the Board member dies while in service.

Table of Contents**THERAVANCE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. Stock-Based Compensation (Continued)***Stock-Based Compensation Expense*

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

(in thousands)	Year Ended December 31,		
	2012	2011	2010
Research and development	\$ 13,667	\$ 13,422	\$ 10,322
General and administrative	10,116	11,494	8,687
<b>Total stock-based compensation expense</b>	<b>\$ 23,783</b>	<b>\$ 24,916</b>	<b>\$ 19,009</b>

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

(in thousands)	Year Ended December 31,		
	2012	2011	2010
Employee stock options	\$ 3,417	\$ 4,528	\$ 7,003
Employee RSUs	11,546	13,290	9,783
Employee RSAs	7,968	5,498	398
Non-employee options and RSUs		307	1,186
ESPP	852	1,293	639
<b>Total stock-based compensation expense</b>	<b>\$ 23,783</b>	<b>\$ 24,916</b>	<b>\$ 19,009</b>

Total stock-based compensation expense capitalized to inventory was \$0.4 million for the year ended December 31, 2012, and none for each of the years ended December 31, 2011 and 2010.

In connection with the retirement of the Company's former chairman of the Board of Directors in April 2010, the Company entered into a consulting agreement that provided for, among other things, the acceleration of an RSU that was scheduled to vest through April 2012 and an extension of the period of time in which vested stock options may be exercised until to the stated expiration date of the stock options. As a result of the stock option modification, the Company recorded an expense of \$0.9 million in June 2010.

As of December 31, 2012, the unrecognized stock-based compensation cost, net of expected forfeitures, and the estimated weighted-average amortization period, using the straight-line attribution method, was as follows:

(in thousands, except amortization period)	Unrecognized Compensation Cost	Weighted-average amortization period (years)
Stock options	\$ 6,442	2.6
RSUs	14,027	2.1
RSAs	23,525	3.5
<b>Total unrecognized stock-based compensation expense</b>	<b>\$ 43,994</b>	

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## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 8. Stock-Based Compensation (Continued)

*Compensation Awards*

The following table summarizes equity award activity under the 2008 Plan and the 2004 Plan, and related information:

(in thousands, except per share data)	Number of Shares Subject to Outstanding Options	Weighted-average Exercise Price of Outstanding Options	Number of Shares Subject to Outstanding RSUs	Weighted-average Fair Value per Share at Grant	Number of Shares Outstanding Subject to Vesting or Performance Conditions with Vesting	Weighted-average Fair Value per Share at Grant
Balance at December 31, 2009	8,414	\$ 16.63	2,042	\$ 14.15	57	\$ 25.87
Granted	321	14.90	1,170	10.55		
Exercised	(784)	9.60				
Released RSUs/RSAs			(657)	13.20	(24)	25.55
Forfeited	(297)	26.17	(658)	26.26		
Balance at December 31, 2010	7,654	16.91	1,897	12.45	33	26.10
Granted	629	21.98	471	24.96	2,483	24.61
Exercised	(1,265)	8.87				
Released RSUs/RSAs			(797)	13.89	(74)	24.96
Forfeited	(127)	29.15	(29)	15.35		
Balance at December 31, 2011	6,891	18.62	1,542	15.47	2,442	24.62
Granted	335	21.91	528	18.45	447	18.11
Exercised	(947)	7.98				
Released RSUs/RSAs			(752)	14.19	(388)	24.77
Forfeited	(159)	24.43	(78)	18.48		
Balance at December 31, 2012	6,120	20.30	1,240	17.32	2,501	23.43

As of December 31, 2012, the aggregate intrinsic value of the options outstanding was \$30.0 million and the aggregate intrinsic value of the options exercisable was \$28.1 million.

The total intrinsic value of the options exercised was \$15.2 million in 2012, \$17.1 million in 2011, and \$7.2 million in 2010. The total estimated fair value of options vested was \$4.1 million in 2012, \$6.4 million in 2011, and \$8.2 million in 2010.

