

THERAVANCE INC  
Form 10-K  
March 01, 2007

# 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, 2006

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

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

**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 whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark whether 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

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

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

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, 2006 was \$900,065,635. 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, 2006 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, 2007 there were 50,794,120 shares of the registrant's Common Stock and 9,401,498 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 2007 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2006, 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.**  
**2006 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, estimates, expects, intends, may, plans, projects, will, would and similar expressions 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 five programs in development, two are in late stage our telavancin program focusing on treating serious Gram-positive bacterial infections with Astellas Pharma Inc. (Astellas) and our Beyond Advair collaboration with GlaxoSmithKline plc (GSK). By leveraging our proprietary insight of multivalency to drug discovery focused on validated targets, we are pursuing a next generation drug discovery strategy designed to discover superior medicines in large markets. 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 products 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 superiority 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

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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 2006, 2005 and 2004 were \$166.6 million, \$137.9 million and \$91.6 million, respectively.

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 complicated skin and skin structure infections (cSSSI) caused by Gram-positive bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA). Telavancin is a rapidly bactericidal, injectable antibiotic with multifunctional mechanisms of action. The NDA submission was based on positive Phase 3 cSSSI results. In addition to the cSSSI indication, telavancin is currently in Phase 3 clinical studies for hospital-acquired pneumonia (HAP) designed to demonstrate non-inferiority of telavancin compared to standard therapy for the treatment of serious Gram-positive infections and superiority over vancomycin in those patients whose infections are due to MRSA. Our goal is for telavancin to become first-line therapy in treating these serious 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, 2006, we have received \$101.0 million in upfront and milestone payments from Astellas and we are eligible to receive up to \$126.0 million in remaining clinical and regulatory 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 addition to the license rights to telavancin, Astellas also received an option to further develop and commercialize TD-1792, our heterodimer antibiotic compound that entered Phase 2 clinical studies in December 2006.

In November 2002, we entered into our Beyond Advair collaboration with GSK to develop and commercialize long-acting beta2 agonist (LABA) product candidates for the treatment of asthma and chronic obstructive pulmonary disease (COPD). These product candidates are 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 \$6.1 billion of sales for 2006 as reported by GSK in early 2007. Each company contributed four LABA product candidates to the collaboration and two product candidates are in a Phase 2b program.

In March 2004, we entered into a strategic alliance agreement with GSK. Under this alliance GSK received an option to license 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. 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 and we have discovered and delivered to GSK two structurally different product candidates for both of these programs. In August 2004, GSK exercised its right to license our long-acting muscarinic antagonist (LAMA) program and informed us of its decision not to license our bacterial infections program, in each case pursuant to the terms of the strategic alliance. In March 2005, GSK exercised its right to license our bifunctional muscarinic antagonist beta2 agonist (MABA) program pursuant to the terms of the strategic alliance, and notified us of its decision not to license our anesthesia program.

GSK currently owns all of our Class A common stock, which represents approximately 15.6% of our outstanding stock as of February 15, 2007. Under the terms of the strategic alliance, GSK's ownership of our stock could increase to approximately 59.4% through the issuance by us to GSK of the number of shares of our common stock that we may be required to redeem from our stockholders. In July 2007,

GSK has the right to require us to redeem, and upon notice of such redemption, each stockholder (including GSK, to the extent GSK holds common stock) will automatically be deemed to have submitted for redemption, 50% of our common stock held by such stockholder at \$54.25 per share. This right is referred to as the call. If GSK does not exercise this right, then in August 2007, our stockholders (including GSK, to the extent GSK holds common stock) have the right to require us to redeem up to 50% of their common stock at \$19.375 per share. This right is referred to as the put. In either case, GSK is obligated to pay to us the funds necessary for us to redeem the shares of common stock from our stockholders; however, GSK's maximum obligation for the shares subject to the put is capped at \$525 million. Alternatively, if our stockholders exercise the put, GSK may elect to purchase such shares directly from our stockholders. We are under no obligation to redeem our shares under the call or the put until we receive such funds from GSK. If GSK's ownership of our stock increases to more than 50% as a result of the call or put, GSK will receive a five-year extension of its exclusive option to our programs, so that the option would cover all of our full drug discovery programs initiated prior to September 1, 2012.

### **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.

In the table above:

- Preclinical refers to formulation development or to safety testing in animal models required prior to initiating human clinical studies.

- 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.
- Based upon our strategy of pursuing new compounds for validated targets, we consider compounds that have 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, 2006, we have received \$101.0 million in upfront and milestone payments from Astellas and we are eligible to receive up to an additional \$126.0 million in clinical and regulatory milestone payments, which includes up to \$116.0 million for completion of clinical studies and filing and approval of new drug applications for cSSSI and HAP, and \$10 million if the Phase 3 data demonstrates telavancin's superiority over vancomycin for HAP patients infected with MRSA.

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. In addition to the license rights to telavancin, Astellas also received an option to further develop and commercialize TD-1792, our heterodimer antibiotic compound that entered Phase 2 clinical studies in December 2006.

#### **Our Relationship with GlaxoSmithKline**

##### ***2002 Beyond Advair Collaboration***

In November 2002, we entered into our Beyond Advair collaboration with GSK to develop and commercialize long-acting beta2 agonist (LABA) product candidates for the treatment of asthma and COPD. These product candidates are 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, and two product candidates are in Phase 2b clinical programs.

