

THERAVANCE INC  
Form 10-K  
February 27, 2008

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2007

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

**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**

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

**Title of Each Class**

**Name of Each Exchange On Which Registered**

**Common Stock \$0.01 Par Value**

**Nasdaq Global Market**

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: **NONE**

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

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

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

Indicate by check mark 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

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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 (consisting of Common Stock, \$0.01 par value and Class A Common Stock, \$0.01 par value) held by non-affiliates of the registrant based upon the closing price of the Common Stock on the Nasdaq Global Market on June 30, 2007 was \$991,687,968. Shares of Common Stock and Class A Common Stock held by each executive officer and director and by each person or group who owns 5% or more of the outstanding Common Stock or Class A Common Stock at June 30, 2007 have been excluded. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

On February 15, 2008, there were 51,696,607 shares of the registrant's Common Stock and 9,401,499 shares of the registrant's Class A 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 2008 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2007, 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.**

**2007 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," "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 and the risks discussed in our other filings with the Securities and Exchange Commission (SEC). 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. 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 gastrointestinal motility dysfunction. Of our six programs in development, four are in late stage our telavancin program focusing on treating serious Gram-positive bacterial infections with Astellas Pharma Inc. (Astellas), our Horizon program (formerly referred to as Beyond Advair) with GlaxoSmithKline plc (GSK), our Gastrointestinal Motility Dysfunction program, and TD-1792, our investigational antibiotic for the treatment of serious Gram-positive bacterial infections. By leveraging our proprietary insight of multivalency to drug discovery focused primarily on validated targets, we are pursuing a next generation 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. None of our product candidates have been approved for marketing and sale to patients and we have not received any product revenue to date.

Our strategy focuses on the discovery, development and commercialization of medicines with superior efficacy, convenience, tolerability and/or safety. By primarily focusing on biological targets that have been clinically validated either by existing medicines or by potential medicines in late-stage clinical studies, we can leverage years of available knowledge regarding a target's activity and the animal models used to test potential medicines against such targets. We move a product candidate into development after it demonstrates the potential to be superior to existing medicines or drug candidates in animal models that we believe correlate to human clinical experience. This strategy of developing the next generation of existing medicines or potential medicines is designed to reduce technical risk and

increase productivity. 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. In total, our research and development expenses, including stock-based compensation expense in 2007 and 2006 associated with the adoption of the Financial Accounting Standards Board's Statement No. 123 (revised 2004), "Share-Based Payment" (SFAS 123(R)), incurred for all of our therapeutic programs in 2007, 2006 and 2005 were \$155.3 million, \$166.6 million and \$137.9 million, respectively.

Based on results from ATLAS 1 and ATLAS 2, our large Phase 3 clinical studies with telavancin in complicated skin and skin structure infections (cSSSI), in December 2006 we submitted our first new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for telavancin for the treatment of cSSSI caused by Gram-positive bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA). Telavancin is a rapidly bactericidal, injectable antibiotic with a multifunctional mechanism of action. In October 2007, we announced that the FDA issued an approvable letter for our NDA filing. On January 11, 2008, we announced that the Anti-Infective Drugs Advisory Committee (AIDAC) to the FDA was scheduled to meet to discuss telavancin for the proposed indication to treat cSSSI on February 27, 2008. On February 23, 2008, the FDA informed us that the AIDAC meeting was cancelled. On February 25, 2008, the FDA issued a public notice stating that the AIDAC meeting had been cancelled to allow time for the FDA to review and resolve several outstanding issues. The public notice further stated that the FDA intends to continue evaluating the telavancin NDA and will schedule an AIDAC meeting in the future, as needed. We are planning to meet with the FDA to discuss these issues. Telavancin is also under review for its safety and efficacy by regulatory authorities in the European Union for the treatment of complicated skin and soft tissue infections and in Canada for the treatment of cSSSI.

In December 2007, we announced results from ATTAIN 1 and ATTAIN 2, our large Phase 3 clinical studies with telavancin in hospital-acquired pneumonia (HAP). In each study, telavancin achieved its objective of non-inferiority in the all-treated and clinically evaluable patient populations. Currently, we plan to submit an NDA for the HAP indication to the FDA in 2008. Our goal is for telavancin to become first-line therapy in treating serious Gram-positive cSSSI and HAP infections.

In November 2005, we entered into a collaboration arrangement with Astellas for the development and commercialization of telavancin. In July 2006, Japan was added to our telavancin collaboration, thereby giving Astellas worldwide rights to this potential medicine. Through December 31, 2007, we have received \$158.0 million in upfront, milestone and other fees from Astellas and we are eligible to receive up to \$60.0 million in remaining milestone payments. If telavancin is commercialized, we will be entitled to receive royalties on global sales of telavancin ranging, on a percentage basis, from the high teens to the upper twenties depending on sales volume.

In November 2002, we entered into our Horizon collaboration with GSK to develop and commercialize a long-acting beta<sub>2</sub> agonist (LABA) product candidate for the treatment of asthma and chronic obstructive pulmonary disease (COPD). This product candidate is intended to be administered via inhalation once daily both as a single new medicine and as part of a new combination medicine with an inhaled corticosteroid (ICS). The collaboration intends to develop a new generation product to replace Advair®, which had approximately \$7.0 billion of sales for 2007 as reported by GSK in February 2008. Each company contributed four LABA product candidates to the collaboration. In April 2007, the collaboration reported results from the Phase 2b clinical program, in which two LABA product candidates, dosed once daily, achieved clinically significant increases in bronchodilation at least equivalent to that of salmeterol dosed twice daily. In late December 2007 the lead compound in development, a GSK-discovered compound GW642444 ('444), progressed into a 28-day Phase 2b study designed to enroll 600 patients with asthma and progressed into a 28-day Phase 2b study designed to enroll 600 patients with COPD in late February 2008. In addition, in a recent 8-week, 650-patient Phase 2 study of the lead ICS, GW685698 ('698), both doses studied (200 mcg and 400 mcg) showed

improved lung function dosed once daily compared to placebo, with no adverse effect on cortisol excretion. Based on these results, three 8-week studies with '698 comprising a Phase 2b program designed to enroll a total of 1,800 patients with mild, moderate and severe asthma, began enrolling patients in late December 2007. In parallel, combination studies to enable Phase 3 studies with both '444 and '698 are scheduled to initiate in 2008.

In March 2004, we entered into a strategic alliance agreement with GSK. Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from all of our full drug discovery programs initiated prior to September 1, 2007, on pre-determined terms and on an exclusive, worldwide basis. The remaining programs that GSK has the right to license are (i) our peripheral Opioid-Induced Bowel Dysfunction (PUMA) program, (ii) our AT1 Receptor Neprilysin Inhibitor hypertension (ARNI) program and (iii) our MonoAmine Reuptake Inhibitor chronic pain (MARIN) program. When GSK exercises its option to license any of our programs, we receive an upfront payment, additional payments upon achievement of future milestones and royalties on any future sales. In addition, GSK funds all of the subsequent development and commercialization costs for product candidates in such programs. Consistent with our strategy, we will be obligated at our sole cost to discover two structurally different product candidates for any programs that are licensed by GSK under the alliance. To date, GSK has licensed our two COPD programs under the terms of the strategic alliance, our long-acting muscarinic antagonist (LAMA) program and our bifunctional muscarinic antagonist betaagonist (MABA) program, and we have discovered and delivered to GSK two structurally different product candidates for both of these programs. In September 2007, we announced that we retained full ownership rights of our Gastrointestinal Motility Dysfunction program as a result of GSK's decision not to exercise its right to license the program under the strategic alliance.

GSK currently owns all of our Class A common stock, which represents approximately 15.4% of our outstanding stock as of February 15, 2008.

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

In the table above:

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

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.

NDA indicates that a new drug application has been submitted to and accepted for filing by the FDA.

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.



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

## **Our Relationship with Astellas**

### ***2005 License, Development and Commercialization Agreement***

In November 2005, we entered into a collaboration arrangement with Astellas for the development and commercialization of telavancin. In July 2006, Japan was added to our telavancin collaboration, thereby giving Astellas worldwide rights to this potential medicine. Through December 31, 2007, we have received \$158.0 million in upfront, milestone and other fees from Astellas and we are eligible to receive up to an additional \$60.0 million in remaining milestone payments related to regulatory filings and approvals in various regions of the world.

If telavancin is commercialized, we will be entitled to receive royalties on global sales of telavancin that, on a percentage basis, range from the high teens to the upper twenties depending on sales volume. Under this arrangement, we will be responsible for substantially all costs to develop and obtain U.S. regulatory approval for telavancin for cSSSI and HAP, and Astellas will be responsible for substantially all costs associated with commercialization and further development of telavancin.

## **Our Relationship with GlaxoSmithKline**

### ***Horizon Program***

In November 2002, we entered into our Horizon collaboration with GSK to develop and commercialize a LABA product candidate for the treatment of asthma and COPD. This product candidate is intended to be administered via inhalation once daily both as a single new medicine and as part of a new combination medicine with an ICS. Each company contributed four LABA product candidates to the collaboration.

In connection with the Horizon program, in 2002 we received from GSK an upfront payment of \$10.0 million and sold to an affiliate of GSK shares of our Series E preferred stock for an aggregate purchase price of \$40.0 million. In addition, we were eligible to receive up to \$495.0 million in development, approval, launch, and sales milestones and royalties on the sales of any product resulting from this program. As of December 31, 2007, we have received a total of \$60.0 million in upfront and development milestone payments. GSK has determined to focus the collaboration's resources on the development of the lead LABA, GW642444, a GSK-discovered compound, together with the lead ICS. Accordingly, we do not expect to receive any further milestone payments from the Horizon program. In the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple regions in the world, we will be obligated to make milestone payments to GSK of up to \$220.0 million. Based on available information, we do not estimate that a significant portion of these potential milestone payments to GSK are likely to be made in the next three years. In addition, we are entitled to receive the same royalties on product sales of medicines from the Horizon program, regardless of whether the product candidate originated with Theravance or with GSK. The royalty structure is downward-tiering and would result in an average percentage royalty rate in the low- to mid-teens at annual net sales of up to approximately \$4.0 billion and the average royalty rate would decline to single digits at annual net sales of more than \$6.0 billion. Sales of single agent LABA medicines and combination LABA/ICS medicines would be combined for the purposes of this royalty calculation.

### ***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 all

of our full drug discovery programs initiated prior to September 1, 2007, on pre-determined terms and on an exclusive, worldwide basis. We are obligated to use diligent efforts to discover and deliver compounds for the alliance and, pursuant to our obligations, we initiated three new full discovery programs between May 2004 and August 2007. These three programs are (i) our peripheral Opioid-Induced Bowel Dysfunction (PUMA) program, (ii) our AT1 Receptor Nephrylsin Inhibitor hypertension (ARNI) program and (iii) our MonoAmine Reuptake Inhibitor chronic pain (MARIN) program. GSK has the right to license product candidates from these three programs, and must exercise this right no later than sixty days subsequent to the "proof-of-concept" stage (generally defined as the successful completion of a Phase 2a clinical study showing efficacy and tolerability if the biological target for the drug has been clinically validated by an existing medicine, and successful completion of a Phase 2b clinical study showing efficacy and tolerability if the biological target for the drug has not been clinically validated by an existing medicine). Under the terms of the strategic alliance, GSK has only one opportunity to license each of our programs. Upon its 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. Consistent with our strategy, we are obligated at our sole cost to discover two structurally different product candidates for any programs that are licensed by GSK under the alliance. If these programs are 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 these programs. For product candidates licensed to date under this agreement, the royalty structure for a product containing one of our compounds as a single active ingredient would result in an average percentage royalty rate in the low double digits. If a product is successfully commercialized, in addition to any royalty revenue that we receive, the total upfront and milestone payments that we could receive in any given program that GSK licenses range from \$130.0 million to \$162.0 million for programs with single-agent medicines and up to \$252.0 million for programs with both a single-agent and a combination medicine. 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. To date, GSK has licensed our two COPD programs: LAMA and MABA. We received a \$5.0 million payment from GSK in connection with its license of each of our LAMA and MABA programs in August 2004 and March 2005, respectively. GSK has chosen not to license our bacterial infections program, our anesthesia program and our Gastrointestinal Motility Dysfunction program. There can be no assurance that GSK will license any other programs under the terms of the alliance agreement or at all, which could have an adverse effect on our business and financial condition.

In connection with the strategic alliance with GSK, we received from GSK a payment of \$20.0 million. In May 2004, GSK purchased through an affiliate 6,387,096 shares of our Class A common stock for an aggregate purchase price of \$108.9 million. Through December 31, 2007, we have received \$36.0 million in upfront and milestone payments from GSK relating to the strategic alliance agreement. In addition, pursuant to a partial exercise of its rights under the governance agreement, upon the closing of our initial public offering on October 8, 2004, GSK purchased through an affiliate an additional 433,757 shares of Class A common stock. GSK's ownership position of our outstanding stock was approximately 15.4% as of February 15, 2008.

Under the alliance, GSK had the right between June 1 and July 1, 2007, to elect to acquire (call) half of Theravance's outstanding shares of common stock at \$54.25 per share. On June 29, 2007, GSK elected not to exercise the call, which triggered the right of our stockholders to require us to redeem (put) up to 50% of their common stock at \$19.375 per share between August 1 and September 12, 2007 with funds provided by GSK. One stockholder exercised his put right for one share of common stock. In exchange for GSK providing the funds to pay the redemption price for the one share of common stock, and pursuant to our certificate of incorporation, we issued to GSK one share of our Class A

common stock. The common share that we redeemed pursuant to the stockholder's exercise of the put right was retired and cancelled.

## **Our Relationship with AstraZeneca AB**

### ***2006 License Agreement with AstraZeneca AB***

In May 2006, we entered into a license agreement with AstraZeneca AB (AstraZeneca) pursuant to which we granted an exclusive, worldwide license to AstraZeneca to develop and commercialize our intravenous anesthetic compound TD-4756. We received a \$1.0 million upfront payment from AstraZeneca and we are eligible to receive milestone payments and royalties on global sales. Through December 31, 2007, we have fully recognized the upfront payment as revenue (\$0.4 million and \$0.6 million in 2007 and 2006, respectively), due to the completion of our performance obligations under the contract.

## **Development Programs**

### ***Bacterial Infections***

Our bacterial infections program has been dedicated to finding new antibiotics for serious infections due to *Staphylococcus aureus* and other Gram-positive bacteria, including MRSA. Our program resulted in the discovery of telavancin and TD-1792, both investigational antibiotics for the treatment of serious Gram-positive bacterial infections including resistant pathogens such as MRSA.

#### *Telavancin Status*

Telavancin, the lead product candidate in our bacterial infections program targeting resistant Gram-positive pathogens, is a bactericidal, once-daily injectable antibiotic with a multifunctional mechanism of action. Our goal is for telavancin to become first-line therapy in treating serious Gram-positive cSSSI and HAP bacterial infections.

Based on results from ATLAS 1 and ATLAS 2, our large, multi-center, multinational, double-blind, randomized Phase 3 clinical studies in which 1,867 patients were enrolled and treated, 719 of whom were infected with MRSA, in December 2006 we submitted our first NDA to the FDA for telavancin for the treatment of cSSSI caused by Gram-positive bacteria. In October 2007, the FDA issued an approvable letter for our NDA filing. The FDA letter indicated that the telavancin application is approvable, subject to: resolution of current good manufacturing practices (cGMP) compliance issues not specifically related to telavancin at a third-party manufacturer; and submission of revised labeling or re-analyses of clinical data or additional clinical data. On January 11, 2008, we announced that the Anti-Infective Drugs Advisory Committee (AIDAC) to the FDA was scheduled to meet to discuss telavancin for the proposed indication to treat cSSSI on February 27, 2008. On February 23, 2008, the FDA informed us that the AIDAC meeting was cancelled. On February 25, 2008, the FDA issued a public notice stating that the AIDAC meeting had been cancelled to allow time for the FDA to review and resolve several outstanding issues. The public notice further stated that the FDA intends to continue evaluating the telavancin NDA and will schedule an AIDAC meeting in the future, as needed. We are planning to meet with the FDA to discuss these issues. Telavancin is also under review for its safety and efficacy by regulatory authorities in the European Union for the treatment of complicated skin and soft tissue infections and in Canada for the treatment of cSSSI.

In December 2007 we announced results from ATTAIN 1 and ATTAIN 2, our large, multi-center, multinational, double-blind, randomized Phase 3 clinical studies in HAP in which 1,503 patients were enrolled and treated, 464 of whom were infected with MRSA. In each study, telavancin achieved its objective of non-inferiority in the all-treated and clinically evaluable patient populations. Currently, we plan to submit an NDA for the HAP indication to the FDA in 2008.

*TD-1792 Status*

TD-1792 is an investigational heterodimer antibiotic that combines the antibacterial activities of a glycopeptide and a beta-lactam in one molecule. The goal of our program with TD-1792 is to develop a next-generation antibiotic for the treatment of serious infections caused by MRSA. In July 2007, we announced results from an approximately 200-patient study in cSSSI with TD-1792. In September 2007, we announced that we retained full ownership rights of TD-1792 as a result of Astellas' decision not to exercise its right to license the compound under our telavancin collaboration arrangement. We are currently conducting further studies with TD-1792 to evaluate the potential of this compound in more serious infections such as bacteremia.

***Respiratory***

We have three development programs directed toward asthma and/or chronic obstructive pulmonary disease (COPD): our Horizon program with GSK, and our MABA and our LAMA programs, each of which have been licensed to GSK under our strategic alliance.

*Horizon Program with GSK*

The goal of our Horizon program with GSK is to develop and commercialize a LABA product candidate intended for once-daily administration as a single agent for treatment of COPD or in combination with an ICS for the treatment of asthma and COPD. We believe once-a-day dosing would be a significant convenience and compliance- enhancing advantage leading to improved overall clinical outcomes in patients with asthma or COPD.

The collaboration intends to develop a new generation product to replace GSK's Advair®, an inhaled combination medicine consisting of a long-acting beta<sub>2</sub> agonist (salmeterol) and an ICS (fluticasone) taken twice daily, which had sales of approximately \$7.0 billion for 2007 as reported by GSK in February 2008. Each company contributed four LABA product candidates to the collaboration. Beta<sub>2</sub> agonists are medicines that work by relaxing the muscles that line the bronchial airways, allowing the capacity of the airways to expand (known as bronchodilation), leading to the relief and/or prevention of many of the symptoms of asthma and COPD. Beta<sub>2</sub> agonists, like many other medications to treat asthma and COPD, are administered by inhalation. Patients typically self-administer these medications by breathing in a measured amount of drug using hand-held devices, such as a metered dose inhaler (MDI), or a dry powder inhaler (DPI).

*Horizon Status*

In April 2007 the collaboration reported results from the Phase 2b clinical program, in which two LABA product candidates, dosed once daily, achieved clinically significant increases in bronchodilation at least equivalent to that of salmeterol dosed twice daily. Based on these results, in late December 2007 the lead LABA compound in development, a GSK-discovered compound GW642444 ('444), progressed into a 28-day Phase 2b study designed to enroll 600 patients with asthma and progressed into a 28-day Phase 2b study designed to enroll 600 patients with COPD in late February 2008. In addition, in a recent 8-week, 650-patient Phase 2 study of the lead ICS, GW685698 ('698), both doses studied (200 mcg and 400 mcg) showed improved lung function dosed once daily compared to placebo, with no adverse effect on cortisol excretion. Based on these results, three 8-week studies with '698 comprising a Phase 2b program designed to enroll a total of 1,800 patients with mild, moderate and severe asthma, began enrolling patients in late December 2007. In parallel, combination studies to enable Phase 3 studies with both '444 and '698 are scheduled to initiate in 2008.