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## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 8. Stock-Based Compensation (Continued)

*Valuation Assumptions*

The Company based the range of weighted-average estimated values of employee stock option grants and rights granted under the employee stock purchase plan, as well as the weighted-average assumptions used in calculating these values, on estimates at the date of grant, as follows:

	Year Ended December 31,		
	2012	2011	2010
<b>Employee stock options</b>			
Risk-free interest rate	0.74% - 1.17%	1.10% - 2.57%	1.11% - 2.82%
Expected life (in years)	5 - 6	5 - 6	5 - 6
Volatility	55% - 60%	49% - 55%	48% - 52%
Dividend yield	%	%	%
Weighted-average estimated fair value of stock options granted	\$11.50	\$11.11	\$7.41
<b>Employee stock purchase plan issuances</b>			
Risk-free interest rate	0.14% - 0.29%	0.05% - 0.54%	0.19% - 0.79%
Expected life (in years)	0.5 - 2	0.5 - 2	0.5 - 2
Volatility	51% - 64%	48% - 59%	50% - 69%
Dividend yield	%	%	%
Weighted-average estimated fair value of ESPP issuances	\$8.07	\$9.46	\$7.63

*Range of Stock Option Exercise Prices*

As of December 31, 2012, all outstanding options to purchase common stock of the Company are summarized in the following table (in thousands, except years and per share data):

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number Outstanding	Weighted-average Remaining Contractual Life in Years	Weighted-average Exercise Prices	Options Exercisable	Weighted-average Remaining Contractual Life in Years	Weighted-average Exercise Price
\$3.10	191	0.8	\$ 3.10	191	0.8	\$ 3.10
\$6.15 - \$6.70	25	5.9	6.15	25	5.9	6.15
\$9.69	1,140	1.3	9.69	1,140	1.3	9.69
\$9.70 - \$16.00	839	4.1	14.71	768	3.8	14.87
\$16.01 - \$19.80	1,228	4.5	18.17	956	3.3	18.13
\$19.81 - \$24.71	594	7.2	22.16	316	5.7	22.38
\$24.72 - \$29.70	1,124	4.1	28.29	1,038	3.6	28.42
\$29.71 - \$35.46	979	4.1	33.52	979	4.1	33.52
Total	6,120	3.8	20.30	5,413	3.2	20.31



Table of Contents**THERAVANCE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****9. Income Taxes**

Due to ongoing operating losses and the inability to recognize any income tax benefit, there is no provision for income taxes for any periods presented.

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

(in thousands)	December 31,	
	2012	2011
Deferred tax assets:		
Net operating loss carryforwards	\$ 411,000	\$ 359,000
Deferred revenues	4,000	56,000
Capitalized research and development expenditures	35,000	35,000
Research and development tax credit carryforwards	38,000	37,000
Other	33,000	31,000
Valuation allowance	(521,000)	(518,000)
Net deferred tax assets	\$	\$

The differences between the U.S. federal statutory income tax rate to the Company's effective tax rate are as follows:

	Year Ended December 31,		
	2012	2011	2010
U.S. federal statutory income tax rate	34.00%	34.00%	34.00%
State income taxes, net of federal benefit			5.83
Federal and state research credits	(4.21)	1.67	2.91
Non-deductible executive compensation	(13.24)		
Stock-based compensation	(1.36)	(0.32)	2.29
Expiration of net operating loss	(1.81)	(0.42)	
Other	(2.09)	0.75	(0.05)
Change in valuation allowance	(11.29)	(35.68)	(44.98)
Effective tax rate	(0.00)%	(0.00)%	(0.00)%

Realization of deferred tax assets is dependent on future taxable income, if any, the timing and the amount of which are uncertain. Accordingly, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$3.0 million in 2012, \$50.0 million in 2011, and \$35.0 million in 2010.

As of December 31, 2012, the Company had federal net operating loss carryforwards of approximately \$1,221.4 million, which will expire from 2018 through 2032, and federal research and development tax credit carryforwards of approximately \$43.2 million, which will expire from 2018 through 2031. The Company also had state net operating loss carryforwards of approximately \$563.4 million expiring in the years 2014 through 2032 and state research tax credits of approximately \$52.2 million, which do not expire.