In connection with this collaboration, 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 collaboration. As of December 31, 2006, we have received a total of \$50.0 million in development milestones and have up to \$445.0 million in remaining milestones allocated as follows: up to \$75.0 million related to the achievement of certain clinical milestones by a Theravance-discovered LABA compound, up to \$220.0 million related to approval and launch of a product containing a Theravance-discovered LABA

in multiple regions in the world, and up to \$150.0 million related to the achievement of certain sales thresholds, whether the LABA compound was discovered by Theravance or 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 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 Beyond Advair collaboration, 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 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 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 have committed to initiating at least three new full discovery programs from May 2004 through August 2007. We maintain sole decision-making authority with respect to our discovery programs, including without limitation, decisions relating to initiation and termination of discovery programs, and staffing and resource allocation among discovery programs. Since May 2004 we have initiated three new full discovery programs. 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, 2006, we have received \$36.0 million in upfront and milestone payments from GSK relating to the strategic alliance agreement.

GSK must exercise its right to license no later than sixty days subsequent to (i) for our inhaled respiratory discovery programs, the development candidate stage (generally defined as the point when the lead candidate is selected for preclinical studies and preparation for entry into a Phase 1 clinical study), or (ii) for programs other than inhaled respiratory programs, 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. 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. 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.

As part of the strategic alliance, we amended our certificate of incorporation to provide for the redemption of our common stock under certain circumstances. In July 2007, GSK has a call right to require us to redeem, and upon notice, each stockholder (including GSK, to the extent GSK holds common stock) will automatically be deemed to have submitted for redemption, 50% of our common stock held by such stockholder at \$54.25 per share. If GSK does not exercise this call right, then in August 2007, our stockholders (including GSK, to the extent GSK holds common stock) have a put right to cause us to redeem up to 50% of their common stock at \$19.375 per share. In either case, GSK is contractually obligated to pay to us the funds necessary for us to redeem the shares of common stock from our stockholders; however, GSK's maximum obligation for the shares subject to the put is capped at \$525 million. We are under no obligation to redeem our shares under the call or the put until we receive funds to redeem such shares from GSK. Alternatively, if our stockholders exercise the put, GSK may elect to purchase the shares of common stock that are put directly from our stockholders. GSK's ownership of our stock could increase to approximately 59.4% through the concurrent issuance to GSK of the number of shares of stock that we may be required to redeem from our stockholders. In addition, if GSK's ownership of our stock increases to more than 50% as a result of the call right or put right, GSK will receive an extension of its exclusive option to our full drug discovery programs initiated prior to September 1, 2012; otherwise, this exclusive option does not apply to programs initiated after September 1, 2007.

The effect of the redemption of our common stock pursuant to the call or the put would not cause a decrease to the Company's cash balances, total assets, or total stockholders' equity. Accordingly, the Company has classified its common stock within stockholders' equity.

In addition, we entered into a governance agreement with GSK which, among other matters, (i) gives GSK the right to nominate directors to our board of directors, (ii) provides GSK with rights regarding certain corporate governance matters, including the right to restrict our ability to take specified significant corporate actions, such as the issuance of debt and equity securities above specified limitations, the sale of significant assets, acquisitions by us and the redemption of our common stock, and (iii) governs future acquisitions or dispositions of our securities by GSK. 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 15.6% as of February 15, 2007.

## **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. Through December 31, 2006, we received a \$1.0 million upfront payment from AstraZeneca and are eligible to receive milestone payments and royalties on global sales.

## **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 methicillin-resistant *Staphylococcus aureus* (MRSA). Our program resulted in the discovery of telavancin and a unique heterodimer antibiotic, TD-1792.

*Telavancin Status*

Telavancin is a rapidly bactericidal, injectable antibiotic with multiple mechanisms of action: the inhibition of bacterial cell wall synthesis and the disruption of bacterial cell membrane integrity. We believe the additive mechanisms of action seen with telavancin speed bacterial killing while also reducing the risks of inducing resistance to telavancin or cross-resistance with other antibiotics.

In December 2006, we submitted a NDA for telavancin to the FDA for the treatment of complicated skin and skin structure infections (cSSSI) caused by Gram-positive bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA). The NDA submission was based on positive Phase 3 cSSSI results, released in August 2006, in which telavancin's rates of clinical cure, microbiological eradication, and overall therapeutic response compared favorably to those for vancomycin. In addition to the cSSSI indication, telavancin is currently in Phase 3 clinical studies for hospital-acquired pneumonia (HAP). The HAP program consists of two studies targeting approximately 750 patients each for a total of approximately 1,500 patients. Our goal in the design and execution of the HAP program is to demonstrate non-inferiority compared to standard therapy in the treatment of Gram-positive infections and to demonstrate superiority over vancomycin in those patients infected by MRSA. Our goals with telavancin are to complete enrollment for the HAP program in the first half of 2007 and, if we receive FDA approval, commercially launch telavancin for the treatment of cSSSI with our partner Astellas in the second half of 2007.

*Heterodimer Status*

TD-1792 is a unique 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 that is more efficacious than vancomycin, the current standard of care for the treatment of serious infections caused by MRSA, and which has an improved resistance profile relative to other antibiotics. In December 2006, we initiated Phase 2 clinical studies with TD-1792 for the treatment of cSSSI caused by Gram-positive bacteria, including MRSA. Our goal is to report Phase 2 data in the second half of 2007.

*Respiratory*

Our respiratory franchise has three development programs directed toward asthma and/or COPD: our Beyond Advair collaboration with GSK, and our LAMA and MABA programs, both of which GSK has licensed pursuant to the terms of our strategic alliance.