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

In our MABA program, we are developing with GSK a long-acting inhaled bronchodilator that is bifunctional, meaning that one small molecule functions both as a muscarinic antagonist and as a beta<sub>2</sub> receptor agonist. By combining bifunctional activity and high lung selectivity, we intend to develop a medicine with greater efficacy than single-mechanism bronchodilators (such as tiotropium or salmeterol) and with equal or better tolerability. This bifunctional bronchodilator could potentially then serve as a basis for improved "triple therapy" through co-formulation with another inhaled respiratory compound into a single product that could potentially deliver three complementary therapeutic effects for patients with respiratory disease.

GSK is obligated to fund all development, manufacturing and commercialization activities for product candidates in this program.

*MABA Status*

The first compound in the MABA program, GSK961081, successfully completed single- and multiple-dose Phase 1 studies in healthy volunteers and commenced a Phase 2 study in late October 2007. We expect to complete and report results from this study in late 2008.

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

Inhaled muscarinic antagonists are frequently used as bronchodilators for COPD. Inhaled muscarinic antagonists work by inhibiting muscarinic receptors in the bronchial airways, which leads to muscle relaxation and improved lung function. We are developing with GSK an inhaled LAMA designed to produce a prolonged blockade of the relevant receptor sub-types while also being highly lung-selective, which means that lower concentrations of drug should get into the systemic circulation. Higher lung selectivity should result in improved tolerability.

GSK is obligated to fund all development, manufacturing and commercialization activities for product candidates in this program.

*LAMA status*

The investigational inhaled bronchodilator GSK1160724 commenced a Phase 1 study in December 2007. We expect to complete and report results from this study in 2008. GSK currently has at least one competing LAMA product candidate that is further advanced in development than our LAMA product candidate, which is the second LAMA compound we delivered to GSK under this program.

***Gastrointestinal (GI) Motility Dysfunction***

Our Gastrointestinal (GI) Motility Dysfunction program is dedicated to finding new medicines for GI motility disorders such as chronic idiopathic constipation (CIC), constipation-predominant irritable bowel syndrome (C-IBS), functional dyspepsia and delayed gastric emptying.

Our lead compound in this area is TD-5108, a highly selective 5-HT<sub>4</sub> receptor agonist. We believe that the high degree of selectivity of TD-5108 provides the potential for it to become a next-generation medicine for the treatment of severe constipation and possibly C-IBS.

*TD-5108 Status*

In June 2007 we announced results from our approximately 400-patient ACCORD Phase 2 clinical study in chronic constipation with TD-5108. In September 2007, we announced that we retained full ownership rights of our GI Motility Dysfunction program as a result of GSK's decision not to exercise its right to license the program under the strategic alliance. At our end-of-Phase 2 meeting with the FDA for TD-5108 in late 2007, the FDA confirmed that the TD-5108 data package from the ACCORD study was adequate to progress TD-5108 into Phase 3 efficacy and safety studies in patients

with CIC. The FDA also indicated that the size of the clinical program should be consistent with the International Conference on Harmonisation (ICH) guidelines for the development of drugs for chronic use. We recently completed enrollment in a thorough QTc study on this compound. Our preliminary review of the electrocardiogram data from the study suggests that such data is unreliable due to problems with the conduct of the study, not with the intrinsic properties of TD-5108. We believe that lack of assay sensitivity in the active control arm of the study (moxifloxacin) renders the results uninterpretable, and that the study will need to be repeated in order to generate scientifically valid results. We currently intend to initiate a repeat of the study later this year.

### Research Programs

Currently we have three full discovery programs:

Our Peripheral Opioid-Induced Bowel Dysfunction (or PUMA) Program aims to generate a once-daily oral treatment to prevent bowel dysfunction in patients treated with opioid agonists. The Investigational New Drug (IND) application for the lead compound in the PUMA Program was submitted to the FDA on February 26, 2008.

Our AT1 Receptor Nephilysin Inhibitor (or ARNI) Program seeks to produce an effective monotherapy for hypertension. The ARNI Program is in discovery stage.

Our MonoAmine Reuptake Inhibitor (or MARIN) Program is attempting to identify an efficacious oral treatment of chronic pain. The MARIN Program is in discovery stage.

### Multivalency

Our proprietary approach combines chemistry and biology to efficiently 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.

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 primarily to validated targets to efficiently 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; and

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; and

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 global pharmaceutical companies.*** Our strategy is to seek collaborations with leading global pharmaceutical companies to accelerate development and commercialization of our product candidates at the strategically appropriate time. Our Horizon program and our strategic alliance with GSK, and our telavancin collaboration with Astellas, 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, Merck & Co., Millennium Pharmaceuticals, Inc., Pfizer Inc, Gilead Sciences, Inc. and ICOS Corporation.

***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 multivalency and other technologies to maintain what we believe are our competitive advantages in drug discovery.

## Manufacturing

We currently rely on a number of third parties, including contract manufacturing organizations and our collaborative partners, to produce our compounds. Manufacturing of compounds in our Horizon, LAMA and MABA programs is handled by GSK. Additionally, GSK will be responsible for the manufacturing of any additional product candidates associated with the programs that it licenses under the strategic alliance agreement. For telavancin, we are responsible for the manufacture of active pharmaceutical ingredient (API) and drug product for the first six months of commercialization if telavancin is approved for sale by regulatory authorities. The October 2007 FDA approvable letter regarding telavancin indicated that our third-party manufacturer for telavancin drug product would have to resolve cGMP compliance issues not specifically related to telavancin prior to the approval of telavancin. This supplier subsequently received a warning letter from the FDA related to these issues and, to date, the supplier has been unable to reach formal resolution of these issues with the FDA.

Astellas is responsible for manufacturing API and drug product for commercial sale or any further development thereafter.

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 develop internal manufacturing capacity in order to successfully 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.

### **Government Regulation**

The development and commercialization of 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 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 approves the Investigational New Drug application, clinical studies are usually carried out in three phases and must be conducted under FDA oversight. These phases generally include the following:

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

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

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

The results of product development, preclinical studies and clinical studies must be submitted to the FDA as part of a new drug application, or NDA. The NDA also must contain extensive manufacturing information. NDAs for new chemical entities are subject to timelines governed by the Prescription Drug User Fee Act (PDUFA) which requires FDA action within six months of acceptance for filing for applications that are granted priority review and ten months for applications that receive standard review. At the end of the applicable period, FDA must take action stating that the application is (i) approved, (ii) approvable, or (iii) not approvable. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur 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 or recall products, withdraw approvals, enjoin violations, and institute criminal prosecution.



If we obtain regulatory approval for a medicine, this clearance will be limited to those diseases and conditions for which the medicine is effective, as demonstrated through clinical studies. 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. 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 or recall 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. The regulatory approval process in other countries includes all of the risks associated with FDA approval described above.

### **Patents and Proprietary Rights**

We will be able to protect our technology from unauthorized use by third parties only to the extent that our technology is covered by valid and enforceable patents or is effectively maintained as trade secrets. Our success in the future will depend in part on obtaining patent protection for our product candidates. Accordingly, patents and other proprietary rights are essential elements of our business. Our policy is to seek in the United States and selected foreign countries patent protection for novel technologies and compositions of matter that are commercially important to the development of our business. For proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery process that involve proprietary know-how and technology that is not covered by patent applications, we rely on trade secret protection and confidentiality agreements to protect our interests. We require all of our employees, consultants and advisors to enter into confidentiality agreements. Where it is necessary to share our proprietary information or data with outside parties, our policy is to make available only that information and data required to accomplish the desired purpose and only pursuant to a duty of confidentiality on the part of those parties.

As of December 31, 2007, we own 111 issued United States patents and 377 granted foreign patents. In addition, we have 141 United States patent applications pending and 788 foreign patent applications pending. 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.

United States issued patents and foreign patents generally expire 20 years after filing. The patent rights relating to telavancin owned by us and licensed to Astellas currently consist of United States patents that expire between 2019 and 2024, 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 Pharmaceutical 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. Astellas has agreed to assume responsibility for these payments under the terms of our license agreement with them. The license is terminable by us upon prior written notice to Janssen or upon an uncured breach or a liquidation event of one of the parties.

## Competition

Our objective is to discover, develop and commercialize new medicines with superior efficacy, convenience, tolerability and/or safety. To the extent that we are able to develop medicines, they are likely to compete with existing drugs that have long histories of effective and safe use and with new therapeutic agents. We expect that any medicines that we commercialize with our collaborative partners or on our own will compete with existing, 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.

*Telavancin.* We anticipate that, if approved, telavancin will compete with vancomycin, a generic drug that is manufactured by a variety of companies, as well as other drugs targeted at Gram-positive bacterial infections. Currently marketed products include but are not limited to daptomycin (marketed by Cubist Pharmaceuticals, Inc.), linezolid (marketed by Pfizer Inc) and tigecycline (marketed by Wyeth). In addition, NDAs for two additional compounds, dalbavancin (marketed by Pfizer Inc; received an approvable letter from the FDA in June 2006) and ceftobiprole (developed by Basilea Pharmaceuticals and marketed by Johnson & Johnson; NDA submitted in May 2007) are currently being reviewed by the FDA. Additional compounds in late-stage development that represent potential competition for telavancin include, but are not limited to: oritavancin (being developed by Targanta Therapeutics), iclaprim (being developed by Arpida Ltd), and ceftaroline (being developed by Forest Laboratories).

*Horizon Program with GSK.* We anticipate that, if approved, any product from our Horizon program with GSK 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 salmeterol and fluticasone (marketed by GSK), formoterol and budesonide (marketed by Novartis and AstraZeneca), and tiotropium (marketed by Boehringer Ingelheim and Pfizer Inc). Indacaterol as a single agent and in combination with an ICS (mometasone), is being developed by Novartis and Schering-Plough. In addition, indacaterol combined with a muscarinic antagonist is being developed by

Novartis. New combinations of formoterol with ciclesonide, fluticasone or mometasone are being developed by Sanofi-Aventis, Abbott (with SkyePharma), and Novartis (with Schering-Plough) respectively. All of these efforts represent potential competition for any product from our Horizon program.

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

## Employees

As of December 31, 2007, we had 311 full-time employees, over 252 of which were primarily engaged 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 investors 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.

## 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 telavancin is not approved by regulatory agencies, including the U.S. Food and Drug Administration, our business will be adversely affected and the price of our securities will decline.**

Telavancin is the first product candidate for which we submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA). On October 19, 2007 we received an approvable letter from the FDA indicating that our telavancin NDA is approvable, subject to: resolution of current good manufacturing practices (cGMP) compliance issues not specifically related to telavancin at our third-party manufacturer; and submission of revised labeling or re-analyses of clinical data or additional clinical data. Although we believe that no additional clinical studies will need to be initiated to respond to the approvable letter, there can be no assurance that we will be able to respond fully or adequately to the FDA's requests using currently existing clinical data, that our third-party manufacturer will successfully resolve the cGMP issues that the FDA noted, or that the FDA will approve the current telavancin NDA on the basis of existing preclinical and clinical data or at all. If we are required to undertake additional clinical trials or to identify and qualify a new contract manufacturer for telavancin, we would incur significant additional cost and regulatory action on our NDA would be materially delayed. On January 11, 2008, we announced that the Anti-Infective Drugs Advisory Committee (AIDAC) to the FDA was scheduled to meet to discuss telavancin for the proposed indication to treat complicated skin and skin structure infections (cSSSI) on February 27, 2008, and on February 23, 2008, the FDA informed us that the AIDAC meeting was cancelled. On February 25, 2008, the FDA issued a public notice stating that the AIDAC meeting had been cancelled to allow time

for the FDA to review and resolve several outstanding issues. The public notice further stated that the FDA intends to continue evaluating the telavancin NDA and will schedule an AIDAC meeting in the future, as needed. We are planning to meet with the FDA to discuss these issues. Any adverse developments or results or perceived adverse developments or results with respect to our telavancin NDA and, if rescheduled, the AIDAC meeting could adversely affect the prospects of telavancin and would cause the price of our securities to fall.

Telavancin is also under review by European Union and Canadian regulatory agencies. If the regulatory authorities require additional clinical data, or the labeling for telavancin that is ultimately approved by regulatory authorities materially limits the targeted patient population, our business will be harmed and the price of our securities will fall. Furthermore, if our third party manufacturer's cGMP issues are not satisfactorily resolved or regulatory action on telavancin is otherwise delayed for a lengthy period, or if a regulatory authority does not approve telavancin, our business will be harmed and the price of our securities will fall.

In addition, in 2008 we plan to submit an NDA to the FDA for the additional indication of hospital-acquired pneumonia (HAP) for telavancin. Regulatory action with respect to this application could take a significant amount of time and could require that we undertake additional studies. Any adverse developments or results or perceived adverse developments or results with respect to our efforts to obtain approval of telavancin for this indication will cause the price of our securities to fall.

**If our product candidates, in particular telavancin, are determined to be unsafe or ineffective in humans, our business will be adversely affected and the price of our securities will decline.**

We have never commercialized any of our product candidates. We are uncertain whether any of our compounds or 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 compounds and 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, based on the results of Phase 1 studies. To date, the data supporting our drug discovery and development programs is derived solely from laboratory experiments, preclinical studies and clinical studies. A number of other compounds remain in the lead identification, lead optimization, preclinical testing or early clinical testing stages.

Several recent, well-publicized safety-related product withdrawals, suspensions, post-approval labeling revisions to include black-box warnings and changes in approved indications, as well as growing public and governmental scrutiny of safety issues, have created an increasingly conservative regulatory environment. Therefore, there is a risk that the FDA may implement new standards or change their interpretation of existing requirements for demonstrating that a product candidate is safe and effective, which could cause non-approval or delays in its approval of product candidates, including telavancin. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. If we are unable to discover and develop medicines that are effective and safe in humans, our business will fail.

**Any failure of a product candidate in clinical studies or any delay in commencing or completing clinical studies for our product candidates would harm our business and cause our stock price to decline.**

Each of our product candidates must undergo extensive preclinical and clinical studies as a condition to regulatory approval. Preclinical and clinical studies are expensive and take many years to

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complete. The commencement and completion of clinical studies for our product candidates may be delayed by many factors, including:

poor effectiveness of product candidates during clinical studies;

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

our inability or the inability of our collaborators or licensees to manufacture or obtain from third parties materials sufficient for use in preclinical 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;

unreliable results from clinical studies, which we recently experienced with our thorough QTc study on TD-5108;

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

inability to enter into corporate partnering arrangements relating to the development and commercialization of our later-stage programs;

delays in patient enrollment, which we experienced in our Phase 3 HAP program for telavancin, 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;

a regional disturbance where we are enrolling patients in our clinical trials, such as a pandemic, terrorist activities or war, or a natural disaster; and

varying interpretation of data by the FDA and similar foreign regulatory agencies.

If our product candidates fail to demonstrate safety and effectiveness in clinical trials, or if our clinical trials are materially delayed, our business and financial condition will be adversely affected.

**If our product candidates that we develop on our own or through collaborative partners are not approved by regulatory agencies, 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. In order to market our medicines in the European Union and other 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 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 studies. In addition, clinical studies of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates. If our clinical studies are substantially delayed or fail to prove the safety and effectiveness of our product candidates, we may not receive regulatory approval of any of our product candidates and our business and financial condition will be materially harmed.

**We rely on a number of manufacturers for our product candidates and we rely on a single manufacturer for supply of telavancin, and our business will be seriously harmed if these manufacturers are not able to satisfy our demand and alternative sources are not available.**

We have limited in-house production capabilities and depend entirely on a number of third-party active pharmaceutical ingredient (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, we may not be able to locate alternative manufacturers or enter into favorable 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, and adversely affect the commercial introduction of any approved products. 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.

We are in the process of having telavancin API and drug product manufactured for us in order to meet our obligations to Astellas in connection with commercial launch in the event telavancin is approved for sale by regulatory authorities. We have a single source of supply of telavancin API and a single source of supply of telavancin drug product. If we are unable to have telavancin manufactured in a timely manner, or if Astellas is unable to arrange for the expanded commercial manufacture of telavancin, the commercial introduction of telavancin, if approved, would be adversely affected. During a mid-2007 audit of our supplier for telavancin drug product, a district office of the FDA noted deficiencies, not specifically related to the manufacture of telavancin drug product, with the supplier's quality and laboratory systems at the plant where telavancin is manufactured. Although the supplier reported to us that it had responded to all noted deficiencies and had obtained verbal acknowledgment from the FDA's district office that it was in compliance, on November 16, 2007 the supplier received a warning letter from the FDA related to these issues and, to date, the supplier has been unable to reach formal resolution of these issues with the FDA. On October 19, 2007 we received an approvable letter from the FDA indicating that the telavancin NDA is approvable subject to, among other things, resolution of these cGMP compliance issues at our supplier. It is impossible to predict the amount of time it will take for the supplier and the FDA to resolve these compliance issues, and any material delay will harm our business and cause the price of our securities to fall. In addition, if this manufacturer is unable to resolve its issues with the FDA, we might be required to identify and qualify an alternative manufacturer for telavancin, which would involve significant costs and material delays.

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 and validation activities for the new manufacturer;

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

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

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

In addition, we are using a single source for the supply of our APIs and a single source for the supply of drug product for TD-1792, our investigational heterodimer antibiotic, as well as for TD-5108 in our GI Motility Dysfunction program. If any supplier fails to continue to produce supplies for our development activities for these compounds in acceptable quantity and/or quality, our clinical studies could be delayed.

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

If approved by the relevant regulatory agencies, the commercial success of telavancin will depend upon its acceptance by physicians, patients, third party payors and the medical community in general. We cannot be sure that telavancin will be accepted by these parties even if it is approved by the relevant regulatory authorities. If approved, telavancin will compete with vancomycin, a relatively inexpensive generic drug that is manufactured by a variety of companies, a number of existing anti-infectives manufactured and marketed by major pharmaceutical companies and others, and potentially against new anti-infectives that are not yet on the market. Even if the medical community accepts that telavancin is safe and efficacious for its approved indications, physicians may choose to restrict the use of telavancin. If we and our partner, Astellas, are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, telavancin is preferable to vancomycin and other existing or subsequently-developed anti-infective drugs, we may never generate meaningful revenue from telavancin. The degree of market acceptance of telavancin, if approved by the relevant regulatory agencies, will depend on a number of factors, including, but not limited to:

the demonstration of the clinical efficacy and safety of telavancin;

the labeling for telavancin that ultimately is approved by regulatory authorities;

the advantages and disadvantages of telavancin compared to alternative therapies;

our and Astellas' ability to educate the medical community about the safety and effectiveness of telavancin;

the reimbursement policies of government and third party payors; and

the market price of telavancin relative to competing therapies.

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

Even if we receive regulatory approval, 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. Further, if we obtain regulatory approval, a marketed medicine and its manufacturer are subject to continual review, including review and approval of the manufacturing facilities. Discovery of previously unknown problems with a medicine may result in restrictions on its permissible uses, or on the manufacturer, including withdrawal of the medicine from the market. The FDA and similar foreign



regulatory authorities may also implement new standards, or change their interpretation and enforcement of existing standards and requirements for the manufacture, packaging or testing of products at any time. If we 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.