Table of Contents**THERAVANCE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****9. Income Taxes (Continued)**

The net operating loss deferred tax asset balances as of December 31, 2012 and 2011 do not include excess tax benefits from stock option exercises. Stockholders' equity (net capital deficiency) will be credited if and when such excess tax benefits are ultimately realized.

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

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. As of December 31, 2012 and 2011, the Company had no accrued interest or penalties due to the Company's net operating losses available to offset any tax adjustment.

The Company conducted an analysis through 2012 to determine whether an ownership change had occurred since inception. The analysis indicated that two ownership changes occurred in prior years. However, notwithstanding the applicable annual limitations, no portion of the net operating loss or credit carryforwards are expected to expire before becoming available to reduce federal and state income tax liabilities.

*Uncertain Tax Positions*

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

Unrecognized tax benefits as of December 31, 2009	\$ 39,600
Gross decrease for tax positions for prior years	
Gross increase in tax positions for current year	3,000
Unrecognized tax benefits as of December 31, 2010	42,600
Gross decrease for tax positions for prior years	
Gross increase in tax positions for current year	4,300
Unrecognized tax benefits as of December 31, 2011	46,900
Gross decrease for tax positions for prior years	
Gross increase in tax positions for current year	5,600
Unrecognized tax benefits as of December 31, 2012	\$ 52,500

If the Company eventually is able to recognize these uncertain positions, most of the \$52.5 million of the unrecognized benefit would reduce the effective tax rate, except for excess tax benefits related to stock-based payments. The Company currently has a full valuation allowance against its deferred tax asset which would impact the timing of the effective tax rate benefit should any of these uncertain positions be favorably settled in the future. The Company does not believe it is reasonably possible that its unrecognized tax benefits will significantly change within the next twelve months.

The Company is subject to taxation in the U.S. and various state jurisdictions. The tax years 1996 and forward remain open to examination by the federal and most state tax authorities due to net operating loss and overall credit carryforward positions.

Table of Contents**THERAVANCE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. Commitments and Contingencies***Operating Leases and Subleases*

The Company entered into amendments to its South San Francisco, CA facility leases in June 2010. These amendments extend the lease terms through May 2020 and the Company may extend the terms for two additional five-year periods. The Company leases approximately 130,000 square feet of office and laboratory space in two buildings.

The Company leases its South San Francisco, California, facilities under a non-cancelable operating lease. Future minimum lease payments under this lease, exclusive of executory costs, at December 31, 2012, were as follows:

*(in thousands)*

Years ending December 31:

2013	\$ 5,029
2014	4,859
2015	5,005
2016	5,155
2017	5,310
Thereafter	13,497

Total	\$ 38,855
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Expenses and income associated with operating leases were as follows:

<i>(in thousands)</i>	Year Ended December 31,		
	2012	2011	2010
Rent expense	\$ 5,720	\$ 6,702	\$ 6,779
Sublease income, net	(160)	(637)	(622)
<i>Purchase Obligations</i>			

As of December 31, 2012, the Company had outstanding purchase obligations on commercially reasonable terms, primarily for services under contract research, development and clinical and commercial supply agreements totaling \$2.5 million.

In 2012, the Company issued purchase orders to Astellas for the purchase of VIBATIV® active pharmaceutical ingredient and other raw materials of up to \$7.7 million, and as of December 31, 2012 the Company had purchased \$5.8 million pursuant to these orders. The remaining active pharmaceutical ingredient and other raw materials will not be purchased. Also in 2012, the Company issued purchase orders to Astellas for the purchase of VIBATIV® finished goods inventories of up to \$4.2 million, and as of December 31, 2012 these finished goods inventories remained subject to release.

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

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

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**THERAVANCE, INC.**

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

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

employment. The maximum potential expense associated with this program is \$31.9 million related to stock-based compensation expense and \$38.2 million related to cash bonus expense, which would be recognized in increments based on achievement of the performance conditions. As of December 31, 2012, the Company's management determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense has been recognized. If sufficient performance conditions are achieved in 2013, then the Company would recognize up to \$15.6 million in stock-based compensation expense associated with these RSAs and \$18.7 million related to cash bonus expense in 2013.

*Guarantees and Indemnifications*

The Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recognized any liabilities relating to these agreements as of December 31, 2012.