*Beyond Advair Collaboration*

Our Beyond Advair collaboration with GSK is currently developing several long-acting beta2 agonist (LABA) product candidates 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 beta2 agonist (salmeterol) and an ICS (fluticasone) taken twice daily, which had sales of approximately \$6.1 billion for 2006 as reported by GSK in early 2007.

Beta2 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. Beta2 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).

*Beyond Advair Status*

The Beyond Advair collaboration has a development pool consisting of eight compounds, five of which are in Phase 2. Two of these compounds, GSK159797 ( 797) and GSK542444 ( 444) are in Phase 2b programs designed to evaluate the safety and efficacy of these compounds in multi-day administration to mild-to-moderate asthmatics, and to assess potential commercial dosing. We expect to report data from the ongoing Phase 2b program for 797 and 444 in the first half of 2007.

***Bifunctional Muscarinic Antagonist-Beta2 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 beta2 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, has successfully completed single- and multiple-dose Phase 1 studies in healthy volunteers. Our goal is to complete the analysis of Phase 1 data and to move into Phase 2 studies.

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

Inhaled muscarinic antagonists are among the most frequently used bronchodilators for COPD. Inhaled muscarinic antagonists work by inhibiting muscarinic receptors on the bronchial airways, which lead to muscle relaxation, bronchodilation 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. We believe this approach will result in improved tolerability over currently available medicines at doses with comparable efficacy.

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

*LAMA status*

In 2005, the initial results from Phase 1 studies with our first compound TD-5742 suggested that the compound was less potent than we had expected. As a result, the joint steering committee comprised of representatives of GSK and Theravance decided to terminate further development of this compound. Subsequently, we delivered to GSK a second, structurally different, product candidate for this program pursuant to the terms of the strategic alliance. Currently, GSK is evaluating this compound in preclinical studies.

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

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

#### *GI Status*

In October 2006, we initiated a Phase 2 clinical study to evaluate the safety and efficacy of a range of doses of TD-5108, an investigational selective 5-HT<sub>4</sub> agonist for the treatment of chronic constipation and other disorders related to reduced GI motility. The Phase 2 study is being conducted in the United States with a goal of enrolling approximately 350 patients. We expect to report Phase 2 data in the second half of 2007.

### **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 PUMA Program is currently in IND-enabling studies.
- Our AT1 Receptor Neprilysin 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 for validated targets 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 large markets.*

We intend to continue to concentrate our efforts on discovering and developing product candidates for validated targets 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 are likely 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 Beyond Advair collaboration 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, GSK and Gilead Sciences, Inc.

*Improve, expand and protect our technical capabilities.* We have created a substantial body of know-how and trade secrets in the application of our multivalency 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 Beyond Advair, 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 HAP clinical studies as well as for the first six months of commercialization if telavancin is approved for sale by regulatory authorities. Astellas is responsible for manufacturing API and drug product for commercial sale 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, 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 will be 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 United States Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act. Outside the United States, our ability to market a product depends upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical studies, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, however, we will only be permitted to commercialize our medicines 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. Once the submission has been accepted for filing, the FDA typically takes one year to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. 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, 2006, we had 86 issued United States patents and have received notices of allowance for 10 other United States patent applications. As of that date, we had 100 pending patent applications in the United States and 316 granted foreign patents. We also have 24 Patent Cooperation Treaty applications that permit us to pursue patents outside of the United States and 656 foreign national patent applications. The claims in these various patents and patent applications are directed to compositions of matter, including claims covering product candidates, lead compounds and key intermediates, pharmaceutical compositions, methods of use, and processes for making our compounds along with methods of design, synthesis, selection and use relevant to multivalency in general and to our research and development programs in particular.

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 18 issued United States patents that expire between 2019 and 2023, 2 allowed United States patent applications and 9 pending United States patent applications, and counterpart patents and patent applications in a number of jurisdictions, including Europe. The patent rights relating to GSK 159797 owned by us and licensed to GSK consist of 5 issued United States patents that expire in 2019 and 4 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), linezolid (marketed by Pfizer) and tigecycline (marketed by Wyeth). In addition, several additional compounds are under development, including but not limited to dalbavancin (a Pfizer product which received an approvable letter from the FDA in June 2006) and ceftobiprole (in late-stage clinical development by Basilea Pharmaceutica and Johnson & Johnson) represent potential competition for telavancin.

*GSK Beyond Advair Collaboration.* We anticipate that, if approved, any product from our Beyond Advair collaboration 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 (marketed by Novartis and AstraZeneca), and tiotropium (marketed by Boehringer Ingelheim and Pfizer). 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. All of these efforts represent potential competition for any product from our Beyond Advair collaboration.

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, 2006, we had 285 full-time employees, over 220 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 our product candidates, in particular telavancin, are determined to be unsafe or ineffective in humans, our business will be adversely affected and our stock price 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 is unproven and 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. 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 and early clinical testing stages.

Although our new drug application (NDA) for telavancin is currently under review by the U.S. Food and Drug Administration (FDA), it is impossible to predict when or if any of our compounds and 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, such as a failure of either 797 or 444 in our Beyond Advair collaboration, or any delay in commencing or completing clinical studies for our product candidates, such as a further delay in completing our Phase 3 HAP clinical studies for telavancin, would likely 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 complete. The commencement and completion of clinical studies for our product candidates may be delayed by many factors, including:

- delays in patient enrollment, which we have experienced in our Phase 3 HAP program for telavancin, and variability in the number and types of patients available for clinical studies;
- 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;
- 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;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- varying interpretation of data by the FDA and similar foreign regulatory agencies; and
- failure of our partners to advance our product candidates through clinical development.