**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. We have not generated any product revenue to date. We may never generate revenue from selling medicines or achieve profitability. As of December 31, 2007, we had an accumulated deficit of approximately \$937.8 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. 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 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 current operating plans, 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. We are likely to require additional capital to fund operating needs thereafter. In addition, in the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple regions in the world, we are obligated to pay GSK milestone payments of up to an aggregate of \$220.0 million under our Horizon program (formerly referred to as Beyond Advair). The current lead LABA candidate, GW642444, is a GSK-discovered compound and GSK has determined to focus the collaboration's LABA development resources on the development of this compound only. If this GSK-discovered compound is advanced through regulatory approval, we would not be entitled to any further milestone payments from GSK with regard to the Horizon program. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will 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.

**If our partners do not satisfy their obligations under our agreements with them, we will be unable to develop our partnered product candidates as planned.**

We entered into our collaboration agreement for the Horizon program with GSK in November 2002, our strategic alliance agreement with GSK in March 2004, and our telavancin development and commercialization agreement with Astellas in November 2005. 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 any product candidates in the programs that it has in-licensed, including Horizon, LAMA and MABA. 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 commercial launch. In connection with our Astellas telavancin agreement, Astellas is responsible for the commercialization of telavancin and any royalties to us from this program will depend upon Astellas' ability to launch and sell the medicine if it is approved.

Our partners might not fulfill all of their obligations under these agreements. In that 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. In addition, with the exception of product candidates in our Horizon program, our partners generally are not restricted from developing and commercializing their own products and product candidates that compete with those licensed from us. For example, GSK currently has at least one competing LAMA product candidate that is further advanced in development than our LAMA product candidate which they licensed from us. 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 our product candidates would be materially and adversely affected.

In addition, while our strategic alliance with GSK sets forth pre-agreed upfront payments, development obligations, milestone payments and royalty rates under which GSK may obtain exclusive rights to develop and commercialize our product candidates, GSK may in the future seek to negotiate more favorable terms on a project-by-project basis. To date, GSK has licensed our LAMA program and our MABA program under the terms of the strategic alliance agreement and has chosen not to license our bacterial infections program, our anesthesia program and our GI Motility Dysfunction program. There can be no assurance that GSK will license any other development program under the terms of the strategic alliance agreement, or at all. GSK's failure to license our development programs could adversely affect the perceived prospects of the product candidates that are the subject of these development programs, which could negatively affect both our ability to enter into collaborations for these product candidates with third parties and the price of our securities.

**Our relationship with GSK may have a negative effect on our ability to enter into relationships with third parties.**

As of December 31, 2007, GSK beneficially owned approximately 15.4% of our outstanding capital stock. Pursuant to our strategic alliance with GSK, GSK has the right to license exclusive development and commercialization rights to our product candidates arising from (i) our peripheral Opioid-Induced Bowel Dysfunction (PUMA) program, (ii) our AT1 Receptor Neprilysin Inhibitor hypertension (ARNI) program and (iii) our MonoAmine Reuptake Inhibitor chronic pain (MARIN) program. Because GSK may license these three development programs at any time prior to successful completion of a Phase 2 proof-of-concept study, we may be unable to collaborate with other partners with respect to these programs until we have expended substantial resources to advance them through clinical studies. We may not have sufficient funds to pursue such programs in the event GSK does not license them at an early stage. Pharmaceutical companies other than GSK that may be interested in developing

products with us may be less inclined to do so because of our relationship with GSK, or because of the perception that development programs that GSK does not license pursuant to our strategic alliance agreement are not promising programs. If our ability to work with present or future strategic partners or collaborators is adversely affected as a result of our strategic alliance with GSK, our business prospects may be limited and our financial condition may be adversely affected.

**If we are unable to enter into future collaboration arrangements or if any such collaborations with third parties are unsuccessful, our profitability may be delayed or reduced.**

To date, we have entered into collaborations with GSK for the Horizon, LAMA and MABA programs and with Astellas for telavancin, and we have licensed our anesthesia compound to AstraZeneca AB (AstraZeneca). Each of TD-5108 and TD-1792 has successfully completed a Phase 2 proof-of-concept study and we currently intend to pursue collaboration arrangements for the development and commercialization of these compounds. 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. 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 and 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 could limit the likelihood of successful commercialization of our product candidates.

**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 preclinical and clinical studies for our product candidates. We rely heavily on these parties for execution of our preclinical 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 agencies, and the applicable protocol. Failure by these parties to comply with applicable regulations, GCPs and protocols in conducting studies of our product candidates can delay our development programs. For example, in December 2007 we completed enrollment in our thorough QTc study on TD-5108, the lead compound in our GI Motility Dysfunction program. Our preliminary review of the electrocardiogram data from the study suggests that such data is unreliable due to problems with the conduct of the study, not with the intrinsic properties of TD-5108. We believe that lack of assay sensitivity in the active control arm of the study (moxifloxacin) renders the results uninterpretable, and that the study will need to be repeated in order to generate scientifically valid results. We currently intend to initiate a repeat of the study later this year.

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 NDA for the treatment of cSSSI, the FDA conducted inspections of Theravance and certain of our study sites and clinical investigators and a CRO. 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 and we or the FDA may decide to conduct additional audits or require additional clinical studies, which could delay our development programs.

**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. Because our strategy is to develop new product candidates primarily for biological targets that have been validated by existing medicines or potential medicines in late stage clinical studies, to the extent that we are able to develop medicines, they are likely to compete with existing drugs that have long histories of effective and safe use. We expect that any medicines that we commercialize with our collaborative partners or on our own 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 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.

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. We are also aware of other companies that 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 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. If approved, telavancin must demonstrate these advantages, as it will compete with vancomycin, a relatively inexpensive generic drug that is manufactured by a number of companies, and a number of existing anti-infectives marketed by major pharmaceutical companies. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

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.

**We have no experience selling or distributing products and no internal capability to do so.**

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. If we receive regulatory approval to commence commercial sales of any of our product candidates that

are not covered by our current agreements with GSK, Astellas or AstraZeneca, we will have to establish a sales and marketing organization with appropriate technical expertise and supporting distribution capability. At present, we have no sales personnel and a limited number of marketing personnel. Factors that may inhibit our efforts to commercialize our products without strategic partners or licensees include:

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

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

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

unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are not able to partner with a third party and are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition.

**If we lose key scientists or management personnel, or if we fail to recruit additional highly skilled personnel, it will impair our ability to discover, develop and commercialize product candidates.**

We are highly dependent on principal members of our management team and scientific staff, including our Chairman of the board of directors, P. Roy Vagelos, our Chief Executive Officer, Rick E Winningham, and our Senior Vice President of Development, Michael Kitt. These executives each have significant pharmaceutical industry experience. The unexpected loss of Dr. Vagelos, Mr. Winningham or Dr. Kitt could impair our ability to discover, develop and market new medicines.

Our scientific team has expertise in many different aspects of drug discovery and development. Our company is located in northern California, which is headquarters to many other biopharmaceutical companies and many academic and research institutions. There is currently a shortage of experienced scientists, which is likely to continue, and competition for skilled personnel in our market is very intense. Competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. In addition, none of our employees have employment commitments for any fixed period of time and could leave our employment at will.

If we fail to identify, attract and retain qualified personnel, we may be unable to continue our development and commercialization activities.

**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 currently 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.

#### **Risks Related to our Alliance with GSK**

**GSK's ownership of a significant percentage of our stock and its right to membership on our board of directors 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 December 31, 2007, GSK beneficially owned approximately 15.4% of our outstanding capital stock, and GSK has the right to maintain its percentage ownership of our capital stock. In addition, GSK currently has the right to designate one member to our board of directors. There are currently no GSK designated directors on our board of directors. 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 constituted 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 rights under the strategic alliance and governance agreements may deter or prevent efforts by other companies to acquire us, which could prevent our stockholders from realizing a control premium.**

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. In addition, pursuant to our strategic alliance agreement with GSK, GSK has the right to license (i) our PUMA program, (ii) our ARNI program and (iii) our MARIN program. As a result of these rights, 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.

**After September 2008, 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.**

Beginning in September 2008, GSK may sell or transfer our common stock either pursuant to a public offering registered under the Securities Act of 1933, as amended (the "1933 Act"), or pursuant to Rule 144 of the 1933 Act. In addition, beginning in September 2012, GSK will have no restrictions on its ability to sell or transfer our common stock on the open market, in privately negotiated transactions or otherwise, and these sales or transfers could create substantial declines in the price of our securities or, if these sales or transfers were made to a single buyer or group of buyers, could contribute to a transfer of control of our company to a third party.

#### **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, 2007, we owned 111 issued United States patents and 377 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 all of 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.

**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 our not infringing the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology 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 may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. 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.

**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 of pharmaceutical products. 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 those 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.

**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 ability to set a price we believe is fair for our potential medicines;

our ability to generate revenues and achieve profitability; and

the availability of capital.

In the United States, the Medicare Prescription Drug Improvement and Modernization Act of 2003 (the MMA) will likely result in decreased reimbursement for prescription drugs, which may intensify industry-wide pressure to reduce prescription drug prices. This could harm our ability to market our potential medicines and generate revenues. The MMA, associated cost containment measures that health care payors and providers are instituting and the effect of probable further health care reform 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.

**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.

### General Company Related Risks

#### **The price of our securities may be extremely volatile and purchasers of our securities could incur substantial losses.**

The price of our securities may be extremely volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our securities:

any adverse developments or perceived adverse developments with respect to our telavancin NDA, our response to the FDA's approvable letter or, if rescheduled, our meeting with the Anti-Infective Drugs Advisory Committee to the FDA;

any delay in the commercial distribution of telavancin if our NDA is approved by the FDA;

any delay in filing our telavancin NDA for the HAP indication with the FDA and any adverse development or perceived adverse development with respect to the FDA's review of the NDA, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;

any adverse developments or results or perceived adverse developments or results with respect to the Horizon program;

the extent to which GSK advances (or does not advance) our product candidates through development into commercialization;

any adverse developments or perceived adverse developments with respect to our relationship with GSK or Astellas;

any adverse developments or results or perceived adverse developments or results with respect to our GI Motility Dysfunction program or TD-1792;

announcements regarding GSK's decisions whether or not to license any of our development programs;

announcements regarding GSK or Astellas generally;

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

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

publicity regarding actual or potential testing or 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; and

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sales of stock by us or by our stockholders, including sales by certain of our executive officers and directors pursuant to written pre-determined selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, some of which plans are currently in effect and others of which may be entered into.

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

As of December 31, 2007, GSK beneficially owned approximately 15.4% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 14.0% of our outstanding capital stock. These stockholders could substantially control the outcome of actions taken by us that require stockholder approval. In addition, pursuant to our governance agreement with GSK, GSK currently has the right to nominate one member of our board of directors. For these reasons, 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 changes in our business.

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

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

requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and bylaws;

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

prohibiting stockholder action by written consent; and

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

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 are located in South San Francisco, California, and consist of two leased buildings of approximately 110,000 and 60,000 square feet, respectively. The leases expire in March 2012 and may be extended for two additional five-year periods. The current annual rental expense under these leases is approximately \$6.1 million, subject to annual increases. We may require additional space as our business expands.

**ITEM 3. LEGAL PROCEEDINGS**

None.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of stockholders during the fourth quarter of the fiscal year covered by this report.

## 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 "THR" since October 5, 2004. The following table sets forth the high and low closing prices of the Company's Common Stock on a per share basis for the periods indicated and as reported on the Nasdaq Global Market:

Calendar Quarter	High	Low
<b>2007</b>		
First Quarter	\$ 36.74	\$ 29.22
Second Quarter	\$ 36.81	\$ 28.74
Third Quarter	\$ 33.13	\$ 24.44
Fourth Quarter	\$ 27.99	\$ 19.33
<b>2006</b>		
First Quarter	\$ 29.88	\$ 20.43
Second Quarter	\$ 29.90	\$ 22.06
Third Quarter	\$ 28.02	\$ 22.40
Fourth Quarter	\$ 32.66	\$ 27.38

As of February 15, 2008, there were 271 stockholders of record of our common stock. There is no established public trading market for our Class A common stock, all of which is owned by GSK. We did not make any unregistered sales of equity securities during the fourth quarter of 2007.

*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 and do not intend to declare or pay cash dividends on our common stock or Class A common stock in the foreseeable future.

*Equity Compensation Plans*

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2007:

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	13,480,669(1)\$	16.63(2)	1,074,079(3)
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>13,480,669(1)\$</b>	<b>16.63(2)</b>	<b>1,074,079(3)</b>

(1)

Includes 11,435,786 shares issuable upon exercise of outstanding options and 2,044,883 shares issuable upon vesting of outstanding restricted stock units.

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- (2) Does not take into account outstanding restricted stock units as these awards have no exercise price.
- (3) Includes 480,929 shares of common stock available under our Employee Stock Purchase Plan, including 300,000 shares approved by the Compensation Committee of our board of directors on December 11, 2007 and subject to stockholders' approval at the annual stockholders' meeting in April 2008.

*Stock Performance Graph*

The graph set forth below compares the cumulative total stockholder return on our common stock for the period commencing on October 5, 2004 and ending on December 31, 2007, with the cumulative total return of (i) the Nasdaq Composite Index and (ii) the AMEX Biotechnology Index, over the same period. This graph assumes the investment of \$100.00 on October 5, 2004 in our common stock and \$100.00 on September 30, 2004 in the Nasdaq Composite Index and the AMEX 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. The Company cautions 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 the Company is not responsible for any errors or omissions in such information.

Notwithstanding anything to the contrary set forth in any of the Company's 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 the Company 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 the Company under those statutes.

**COMPARISON OF 39 MONTH CUMULATIVE TOTAL RETURN\***

**Among Theravance, Inc., The NASDAQ Composite Index**

**And The AMEX Biotechnology Index**

\* \$100 invested on 10/5/04 in stock or 9/30/04 in index-including reinvestment of dividends.  
Fiscal year ending December 31.

**ITEM 6. SELECTED FINANCIAL DATA**

The following tables reflect selected consolidated summary financial data for each of the last five fiscal years and are derived from our audited financial statements. This data should be read in conjunction with Item 8, "Financial Statements and Supplementary Data," and with Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2007	2006	2005	2004	2003
(in thousands, except per share data)					
<b>CONSOLIDATED STATEMENT OF OPERATIONS DATA:</b>					
Revenue	\$ 22,002	\$ 19,587	\$ 12,054	\$ 8,940	\$ 3,605
Operating expenses:					
Research and development(1)	155,254	166,564	137,936	91,627	63,004
General and administrative(1)	35,313	32,193	23,674	23,708	13,067
Total operating expenses	190,567	198,757	161,610	115,335	76,071
Loss from operations	(168,565)	(179,170)	(149,556)	(106,395)	(72,466)
Interest and other income, net(2)	8,661	13,319	6,687	4,326	3,242
Interest expense(2)	(93)	(193)	(295)	(585)	(1,359)
Net loss	\$ (159,997)	\$ (166,044)	\$ (143,164)	\$ (102,654)	\$ (70,583)
Basic and diluted net loss per common share	\$ (2.64)	\$ (2.81)	\$ (2.69)	\$ (3.08)	\$ (10.37)
Shares used in computing net loss per common share(3)(4)(5)(6)	60,498	59,013	53,270	33,283	6,809

**CONSOLIDATED BALANCE SHEET DATA:**

Cash, cash equivalents and marketable securities	\$ 129,272	\$ 235,570	\$ 200,009	\$ 257,141	\$ 89,152
Working capital	78,554	147,582	118,677	231,661	71,208
Total assets	161,983	262,424	224,835	286,022	125,449
Long-term liabilities(7)	172,714	139,505	117,078	61,717	37,494
Convertible preferred stock					367,358
Accumulated deficit	(937,809)	(777,812)	(611,768)	(468,604)	(365,950)
Total stockholders' equity (net capital deficiency)	(66,264)	63,310	59,584	190,367	(299,566)

- (1) Stock-based compensation, consisting of stock-based compensation expense under SFAS 123(R), the amortization of deferred stock-based compensation and the value of options issued to non-employees for services rendered, is allocated as follows (in thousands):

	Year Ended December 31,				
	2007	2006	2005	2004	2003
Research and development	\$ 13,133	\$ 12,635	\$ 3,259	\$ 4,631	\$ 1,300

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	Year Ended December 31,				
General and administrative	9,361	9,196	2,364	3,890	914
Total stock-based compensation	\$ 22,494	\$ 21,831	\$ 5,623	\$ 8,521	\$ 2,214

- (2) Interest and other income, net, includes investment management fees that were reclassified from interest expense as follows (in thousands):

	Year Ended December 31,				
	2007	2006	2005	2004	2003
Interest and other income, net	\$ 270	\$ 331	\$ 281	\$ 238	\$ 131



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- (3) In May 2004, all shares of convertible preferred stock were converted into common stock.
- (4) In May 2004, GSK, through an affiliate, purchased approximately 6.4 million shares of Class A common stock for \$108.9 million.
- (5) On October 5, 2004, the Company completed its initial public offering with the sale of 7,072,500 shares of common stock. Net proceeds, after underwriters' commissions and offering expenses, totaled \$102.1 million. Contemporaneously with the closing of its initial public offering, the Company sold 433,757 shares of its Class A common stock to an affiliate of GSK in a private transaction for total proceeds of \$6.9 million.
- (6) In February 2006, the Company completed its secondary offering with the sale of 5,200,000 shares of common stock. Net proceeds, after underwriters' commission and offering expenses, totaled \$139.9 million.
- (7) Long-term liabilities includes the long-term portion of deferred revenue as follows (in thousands):

	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>	<u>2003</u>
Deferred revenue	\$ 166,136	\$ 134,383	\$ 111,251	\$ 56,339	\$ 30,965

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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, 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.*

**Executive Summary**

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates. 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 gastrointestinal motility dysfunction. Of our six programs in development, four are in late stage our telavancin program focusing on treating serious Gram-positive bacterial infections with Astellas, our Horizon program (formerly referred to as Beyond Advair) with GSK, our Gastrointestinal Motility Dysfunction program and TD-1792, our investigational antibiotic for the treatment of serious Gram-positive bacterial infections. By leveraging our proprietary insight of multivalency to drug discovery focused primarily on validated targets, we are pursuing a next generation strategy designed to discover superior medicines in areas of significant unmet medical need.

We commenced operations in 1997, and as of December 31, 2007, we had an accumulated deficit of \$937.8 million. In December 2006, we submitted our first NDA to the FDA for telavancin for the treatment of complicated skin and skin structure infections (cSSSI). In October 2007, we announced that the FDA issued an approvable letter for our NDA and in January 2008, we announced that the Anti-Infective Drugs Advisory Committee (AIDAC) to the FDA was scheduled to meet to discuss telavancin for the proposed indication to treat cSSSI on February 27, 2008. On February 23, 2008, the FDA informed us that the AIDAC meeting was cancelled. On February 25, 2008, the FDA issued a public notice stating that the AIDAC meeting had been cancelled to allow time for the FDA to review and resolve several outstanding issues. The public notice further stated that the FDA intends to continue evaluating the telavancin NDA and will schedule an AIDAC meeting in the future, as needed. We are planning to meet with the FDA to discuss these issues. None of our product candidates have been approved for marketing and sale to patients and we have not received any product revenue to date. Most of our spending to date has been for research and development activities and general and administrative expenses. We expect to incur substantial losses for at least the next several years as we continue to invest in research and development.