**11. Subsequent Events**

*Convertible Subordinated Notes Due 2023*

On January 24, 2013, the Company completed an underwritten public offering of \$287.5 million aggregate principal amount of unsecured 2.125% convertible subordinated notes due 2023, which includes the full exercise of the underwriters' over-allotment option for \$37.5 million aggregate principal amount. The financing raised proceeds, net of issuance costs, of approximately \$244.4 million. The notes are convertible into shares of the Company's common stock at an initial conversion rate of 35.9903 shares per \$1,000 principal amount of the notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately \$27.79 per share.

In connection with the offering of the notes, the Company entered into privately-negotiated capped call option transactions. The capped call option transaction is an integrated instrument consisting of a call option purchased by the Company with a strike price equal to the conversion price of \$27.79 per share for the underlying number of shares and a cap price of \$38.00 per share. The cap component is economically equivalent to a call option sold by the Company for the underlying number of shares with a strike price of \$38.00 per share. As an integrated instrument, the settlement of the capped call coincides with the due date of the convertible debt. At settlement, the Company will receive from its hedge counterparty a number of our common shares that will range from zero, if the stock price is below \$27.79 per share, to a maximum of 2,779,659 shares, if the stock price is above \$38.00 per share. However, if the market price of our common stock, as measured under the terms of the capped call transactions, exceeds \$38.00 per share, there is no incremental anti-dilutive benefit from the capped call. The aggregate cost of the capped call options was \$36.8 million.

*Sale of Stock*

On February 15, 2013, the Company and GSK entered into an agreement pursuant to which GSK agreed to purchase through an affiliate, in a private placement, 116,527 shares of the Company's common stock at \$22.03 per share, for an aggregate purchase price of approximately \$2.6 million, pursuant to its rights under the Company's governance agreement with GSK dated June 4, 2004, as amended.

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**SUPPLEMENTARY FINANCIAL DATA (UNAUDITED)**  
**(In thousands, except per share amounts)**

The following table presents certain unaudited consolidated quarterly financial information for the eight quarters in the period ended December 31, 2012. This information has been prepared on the same basis as the audited Consolidated Financial Statements and includes all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the unaudited quarterly results of operations set forth herein.

	For the Quarters Ended(1)			
	March 31	June 30	September 30	December 31
	(in thousands except per share data)			
<b>2012:</b>				
Revenue	\$ 127,099	\$ 1,430	\$ 1,430	\$ 5,799
Operating expenses	(41,059)	(37,139)	(34,780)	(35,778)
Income (loss) from operations	86,040	(35,709)	(33,350)	(29,979)
Net income (loss)	84,594	(37,120)	(34,692)	(31,323)
Basic net income (loss) per share	\$ 1.01	\$ (0.42)	\$ (0.37)	\$ (0.33)
Diluted net income (loss) per share	\$ 0.93	\$ (0.42)	\$ (0.37)	\$ (0.33)
<b>2011:</b>				
Revenue	\$ 6,331	\$ 6,389	\$ 6,431	\$ 5,361
Operating expenses	(27,633)	(30,046)	(35,633)	(40,937)
Loss from operations	(21,302)	(23,657)	(29,202)	(35,576)
Net loss	(22,667)	(25,045)	(30,626)	(37,007)
Basic and diluted net loss per share	\$ (0.28)	\$ (0.31)	\$ (0.37)	\$ (0.45)

(1)

The 2012 and 2011 amounts were computed independently for each quarter, and the sum of the quarters may not total the annual amounts.

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**The Board of Directors and Stockholders of Theravance, Inc.**

We have audited the accompanying consolidated balance sheets of Theravance, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (net capital deficiency) and cash flows for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Theravance, Inc. at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Theravance Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 26, 2013 expressed an unqualified opinion therein.

/s/ ERNST & YOUNG LLP

Redwood City, California  
February 26, 2013

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

Not applicable.

**ITEM 9A. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures.*

We conducted an evaluation as of December 31, 2012, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (Exchange Act) is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

*Management's Report on Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) of the Exchange Act. Internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management's assessment included evaluation of such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2012.