For example, in the second quarter of 2006, we announced that it would be challenging to complete enrollment of our Phase 3 HAP clinical program for telavancin by the end of the year. Although it now appears likely that the HAP program will complete enrollment during the first half of 2007, there can be no assurance that delays in this program or other programs will not occur in the future. Such clinical study delays could impede the commercialization of our compounds and therefore would likely cause our stock price to decline.

**If telavancin or our other product candidates that we develop on our own or through collaborative partners are not approved by regulatory agencies, including the Food and Drug Administration, 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.

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.

Telavancin is the first product candidate for which we have conducted clinical studies, and it is the first product candidate for which we have submitted a NDA to the FDA. We may not obtain regulatory approval to commercialize telavancin in the United States. In addition, we plan to seek U.S. regulatory approval for the additional indication of hospital acquired pneumonia for telavancin and our telavancin collaborator Astellas Pharma Inc. (Astellas) plans to seek foreign regulatory approvals for telavancin. We will be unable to generate any revenues from royalty payments from the commercialization and sale of telavancin if we fail to obtain these approvals.

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

We do not have in-house manufacturing 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 our compounds in a timely manner from these third parties could delay clinical studies and prevent us from developing our product candidates in a cost-effective manner or on a timely basis. In addition, manufacturers of our API and drug product are subject to the FDA's current Good Manufacturing Practices regulations and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers.

Our manufacturing strategy presents the following additional risks:

- because of the complex nature of our compounds, our manufacturers may not be able to successfully manufacture our compounds in a cost effective and/or timely manner;
- the processes required to manufacture certain of our compounds are specialized and available only from a limited number of third-party manufacturers;
- some of the manufacturing processes for our compounds 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 compounds; and
- because some of the third-party manufacturers and formulators are located outside of the U.S., there may be difficulties in importing our compounds 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.

We have sufficient quantities of drug product to complete all of the currently planned clinical studies of telavancin. We plan to manufacture additional API and drug product intended to meet our obligations to Astellas in connection with commercial launch in the event telavancin is approved for sale by regulatory authorities. If we are unable to do so 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.

For our heterodimer compound as well as the development compounds in our GI program, we are using a limited number of sources to manufacture the API and drug product. 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 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 depends on a number of factors, including, but not limited to:

- the demonstration of the clinical efficacy and safety of telavancin;
- the advantages and disadvantages of telavancin compared to alternative therapies;
- our and our collaborative partner's 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.

**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. 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 bodies 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, 2006, we had an accumulated deficit of approximately \$777.8 million.

We expect our research and development expenses to keep increasing as we continue to initiate new discovery programs and expand our development programs. 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 common stock 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 eighteen months. We may 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 Beyond Advair collaboration. We may also need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate. Prior to the termination of the call and put arrangements with GSK, we may seek to sell debt securities or incur other indebtedness. After the termination of the call and put arrangements with GSK, we may seek to sell additional equity or debt securities, or both, or incur other indebtedness. The sale of additional equity or debt securities, if convertible, could result in the issuance of additional shares of our capital stock and could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, our ability to raise debt and equity financing is constrained by our alliance with GSK and we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all.

In particular, until the expiration of the put and call provisions with GSK, we are contractually prohibited from selling significant additional equity securities to raise capital. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from exploiting other corporate opportunities. This could harm our business, prospects and financial condition and cause the price of our common stock 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 Beyond Advair collaboration agreement 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. In connection with our GSK strategic alliance agreement, upon exercise of its license with respect to a particular development program, GSK will have full responsibility for development and commercialization of any product candidates in that program. Any future milestone payments or royalties to us from these programs will depend on the extent to which GSK advances the product candidate through development and 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 Beyond Advair collaboration, our partners generally are not restricted from developing and commercializing their own products and product candidates that compete with those 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 only 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 and our anesthesia 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 common stock.

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

As of February 15, 2007, GSK beneficially owned approximately 15.6% of our outstanding capital stock, and will have the right in July 2007 to increase its ownership of our stock up to approximately 59.4% through the exercise of its call right. Other than our bacterial infections program and our anesthesia program, which GSK has decided not to license under the strategic alliance, GSK has the right to license exclusive development and commercialization rights to our product candidates arising from all of our full drug discovery and development programs initiated prior to September 1, 2007. This right will extend to our programs initiated prior to September 1, 2012 if GSK owns more than 50% of our common stock due to exercise of the call right or the put right. In brief, (i) the call right is GSK's right, in July 2007, to require us to redeem 50% of our common stock held by each stockholder at \$54.25 per share, and (ii) the put right is the right of each of our stockholders in August 2007, if GSK has not exercised its call right in July 2007, to require us to redeem up to 50% of their common stock at \$19.375 per share. Pharmaceutical companies other than GSK that may be interested in developing products with us are likely to 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.