Our net loss for the year ended December 31, 2007 was \$160.0 million compared to \$166.0 million in 2006, a decrease of \$6.0 million. This decrease was primarily due to lower research and development costs. Research and development spending for the year ended December 31, 2007 decreased to \$155.3 million compared to \$166.6 million in 2006. This decrease was primarily driven by lower external research and development costs due to the completion of patient enrollment in our Phase 3 cSSSI studies for telavancin in 2006. Cash, cash equivalents, and short-term investments totaled \$129.3 million at December 31, 2007, a decrease of \$37.2 million during the fourth quarter 2007 and a decrease of \$106.3 million since December 31, 2006. On January 23, 2008, we announced the closing of a

convertible subordinated notes offering with net proceeds to us of approximately \$166.7 million which are not reflected in the December 31, 2007 cash, cash equivalents, and marketable securities balance.

### **Critical Accounting Policies**

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 to our consolidated financial statements contained in 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, share-based payment charges, bonus accruals and the capitalization of inventory costs are most critical in fully understanding and evaluating our reported financial results.

#### *Revenue Recognition*

In connection with our agreements with GSK, Astellas and AstraZeneca, we recognize revenue from non-refundable, upfront fees and development milestone payments ratably over the term of our performance under the agreements. These advance payments are recorded as deferred revenue pending recognition and are classified as a short or long-term liability on the balance sheet. When the period of deferral cannot be specifically identified from the agreement, management estimates the period based upon provisions contained within the agreement and other relevant facts. We periodically review the estimated performance period, which could impact the deferral period and, therefore, the timing and the amount of revenue recognized. Significant milestones in the development process typically include initiation or completion of various phases of clinical studies and approvals by regulatory agencies. We have made various changes to our performance periods under our agreements based upon updated product development timelines. During 2007, we revised the performance periods related to our agreement with Astellas based on the progress of telavancin. We do not expect that these revisions will have a material impact on the timing of revenue recognized under this agreement in future years. It is possible that future adjustments will be made if actual conditions differ from our current plan and development assumptions.

We have been reimbursed by GSK and Astellas for certain external development costs under their respective collaboration agreements. Such reimbursements have been reflected as a reduction of research and development expense and not as revenue.

#### *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. To date, we have not recorded any material adjustments as a result of changes to our estimates.

*Fair Value of Share-based Payment Awards*

We use the fair value method of accounting for share-based compensation arrangements in accordance with Financial Accounting Standards Board Statement No. 123(R), Share-based Payment (SFAS123(R)). We adopted SFAS 123(R) on January 1, 2006 using the modified prospective method of transition. Under this method, compensation expense is recognized beginning with the effective date of adoption of SFAS 123(R) for all share-based payments (i) granted after the effective date of adoption and (ii) granted prior to the effective date of adoption and that remained unvested on the date of adoption. Share-based compensation arrangements covered by SFAS 123(R) currently include stock options granted, restricted shares issued and performance-contingent restricted stock unit awards (RSUs) granted under the 2004 Equity Incentive Plan, as amended, and purchases of common stock by our employees at a discount to the market price during offering periods under our Employee Stock Purchase Plan (ESPP). The estimated fair value of stock options and restricted shares under SFAS 123(R) is expensed on a straight-line basis over the vesting term of the grant and the fair value of RSUs is expensed during the term of the award when we determine that it is probable that certain performance conditions will be met. Compensation expense for purchases under the ESPP is recognized based on the estimated fair value of the common stock during each offering period and the percentage of the purchase discount.

In conjunction with the adoption of SFAS 123(R), we changed our method of expensing the value of stock-based compensation from the accelerated method to the straight-line single-option method. Compensation expense for all share-based payment awards granted prior to January 1, 2006 will continue to be recognized using the accelerated expense attribution method over the vesting period while the compensation expense for all share-based payment awards granted on or subsequent to January 1, 2006 is recognized using the straight-line single-option method. Stock-based compensation expense for stock options has been reduced for estimated forfeitures so that compensation expense is based on options ultimately expected to vest. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Our estimated annual forfeiture rate for stock options is 3.6%, based on our historical forfeiture experience.

*Bonus Accruals*

We have short- and long-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. 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, in some cases over a period of time in excess of twelve months, it is possible for bonus expense to vary significantly in future periods if changes occur in those management estimates. In September 2007, we achieved the last clinical milestone under a long-term bonus plan established in 2004 for eligible non-officer employees. This achievement resulted in a cumulative increase in bonus expense and liability of \$8.5 million, which included the effect of a change in estimate of \$7.1 million recorded in the second quarter of 2007.

*Inventory*

Inventory is stated at the lower of cost or market and is included with prepaid and other current assets. Inventory at December 31, 2007 consists of \$4.4 million of commercial launch supplies of our product candidate telavancin which is currently under regulatory review. Under our 2005 License, Development and Commercialization Agreement with Astellas, we are responsible to deliver to Astellas approximately six months of first commercial sale stock (as defined) in preparation for the regulatory approval and commercialization of telavancin. If our product candidate is approved by the FDA, the inventory costs incurred would be reimbursed through a milestone payment.

If the regulatory approval of telavancin is substantially delayed or denied by the necessary regulatory bodies, or if new information becomes available that suggests that our telavancin inventory will not be realisable, we may be required to expense a portion or all of the capitalized inventory costs. A portion of the amount that may be expensed would be eligible for reimbursement through alternative arrangements with Astellas under terms of our collaboration agreement. During 2007, we expensed approximately \$0.9 million of inventory capitalized during the fiscal year as we determined these inventories were not realisable for commercial launch supplies.

**Collaboration Arrangements**

*2005 License, Development and Commercialization Agreement with Astellas*

In November 2005, we entered into a collaboration arrangement with Astellas for the development and commercialization of telavancin. In July 2006, Japan was added to our telavancin collaboration, thereby giving Astellas worldwide rights to this potential medicine. Through December 31, 2007, we have received \$158.0 million in upfront, milestone and other fees from Astellas and we are eligible to receive up to an additional \$60.0 million in remaining milestone payments related to regulatory filings and approvals in various regions of the world. We recorded the payments as deferred revenue to be amortized ratably over our estimated period of performance (development and commercialization period). We recognized \$10.3 million, \$6.5 million and \$0.4 million in revenue under this agreement in 2007, 2006 and 2005, respectively.

If telavancin is commercialized, we will be entitled to receive royalties on global sales of telavancin by Astellas that, on a percentage basis, range from the high teens to the upper twenties depending on sales volume. Under this arrangement, we will be responsible for substantially all costs to develop and obtain U.S. regulatory approval for telavancin for cSSSI and HAP, and Astellas will be responsible for substantially all other costs associated with commercialization and further development of telavancin.

In addition to the license rights to telavancin, Astellas had an option to license TD-1792, our investigational antibiotic, for further development and commercialization on substantially the same terms under which Astellas licensed telavancin. In September 2007, we announced that we retained full ownership rights of TD-1792 as a result of Astellas' decision not to exercise its right to license the compound. We are currently reviewing plans for the future development of TD-1792.

*Horizon Program with GSK*

In November 2002, we entered into our Horizon collaboration with GSK to develop and commercialize a long-acting beta<sub>2</sub> agonist (LABA) product candidate for the treatment of asthma and chronic obstructive pulmonary disease (COPD). This product candidate is intended to be administered via inhalation once daily both as a single new medicine and as part of a new combination medicine with an inhaled corticosteroid (ICS). Each company contributed four LABA product candidates to the collaboration. The lead LABA, GW642444, and the lead ICS, GW685698, entered into large Phase 2b studies in December 2007.

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In connection with the Horizon program, in 2002 we received from GSK an upfront payment of \$10.0 million and sold to an affiliate of GSK shares of our Series E Preferred Stock for an aggregate purchase price of \$40.0 million. In addition, we were eligible to receive up to \$495.0 million in development, approval, launch, and sales milestones and royalties on the sales of any product resulting from this program. As of December 31, 2007, we have received a total of \$60.0 million in upfront and development milestone payments. GSK has determined to focus the collaboration's resources on the development of the lead LABA, GW642444, a GSK-discovered compound, together with the lead ICS. Accordingly, we do not expect to receive any further milestone payments from the Horizon program. In the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple regions in the world, we will be obligated to make milestone payments to GSK of up to \$220.0 million. Based on available information, we do not estimate that a significant portion of these potential milestone payments to GSK are likely to be made in the next three years. In addition, we are entitled to receive the same royalties on product sales of medicines from the Horizon program, regardless of whether the product candidate originated with Theravance or with GSK. The royalty structure is downward-tiering and would result in an average percentage royalty rate in the low- to mid-teens at annual net sales of up to approximately \$4.0 billion and the average royalty rate would decline to single digits at annual net sales of more than \$6.0 billion. Sales of single agent LABA medicines and combination LABA/ICS medicines would be combined for the purposes of this royalty calculation.

We recorded the initial cash payment and subsequent milestone payments as deferred revenue to be amortized ratably over our estimated period of performance (the product development period). Collaboration revenue from GSK was \$6.8 million, \$7.8 million and \$7.6 million in 2007, 2006 and 2005, respectively. Additionally, as an offset to research and development expense for certain costs related to the collaboration that were reimbursable by GSK, we accrued reimbursements of \$0.3 million in 2005; there were none in 2007 and 2006.

### *2004 Strategic Alliance with GSK*

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 all of our full drug discovery programs initiated prior to September 1, 2007, on pre-determined terms and on an exclusive, worldwide basis. We are obligated to use diligent efforts to discover and deliver compounds for the alliance and, pursuant to our obligations, we initiated three new full discovery programs between May 2004 and August 2007. These three programs are (i) our peripheral Opioid-Induced Bowel Dysfunction (PUMA) program, (ii) our AT1 Receptor Neprilysin Inhibitor hypertension (ARNI) program and (iii) our MonoAmine Reuptake Inhibitor chronic pain (MARIN) program. GSK has the right to license product candidates from these three programs, and must exercise this right no later than sixty days subsequent to the "proof-of-concept" stage (generally defined as the successful completion of a Phase 2a clinical study showing efficacy and tolerability if the biological target for the drug has been clinically validated by an existing medicine, and successful completion of a Phase 2b clinical study showing efficacy and tolerability if the biological target for the drug has not been clinically validated by an existing medicine). Under the terms of the strategic alliance, GSK has only one opportunity to license each of our programs. Upon its 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. Consistent with our strategy, we are obligated at our sole cost to discover two structurally different product candidates for any programs that are licensed by GSK under the alliance. If these programs are 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 these programs. For product candidates licensed to date under this agreement, the royalty structure for a product containing one of

our compounds as a single active ingredient would result in an average percentage royalty rate in the low double digits. If a product is successfully commercialized, in addition to any royalty revenue that we receive, the total upfront and milestone payments that we could receive in any given program that GSK licenses range from \$130.0 million to \$162.0 million for programs with single-agent medicines and up to \$252.0 million for programs with both a single-agent and a combination medicine. 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. To date, GSK has licensed our two COPD programs: long-acting muscarinic antagonist (LAMA) and muscarinic antagonist-beta<sub>2</sub> agonist (MABA). We received a \$5.0 million payment from GSK in connection with its license of each of our LAMA and MABA programs in August 2004 and March 2005, respectively. GSK has chosen not to license our bacterial infections program, our anesthesia program and our Gastrointestinal Motility Dysfunction program. There can be no assurance that GSK will license any other programs under the terms of the alliance agreement or at all, which could have an adverse effect on our business and financial condition.

Under the alliance, GSK had the right between June 1 and July 1, 2007, to elect to acquire (call) half of Theravance's outstanding shares of common stock at \$54.25 per share. On June 29, 2007, GSK elected not to exercise the call, which triggered the right of our stockholders to require us to redeem (put) up to 50% of their common stock at \$19.375 per share between August 1 and September 12, 2007 with funds provided by GSK. One stockholder exercised his put right for one share of common stock. In exchange for GSK providing the funds to pay the redemption price for the one share of common stock, and pursuant to our certificate of incorporation, we issued to GSK one share of our Class A common stock. The common share that we redeemed pursuant to the stockholder's exercise of the put right was retired and cancelled.

In connection with the strategic alliance with GSK, we received from GSK an upfront payment of \$20.0 million. The upfront payment is being amortized over the initial performance period during which GSK may exercise its right to license certain of our programs under the agreement, which we currently estimate to be through September 2011. In connection with the strategic alliance, we recognized \$2.7 million in revenue for each of the years ending December 31, 2007, 2006 and 2005. In addition, in May 2004, GSK purchased through an affiliate 6,387,096 shares of our Class A common stock for an aggregate purchase price of \$108.9 million.

Through December 31, 2007, we have received \$36.0 million in upfront and milestone payments from GSK relating to the strategic alliance agreement. In addition, pursuant to a partial exercise of its rights under the governance agreement, upon the closing of our initial public offering on October 8, 2004, GSK purchased through an affiliate an additional 433,757 shares of Class A common stock for \$6.9 million.

In August 2004, GSK exercised its right to license our LAMA program pursuant to the terms of the strategic alliance. We received a \$5.0 million payment from GSK in connection with its licensing of our LAMA program. Through December 31, 2007, we received a milestone payment from GSK of \$3.0 million related to clinical progress of our candidate. These payments are being amortized ratably over the estimated period of performance (the product development period). We recognized \$0.8 million, \$1.0 million and \$0.9 million in revenue related to the LAMA program in 2007, 2006 and 2005, respectively. Additionally, as an offset to research and development expense for certain costs related to the LAMA program that were reimbursable by GSK, we accrued reimbursements of \$70,000, \$0.4 million and \$0.5 million in 2007, 2006 and 2005, respectively.

In March 2005, GSK exercised its right to license our MABA program pursuant to the terms of the strategic alliance. We received a \$5.0 million payment from GSK in connection with the license of our MABA program. Through December 31, 2007, we received a milestone payment from GSK of \$3.0 million related to clinical progress of our candidate. These payments are being amortized ratably over the estimated period of performance (the product development period). We recognized \$1.0 million, \$0.9 million and \$0.5 million in revenue related to the MABA program in 2007, 2006 and 2005, respectively. Additionally, as an offset to research and development expense for certain costs related to the MABA program that were reimbursable by GSK, we accrued reimbursements of \$2.9 million in 2005; there were none in 2007 and 2006.

## Results of Operations

**Revenue** We recognized revenue of \$22.0 million, \$19.6 million and \$12.1 million in 2007, 2006 and 2005, respectively, from the amortization of upfront and milestone payments from GSK related to our Horizon collaboration and strategic alliance agreements and from Astellas related to our telavancin collaboration. The table below reflects the upfront and milestone payments received from GSK under the Horizon program and strategic alliance agreements, from Astellas under the telavancin collaboration and from AstraZeneca under our license agreement through December 31, 2007 (in millions).

Agreements/Programs	Signed Agreement/Licensed Program	Upfront and Milestone Payments
<i>GSK Collaborations</i>		
Horizon program	2002	\$ 60.0
Strategic Alliance agreement execution	2004	20.0
Strategic Alliance LAMA license	2004	8.0
Strategic Alliance MABA license	2005	8.0
<i>Astellas License agreement</i>	2005	158.0
<i>AstraZeneca License agreement execution</i>	2006	1.0
		\$ 255.0
Total		\$ 255.0

Upfront fees and milestone payments received have been deferred and are being amortized ratably into revenue over the applicable estimated performance period with end dates ranging between 2011 and 2020. Revenue in 2008 is expected to be comprised of the ongoing amortization of deferred revenue that relates to the \$255.0 million of upfront and milestone payments received through December 31, 2007, under our agreements with GSK and Astellas, and to any additional upfront or milestone payments earned under current or new agreements with GSK, Astellas or other partners. We periodically review the estimated performance periods of our contracts and as such, during 2007, we revised the performance periods related to our agreement with Astellas based on the progress of telavancin. We do not expect that this will have a material impact on future revenue recognized under this agreement.

### Research & Development

Research and development expenses (in millions, except percentages):

	Year Ended December 31,			Change 2007/2006		Change 2006/2005	
	2007	2006	2005	\$	%	\$	%
External research and development	\$ 68.3	\$ 94.0	\$ 78.7	\$ (25.7)	(27)%	\$ 15.3	19%
Employee-related	49.4	37.5	35.6	11.9	32%	1.9	5%
Stock-based compensation	13.1	12.6	3.3	0.5	4%	9.3	282%
Facilities, depreciation and other allocated	24.5	22.5	20.3	2.0	9%	2.2	11%
Total research and development expenses	\$ 155.3	\$ 166.6	\$ 137.9	\$ (11.3)	(7)%	\$ 28.7	21%

Research and development expenses decreased in 2007 compared to 2006 primarily as a result of lower external research and development expenses, offset by higher employee-related expenses and higher facilities-related costs. The lower external development costs were primarily a result of our completion of patient enrollment in our Phase 3 cSSSI studies for telavancin in 2006, offset by increased external research and development costs associated with our Phase 3 HAP studies for



telavancin and our two Phase 2 clinical studies for TD-5108, our GI motility dysfunction compound, and TD-1792, our investigational antibiotic, in 2007.

Research and development expenses increased in 2006 compared to 2005 primarily as a result of higher external research and development expenses, higher stock-based compensation expenses associated with the implementation of SFAS 123(R) and higher facilities-related costs. The higher external development costs were primarily related to increased clinical services and contract manufacturing activities supporting our two Phase 3 clinical programs for telavancin, as well as a Phase 2 clinical study for TD-5108 and other various development and discovery programs.

Employee-related expenses increased in 2007 compared to 2006 primarily due to higher costs of non-officer incentive programs and increased headcount to support our clinical research programs. We have short- and long-term bonus programs in place for eligible non-officer employees related to the achievement of certain clinical milestones. In September 2007, we achieved the last clinical milestone under a long-term bonus plan established in 2004 for eligible non-officer employees. This achievement resulted in a cumulative increase in bonus expense and liability of \$8.5 million in 2007, which included the effect of a change in estimate of \$7.1 million recorded in the second quarter of 2007. As of December 31, 2007, we had fully expensed our bonus liability of approximately \$12.4 million relating to this long-term bonus program, which ended in September 2007, of which \$8.3 million remaining is scheduled to be paid to the eligible employees in December of 2008 and 2009.

Employee-related expenses increased in 2006 from 2005 due to higher salary and benefits costs in 2006 partially offset by lower recruiting and relocation costs.

Facilities, depreciation and other allocated expenses increased in 2007 from 2006 and in 2006 from 2005 due primarily to higher supplies and materials costs used to support our clinical programs, as well as higher facilities-related expenses.

During 2007, we granted performance-contingent restricted stock unit awards (RSUs) to certain employees, the vesting of which is tied to the successful achievement of certain clinical development milestones during 2008 and 2009, as well as a requirement for continued employment through 2009 and 2010. Expense associated with RSUs will be recognized, if at all, during 2008 through 2009, depending on the probability of meeting the performance milestones. The maximum potential expense associated with these RSUs could be up to approximately \$38.3 million, if all of the milestones are successfully achieved on time. As of December 31, 2007, the Company had determined that none of the requisite performance milestones were probable and as a result, no compensation expense has been recognized.

Total stock-based compensation expense for 2007 and 2006 consisted of stock-based compensation expense related to employee stock options, employee stock purchases and the value of options issued to non-employees for services rendered. For the year ended December 31, 2007, the fair value of options vested was significantly higher when compared to 2006 due to the number of options that vested at the expiration of the put period in September 2007. Stock-based compensation expense recognized for 2005 consisted of the amortization expense of deferred stock-based compensation related to employees and the value of stock options granted to non-employees. In accordance with the modified-prospective-transition method, the research and development expenses for 2005 have not been restated to reflect, and do not include, the impact of SFAS 123(R).