Our independent registered public accounting firm, Ernst & Young LLP, has audited our internal control over financial reporting as of December 31, 2012. Their attestation report on the audit of our internal control over financial reporting is included below.

*Limitations on the Effectiveness of Controls*

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

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effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

*Changes in Internal Control over Financial Reporting*

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act, which occurred during the fourth fiscal quarter of the year ended December 31, 2012 which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**The Board of Directors and Stockholders of Theravance, Inc.**

We have audited Theravance, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Theravance, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Theravance, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Theravance, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (net capital deficiency) and cash flows for each of the three years in the period ended December 31, 2012 of Theravance, Inc. and our report dated February 26, 2013, expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Redwood City, California  
February 26, 2013

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**ITEM 9B. OTHER INFORMATION**

None.

**PART III**

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

For the information required by this Item, see "Questions and Answers About this Proxy Material and Voting", "Election of Directors", "Nominees", "Audit Committee", "Meetings of the Board of Directors", "Code of Business Conduct", "Executive Officers", and "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

**ITEM 11. EXECUTIVE COMPENSATION**

For the information required by this Item, see "2012 Director Compensation", "Compensation of Named Executive Officers", "Compensation Committee Report" and "Compensation Committee Interlocks and Insider Participation" in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

For the information required by this Item, see "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans" in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

For the information required by this Item, see "Independence of the Board of Directors" and "Review, Approval or Ratification of Transactions with Related Persons" in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

For the information required by this Item, see "Ratification of Selection of Independent Registered Public Accounting Firm" and "Pre-Approval Policies and Procedures" in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

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**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a)

The following documents are filed as part of this Annual Report on Form 10-K:

1.

Financial Statements:

The following financial statements and schedules of the Registrant are contained in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K:

<u>Consolidated Balance Sheets as of December 31, 2012 and 2011</u>	<u>59</u>
<u>Consolidated Statements of Operations for each of the three years in the period ended December 31, 2012</u>	<u>60</u>
<u>Consolidated Statements of Comprehensive Loss for each of the three years in the period ended December 31, 2012</u>	<u>61</u>
<u>Consolidated Statements of Stockholders' Equity (Net Capital Deficiency) for each of the three years in the period ended December 31, 2012</u>	<u>62</u>
<u>Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2012</u>	<u>63</u>
<u>Notes to Consolidated Financial Statements</u>	<u>64</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>93</u>

2.

Financial Statement Schedules:

All schedules are omitted because they are either not applicable or the required information is shown in the Consolidated Financial Statements or notes thereto.

(b)

Exhibits required by Item 601 of Regulation S-K

The information required by this Item is set forth on the exhibit index that follows the signature page of this report.

Table of Contents**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 26, 2013

THERAVANCE, INC.

By: /s/ RICK E WINNINGHAM

Rick E Winningham  
*Chief Executive Officer*

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Rick E Winningham and Michael W. Aguiar, each of whom may act without joinder of the other, as their true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for such person and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to the annual report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ RICK E WINNINGHAM</u> Rick E Winningham	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	February 26, 2013
<u>/s/ MICHAEL W. AGUIAR</u> Michael W. Aguiar	Senior Vice President, Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	February 26, 2013
<u>/s/ HENRIETTA HOLSMAN FORE</u> Henrietta Holsman Fore	Director	February 26, 2013
<u>/s/ ROBERT V. GUNDERSON, JR.</u> Robert V. Gunderson, Jr.	Director	February 26, 2013

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Signature	Title	Date
<u>/s/ ARNOLD J. LEVINE, PH.D.</u> Arnold J. Levine, Ph.D.	Director	February 26, 2013
<u>/s/ BURTON G. MALKIEL, PH.D.</u> Burton G. Malkiel, Ph.D.	Director	February 26, 2013
<u>/s/ PETER S. RINGROSE, PH.D.</u> Peter S. Ringrose, Ph.D.	Director	February 26, 2013
<u>/s/ WILLIAM H. WALTRIP</u> William H. Waltrip	Director	February 26, 2013
<u>/s/ GEORGE M. WHITESIDES, PH.D.</u> George M. Whitesides, Ph.D.	Director	February 26, 2013
<u>/s/ WILLIAM D. YOUNG</u> William D. Young	Director	February 26, 2013