In addition, because GSK may license our 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. Given the restrictions on our ability to raise capital provided for in our agreements with GSK, we may not have sufficient funds to pursue such programs in the event GSK does not license them at an early stage. 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 only entered into collaborations with GSK for the Beyond Advair, LAMA and MABA programs and with Astellas for telavancin, and we have licensed our anesthesia compound to AstraZeneca. As a result, we may be required to enter into collaborations with other third parties regarding our other programs whereby we have to relinquish material rights, including revenue from commercialization of our medicines, on terms that are less attractive than our current arrangements with these parties. Furthermore, our ability to raise additional capital to fund our drug discovery and development efforts is greatly limited as a result of our agreements with GSK. In addition, we may not be able to control the amount of time and resources that our collaborative partners devote to our product candidates and our partners may choose to pursue alternative products. Moreover, these collaboration arrangements are complex and time-consuming to negotiate. 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. 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 each of our studies is conducted in accordance with the applicable protocol. The failure of these third parties to complete activities on schedule or to conduct our studies in accordance with regulatory requirements and our protocols could delay or prevent the further development, approval and commercialization of our product candidates, which could severely harm our business and financial condition. For example, in late 2005 we expanded the number of clinical research organizations working on our Phase 3 HAP program for telavancin due to slower than anticipated enrollment. Retaining alternative or additional service providers involves delays and additional costs. In addition, if we lose our relationship with any one or more of these third parties, we could experience a significant delay in both identifying another comparable service provider and then contracting for its services. We may be unable to retain an alternative service provider on reasonable terms, if at all. Even if we locate an alternative service provider, it is likely that this provider will need additional time to respond to our needs and may not provide the same level of service as the original service provider.

**We face substantial competition from companies with more resources and experience than we have, which may result in others discovering, developing 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 medicines with superior efficacy, convenience, tolerability and/or safety. Because our strategy is to develop new product candidates 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 may currently be engaged in the discovery of medicines that will 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, our Executive Vice President of Research, Patrick P.A. Humphrey, and our Senior Vice President of Development, Michael Kitt. These executives each have significant pharmaceutical industry experience and Dr. Vagelos and Dr. Humphrey are prominent scientists. The unexpected loss of Dr. Vagelos, Mr. Winningham, Dr. Humphrey or Dr. Kitt could impair our ability to discover, develop and market new medicines. Dr. Humphrey plans to transition out of his position at Theravance in late 2007 or early 2008. The Company has initiated a search to evaluate internal and external candidates to replace Dr. Humphrey as head of Research.

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 GSK's Ownership of Our Stock

**GSK's right to become a controlling stockholder of the Company 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 February 15, 2007, GSK beneficially owned approximately 15.6% of our outstanding capital stock. In addition, GSK has certain rights to maintain its percentage ownership of our capital stock and in July of this year, GSK may exercise its call right to acquire additional shares and thereby increase its ownership up to approximately 59.4% of our then outstanding capital stock. If GSK exercises this call right, or a sufficient number of our stockholders exercise the put right provided for in our certificate of incorporation, GSK could own a majority of our capital stock. In addition, GSK currently has the right to designate one member to our board of directors and, depending on GSK's ownership percentage of our capital stock after September 2007, GSK will have the right to nominate up to one-third of the members of our board of directors and up to one-half of the independent members of our board of directors. There are currently no GSK designated directors on our board of directors. GSK's control relationship could give rise to conflicts of interest, including:

- conflicts between GSK, as our controlling stockholder, and our other stockholders, whose interests may differ with respect to our strategic direction or significant corporate transactions; and
- conflicts related to corporate opportunities that could be pursued by us, on the one hand, or by GSK, on the other hand.

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 all of our full drug discovery and development programs initiated prior to September 1, 2007 or, if GSK acquires more than 50% of our stock in 2007, prior to September 1, 2012. As a result, 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.

**Our governance agreement with GSK limits our ability to raise debt and equity financing, undertake strategic acquisitions or dispositions and take certain other actions, which could significantly constrain and impair our business and operations.**

Our governance agreement with GSK limits the number of shares of capital stock that we may issue and the amount of debt that we may incur. Prior to the termination of the call and put arrangements with GSK in 2007, without the prior written consent of GSK, we may not issue any equity securities if it would cause more than approximately 54.2 million shares of common stock, or securities that are vested and exercisable or convertible into shares of common stock, to be outstanding as of the put date. Until the

expiration of the put and call provisions with GSK, we will be contractually prohibited from selling significant additional equity securities to raise capital. In addition:

- If, on or immediately after the termination of the call and put arrangements with GSK in 2007, GSK directly or indirectly controls more than 35.1% of our outstanding capital stock, then without the prior written consent of GSK, we may not issue more than an aggregate of approximately 16.1 million shares of our capital stock after September 1, 2007 through August 2012; and
- Prior to the termination of the call and put arrangements with GSK in 2007, we may not borrow money or otherwise incur indebtedness of more than \$100.0 million or if such indebtedness would cause our consolidated debt to exceed our cash, cash equivalents and marketable securities.

These limits on issuing equity and debt could leave us without adequate financial resources to fund our discovery and development efforts if GSK does not license additional development programs pursuant to our strategic alliance agreement, if we do not enter into alliances with third parties on similar or better terms for these programs, or if we do not earn any of the potentially significant milestones in the programs that we have currently partnered with GSK and Astellas.

These events could result in a reduction of our discovery and development efforts or could result in our having to enter into collaborations with other companies that could require us to share commercial rights to our medicines to a greater extent than we currently intend. In addition, if GSK's ownership of our capital stock exceeds 50% as a result of the call and put arrangements, we will be prohibited from engaging in certain acquisitions, the disposition of material assets or repurchase of our outstanding stock without GSK's consent. These restrictions could cause us to forego transactions that would otherwise be advantageous to us and our other stockholders.