Research and development expenses for 2008 are expected to be driven largely by costs associated with the preparation and submission of our telavancin NDA for HAP, our ongoing development efforts in our GI program and with TD-1792, our investigational antibiotic, as well as costs associated with our drug discovery programs. Under our agreement with Astellas, we are responsible for completion of the cSSSI and HAP telavancin Phase 3 programs, publication of the results of these studies, preparation and submission of a NDA to the FDA for the cSSSI indication and subsequently for the HAP indication, and manufacture of approximately six months of first commercial sale stock for launch. The

telavancin cSSSI NDA remains under regulatory review and we plan to submit our telavancin NDA for HAP in 2008. We are reliant on the efforts of third parties, including contract research organizations, consultants and contract manufacturing organizations for the completion of these obligations. While we cannot predict the time frame in which all of these responsibilities will be completed, we anticipate that our aggregate external costs associated with our obligations with regard to telavancin described above, will be towards the upper end of the range of \$150.0 million to \$155.0 million.

Other external research and development expenses in 2008 are expected to be driven by our ongoing development efforts with TD-5108 in our GI program, with TD-1792, and with our discovery programs. In the fourth quarter of 2007, we completed enrollment in a thorough QTc study for our TD-5108 compound. Our preliminary review of electrocardiogram data from the study suggests that such data is unreliable due to problems with the conduct of the study, not with the intrinsic properties of TD-5108. As a result, the study will need to be repeated in order to generate scientifically valid results. We currently intend to initiate a repeat of the study later in 2008. Actual expenses for our various programs may vary considerably based upon the timing of program initiation, study enrollment rates and the timing and structure of any collaboration in which a partner may incur a portion of these expenses.

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 and administrative*

General and administrative expenses (in millions, except percentages):

	Year Ended December 31,			Change 2007/2006		Change 2006/2005	
	2007	2006	2005	\$	%	\$	%
Total general and administrative	\$ 35.3	\$ 32.2	\$ 23.7	\$ 3.1	10%	\$ 8.5	36%

General and administrative expenses increased in 2007 from 2006 primarily due to an increase of \$1.7 million in external consulting expenses related to telavancin marketing preparations and costs associated with preparation for the call and the put rights under the strategic alliance with GSK, as well as an increase of \$1.6 million in employee-related costs.

General and administrative expenses increased in 2006 from 2005 due primarily to an increase in stock-based compensation expense of \$6.8 million, as well as higher costs for external consulting, employee-related expenses and facilities costs of \$1.7 million. External consulting costs increased by \$0.6 million in 2006 compared to 2005, due primarily to the use of outside consultants to assist us in preparing the telavancin cSSSI NDA.

The total general and administrative stock-based compensation expense recognized for 2007 and 2006 was \$9.4 million and \$9.2 million, respectively, consisting of stock-based compensation expense related to: employee stock options; employee stock purchases; the value of options issued to non-employees for services rendered; and stock-based compensation expense related to restricted stock. Stock-based compensation expense for 2005 was \$2.4 million, consisting of the amortization of deferred stock-based compensation related to employees, the value of stock options granted to non-employees and stock-based compensation expense related to restricted stock. In accordance with the modified-prospective transition method, the general and administrative expenses for 2005 have not been restated to reflect, and do not include, the impact of SFAS 123(R).

During 2007, we granted RSUs to certain employees, the vesting of which is tied to the successful achievement of certain clinical development milestones during 2008 and 2009, as well as a requirement

for continued employment through 2009 and 2010. Expense associated with RSUs will be recognized, if at all, during 2008 through 2009, depending on the probability of meeting the performance milestones. The maximum potential expense associated with these RSUs could be up to approximately \$28.0 million, if all of the milestones are successfully achieved on time. As of December 31, 2007, the Company had determined that none of the requisite performance milestones were probable and as a result, no compensation expense has been recognized.

We anticipate general and administrative expenses will increase in 2008 and subsequent years to support our discovery and development efforts and commercial development activities.

**Interest and other income, net** Interest and other income, net, on cash and investments decreased to \$8.7 million in 2007 from \$13.3 million in 2006 primarily due to lower interest income earned on lower average cash balances in 2007. In addition, a \$1.1 million impairment charge was recorded during the fourth quarter of 2007 for an other-than-temporary decline in the fair value of a structured investment vehicle (SIV) security as a result of the deterioration of the SIV financial market and evidence indicating that the security's carrying value was not recoverable within a reasonable period of time. This SIV investment was subsequently sold on February 11, 2008 for the revised carrying basis that was determined at the end of 2007. Interest and other income, net, increased to \$13.3 million in 2006 from \$6.7 million in 2005 due to higher average cash balances in 2006 which included proceeds from the closing of our public offering in February 2006. Interest and other income, net, includes interest income earned on cash and marketable securities, investment management fees on investments, net realized gains on marketable securities and net sublease income on facilities. In order to conform to the current period presentation, investment management fees of approximately \$0.3 million for each of the years ending 2007, 2006 and 2005 were netted against interest and other income. This reclassification had no impact on previously reported amounts of net loss or stockholders' equity.

**Interest expense** Interest expense includes interest expense on capital lease and debt arrangements. Interest expense decreased to \$93,000 in 2007 from \$193,000 while interest expense decreased to \$193,000 in 2006 from \$295,000 in 2005, in both cases due to declining capital lease and debt balances.

#### **Income Taxes**

At December 31, 2007, we had net operating loss carryforwards for federal income taxes of \$637.8 million and federal research and development tax credit carryforwards of \$30.7 million. Our utilization of the net operating loss and tax credit carryforwards may be subject to annual limitations due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. The annual limitations may result in the expiration of net operating losses and credits prior to utilization. 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 adopted FIN 48 effective January 1, 2007. The adoption of FIN 48 did not result in an adjustment to the beginning balance of our accumulated deficit.

Under the implementation of FIN 48, we increased our unrecognized tax benefits by \$6.5 million. We had unrecognized tax benefits of \$26.7 million and \$33.2 million as of January 1, 2007 and December 31, 2007, respectively. If we are eventually able to recognize these uncertain positions, \$33.2 million of the unrecognized benefit would reduce our effective tax rate.

#### **Liquidity and Capital Resources**

As of December 31, 2007 and December 31, 2006, we had \$129.3 million and \$235.6 million in cash, cash equivalents and marketable securities, respectively, excluding \$3.8 million and \$3.9 million in restricted cash and cash equivalents at December 31, 2007 and December 31, 2006, respectively, that was pledged as collateral for certain of our leased facilities and equipment. During 2007, we received

payments of \$57.0 million from Astellas primarily as a result of achieving certain clinical milestones under the terms of our collaboration agreement with Astellas. In addition, in January 2008, we raised proceeds of \$166.7 million, net of issuance costs, upon the closing of an underwritten public offering of \$172.5 million aggregate principal amount of unsecured 3% convertible subordinated notes due 2015. The notes are convertible 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. In February 2006, we raised proceeds of \$139.9 million, net of issuance costs, upon the closing of an underwritten public offering of 5.2 million shares of common stock at a price per share of \$28.50.

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 clinical studies, which are very expensive.

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 and spending assumptions. Each of TD-5108 and TD-1792 has successfully completed a Phase 2 proof-of-concept study and we may pursue collaboration arrangements for the development and commercialization of these compounds. If we are unable to enter into such collaboration arrangements, or if those agreements require that we assume future development responsibilities, then our operating expenses will increase significantly. As a result, we may raise additional funds in advance of actual cash needs if we choose to expand more rapidly than we presently anticipate, or if our operating costs exceed our expectations. We cannot guarantee that future financing will be available in amounts or on terms acceptable to us, if at all.

### **Cash Flows**

Net cash used in operating activities was \$104.4 million and \$104.8 million in 2007 and 2006, respectively. Net cash used in operating activities was \$104.8 million and \$58.6 million in 2006 and 2005, respectively. This increase in cash used in operations of \$46.2 million was primarily due to an increase in research and development expenses, partially offset by cash receipts of \$36.0 million from Astellas.

Investing activities provided cash of \$110.6 million and used cash of \$18.6 million in 2007 and 2006, respectively. The increase in 2007 primarily results from an increase in proceeds from net sales and maturities of marketable securities. Investing activities used cash of \$18.6 million and provided cash of \$3.3 million in 2006 and 2005, respectively. The increase in 2006 primarily results from increased purchases of marketable securities and increased capital expenditures compared to 2005.

Financing activities provided cash of \$7.8 million and \$146.0 million in 2007 and 2006, respectively. The cash provided by financing activities during 2007 was primarily due to proceeds received from the issuance of common shares under our employee stock plans, while the cash provided by financing activities during 2006 was substantially higher due primarily to proceeds, net of issuance costs, of approximately \$139.8 million received from our public offering of common stock in February 2006. Financing activities provided cash of \$146.0 million and \$3.7 million in 2006 and 2005, respectively. The increase in cash provided by financing activities was primarily due to our public offering in February 2006.

**Contractual Obligations and Commitments**

Our major outstanding contractual obligations relate to our note payable, operating leases and fixed purchase commitments under contract research, development and clinical supply agreements. These contractual obligations as of December 31, 2007, are as follows (in millions):

	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>4-5 years</u>	<u>After 5 years</u>	<u>Total</u>
Note payable	\$ 0.1	\$ 0.3	\$ 0.2	\$	\$ 0.6
Operating leases	6.1	12.7	8.3		27.1
Purchase obligations	2.9	0.8			3.7
<b>Total</b>	<b>\$ 9.1</b>	<b>\$ 13.8</b>	<b>\$ 8.5</b>	<b>\$</b>	<b>\$ 31.4</b>

The current annual rental expense under our combined operating leases for our Company's headquarters is approximately \$6.1 million, subject to annual increases. As security for our performance under the operating leases, we have issued letters of credit totaling \$3.8 million, collateralized by an equal amount of restricted cash.

Pursuant to our Horizon collaboration with GSK, in the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple regions in the world, we will be obligated to make milestone payments to GSK of up to an aggregate of \$220.0 million. The current lead LABA candidate, GW642444, is a GSK-discovered compound. Based on available information, we do not estimate that any significant portion of these potential milestone payments to GSK is likely to be made in the next three years.

**Recent Accounting Pronouncements**

In November 2007, the Emerging Issues Task Force (EITF) ratified a consensus on EITF Issue No. 07-1 (EITF 07-1), "Accounting for Collaborative Arrangements", which requires participants in a collaboration to make separate disclosures regarding the nature and purpose of an arrangement, their rights and obligations under the arrangement, the accounting policy for the arrangement and the income statement classification and amounts arising from the arrangement between participants for each period an income statement is presented. EITF 07-1 is effective for us beginning in the first quarter of fiscal year 2009. We are currently evaluating the impact of the provisions of EITF 07-1 on our financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

In June 2007, the EITF ratified a consensus on EITF Issue No. 07-3 (EITF 07-3), "Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities", which concluded that non-refundable advance payments for goods or services for use in research and development activities should be deferred and capitalized. EITF 07-3 is effective for us beginning in the first quarter of fiscal year 2008. We are currently evaluating the impact of the provisions of EITF 07-3 on our financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for us beginning in the first quarter of fiscal year 2008. We are currently evaluating the impact of the provisions of SFAS 157 on our financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

In July 2006, the FASB issued Financial Interpretation No. (FIN) 48, "Accounting for Uncertainty in Income Taxes" (FIN 48) as an interpretation of SFAS No. 109, "Accounting for Income Taxes"

(SFAS 109) and in May 2007, the FASB issued FASB Staff Position FIN 48-1, "Definition of *Settlement* in FASB Interpretation No. 48". FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109 and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognizing, classification, interest and penalties, accounting in interim periods, disclosure and transition. We adopted FIN 48 effective January 1, 2007.

**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 and clinical studies, and manufacture some active pharmaceutical ingredient 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 rate undergoes a change of 10%, we do not believe that it would have a material impact on our results of operations or cash flows.

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

Consolidated Balance Sheets at December 31, 2007 and December 31, 2006	50
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Consolidated Statements of Stockholders' Equity (net capital deficiency) for each of the three years in the period ended December 31, 2007	52
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## THERAVANCE, INC.

## Consolidated Balance Sheets

(in thousands, except per share amounts)

	December 31,	
	2007	2006
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 86,433	\$ 72,388
Marketable securities	40,383	128,692
Receivable from related party	316	608
Notes receivable	223	1,142
Prepaid and other current assets	6,732	4,361
	<b>134,087</b>	<b>207,191</b>
Marketable securities	2,456	34,490
Restricted cash	3,810	3,860
Property and equipment, net	20,091	15,101
Notes receivable	1,539	1,782
	<b>161,983</b>	<b>262,424</b>
<b>Liabilities and stockholders' equity (net capital deficiency)</b>		
Current liabilities:		
Accounts payable	\$ 6,957	\$ 16,011
Accrued personnel-related expenses	11,841	8,316
Accrued clinical and development expenses	11,318	13,608
Other accrued liabilities	2,797	2,314
Current portion of note payable	101	87
Current portion of deferred revenue	22,519	19,273
	<b>55,533</b>	<b>59,609</b>
Deferred rent	2,003	2,298
Note payable	435	538
Deferred revenue	166,136	134,383
Other long term liabilities	4,140	2,286
Commitments and Contingencies (Notes 3, 7 and 8)		
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; 200,000 shares authorized, issuable in series; 51,684 and 50,746 shares issued and outstanding at December 31, 2007 and December 31, 2006, respectively	516	507
Class A Common Stock, \$0.01 par value, 30,000 shares authorized, 9,402 issued and outstanding at December 31, 2007 and December 31, 2006.	94	94
Additional paid-in capital	870,878	840,498
Notes receivable from stockholders		(3)
Accumulated other comprehensive income	57	26
Accumulated deficit	(937,809)	(777,812)
	<b>(66,264)</b>	<b>63,310</b>
Total stockholders' equity (net capital deficiency)	<b>(66,264)</b>	<b>63,310</b>



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December 31,

Total liabilities and stockholders' equity (net capital deficiency)	\$	161,983	\$	262,424
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See accompanying notes to consolidated financial statements.

## THERAVANCE, INC.

## Consolidated Balance Sheets

(in thousands, except per share amounts)

## THERAVANCE, INC.

## Consolidated Statements of Operations

(in thousands, except per share amounts)

	Year Ended December 31,		
	2007	2006	2005
Revenue (includes amounts from GSK, a related party, of \$11,297, \$12,565 and \$11,685 in 2007, 2006 and 2005, respectively)	\$ 22,002	\$ 19,587	\$ 12,054
Operating expenses:			
Research and development	155,254	166,564	137,936
General and administrative	35,313	32,193	23,674
Total operating expenses	190,567	198,757	161,610
Loss from operations	(168,565)	(179,170)	(149,556)
Interest and other income, net	8,661	13,319	6,687
Interest expense	(93)	(193)	(295)
Net loss	\$ (159,997)	\$ (166,044)	\$ (143,164)
Basic and diluted net loss per common share	\$ (2.64)	\$ (2.81)	\$ (2.69)
Shares used in computing net loss per common share	60,498	59,013	53,270

See accompanying notes to consolidated financial statements.

## THERAVANCE, INC.

## Consolidated Statements of Stockholders' Equity (net capital deficiency)

(in thousands)

	Common Stock		Class A Common Stock		Additional Paid-In Capital	Notes Receivable from Stockholders	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Net Capital Deficiency)
	Shares	Amount	Shares	Amount						
<i>Balance at December 31, 2004</i>	43,522	\$ 435	9,402	\$ 94	\$ 669,698	\$ (495)	\$ (10,079)	\$ (682)	\$ (468,604)	\$ 190,367
Common stock issuances from employee stock option and purchase plans, net of repurchases, restricted stock award and net of unvested stock options exercised early	945	9			6,067					6,076
Exercise of warrants to purchase shares of common stock	8				25					25
Forgiveness and repayments of notes receivable						478				478
Stock-based compensation related to grants of stock options to nonemployees					927					927
Reversal of deferred stock-based compensation related to employee terminations					(1,314)		807			(507)
Amortization of deferred stock-based compensation							5,203			5,203
Deferred stock-based compensation					896		(896)			
Comprehensive loss:										
Net loss									(143,164)	(143,164)
Net unrealized gain on marketable securities								179		179
Total comprehensive loss										(142,985)
<i>Balance at December 31, 2005</i>	44,475	444	9,402	94	676,299	(17)	(4,965)	(503)	(611,768)	59,584

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	Class A Common Stock								
Common stock issuances from employee stock option and purchase, net of repurchases and early exercised stock vested	1,071	11			7,522			7,533	
Issuance of common stock for cash in secondary stock offering, net of expenses of \$0.1 million	5,200	52			139,811			139,863	
FAS 123(R) employee stock-based compensation					19,433			19,433	
Forgiveness and repayments of notes receivable						14		14	
Stock-based compensation related to grants of stock options to nonemployees					2,104			2,104	
Amortization of deferred stock-based compensation					294			294	
Reversal of deferred stock-based compensation					(4,965)	4,965			
Comprehensive loss:									
Net loss							(166,044)	(166,044)	
Net unrealized gain on marketable securities							529	529	
Total comprehensive loss								(165,515)	
<i>Balance at December 31, 2006</i>	50,746	507	9,402	94	840,498	(3)	26	(777,812)	63,310
Common stock issuances from employee stock option and purchase plans, net of repurchases, restricted stock awards and early exercised stock vested	892	9			7,924			7,933	
FAS 123(R) employee stock-based compensation					22,494			22,494	
Forgiveness and repayments of notes receivable					(38)	3		(35)	

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	Class A Common Stock															
Comprehensive loss:																
Net loss											(159,997)	(159,997)				
Net unrealized gain on marketable securities											31	31				
Total comprehensive loss												(159,966)				
Balance at December 31, 2007	51,638	\$	516	9,402	\$	94	\$	870,878	\$	\$	\$	57	\$	(937,809)	\$	(66,264)

See accompanying notes to consolidated financial statements.

## THERAVANCE, INC.

## Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,		
	2007	2006	2005
<b>Cash flows provided by (used in) operating activities</b>			
Net loss	\$ (159,997)	\$ (166,044)	\$ (143,164)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	4,058	4,198	4,107
Stock-based compensation	22,494	21,831	5,623
Other-than-temporary impairment loss on marketable security	1,140		
Forgiveness of notes receivable	3	53	179
Change in accrued interest receivable on marketable securities	(610)	709	403
Changes in operating assets and liabilities:			
Receivables, prepaid and other assets	(177)	12	2,374
Accounts payable and accrued liabilities	(11,383)	7,203	9,664
Accrued personnel-related expenses	3,525	2,275	(475)
Deferred rent	(295)	(240)	138
Deferred revenue	34,999	25,411	60,947
Other liabilities	1,871	(199)	1,559
Net cash used in operating activities	(104,372)	(104,791)	(58,645)
<b>Cash flows provided by (used in) investing activities</b>			
Purchases of property and equipment	(9,818)	(5,708)	(3,443)
Purchases of marketable securities	(93,329)	(190,974)	(152,260)
Maturities of marketable securities	121,804	124,715	89,330
Sales of marketable securities	90,760	53,828	68,617
Restricted cash and cash equivalents	50		677
Additions to notes receivable	(250)	(850)	(160)
Decrease in notes receivable	1,375	407	578
Net cash provided by (used in) investing activities	110,592	(18,582)	3,339
<b>Cash flows provided by (used in) financing activities</b>			
Payments on notes payables and capital leases	(88)	(1,250)	(2,525)
Net proceeds from issuances of common stock	7,913	147,224	6,207
Net cash provided by financing activities	7,825	145,974	3,682
Net increase (decrease) in cash and cash equivalents	14,045	22,601	(51,624)
Cash and cash equivalents at beginning of period	72,388	49,787	101,411
Cash and cash equivalents at end of period	\$ 86,433	\$ 72,388	\$ 49,787
<b>Supplemental Disclosures of Cash Flow Information</b>			
Cash paid for interest	\$ 86	\$ 193	\$ 309
Non-cash investing and financing activities:			

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	Year Ended December 31,			
Addition to (reversal of) deferred stock-based compensation	\$	\$	(4,965)	\$ 896

See accompanying notes to consolidated financial statements.