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### Exhibits

Exhibit Number	Description	Incorporated by Reference	
		Form	Filing Date/Period End Date
3.3	Amended and Restated Certificate of Incorporation	S-1	7/26/04
3.4	Certificate of Amendment of Restated Certificate of Incorporation	10-Q	3/31/07
3.5	Amended and Restated Bylaws (as amended by the board of directors April 25, 2007)	10-Q	9/30/08
4.1	Specimen certificate representing the common stock of the registrant	10-K	12/31/06
4.2	Amended and Restated Rights Agreement between the registrant and The Bank of New York, as Rights Agent, dated as of June 22, 2007	10-Q	6/30/07
4.3	Indenture dated as of January 23, 2008 by and between Theravance, Inc. and The Bank of New York Trust Company, N.A., as trustee	8-K	1/23/08
4.4	Form of 3.0% Convertible Subordinated Note Due 2015 (included in Exhibit 4.3)		
4.5	Amendment to Amended and Restated Rights Agreement between the registrant and The Bank of New York Mellon Corporation, as Rights Agent, dated November 21, 2008	8-K	11/25/08
10.1+	1997 Stock Plan	S-1	6/10/04
10.2+	Long-Term Stock Option Plan	S-1	6/10/04
10.3+	2004 Equity Incentive Plan, as amended by the board of directors February 10, 2010 and approved by stockholders April 27, 2010 and forms of equity award	10-K	12/31/11
10.4	Employee Stock Purchase Plan, as amended April 27, 2010	10-Q	6/30/10
10.5+	Change in Control Severance Plan, as amended and restated on July 27, 2007	10-Q	6/30/08
10.6	Amended and Restated Lease Agreement, 951 Gateway Boulevard, between the registrant and HMS Gateway Office L.P., dated January 1, 2001	S-1	6/10/04
10.7	Lease Agreement, 901 Gateway Boulevard, between the registrant and HMS Gateway Office L.P., dated January 1, 2001	S-1	6/10/04
10.8*	Collaboration Agreement between the registrant and Glaxo Group Limited, dated as of November 14, 2002	S-1	9/29/04
10.9+	Form of Indemnification Agreement for directors and officers of the registrant	S-1	6/10/04
10.10	Class A Common Stock Purchase Agreement between the registrant and SmithKline Beecham Corporation, dated as of March 30, 2004	S-1	6/10/04
10.11	Amended and Restated Investors' Rights Agreement by and among the registrant and the parties listed therein, dated as of May 11, 2004	S-1	6/10/04
10.12	Amended and Restated Governance Agreement by and among the registrant, SmithKline Beecham Corporation and GlaxoSmithKline dated as of June 4, 2004	S-1	7/26/04