**The market price of our common stock is not guaranteed, and could be adversely affected by the put and call arrangements with GSK.**

In July 2007, GSK has the right to require us to redeem 50% of our outstanding common stock for \$54.25 per share and, if GSK does not exercise this right, during August 2007 our stockholders will have the right to cause us to redeem up to the same number of shares for \$19.375 per share. The existence of the call feature on 50% of our common stock at a fixed price of \$54.25 may act as a material impediment to our common stock trading above the \$54.25 per share call price. If the call is exercised, our stockholders would participate in valuations above \$54.25 per share only with respect to 50% of their shares. Therefore, even if our common stock trades above \$54.25 per share, 50% of each stockholder's shares could be called at \$54.25 per share. Similarly, because the put applies to only 50% of our common stock and is not exercisable prior to August of 2007, it is uncertain what effect the put will have on our stock price. Prior to the expiration of the put period, the price at which our common stock will trade may be influenced by the put right. Therefore, after the expiration of the put period, the market price of the common stock may decline significantly. In addition, while GSK is generally prevented from making any unsolicited tender offer for our common stock, any announcement by GSK that it does not intend to exercise the call or any offer GSK may make to our board of directors on terms less favorable than the call right described above could adversely affect our common stock price.

**After September 12, 2012, GSK could sell or transfer a substantial number of shares of our common stock, which could depress our stock price or result in a change in control of our company.**

After September 12, 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 the outstanding shares of our common stock or, if these sales or transfers were made to a single buyer or group of buyers, could transfer control of our company to a third party.

**As a result of the call and put arrangements with GSK, there are uncertainties with respect to various tax consequences associated with owning and disposing of shares of our common stock. Therefore, there is a risk that owning and/or disposing of our common stock may result in certain adverse tax consequences to our stockholders.**

Due to a lack of definitive judicial and administrative interpretation, uncertainties exist with respect to various tax consequences resulting from the ownership of our common stock. These include:

- In the event we pay or are deemed to have paid dividends prior to the exercise and/or lapse of the put and call rights, individual stockholders may be required to pay tax on such dividends at ordinary income rates rather than capital gains rates, and corporate stockholders may be prevented from obtaining a dividends received deduction with respect to such dividend income;
- In the event that a common stockholder's put right were considered to be a property right separate from the common stock, such stockholder may be subject to limitations on recognition of losses and certain other adverse consequences with respect to the common stock and the put right (including the tolling of its capital gains holding period);
- The application of certain actual and constructive ownership rules could cause the redemption of our common stock to give rise to ordinary income and not to capital gain;
- A redemption of our common stock may be treated as a recapitalization pursuant to which a stockholder exchanges shares of common stock for cash and shares of new common stock not subject to call and put rights, in which case the stockholder whose shares were redeemed would be required to recognize gain, but not loss, in connection with this deemed recapitalization in an amount up to the entire amount of cash received (which gain may be taxed as ordinary income and not capital gain); and
- The put right could prevent a stockholder's capital gain holding period for our common stock from running and thereby prevent a stockholder from obtaining long-term capital gain on any gain recognized on the disposition of the common stock.

#### **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, 2006, we had 86 issued United States patents and have received notices of allowance for 10 other United States patent applications. As of that date, we had 100 pending patent applications in the United States and 316 granted foreign patents. We also have 24 Patent Cooperation Treaty applications that permit us to pursue patents outside of the United States, and 656 foreign national patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may 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, the patent lives of the related drug 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 U.S. and international pricing pressures 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. Although we believe that our procedures for use, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with 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

#### **Our stock price may be extremely volatile and purchasers of our common stock could incur substantial losses.**

Our stock price may be extremely volatile. The stock market in general and the market for biotechnology 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 common stock:

- any adverse developments or results or perceived adverse developments or results with respect to any product candidates in the Beyond Advair collaboration, in particular, any delay in completing or an adverse result arising out of the Phase 2b program;
- any adverse development or perceived adverse development with respect to our telavancin NDA filed with the FDA;
- the extent to which GSK advances (or does not advance) our product candidates through development into commercialization;
- any adverse developments or results or perceived adverse developments or results with respect to our telavancin Phase 3 clinical studies for HAP;
- any adverse developments or results or perceived adverse developments or results with respect to our GI program or our heterodimer compound;
- GSK's call right in July of this year for 50% of our common stock at \$54.25 per share (in particular, a decision by GSK not to exercise its call right or a perception on the part of investors that GSK is not likely to exercise its call right);
- the put right and the expiration of the put right in August and September of 2007;
- announcements regarding GSK's decisions whether or not to license any of our product 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 by our competitors;
- regulatory developments in the United States and foreign countries; and
- economic and other external factors beyond our control.

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

As of February 15, 2007, GSK beneficially owned approximately 15.6% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 13.5% of our outstanding capital stock. These stockholders

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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 a director and beginning in September 2007 will have the right to nominate a certain number of directors depending on GSK's ownership percentage of

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our capital stock at the time. 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 management or 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 \$5.8 million, subject to annual increases. We may require additional space as our business expands.

**ITEM 3. LEGAL PROCEEDINGS**

The Company has received a letter dated February 8, 2007 from the United States Environmental Protection Agency ( EPA ) indicating that the EPA is considering an administrative action against the Company for alleged violations of certain laws and regulations regarding organic effluent levels in liquid waste generated by the Company. The EPA has invited the Company to submit further information that we believe the EPA should consider before making a decision to proceed with the proposed administrative action. We are in the process of gathering this information and intend to have discussions with the EPA in the near future concerning this matter. While the Company believes it has information to show it has been in compliance and therefore no penalty should be assessed, if we are unable to convince the EPA that it should not proceed, we may be required to pay monetary penalties to the EPA.