THERAVANCE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**1. Summary of Significant Accounting Policies**

*Description of Operations and Principles of Consolidation*

Theravance, Inc. (the Company or Theravance) is a biopharmaceutical company with a pipeline of internally discovered product candidates. 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 gastrointestinal motility dysfunction. Of the Company's six programs in development, four are in late stage its telavancin program focusing on treating serious Gram-positive bacterial infections with Astellas Pharma Inc. (Astellas), its Horizon program (formerly referred to as Beyond Advair) with GlaxoSmithKline plc (GSK), its Gastrointestinal Motility Dysfunction program and TD-1792, its investigational antibiotic for the treatment of serious Gram-positive bacterial infections. By leveraging the Company's proprietary insight of multivalency to drug discovery focused primarily on validated targets, Theravance is pursuing a next generation strategy designed to discover superior medicines in areas of significant unmet medical need. The Company was incorporated in November 1996 in Delaware under the name Advanced Medicine, Inc. and began operations in May 1997. The Company changed its name to Theravance, Inc. in April 2002. In December 2006, the Company submitted its first new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for telavancin for the treatment of complicated skin and skin structure infections (cSSSI) caused by Gram-positive bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA). In October 2007, the Company announced that the FDA issued an approvable letter for its NDA, and in January 2008, the Company announced that the Anti-Infective Drugs Advisory Committee (AIDAC) to the FDA was scheduled to meet to discuss telavancin for the proposed indication to treat cSSSI on February 27, 2008. On February 23, 2008, the FDA informed the Company that the AIDAC meeting was cancelled. On February 25, 2008, the FDA issued a public notice stating that the AIDAC meeting had been cancelled to allow time for the FDA to review and resolve several outstanding issues. The public notice further stated that the FDA intends to continue evaluating the telavancin NDA and will schedule an AIDAC meeting in the future, as needed. The Company is planning to meet with the FDA to discuss these issues. None of the Company's product candidates have been approved by regulatory agencies and the Company has not received any product revenue to date. 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 accounting principles generally accepted in the United States 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.

*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 used cash and cash equivalents as collateral. There was \$3.8 million and \$3.9 million of restricted cash related to such agreements at December 31, 2007 and 2006, respectively.



THERAVANCE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**1. Summary of Significant Accounting Policies (Continued)**

*Marketable Securities*

The Company classifies its marketable securities as available-for-sale and has the ability and the intent of holding these securities for a period of time sufficient to allow for any anticipated recovery in market value. Available-for-sale securities are carried at estimated fair value, with the unrealized gains and losses reported in stockholders' equity (net capital deficiency) and included in accumulated other comprehensive income. The cost of securities in this category is adjusted for amortization of premiums and accretion of discounts from the date of purchase to maturity. Such amortization is included in interest and other income. Realized gains and losses and declines in value judged to be other than temporary on available-for-sale securities are also included in interest and other income. The cost of securities sold is based on the specific-identification method.

*Other-than-Temporary Impairment Assessment*

The Company reviews its investment portfolio to identify and evaluate investments that have indications of possible impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, credit quality and the Company's ability and intent to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. If the Company determines an investment impairment is other-than-temporary, the investment is written down with a charge recorded in interest and other income, net.

*Fair Value of Financial Instruments*

Financial instruments include cash and cash equivalents, marketable securities, receivable from related party, accounts payable and accrued liabilities. Marketable securities are carried at fair value. Cash and cash equivalents, receivable from related party, accounts payable and accrued liabilities are carried at cost. The Company believes cost approximates fair value due to the relatively short maturities of these instruments.

*Inventory*

Inventory is stated at the lower of cost or market and is included with prepaid and other current assets. Inventory consists of \$4.4 million of commercial launch supplies of the Company's product candidate telavancin which is currently under regulatory review. Under the Company's 2005 License, Development and Commercialization Agreement with Astellas, the Company is responsible to deliver to Astellas approximately six months of first commercial sale stock (as defined) in preparation for the regulatory approval and commercialization of telavancin. If the Company's product candidate is approved by the FDA, the inventory costs incurred would be reimbursed through a milestone payment.

If the regulatory approval of telavancin is substantially delayed or denied by the necessary regulatory bodies, or if new information becomes available that suggests that the telavancin inventory will not be realisable, it may be required to expense a portion or all of the capitalized inventory costs. A portion of the amount that may be expensed would be eligible for reimbursement through alternative arrangements with Astellas under terms of the Company's collaboration agreement. During 2007, the Company expensed approximately \$0.9 million of inventory capitalized during the fiscal year as it was determined these inventories were not realisable for commercial launch supplies.

## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**1. Summary of Significant Accounting Policies (Continued)***Revenue Recognition*

The Company recognizes revenue in accordance with the criteria outlined in Staff Accounting Bulletin No. 101 (SAB 101,) "Revenue Recognition in Financial Statements", as amended by SAB 104 and Emerging Issues Task Force (EITF) Issue 00-21 "Revenue Arrangements with Multiple Deliverables" (EITF 00-21). Under EITF 00-21, the Company has determined that the deliverables under its various collaboration agreements do not meet the criteria required for separate accounting units for the purposes of revenue recognition.

In connection with the Company's agreements with GSK and Astellas, the Company recognizes 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 balance sheet to be amortized over the period of deferral. Deferred revenue that is classified as short-term or long-term liabilities are amortized to revenue and are not settled with cash. When the period of deferral cannot be specifically identified from the agreement, management estimates the period based upon the terms of the agreement and other relevant facts. The Company periodically reviews the estimated performance periods of its contracts based on the progress of its programs. During the third and fourth quarters of 2007, the Company revised the performance period related to the Company's agreement with Astellas based on the progress of regulatory review of the telavancin NDA. The Company expects that the revision of the performance period under this agreement will not have a material impact on the timing of revenue recognized in future years. In addition, the Company has been reimbursed by GSK and Astellas for certain external development costs under their respective collaboration agreements. Such reimbursements have been reflected as a reduction of research and development expense and not as revenue.

*Property and Equipment*

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

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

*Capitalized Software*

The Company capitalizes certain costs related to direct material and service costs for software obtained for internal use in accordance with Statement of Position 98-1 *Accounting for the Costs of Computer Software Developed or 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

THERAVANCE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**1. Summary of Significant Accounting Policies (Continued)**

expected to result from the use of the asset and its eventual disposition are less than its carrying amount.

*Concentration of Credit Risks and Other Uncertainties*

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.

The Company is substantially dependent on third-party vendors and clinical research organizations for clinical studies related to its drug discovery and development efforts, as well as suppliers for the manufacture of its active pharmaceutical ingredient (API) and drug product. The Company may be unable to retain alternative providers on reasonable terms, if at all. If the Company loses its relationship with any one or more of these providers, it could experience a significant delay in both identifying another comparable provider and then contracting for its services. Even if the Company locates an alternative provider, it is likely that this provider will need additional time to respond to the Company's needs and may not provide the same type or level of service as the original provider. For example, due to the complex nature of the Company's compounds, changing manufacturers for APIs or drug products could involve lengthy technology transfer and validation activities for the new manufacturer. The occurrence of any of these events may delay the development or commercialization of the Company's product candidates and have a material adverse effect on the consolidated results of operations.

Future financing may not be available in amounts or on terms acceptable to the Company, if at all. The Company will require significant additional capital to fully implement its business plan.

*Related Parties*

The Company's related parties are its directors, executive officers and GSK. Transactions with executive officers and directors include notes receivable, described below. Transactions with GSK are described in Note 3.

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 are incurred in the ordinary course of business, and were \$0.6 million, \$0.5 million and \$0.5 million the years ended December 31, 2007, 2006 and 2005, respectively.

*Notes Receivable*

The Company has provided loans to its officers and employees primarily to assist them with the purchase of a primary residence, which collateralizes the resulting loans. The Company has also allowed certain option holders to exercise their options by executing stock purchase agreements and full recourse notes payable to the Company. The balance of these notes receivable is included in stockholders' equity (net capital deficiency) on the consolidated balance sheets. The loans issued for the exercise of stock options are dated prior to November 2001 and thus are not subject to variable accounting as required under EITF 00-23 "Issues Related to the Accounting for Stock Compensation under APB No. 25 and FASB Interpretation 44."

Interest receivable related to the notes was \$26,000, \$24,000 and \$25,000 at December 31, 2007, 2006 and 2005, respectively, and is included in other current assets. The Company accrues interest on

THERAVANCE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. Summary of Significant Accounting Policies (Continued)

the notes at rates ranging up to 8%. The outstanding loans have maturity dates ranging from April 2008 through 2012.

*Bonus Accruals*

The Company has short-and long-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, in some cases over a period of time in excess of twelve months, it is possible for bonus expense to vary significantly in future periods if changes occur in those management estimates. During the year ended December 31, 2007, the Company recorded an increase in bonus expense and liability for eligible non-officer employees of \$8.5 million, which included the effect of a change in estimate of \$7.1 million, related to the achievement of the last clinical milestone under a long-term bonus plan established in 2004. As of December 31, 2007, the Company had fully expensed its bonus liability of approximately \$12.4 million relating to its long-term bonus program, which ended in September 2007, of which the \$8.3 million remaining is scheduled to be paid to eligible employees in December of 2008 and 2009. Bonus expense for the Company's short-term bonus program was \$4.9 million, \$5.9 million and \$6.6 million for the years ended December 31, 2007, 2006 and 2005, respectively.

*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 operating leases provide for rent increases over the terms of the leases, average annual rent during the terms exceed the Company's actual cash rent payments of the first 5.5 years of the leases.

*Research and Development Costs*

Research and development costs are expensed as incurred. 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 development costs reimbursed by GSK.

*Preclinical Study and Clinical Study Expenses*

Most 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 obtained for contracts

## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**1. Summary of Significant Accounting Policies (Continued)**

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 Share-based Payment Awards*

The Company uses the fair value method of accounting for share-based compensation arrangements in accordance with Financial Accounting Standards Board Statement No. 123(R), Share-based Payment (SFAS123(R)). The Company adopted SFAS 123(R) on January 1, 2006 using the modified prospective method of transition. Under this method, compensation expense is recognized beginning with the effective date of adoption of SFAS 123(R) for all share-based payments (i) granted after the effective date of adoption and (ii) granted prior to the effective date of adoption and that remained unvested on the date of adoption. Share-based compensation arrangements covered by SFAS 123(R) currently include stock options granted, restricted shares issued and performance-contingent restricted stock unit awards (RSUs) granted under the 2004 Equity Incentive Plan, as amended, and purchases of common stock by the Company's employees at a discount to the market price during offering periods under the Company's Employee Stock Purchase Plan (ESPP). The estimated fair value of stock options and restricted shares under SFAS 123(R) is expensed on a straight-line basis over the vesting term of the grant and the fair value of RSUs is expensed during the term of the award when the Company determines that it is probable that certain performance milestones will be met. Compensation expense for purchases under the ESPP is recognized based on the estimated fair value of the common stock during each offering period and the percentage of the purchase discount.

In conjunction with the adoption of SFAS 123(R), the Company changed its method of expensing the value of stock-based compensation from the accelerated method to the straight-line single-option method. Compensation expense for all share-based payment awards granted prior to January 1, 2006 will continue to be recognized using the accelerated expense attribution method over the vesting period while the compensation expense for all share-based payment awards granted on or subsequent to January 1, 2006 is recognized using the straight-line single-option method. Stock-based compensation expense for stock options has been reduced for estimated forfeitures so that compensation expense is based on options ultimately expected to vest. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company's estimated annual forfeiture rate for stock options is 3.6%, based on its historical forfeiture experience.

*Pro forma Information under SFAS 123 for Periods Prior to Fiscal 2006*

The following table shows the pro forma effect on net loss and net loss per common share if the fair value recognition provisions of SFAS 123, Accounting for Stock-Based Compensation, had been applied to stock-based employee compensation (in thousands, except per share amounts) for the year ended December 31, 2005. For purposes of pro forma disclosures, pursuant to SFAS No. 123 as amended by SFAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure, the

## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 1. Summary of Significant Accounting Policies (Continued)

Company amortized the estimated fair value of stock-based employee compensation to expense over the vesting period of the options using the accelerated expense attribution method:

	<b>Year Ended December 31, 2005</b>
Net loss, as reported	\$ (143,164)
Add: Employee stock-based compensation calculated using the intrinsic value method	4,455
Less: Total employee stock-based compensation calculated using the fair value method	(16,296)
Pro forma net loss	\$ (155,005)
Net loss per common share, as reported	\$ (2.69)
Net loss per common share, pro forma	\$ (2.91)

The foregoing pro forma information regarding net loss and net loss per common share has been determined as if the Company had accounted for its employee stock options and employee stock purchase plan issuances under the fair value method using the Black-Scholes option valuation model. As the Company's common stock had only recently become publicly traded when these estimates were made, certain assumptions regarding stock price volatility and expected life of the award were estimated by considering volatility and expected life assumptions used by similar entities within the Company's industry. In particular, prior to 2006, the volatility estimate of 70% is significantly higher than the Company's actual stock price volatility, which was approximately 30% since the Company's October 2004 initial public offering.

*Segment Reporting*

SFAS No. 131, "Disclosure about Segments of an Enterprise and Related Information", establishes annual and interim reporting standards for an enterprise's operating segments and related disclosures about its products, services, geographic areas and major customers. The Company has determined that it operates in only one segment which is the research and development of human therapeutics. Revenues are primarily generated from the Company's collaborations with GSK and Astellas, located in the United Kingdom and Japan, respectively. All long-lived assets are maintained in the United States.

*Comprehensive Income or Loss*

Comprehensive income or loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) consists of unrealized gains and losses on the Company's available-for-sale securities. Comprehensive income or loss for the years ended December 31, 2007, 2006 and 2005 has been presented in the Company's Consolidated Statements of Stockholders' Equity (net capital deficiency).

*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

THERAVANCE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. 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.

*Recent Accounting Pronouncements*

In November 2007, the Emerging Issues Task Force (EITF) ratified a consensus on EITF Issue No. 07-1 (EITF 07-1), "Accounting for Collaborative Arrangements", which requires participants in a collaboration to make separate disclosures regarding the nature and purpose of an arrangement, their rights and obligations under the arrangement, the accounting policy for the arrangement and the income statement classification and amounts arising from the arrangement between participants for each period an income statement is presented. EITF 07-1 is effective for the Company beginning in the first quarter of fiscal year 2009. The Company is currently evaluating the impact of the provisions of EITF 07-1 on its financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

In June 2007, the EITF ratified a consensus on EITF Issue No. 07-3 (EITF 07-3), "Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities", which concluded that non-refundable advance payments for goods or services for use in research and development activities should be deferred and capitalized. EITF 07-3 is effective for the Company beginning in the first quarter of fiscal year 2008. The Company is currently evaluating the impact of the provisions of EITF 07-3 on its financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for the Company beginning in the first quarter of fiscal year 2008. The Company is currently evaluating the impact of the provisions of SFAS 157 on its financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

In July 2006, the FASB issued Financial Interpretation No. (FIN) 48, "Accounting for Uncertainty in Income Taxes" (FIN 48) as an interpretation of SFAS No. 109, "Accounting for Income Taxes" (SFAS 109) and in May 2007, the FASB issued FASB Staff Position FIN 48-1, "Definition of *Settlement* in FASB Interpretation No. 48". FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109 and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognizing, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company adopted FIN 48 effective January 1, 2007.

*Reclassification of Prior Year Amounts*

Certain prior year amounts for stock-based compensation expenses, interest and other income, net, interest expense and notes receivable have been reclassified to conform to the current period's presentation. These reclassifications had no impact on previously reported net loss or stockholders' equity (net capital deficiency).

## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 2. Net Loss per Share

Basic net loss per common share (Basic EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding, less shares subject to repurchase. Diluted net loss per common share (Diluted EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding, less shares subject to repurchase, plus dilutive potential common shares and shares subject to repurchase. At December 31, 2007, potential common shares consist of approximately 11,436,000 shares issuable upon the exercise of stock options, and approximately 2,045,000 shares issuable under performance-contingent restricted stock unit awards. At December 31, 2006, potential common shares consist of approximately 10,389,000 shares issuable upon the exercise of stock options and 18,000 shares issuable upon the exercise of a warrant. The outstanding warrant was not exercised as of its expiration date of October 5, 2007 and therefore no stock was issued under the warrant. 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.

	Year Ended December 31,		
	2007	2006	2005
	(In thousands, except for per share amounts)		
<b>Basic and diluted:</b>			
Net loss	\$ (159,997)	\$ (166,044)	\$ (143,164)
Weighted average shares of common stock outstanding	60,642	59,187	53,512
Less: weighted average shares subject to repurchase	(144)	(174)	(242)
Weighted average shares used in computing basic and diluted net loss per common share	60,498	59,013	53,270
Basic and diluted net loss per common share	\$ (2.64)	\$ (2.81)	\$ (2.69)

## 3. Collaboration Agreements

*2005 License, Development and Commercialization Agreement with Astellas*

In November 2005, the Company entered into a collaboration arrangement with Astellas for the development and commercialization of telavancin. In July 2006, Japan was added to the collaboration, thereby giving Astellas worldwide rights to this potential medicine. Through December 31, 2007, the Company has received \$158.0 million in upfront, milestone and other fees from Astellas and the Company is eligible to receive up to an additional \$60.0 million in remaining milestone payments related to regulatory filings and approvals in various regions of the world. The Company recorded the payments as deferred revenue to be amortized ratably over its estimated period of performance (development and commercialization period). The Company recognized \$10.3 million, \$6.5 million and \$0.4 million in revenue under this agreement in 2007, 2006 and 2005, respectively.

If telavancin is commercialized, the Company will be entitled to receive royalties on global sales of telavancin by Astellas that, on a percentage basis, range from the high teens to the upper twenties depending on sales volume. Under this arrangement, the Company will be responsible for substantially all costs to develop and obtain U.S. regulatory approval for telavancin for cSSSI and HAP, and Astellas will be responsible for substantially all other costs associated with commercialization and further development of telavancin.



THERAVANCE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**3. Collaboration Agreements (Continued)**

In addition to the license rights to telavancin, Astellas had an option to license TD-1792, the Company's investigational antibiotic, for further development and commercialization on substantially the same terms under which Astellas licensed telavancin. In September 2007, the Company announced that it retained full ownership rights of TD-1792 as a result of Astellas' decision not to exercise its right to license the compound.

*Horizon Program with GSK*

In November 2002, the Company entered into its Horizon collaboration with GSK to develop and commercialize a long-acting beta<sub>2</sub> agonist (LABA) product candidate for the treatment of asthma and chronic obstructive pulmonary disease (COPD).