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Exhibit Number	Description	Incorporated by Reference	
		Form	Filing Date/Period End Date
10.13*	Strategic Alliance Agreement between the registrant and Glaxo Group Limited, dated as of March 30, 2004	S-1	9/30/04
10.14*	License Agreement between the registrant and Janssen Pharmaceutica, dated as of May 14, 2002	S-1	9/29/04
10.15+	Offer Letter with Rick E Winningham dated August 23, 2001	S-1	6/10/04
10.16	Form of Class A Common Stock Purchase Agreement between the registrant and GSK	S-1	9/29/04
10.17+	Offer Letter with Michael W. Aguiar dated as of January 31, 2005	10-K	12/31/04
10.18+	Form of Notice of Grant and Stock Option Agreement under 2004 Equity Incentive Plan	10-K	12/31/04
10.19+	Form of Notice of Restricted Stock Award and Restricted Stock Agreement under 2004 Equity Incentive Plan (form in effect through 2010)	10-Q	6/30/07
10.20+	Description of Cash Bonus Program, as amended	10-K	12/31/09
10.21*	License, Development and Commercialization Agreement between the registrant and Astellas Pharma Inc. dated November 7, 2005	S-3	1/30/06
10.22*	Amendment to License, Development and Commercialization Agreement between the registrant and Astellas Pharma Inc. dated as of July 18, 2006	10-Q	9/30/06
10.23+	Offer letter with Leonard Blum dated July 27, 2007	10-Q	9/30/07
10.24+	Amended and Restated 2008 New Employee Equity Incentive Plan and forms of equity award	10-K	12/31/11
10.25+	Amendment to Offer Letter between the registrant and Leonard Blum dated July 23, 2008	10-K	12/31/08
10.26+	Amendment to Offer Letter between the registrant and Rick E Winningham dated December 23, 2008	10-K	12/31/08
10.27+	Amendment to Change in Control Severance Plan effective December 16, 2009	10-K	12/31/09
10.28+	2010 Change in Control Severance Plan adopted December 16, 2009	10-K	12/31/09
10.29	First Amendment to Lease for 901 Gateway Boulevard effective as of June 1, 2010 between ARE-901/951 Gateway Boulevard, LLC and the registrant	10-Q	6/30/10
10.30	First Amendment to Lease for 951 Gateway Boulevard effective as of June 1, 2010 between ARE-901/951 Gateway Boulevard, LLC and the registrant	10-Q	6/30/10
10.31	Common Stock Purchase Agreement among the registrant, Glaxo Group Limited and GlaxoSmithKline LLC, dated as of November 29, 2010	8-K	11/29/10
10.32	Second Amendment to Amended and Restated Governance Agreement among the registrant, Glaxo Group Limited, GlaxoSmithKline plc and GlaxoSmithKline LLC, dated as of November 29, 2010	8-K	11/29/10

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Exhibit Number	Description	Incorporated by Reference	
		Form	Filing Date/Period End Date
10.33+	Form of Amendment to Restricted Stock Unit Agreements between the registrant and each current member of the Board of Directors outstanding as of December 31, 2010	10-K	12/31/10
10.34*	Amendment to Strategic Alliance Agreement dated October 3, 2011	10-K	12/31/11
10.35	Common Stock Purchase Agreement, dated April 2, 2012, by and among Theravance, Inc., Glaxo Group Limited and GlaxoSmithKline LLC	8-K	4/2/12
10.36+	Form of Notice of Performance-Contingent Restricted Stock Award and Restricted Stock Award Agreement under 2004 Equity Incentive Plan (executive officer form)	10-Q	3/30/12
10.37+	Form of Notice of Performance-Contingent Restricted Stock Award and Restricted Stock Award Agreement under 2004 Equity Incentive Plan	10-Q	3/30/12
10.38+	2012 Equity Incentive Plan, as approved by the board of directors February 8, 2012 and approved by stockholders May 15, 2012 and forms of equity award	10-Q	6/30/12
10.39*	Technology Transfer and Supply Agreement, dated as of May 22, 2012 between Theravance, Inc. and Hospira Worldwide, Inc.	10-Q	6/30/12
21.1	List of Subsidiaries	10-K	12/31/05
23.1	Consent of Independent Registered Public Accounting Firm		
24.1	Power of Attorney (see signature page to this Annual Report on Form 10-K)		
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14 under the Securities Exchange Act of 1934		
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14 under the Securities Exchange Act of 1934		
32	Certifications Pursuant to 18 U.S.C. Section 1350		
101^	The following materials from Registrant's Annual Report on Form 10-K for the year ended December 31, 2012, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Consolidated Balance Sheets at December 31, 2012 and 2011, (ii) Consolidated Statements of Income for the years ended December 31, 2012, 2011, and 2010, (iii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2012, 2011 and 2010, (iv) Consolidated Statements of Stockholders' Equity for the years ended December 31, 2012, 2011 and 2010, (v) Consolidated Statements of Cash Flows for years ended December 31, 2012, 2011 and 2010, and (vi) Notes to Consolidated Financial Statements.		

+ Management contract or compensatory plan or arrangement required to be filed pursuant to Item 15(b) of Form 10-K.

\* Confidential treatment has been requested for certain portions which are omitted in the copy of the exhibit electronically filed with the Securities and Exchange Commission. The omitted information has been filed separately with the Securities and Exchange Commission pursuant to Theravance Inc.'s application for confidential treatment.

^ XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Exchange Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.