In the future, we may become involved in litigation from time to time in the ordinary course of our business.

**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**X 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:

<b>Calendar Quarter</b>	<b>High</b>	<b>Low</b>
<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
<b>2005</b>		
First Quarter	\$ 18.86	\$ 16.53
Second Quarter	\$ 18.31	\$ 16.55
Third Quarter	\$ 21.57	\$ 16.98
Fourth Quarter	\$ 23.50	\$ 20.86

As of February 15, 2007, there were 394 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 2006.

*Dividend Policy*

We currently intend to retain any future earnings to finance our research and development efforts, the development of our proprietary technologies and the expansion of our business. We have never declared or paid cash dividends and do not intend to declare or pay cash dividends on our 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, 2006:

<b>Plan Category</b>	<b>Number of securities to be issued upon exercise of outstanding options</b>	<b>Weighted-average exercise price of outstanding options</b>	<b>Number of securities remaining available for future issuance under equity compensation plans</b>
Equity compensation plans approved by security holders	10,389,343	\$ 12.92	4,864,193 (1)
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>10,389,343</b>	<b>\$ 12.92</b>	<b>4,864,193 (2)</b>

(1) Includes 3,500,000 shares of common stock from the share reserve increase approved by our board of directors on December 6, 2006.

(2) Includes 293,952 shares of common stock issuable under our Employee Stock Purchase Plan.

*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, 2006, 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.

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 27 MONTH CUMULATIVE TOTAL RETURN  
Among Theravance, Inc., The NASDAQ Composite Index  
And The AMEX Biotechnology Index**

**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,				
	2006	2005	2004	2003	2002
	(in thousands, except per share data)				
<b>CONSOLIDATED STATEMENT OF OPERATIONS DATA:</b>					
Revenue	\$ 19,587	\$ 12,054	\$ 8,940	\$ 3,605	\$ 156
Operating expenses:					
Research and development(1)	166,564	137,936	91,627	63,004	69,879
General and administrative(1)	32,193	23,674	23,708	13,067	13,360
Total operating expenses	198,757	161,610	115,335	76,071	83,239
Loss from operations	(179,170 )	(149,556 )	(106,395 )	(72,466 )	(83,083 )
Interest and other income	13,649	6,969	4,564	3,373	4,990
Interest expense	(523 )	(577 )	(823 )	(1,490 )	(1,134 )
Net loss	\$ (166,044 )	\$ (143,164 )	\$ (102,654 )	\$ (70,583 )	\$ (79,227 )
Basic and diluted net loss per common share	\$ (2.81 )	\$ (2.69 )	\$ (3.08 )	\$ (10.37 )	\$ (12.50 )
Shares used in computing net loss per common share(2)(3)(4)(5)	59,013	53,270	33,283	6,809	6,336
<b>CONSOLIDATED BALANCE SHEET DATA:</b>					
Cash, cash equivalents and marketable securities	\$ 235,570	\$ 200,009	\$ 257,141	\$ 89,152	\$ 148,550
Working capital	147,558	118,677	231,661	71,208	112,720
Total assets	262,424	224,835	286,022	125,449	192,715
Long-term liabilities(6)	139,505	117,078	61,717	37,494	18,187
Convertible preferred stock				367,358	367,358
Accumulated deficit	(777,812 )	(611,768 )	(468,604 )	(365,950 )	(295,367 )
Total stockholders' equity (deficit)	63,310	59,584	190,367	(299,566 )	(231,934 )

(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,				
	2006	2005	2004	2003	2002
Research and development	\$ 12,635	\$ 3,259	\$ 4,631	\$ 1,300	\$ 3,398
General and administrative	9,196	2,364	3,890	914	1,543
Total stock-based compensation	\$ 21,831	\$ 5,623	\$ 8,521	\$ 2,214	\$ 4,941

(2) In May 2004, all shares of convertible preferred stock were converted into common stock.

(3) In May 2004, GSK, through an affiliate, purchased approximately 6.4 million shares of Class A common stock for \$108.9 million.

(4) 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.

(5) 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.

(6) Long-term liabilities includes the long-term portion of deferred revenue as follows (in thousands):

	2006	2005	2004	2003	2002
Deferred revenue	\$ 134,383	\$ 111,251	\$ 56,339	\$ 30,965	\$ 8,594

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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 five programs in development, two are in late stage – our telavancin program focusing on treating serious Gram-positive bacterial infections with Astellas and our Beyond Advair collaboration with GSK. By leveraging our proprietary insight of multivalency to drug discovery focused on validated targets, we are pursuing a next generation drug discovery strategy designed to discover superior medicines in large markets. We commenced operations in 1997, and as of December 31, 2006, we had an accumulated deficit of \$777.8 million. 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 complicated skin and skin structure infections (cSSSI). However, none of our products 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, 2006 was \$166.0 million compared to \$143.2 million in 2005, an increase of \$22.8 million. This increase was primarily due to higher research and development costs. Research and development spending for the year ended December 31, 2006 increased to \$166.6 million compared to \$137.9 million in 2005. This increase was primarily driven by higher external research and development costs associated with Phase 3 telavancin clinical programs and Phase 2 clinical studies for our gastrointestinal (GI) motility dysfunction program. Cash, cash equivalents, and short-term investments totaled \$235.6 million at December 31, 2006, a decrease of \$31.5 million during the fourth quarter 2006 and an increase of \$35.6 million since December 31, 2005.