In connection with the Horizon program, in 2002 the Company received from GSK an upfront payment of \$10.0 million and sold to an affiliate of GSK shares of the Company's Series E Preferred Stock for an aggregate purchase price of \$40.0 million. In addition, the Company is eligible to receive up to \$495.0 million in development, approval, launch and sales milestones and royalties on the sales of any product resulting from this program. As of December 31, 2007, the Company has received a total of \$60.0 million in upfront and development milestone payments. GSK has determined to focus the collaboration's resources on the development of the lead LABA, GW642444, a GSK-discovered compound, together with the lead ICS. Accordingly, the Company does not expect to receive any further milestone payments from the Horizon program. In the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple regions in the world, the Company would be obligated to make milestone payments to GSK of up to \$220.0 million. In addition, the Company is entitled to receive the same royalties on product sales of medicines from the Horizon program, regardless of whether the product candidate originated with Theravance or with GSK.

The Company recorded the initial cash payment and subsequent milestone payments as deferred revenue to be amortized ratably over its estimated period of performance (the product development period). Collaboration revenue from GSK was \$6.8 million, \$7.8 million and \$7.6 million in 2007, 2006 and 2005, respectively. Additionally, the Company accrued reimbursements of \$0.3 million in 2005 compared to none in 2007 and 2006 as an offset to research and development expense for certain costs related to the collaboration that were reimbursable by GSK.

*2004 Strategic Alliance with GSK*

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 all of the Company's full drug discovery programs initiated prior to September 1, 2007, on pre-determined terms and on an exclusive, worldwide basis. The Company is obligated to use diligent efforts to discover and deliver compounds for the alliance. Under the terms of the strategic alliance, GSK has only one opportunity to license each of the Company's programs. 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. Consistent with the Company's strategy, it is obligated at its sole cost to discover two structurally different product candidates for any programs that are licensed by GSK under the alliance.

THERAVANCE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**3. Collaboration Agreements (Continued)**

If these programs are 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 these programs. For product candidates licensed to date under this agreement, the royalty structure for a product containing one of its compounds as a single active ingredient would result in an average percentage royalty rate in the low double digits. If a product is successfully commercialized, in addition to any royalty revenue that the Company receives, the total upfront and milestone payments that it could receive in any given program that GSK licenses range from \$130.0 million to \$162.0 million for programs with single-agent medicines and up to \$252.0 million for programs with both a single-agent and a combination medicine. 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. To date, GSK has licensed the Company's two COPD programs: long-acting muscarinic antagonist (LAMA) and muscarinic antagonist-beta<sub>2</sub> agonist (MABA). The Company received a \$5.0 million payment from GSK in connection with its license of each of the Company's LAMA and MABA programs in August 2004 and March 2005, respectively. GSK has chosen not to license the Company's bacterial infections program, anesthesia program or Gastrointestinal Motility Dysfunction program.

Under the alliance, GSK had the right between June 1 and July 1, 2007, to elect to acquire (call) half of Theravance's outstanding shares of common stock at \$54.25 per share. On June 29, 2007, GSK elected not to exercise the call, which triggered the right of the Company's stockholders to require it to redeem (put) up to 50% of their common stock at \$19.375 per share between August 1 and September 12, 2007 with funds provided by GSK. One stockholder exercised his put right for one share of common stock. In exchange for GSK providing the funds to pay the redemption price for the one share of common stock, and pursuant to the Company's certificate of incorporation, the Company issued to GSK one share of its Class A common stock. The common share that the Company redeemed pursuant to the stockholder's exercise of the put right was retired and cancelled.

In connection with the strategic alliance with GSK, the Company received from GSK a payment of \$20.0 million. This payment is being amortized over the initial performance period during which GSK may exercise its right to license certain of the Company's programs under the agreement, which it currently estimates to be through September 2011. In connection with the strategic alliance, the Company recognized \$2.7 million in revenue for each of the years ending December 31, 2007, 2006 and 2005. In addition, in May 2004, GSK purchased through an affiliate 6,387,096 shares of the Company's Class A common stock for an aggregate purchase price of \$108.9 million.

Through December 31, 2007, the Company has received \$36.0 million in upfront and milestone payments from GSK relating to the strategic alliance agreement. In addition, pursuant to a partial exercise of its rights under the governance agreement, upon the closing of the Company's initial public offering on October 8, 2004, GSK purchased through an affiliate an additional 433,757 shares of Class A common stock. GSK's ownership position of the Company's outstanding stock was approximately 15.4% as of December 31, 2007.

In August 2004, GSK exercised its right to license the Company's LAMA program pursuant to the terms of the strategic alliance. The Company received a \$5.0 million payment from GSK in connection with its licensing of the Company's LAMA program. Through December 31, 2007, the Company received a milestone payment from GSK of \$3.0 million related to clinical progress of the Company's product candidate. These payments are being amortized ratably over the estimated period of

## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 3. Collaboration Agreements (Continued)

performance (the product development period). The Company recognized \$0.8 million, \$1.0 million and \$0.9 million in revenue related to the LAMA program in 2007, 2006 and 2005, respectively. Additionally, the Company accrued reimbursements of \$70,000, \$0.4 million and \$0.5 million in 2007, 2006 and 2005, respectively, as an offset to research and development expense for certain costs related to the LAMA program that were reimbursable by GSK.

In March 2005, GSK exercised its right to license the Company's MABA program pursuant to the terms of the strategic alliance. The Company received a \$5.0 million payment from GSK in connection with the license of the Company's MABA program. Through December 31, 2007, the Company received a milestone payment from GSK of \$3.0 million related to clinical progress of its candidate. These payments are being amortized ratably over the estimated period of performance (the product development period). The Company recognized \$1.0 million, \$0.9 million and \$0.5 million in revenue related to the MABA program in 2007, 2006 and 2005, respectively. Additionally, the Company accrued reimbursements of \$2.9 million in 2005 compared to none in 2007 and 2006 as an offset to research and development expense for certain costs related to the MABA program that were reimbursable by GSK.

## 4. Marketable Securities

The Company invests in a variety of highly liquid investment-grade securities. The following is a summary of the Company's available-for-sale securities at December 31, 2007 and December 31, 2006 (in thousands):

	December 31, 2007				December 31, 2006			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government agencies	\$ 74,161	\$ 39	\$	\$ 74,200	\$ 70,060	\$ 38	\$ (60)	\$ 70,038
U.S. corporate notes	21,489	20	(2)	21,507	49,219	10	(5)	49,224
U.S. commercial paper	24,836			24,836	66,343			66,343
Asset-backed securities					42,077	66	(23)	42,120
Certificates of deposit	60			60	1,910			1,910
Money market funds	12,479			12,479	9,795			9,795
<b>Total</b>	<b>133,025</b>	<b>59</b>	<b>(2)</b>	<b>133,082</b>	<b>239,404</b>	<b>114</b>	<b>(88)</b>	<b>239,430</b>
Less amounts classified as cash and cash equivalents	(86,433)			(86,433)	(72,388)			(72,388)
Less amounts classified as restricted cash	(3,810)			(3,810)	(3,860)			(3,860)
<b>Amounts classified as marketable securities</b>	<b>\$ 42,782</b>	<b>\$ 59</b>	<b>\$ (2)</b>	<b>\$ 42,839</b>	<b>\$ 163,156</b>	<b>\$ 114</b>	<b>\$ (88)</b>	<b>\$ 163,182</b>

The estimated fair value amounts have been determined by the Company using available market information. At December 31, 2007, approximately 88% of marketable securities have contractual maturities within twelve months and 12% of marketable securities have contractual maturities between twelve and twenty-four months. Average duration of available-for-sale securities was approximately two months at December 31, 2007.

## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 4. Marketable Securities (Continued)

The following table provides the net realized gains (losses) on available-for-sale securities for the periods presented (in thousands):

	Year Ended December 31,		
	2007	2006	2005
Realized gains	\$ 224	\$ 298	\$
Realized losses	(1,188)	(14)	(80)
Net realized gains (losses)	\$ (964)	\$ 284	\$ (80)

In the year ended December 31, 2007, the Company realized \$67,000 in gains and \$11,000 in losses that were previously classified as unrealized gains and losses in accumulated other comprehensive income at December 31, 2006.

The following table provides the breakdown of the marketable securities with unrealized losses at December 31, 2007 (in thousands):

	In loss position for less than 12 months		In loss position for more than 12 months		Total	
	Fair Value	Gross Unrealized losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. corporate notes	\$ 1,492	\$ (2)	\$	\$	\$ 1,492	\$ (2)

During the fourth quarter of 2007, the Company recorded an impairment charge of \$1.1 million related to the decline in fair value of a structured investment vehicle (SIV) security as a result of the deterioration of the SIV financial market and evidence indicating that the security's carrying value was not recoverable within a reasonable period of time. The Company has determined that the gross unrealized losses on its remaining outstanding marketable securities at December 31, 2007 are temporary in nature.

## 5. Property and Equipment

Property and equipment consists of the following (in thousands):

	December 31,	
	2007	2006
Computer equipment	\$ 3,407	\$ 2,664
Software	4,518	3,503
Furniture and fixtures	3,423	3,407
Laboratory equipment	27,028	21,254
Leasehold improvements	15,107	13,636
	53,483	44,464
Less accumulated depreciation and amortization	(33,392)	(29,363)
Property and equipment, net	\$ 20,091	\$ 15,101



## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**5. Property and Equipment (Continued)**

Depreciation expense was \$4.1 million, \$4.2 million and \$4.1 million for the years ended December 31, 2007, 2006 and 2005, respectively. The change in accumulated depreciation is net of asset retirements.

**6. Long-Term Obligations***Note Payable*

Note payable is as follows (in thousands):

	December 31,	
	2007	2006
Note payable to lessor	\$ 536	\$ 625

In connection with the Company's lease agreement for its 60,000 square foot facility in South San Francisco, California (see Note 7), the Company received approximately \$0.9 million in July 2002 under a tenant improvement loan from the lessor, which is payable in monthly installments through 2012, bears interest at 14.5% per annum and is secured by the underlying leasehold improvements.

The aggregate maturities of the note payable for each of the remaining five years are as follows: \$0.1 million in 2008, \$0.1 million in 2009, \$0.1 million in 2010, \$0.2 million in 2011 and \$42,000 in 2012.

**7. Operating Leases and Subleases**

The Company leases a 110,000 square foot facility and an adjacent 60,000 square foot facility in South San Francisco, California. Both of the leases expire in 2012 and have two renewal options of five years each. As security for performance of its future obligations under these leases, the Company has letters of credit for an aggregate \$3.8 million, collateralized by an equal amount of restricted cash. If the Company's unrestricted cash and marketable securities balance is less than \$50.0 million during the terms of the leases, then the letters of credit must be increased by an aggregate of \$1.0 million. The current annual rental expense under the combined leases for the Company's headquarters is approximately \$6.1 million, subject to annual increases.

At December 31, 2007, the Company's future minimum commitments under noncancelable operating leases, net of sublease income, are as follows (in thousands):

	Minimum Lease Commitments	
Year ending December 31:		
2008	\$	6,126
2009		6,278
2010		6,435
2011		6,596
2012		1,659
Total	\$	27,094

## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**7. Operating Leases and Subleases (Continued)**

Expenses and income associated with operating leases were as follows (in thousands):

	Year Ended December 31,		
	2007	2006	2005
Rent expense	\$ 6,958	\$ 6,756	\$ 6,781
Sublease income, net	(128)	(305)	(438)

**8. Commitments and Contingencies***Guarantees and Indemnifications*

The Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, shareholder suits and tax matters, as such, the Company is unable to estimate the potential exposure related to these indemnification agreements. The Company accrues for such contingencies in accordance with SFAS No. 5, Accounting for Contingencies. The Company has not recognized any liabilities relating to these agreements as of December 31, 2007.

*Purchase Obligations*

At December 31, 2007, the Company had outstanding purchase obligations that are committed through 2008, under commercially reasonable terms, primarily for services from contract research organizations and research laboratories, totaling \$3.7 million.

**9. Stockholders' Equity***Determining Fair Value of Stock-Based Compensation*

Under SFAS 123(R), the Company elected to continue to use the Black-Scholes valuation model for share-based payment awards granted. The Company's determination of the fair value of share-based payment awards on the grant date using the Black-Scholes option valuation model requires the input of highly subjective assumptions, including the expected stock price volatility and the expected life of the award. As the Company has been operating as a public company for a period of time that is shorter than its estimated expected option life, the Company is unable to use actual price volatility or option life data as input assumptions within its Black-Scholes valuation model when determining the fair value of its stock options. As a result, the Company is continuing to use the "simplified" method as described in Staff Accounting Bulletin No.107 relating to SFAS 123(R) for expected option life and peer company price volatility. Both of these assumptions have resulted in Black-Scholes inputs that are higher than actual results to date. The result of this is an increase in the value of estimated stock-based compensation reflected in the Company's consolidated statements of operations.

## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 9. Stockholders' Equity (Continued)

The weighted-average assumptions used to value employee stock-based compensation for stock options granted and employee stock purchase plan issuances were as follows:

	Year Ended December 31,		
	2007	2006	2005
<b>Employee stock options</b>			
Risk-free interest rate	3.48% - 5.03%	4.56% - 5.16%	3.54% - 4.43%
Expected life (in years)	5 - 6	5 - 6	2 - 4
Volatility	0.46 - 0.49	0.48 - 0.51	0.7
Dividend yield	%	%	%
Weighted average estimated fair value of stock options granted	\$ 16.47	\$ 15.65	\$ 8.84
<b>Employee stock purchase plan issuances</b>			
Risk-free interest rate	3.23% - 4.98%	4.70% - 5.08%	2.58% - 4.42%
Expected life (in years)	0.5 - 2	0.5 - 2	2
Volatility	0.26 - 0.41	0.24 - 0.38	0.7
Dividend yield	%	%	%
Weighted average estimated fair value of ESPP issuances	\$ 8.17	\$ 8.73	\$ 9.05

Total stock-based compensation expense recognized for the year ended December 31, 2007 was \$22.5 million, which consisted of \$21.8 million related to employee stock awards and employee stock purchases, \$0.3 million related to the value of options issued to non-employees for services rendered and \$0.4 million related to the value of shares of restricted stock. As of December 31, 2007, there was \$42.1 million of total unrecognized compensation cost related to unvested stock options. This cost is expected to be recognized over a weighted-average period of approximately 2.74 years. Total stock-based compensation expense recognized for the year ended December 31, 2006 was \$21.8 million, which consisted of \$19.5 million related to employee stock options and employee stock purchases, \$2.0 million related to the value of options issued to non-employees for services rendered and \$0.3 million related to the value of shares of restricted stock. The Company has not recognized, and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation costs as a result of the full valuation allowance on the Company's net deferred tax assets including deferred tax assets related to its net operating loss carryforwards.

During the years ended December 31, 2007 and 2006, the Company recognized \$0.8 million and \$0.1 million, respectively, of stock-based compensation expense related to a modification agreement entered into in 2004 with a former executive, which included extended vesting and exercise periods for his option grants.



## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 9. Stockholders' Equity (Continued)

The following table discloses the allocation of stock-based compensation expense included in the consolidated statements of operations:

	Year Ended December 31,		
	2007	2006	2005
Research and development	\$ 13,133	\$ 12,635	\$ 3,259
General and administrative	9,361	9,196	2,364
<b>Total stock-based compensation expense</b>	<b>\$ 22,494</b>	<b>\$ 21,831</b>	<b>\$ 5,623</b>

The Company does not currently pay dividends and does not intend to declare or pay cash dividends on its common stock in the foreseeable future.

*Equity Incentive Plan*

The Company issues stock options, restricted stock awards and restricted stock unit awards (RSU) under the 2004 Equity Incentive Plan (which includes shares remaining available for issuance under the Company's 1997 Stock Option Plan and Long-Term Stock Option Plan), as amended December 6, 2006 (the Plan). On April 25, 2007, an amendment to the Plan which, among other things, increased the number of shares authorized for issuance under the Plan from 3,700,000 to 7,200,000 shares, was approved by the Company's stockholders. As of December 31, 2007, total shares remaining available for issuance under the Plan were 593,150. The Plan provides for the granting of stock options, restricted stock awards, stock appreciation rights and RSU awards to employees, officers, directors and consultants of the Company. Stock options may be granted with an exercise price not less than 100% of the fair market value of the common stock on the date of grant. Stock options are generally granted with terms of up to ten years and vest over a period of four years. During the years ended December 31, 2007, 2006 and 2005, the Company granted stock options to purchase 2,127,256, 1,645,699 and 1,715,534 shares, respectively, at average stock prices of \$32.06, \$28.74 and \$18.67, respectively, under the Plan. During the year ended December 31, 2007, the Company granted 2,061,206 performance-contingent RSUs with a weighted-average fair value of \$32.45 per share, under the Plan.

The Company previously allowed certain stock option holders to exercise their options by executing stock purchase agreements and full-recourse notes payable to the Company. The stock purchase agreements provide the Company with the right to repurchase unvested shares. Certain full-recourse notes payable include forgiveness provisions whereby the Company forgives the unpaid principal of the note on its maturity date if the optionee remains in continuous service until the maturity date on the notes (see Notes Receivable discussion in Note 1).

## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 9. Stockholders' Equity (Continued)

The RSUs granted to date have dual triggers of vesting based upon the successful achievement of certain clinical development milestones during 2008 and 2009, as well as a requirement for continued employment through 2009 and 2010. The issuance of shares underlying the RSUs would occur, if at all, during 2009 and 2010. Expense associated with RSUs will be recognized, if at all, during 2008 through 2009, depending on the probability of meeting the performance milestones. The maximum potential expense associated with the RSUs could be up to approximately \$66.3 million (allocated as \$38.3 million for research and development expense and \$28.0 million for general and administrative expense) if all of the milestones are successfully achieved on time. As of December 31, 2007, the Company had determined that none of the requisite performance milestones were probable and as a result, no compensation expense has been recognized. As vesting of the RSUs is dependent upon the successful achievement of the performance conditions, the expense associated with the RSUs may vary significantly from period to period.

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

	Number of Shares Available for Grant	Number of Shares Subject to Outstanding Options and Other Awards	Weighted-Average Exercise Price of Outstanding Options and Fair Value of Other Awards per Share
(In thousands, except per share amounts)			
Balance at December 31, 2004	3,711	9,435	\$ 7.86
Options granted	(1,716)	1,716	\$ 18.67
Restricted stock award granted	(50)		
Options exercised		(731)	\$ 5.11
Options forfeited	324	(324)	\$ 10.27
Balance at December 31, 2005	2,269	10,096	\$ 9.82
Options granted	(1,646)	1,646	\$ 28.74
Options exercised		(910)	\$ 5.71
Options forfeited	442	(442)	\$ 15.82
Shares repurchased	5		\$ 3.10
Balance at December 31, 2006	1,070	10,390	\$ 12.92
Additional shares authorized	3,500		
Options granted	(2,127)	2,127	\$ 32.06
RSUs and restricted stock awards granted	(2,132)	2,061	\$ 32.45
Options exercised		(815)	\$ 6.93
Options and RSUs forfeited	282	(282)	\$ 25.11
Balance at December 31, 2007	593	13,481	\$ 19.03

No options were granted with exercise prices less than fair value of common stock on the date of grant during the years ended December 31, 2007, 2006 and 2005.

## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 9. Stockholders' Equity (Continued)

As of December 31, 2007, 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 Price	Aggregate Intrinsic Value	Options Exercisable	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$1.32	45	1.9	\$ 1.32		45	1.9	\$ 1.32	
\$3.10	1,212	5.4	\$ 3.10		1,212	5.4	\$ 3.10	
\$8.53	2,647	3.8	\$ 8.53		2,647	3.8	\$ 8.53	
\$9.69	1,858	5.9	\$ 9.69		893	6.3	\$ 9.69	
\$12.40 - \$18.25	1,217	6.8	\$ 16.27		781	7.0	\$ 16.08	
\$18.26 - \$21.70	918	7.2	\$ 19.16		601	7.3	\$ 19.03	
\$21.71 - \$29.65	1,842	8.4	\$ 27.93		682	8.2	\$ 28.66	
\$29.66 - \$35.46	1,697	9.2	\$ 33.59		299	9.2	\$ 33.62	
<b>Total</b>	<b>11,436</b>	<b>6.5</b>	<b>\$ 16.63</b>	<b>\$ 72,645</b>	<b>7,160</b>	<b>5.7</b>	<b>\$ 12.38</b>	<b>\$ 61,697</b>

As of December 31, 2006, the aggregate intrinsic value of the options outstanding and the options exercisable was \$186.8 million and \$116.1 million, respectively.

The total intrinsic value of the options exercised during the years ended December 31, 2007, 2006 and 2005 was \$19.0 million, \$17.7 million and \$9.0 million, respectively, and the total fair value of options vested was \$32.5 million, \$5.1 million and \$6.8 million for the years ended December 31, 2007, 2006 and 2005, respectively. For the year ended December 31, 2007, the fair value of options vested was significantly higher when compared to 2006 due to the number of options that vested at the expiration of the put period in September 2007.

*Employee Stock Purchase Plan*

On May 27, 2004 the Company's board of directors adopted the 2004 Employee Stock Purchase Plan (ESPP) that became effective on the date of the Company's initial public offering. Under the 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> each purchase period. ESPP contributions are limited to a maximum of 15 percent of an employee's eligible compensation. A total of 325,000 shares of common stock were initially reserved for issuance under the ESPP. In June 2005, the Company's stockholders approved an amendment to the ESPP increasing the aggregate number of shares of common stock authorized for issuance under the plan by 300,000 shares.

Through December 31, 2007, the Company issued 444,071 shares under the ESPP at an average price of \$16.09 per share. The total number of remaining shares available for issuance under the plan at December 31, 2007 was 180,929. The total stock-based compensation expense recognized related to

## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 9. Stockholders' Equity (Continued)

the ESPP under SFAS 123(R) for the years ended December 31, 2007 and 2006 was \$1.4 million and \$1.6 million, respectively.

*Reserved Shares*

The Company has reserved shares of common stock for future issuance as follows (shares in thousands):

	December 31,	
	2007	2006
Subject to outstanding warrant		18
Stock option plans:		
Subject to outstanding options and RSUs	13,481	10,390
Available for future grants	593	1,070
Available for future ESPP grants	180	294
	<u>14,254</u>	<u>11,772</u>
Total	14,254	11,772

*Stock Subject to Repurchase*

At December 31, 2007, there were 96,924 shares of the Company's common stock subject to the Company's right to repurchase at the original purchase price. These shares were issued upon the exercise of unvested stock options and the execution of certain stock purchase agreements. The Company's repurchase rights lapse generally over a four-year period.

*Restricted Stock*

During 2007, the Compensation Committee of the Company's board of directors approved restricted stock awards for 71,000 shares of restricted common stock to certain members of the Company's senior management. These restricted shares of stock will vest based on continued service and with pre-determined vesting percentages and anniversary dates. The Company valued the awards at \$1.8 million and will amortize that amount over the respective service periods. The aggregate value of the restricted common stock awards was based on the closing market price of the Company's common stock on the date of the respective awards. Stock-based compensation expense related to these awards for 2007 was \$141,000.

In March 2005, the Company's board of directors approved the grant of 50,000 shares of restricted stock to a member of the Company's senior management. These restricted shares of stock vest based on continued service, with 50% of the shares vesting on September 13, 2007 and 25% of the shares vesting upon each of the next two anniversaries of such date. The value was based on the closing market price of the Company's common stock of \$17.91 on the date of award. The Company recognized stock-based compensation expense of \$0.2 million, \$0.3 million and \$0.2 million related to this award for 2007, 2006 and 2005, respectively. In September 2007, upon the vesting of 25,000 common shares, 16,063 common shares were issued to the officer and the remaining 8,937 common shares were withheld by the Company to satisfy the officer's tax withholding requirements of approximately \$250,000.

THERAVANCE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**9. Stockholders' Equity (Continued)**

*Director Compensation Program*

In April 2007, the Compensation Committee of the board of directors approved an amendment to the director compensation program for the Company's outside directors. Pursuant to this program, each outside director receives an annual retainer plus a fee for attending each board and committee meeting. Also under this program, following the Company's initial public offering in October 2004, each outside director was granted an option to purchase 25,806 shares of common stock. In 2007 this initial option grant was increased to 30,000 shares. In addition, at each annual stockholder meeting beginning in 2005, each outside director was entitled to be granted an option to purchase 12,903 shares of common stock. In 2007 this annual grant was increased to 15,000 shares. The exercise price of options granted under the program is the fair market value of the Company's common stock, subject to the option on the date of the option grant.

Pursuant to the director compensation program, each of the Company's seven outside directors was granted an option to purchase 15,000 shares of common stock with an exercise price of \$33.25, which was the then fair market value of the Company's common stock. Also on April 25, 2007, the Company's Chairman of the Board was granted 86,694 shares of common stock with an exercise price of \$33.25, which was the then fair market value of the Company's common stock. On July 3, 2007, a new outside director was granted an initial option to purchase 30,000 shares of common stock with an exercise price of \$33.13, which was the then fair market value of the Company's common stock.

**Stock Options Exercised Early**

The Company generally allows employees to exercise options issued under the 1997 Stock Plan and the Long-Term Stock Option Plan prior to vesting. In accordance with EITF 00-23, "Issues Related to Accounting for Stock Compensation under APB Opinion No. 25 and FASB Interpretation No. 44," stock options granted or modified after March 21, 2002 that are subsequently exercised for cash prior to vesting are treated differently from prior grants and related exercises. The consideration received for an exercise of an option granted after the effective date of this guidance is considered to be a deposit of the exercise price and the related dollar amount is recorded as a liability. The liability is only reclassified into equity on a ratable basis as the option vests. The Company applied the guidance and recorded a liability of \$3,000 and \$22,000 in the consolidated balance sheets relating to 924 and 7,195 options granted that were exercised and unvested at December 31, 2007 and 2006, respectively. Furthermore, these shares are not presented as outstanding on the consolidated balance sheets, but are disclosed as outstanding options.

**Warrants**

There were no outstanding warrants at December 31, 2007. The warrant outstanding at December 31, 2006 was not exercised as of its expiration date of October 5, 2007 and therefore no stock was issued under the warrant.

**10. Income Taxes**

Due to operating losses and the inability to recognize an income tax benefit, there is no provision for income taxes.

## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 10. Income Taxes (Continued)

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

	December 31,	
	2007	2006
Deferred tax assets:		
Net operating loss carryforwards	\$ 208,000	\$ 176,000
Deferred revenues	75,000	61,000
Capitalized research and development expenditures	33,000	28,000
Research and development tax credit carryforwards	26,000	21,000
Other	21,000	14,000
Valuation allowance	(363,000)	(300,000)
Net deferred tax assets	\$	\$

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 \$63.0 million, \$69.9 million and \$61.2 million for the years ended December 31, 2007, 2006 and 2005, respectively.

As of December 31, 2007, the Company had federal net operating loss carryforwards of approximately \$637.8 million and federal research and development tax credit carryforwards of approximately \$30.7 million, which will expire from 2011 through 2027. The Company also had state net operating loss carryforwards of approximately \$37.2 million expiring in the years 2013 through 2017 and state research tax credits of approximately \$32.5 million, which carry forward indefinitely.

As a result of SFAS 123(R), the deferred tax asset balances at December 31, 2007 and 2006 do not include excess tax benefits from stock option exercises. Equity will be increased 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 the ownership change limitations provided by the Internal Revenue Code and similar state provisions. The annual limitation may result in expiration of net operating loss and tax credit carryforwards before some or all of such amounts have been utilized.

**Uncertain Tax Positions**

The Company adopted FIN 48 effective January 1, 2007. The adoption of FIN 48 did not result in an adjustment to the beginning balance of the Company's accumulated deficit.

## THERAVANCE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 10. Income Taxes (Continued)

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

Gross unrecognized tax benefits at January 1, 2007	\$ 26,700
Gross increase for tax positions for prior years	
Gross decrease for tax positions for prior years	
Gross increase in tax positions for current year	6,500
Settlements	
Reduction for lapse of statute of limitations	
	<hr/>
Unrecognized tax benefits at December 31, 2007	\$ 33,200
	<hr/>

If the Company is eventually able to recognize these uncertain positions, \$33.2 million of the unrecognized benefit would reduce its effective tax rate. 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.

## 11. Quarterly Consolidated Results of Operations (Unaudited)

The following table presents certain unaudited consolidated quarterly financial information for the eight quarters in the period ended December 31, 2007. 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.

	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
	(in thousands except per share data)			
<b>2007:</b>				
Revenue	\$ 5,398	\$ 5,305	\$ 5,669	\$ 5,630
Operating expenses	(57,656)	(53,009)	(40,426)	(39,476)
Loss from operations	(52,258)	(47,704)	(34,757)	(33,846)
Net loss	(49,450)	(45,125)	(32,364)	(33,058)
Net loss per common share:	\$ (0.82)	\$ (0.75)	\$ (0.53)	\$ (0.54)
<b>2006:</b>				
Revenue	\$ 4,296	\$ 4,837	\$ 5,524	\$ 4,930
Operating expenses	(55,982)	(49,650)	(46,971)	(46,154)
Loss from operations	(51,686)	(44,813)	(41,447)	(41,224)
Net loss	(48,952)	(41,475)	(37,780)	(37,837)
Net loss per common share:	\$ (0.86)	\$ (0.70)	\$ (0.63)	\$ (0.63)

THERAVANCE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**12. Subsequent Events**

On January 23, 2008, the Company closed an underwritten public offering of \$172.5 million aggregate principal amount of unsecured 3% convertible subordinated notes due 2015, which includes the full exercise of the underwriters' over-allotment option for \$22.5 million aggregate principal. The financing raised proceeds, net of issuance costs, of approximately \$166.7 million. The notes are convertible 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.



**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
Theravance, Inc.

We have audited the accompanying consolidated balance sheets of Theravance, Inc. (the "Company") as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity (net capital deficiency), and cash flows for each of the three years in the period ended December 31, 2007. 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, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the consolidated financial statements, on January 1, 2006, the Company changed its method of accounting for share-based payments made to employees and directors.

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, 2007, 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 25, 2008 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
February 25, 2008

**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, 2007, 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, 2007.

Our independent registered public accounting firm, Ernst & Young LLP, has audited our internal control over financial reporting as of December 31, 2007. The report on the audit of 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

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) that occurred during the fourth quarter of the year ended December 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**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, 2007, 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, 2007, 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, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity (net capital deficiency), and cash flows for each of the three years in the period ended December 31, 2007 of Theravance, Inc. and our report dated February 25, 2008 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
February 25, 2008

**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", "Nominees", "Executive Officers", "Section 16(a) Beneficial Ownership Reporting Compliance", "Nominating/Corporate Governance Committee", "Audit Committee" and "Code of Business Conduct" in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference. The Company's Code of Business Conduct and Stockholder-Director Communications Policy can be found on our website at [www.theravance.com](http://www.theravance.com).

**ITEM 11. EXECUTIVE COMPENSATION**

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

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

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

## PART IV

## ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)

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

1.

## Financial Statements:

The following financial statements and schedules of the Registrant are contained in Item 8 of this Annual Report on Form 10-K:

Consolidated Balance Sheets at December 31, 2007 and 2006	50
Consolidated Statements of Operations for each of the three years in the period ended December 31, 2007	51
Consolidated Statements of Stockholders' Equity (net capital deficiency) for each of the three years in the period ended December 31, 2007	52
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2007	53
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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.

3.

## Exhibits

The representations and warranties made by the parties to the agreements listed below were made solely for purposes of the agreements and to allocate risk between the parties. You should not rely on the representations, warranties or covenants in these agreements.

Exhibit Footnote	Exhibit Number	Description
(1)	3.3	Amended and Restated Certificate of Incorporation
(2)	3.4	Certificate of Amendment of Restated Certificate of Incorporation
(2)	3.5	Amended and Restated Bylaws (as amended by the board of directors April 25, 2007)
(3)	4.1	Specimen certificate representing the common stock of the registrant
(4)	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
(5)+	10.1	1997 Stock Plan
(5)+	10.2	Long-Term Stock Option Plan
(6)+	10.3	2004 Equity Incentive Plan, as amended December 6, 2006
(7)	10.4	Employee Stock Purchase Plan, as amended April 19, 2005
(3)+	10.5	Amended and Restated Change in Control Severance Plan
(5)	10.8	Amended and Restated Lease Agreement, 951 Gateway Boulevard, between the registrant and HMS Gateway Office L.P., dated January 1, 2001
(5)	10.9	Lease Agreement, 901 Gateway Boulevard, between the registrant and HMS Gateway Office L.P., dated January 1, 2001
(8)*	10.10	Collaboration Agreement between the registrant and Glaxo Group Limited, dated as of November 14, 2002



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(5)+	10.11	Form of Indemnification Agreement for directors and officers of the registrant
(5)	10.12	Class A Common Stock Purchase Agreement between the registrant and SmithKline Beecham Corporation, dated as of March 30, 2004
(5)	10.13	Amended and Restated Investors' Rights Agreement by and among the registrant and the parties listed therein, dated as of May 11, 2004
(1)	10.14	Amended and Restated Governance Agreement by and among the registrant, SmithKline Beecham Corporation and GlaxoSmithKline dated as of June 4, 2004
(9)*	10.15	Strategic Alliance Agreement between the registrant and Glaxo Group Limited, dated as of March 30, 2004
(8)*	10.16	License Agreement between the registrant and Janssen Pharmaceutica, dated as of May 14, 2002
(5)+	10.17	Offer Letter with Rick E Winningham dated August 23, 2001
(10)	10.18	Form of Class A Common Stock Purchase Agreement between the registrant and GSK
(11)+	10.19	Offer Letter with Michael W. Aguiar dated as of January 31, 2005
(12)+	10.20	Form of Notice of Grant and Stock Option Agreement under 2004 Equity Incentive Plan
(13)+	10.21	Form of Notice of Restricted Stock Award and Restricted Stock Agreement under 2004 Equity Incentive Plan
(14)+	10.22	Description of Cash Bonus Program, as amended
(15)*	10.23	License, Development and Commercialization Agreement between the registrant and Astellas Pharma Inc. dated November 7, 2005
(16)+	10.24	Form of Notice of Stock Option Grant and Stock Option Agreement between the Company and P. Roy Vagelos
(17)*	10.25	TD-6424 Active Pharmaceutical Ingredient Supply Agreement among the Company, ScinoPharm Taiwan, Ltd. and Biddle Sawyer Pharma LLC dated as of May 10, 2002
(18)*	10.26	Amendment No. 4 to TD-6424 Supply Agreement among the Company, ScinoPharm Taiwan, Ltd. and Biddle Sawyer Pharma LLC dated as of May 11, 2006
(19)*	10.27	Amendment to License, Development and Commercialization Agreement between the Company and Astellas Pharma Inc. dated as of July 18, 2006
(20)+	10.28	Form of Notice of Stock Option Grant and Stock Option Agreement under 2004 Equity Incentive Plan (form in effect from 2007)
(21)+	10.29	Form of Non-Employee Director Notice of Stock Option Grant and Stock Option Agreement under 2004 Equity Incentive Plan (form in effect through 2006)
(22)+	10.30	Form of Non-Employee Director Notice of Stock Option Grant and Stock Option Agreement under 2004 Equity Incentive Plan (form in effect from 2007)
(23)+	10.31	Form of Performance-Contingent Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement under 2004 Equity Incentive Plan



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(24)+	10.32	Offer letter with Leonard Blum dated July 27, 2007
(25)*	10.33	First Addendum to the Terms & Conditions Dated February 17, 2004 between the Company and Ben Venue Laboratories, Inc. dated September 21, 2007
+	10.34	Form of Time-Based Vesting Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement under 2004 Equity Incentive Plan
+	10.35	2008 New Employee Equity Incentive Plan
+	10.36	Form of Notice of Grant and Stock Option Agreement under 2008 New Employee Equity Incentive Plan
(26)	21.1	List of Subsidiaries
	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

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- (1) Incorporated herein by reference to the exhibit of the same number in the Company's amended Registration Statement on Form S-1 (No. 333-116384) filed with the SEC on July 26, 2004.
- (2) Incorporated herein by reference to the exhibit of the same number in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.
- (3) Incorporated herein by reference to the exhibit of the same number in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006.
- (4) Incorporated herein by reference to the exhibit of the same number in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007.
- (5) Incorporated herein by reference to the exhibit of the same number in the Company's Registration Statement on Form S-1 (No. 333-116384) filed with the SEC on June 10, 2004.
- (6) Incorporated herein by reference to exhibit number 10.38 in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006.
- (7) Incorporated herein by reference to the exhibit of the same number in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005.
- (8) Incorporated herein by reference to the exhibit of the same number in the Company's amended Registration Statement on Form S-1 (No. 333-116384) filed with the SEC on September 29, 2004.
- (9) Incorporated herein by reference to the exhibit of the same number in the Company's amended Registration Statement on Form S-1 (No. 333-116384) filed with the SEC on September 30, 2004.
- (10) Incorporated herein by reference to exhibit number 10.28 in the Company's amended Registration Statement on Form S-1 (No. 333-116384) filed with the SEC on September 29, 2004.
- (11) Incorporated herein by reference to exhibit number 10.29 in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2004.
- (12)

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Incorporated herein by reference to exhibit number 10.30 in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2004.

- (13) Incorporated herein by reference to exhibit number 10.31 in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007.

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- (14) Incorporated herein by reference to exhibit number 10.32 in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006.
- (15) Incorporated herein by reference to the exhibit number 10.1 in the Company's Registration Statement on Form S-3 (No. 333-131359) filed with the SEC on January 30, 2006.
- (16) Incorporated herein by reference to the exhibit to the Company's Current Report on Form 8-K filed on May 2, 2006.
- (17) Incorporated herein by reference to exhibit number 10.35 in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006.
- (18) Incorporated herein by reference to exhibit number 10.36 in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006.
- (19) Incorporated herein by reference to exhibit number 10.37 in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006.
- (20) Incorporated herein by reference to exhibit number 10.39 in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007.
- (21) Incorporated herein by reference to exhibit number 10.40 in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007.
- (22) Incorporated herein by reference to exhibit number 10.41 in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007.
- (23) Incorporated herein by reference to exhibit number 10.42 in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007.
- (24) Incorporated herein by reference to exhibit number 10.43 in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2007.
- (25) Incorporated herein by reference to exhibit number 10.44 in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2007.
- (26) Incorporated herein by reference to the exhibit of the same number in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2005.

+ 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.



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*/s/* BURTON G. MALKIEL

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Director

February 26, 2008

Burton G. Malkiel

*/s/* WILLIAM H. WALTRIP

---

Director

February 26, 2008

William H. Waltrip

*/s/* GEORGE M. WHITESIDES, PH.D

---

Director

February 26, 2008

George M. Whitesides, Ph.D

*/s/* WILLIAM D. YOUNG

---

Director

February 26, 2008

William D. Young

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## Exhibits

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(2)	3.5	Amended and Restated Bylaws (as amended by the board of directors April 25, 2007)
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+ Management contract or compensatory plan or arrangement required to be filed pursuant to Item 15(b) of Form 10-K.

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Commission pursuant to Theravance Inc.'s application for confidential treatment.

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ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

SIGNATURES

POWER OF ATTORNEY

Exhibits