**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 included in research and development expenses, share-based payment charges, general and administrative expenses and bonus accruals 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 critical factors 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 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 the fourth quarter of 2006, we revised the performance periods for certain agreements based on the progress of our programs. We do not expect that these revisions will have a material impact on the timing of revenue recognized under these contracts 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.

#### *Share-based Payments*

On January 1, 2006, we adopted SFAS 123(R), which requires the measurement and recognition of compensation expenses for all share-based payment awards made to employees and directors including stock options and employee stock purchases under our 2004 Employee Stock Purchase Plan (employee stock purchases) based on estimated fair values. SFAS 123(R) supersedes our previous accounting for employee stock options using the intrinsic-value method in accordance APB No. 25, FIN No. 44, Accounting for Certain Transactions Involving Stock Compensation, an interpretation of APB No. 25, and related interpretations, and the disclosure-only provisions of SFAS No. 123.

We adopted SFAS 123(R) using the modified-prospective-transition method. Under this method, compensation costs recognized in 2006 include: a) compensation costs for all share-based payment awards granted prior to, but not yet vested as of January 1, 2006, based on grant-date fair value estimated in accordance with the original provisions of FAS 123; and b) compensation costs for all share-based payment awards granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R).

Options granted and employee stock purchases prior to January 1, 2006, are valued in accordance with SFAS 123. The expected volatility and expected term are based on the volatility and expected life assumptions used by similar entities within our industry. We used the accelerated method for expense attribution and recognized option forfeitures as they occurred as allowed by SFAS 123. Options granted and employee stock purchases after January 1, 2006, are valued in accordance with SFAS 123(R). We estimated forfeitures and only recognized expense for those shares expected to vest. We used the straight-line single-option method for expense attribution. For the year ended December 31, 2006, we estimated our annual forfeiture rate to be 3.6% for stock options, based on our historical forfeiture experience.

In accordance with the modified-prospective-transition method, our consolidated financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). As a result of adopting SFAS 123(R) on January 1, 2006, our net loss for the year ended December 31, 2006 was \$17.4 million higher than if we had continued to account for share-based compensation under APB No. 25 as we did in the comparable prior year periods. Accordingly, basic and diluted net loss per share for the year ended December 31, 2006 was \$0.29 higher than if we had continued to account for share-based compensation under APB No. 25. In conjunction with this adoption, we have elected to use the short-cut method (as defined under SFAS 123(R)) to calculate our windfall pool of tax benefits. We have not recognized, and do 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 our net deferred tax assets, including deferred tax assets related to our net operating loss carryforwards. 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. In addition, as of December 31, 2006, there was \$30.7 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 2.4 years.

For the year ended December 31, 2005, stock-based compensation expense was \$5.6 million, consisting of amortization of deferred stock-based compensation, the value of options issued to non-employees for services rendered, and the amortization of deferred stock-based compensation expense related to the grant of restricted stock.

In 2006, the fair value of each option award is estimated on the grant date using the Black-Scholes valuation model with the weighted average assumptions noted in the table in Note 1. As we have been operating as a public company for a period shorter than our estimated expected option life, we were unable to use actual price volatility or option life data as input assumptions within our Black-Scholes valuation model. Instead we were required to use the simplified method as described in SAB 107 related to SFAS 123(R) for expected term and peer companies' historical price volatility, both of which have been higher than actual results to date. The risk-free rate for periods within the contractual life of the option is based on the U.S. Government securities-Treasury constant maturities in effect at the time of the grant. The use of these assumptions resulted in an increase in the value of estimated stock-based compensation reflected in our consolidated statements of operations.

These assumptions used in the calculation of the fair value of share-based compensation expense represent management's best estimates, but these estimates involve inherent uncertainties and the

application of management's judgment. As a result, if other assumptions had been used, our stock-based compensation expense could have been materially different.

#### *Research and Development Expenses*

Research and development expenses consist of costs of our drug discovery efforts, conducting preclinical studies and clinical studies, activities related to regulatory filings, patent prosecution related to our development programs and manufacturing development efforts. Research and development expenses include: external research and development expenses incurred under agreements with third-party contract research organizations; third-party contract manufacturing organizations and consultants; employee-related expenses such as salaries and benefits; stock-based compensation; and facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment, and laboratory and other supplies. We outsource to third parties a substantial portion of our preclinical studies and all of our clinical studies and manufacturing of raw materials, active pharmaceutical ingredient and finished product.

We anticipate that research and development expenses will remain high in 2007 due, in particular, to our telavancin Phase 3 hospital-acquired pneumonia (HAP) clinical program and our two Phase 2 clinical studies for our GI program and for our heterodimer compound. Also we may experience higher spending on other programs to the extent that we successfully advance product candidates to later stages of discovery or development. Depending on the timing and structure of any corporate collaboration, increases in spending may be partially offset by reimbursements or assumption of development costs by corporate partners.

#### *General and Administrative Expenses*

General and administrative expenses generally include salaries and benefits, stock-based compensation, professional fees and facility costs. We anticipate that general and administrative expenses will increase to support our growing development, manufacturing and commercialization efforts.

#### *Bonus Accruals*

Theravance has short- and long-term bonus programs for certain 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. To date, we have not recorded a material adjustment as a result of changes to our bonus estimates.

#### **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, 2006, we have received \$101.0 million in upfront and milestone payments from Astellas and we are eligible to receive up to an additional \$126.0 million in clinical and regulatory milestone payments, which include up to \$116.0 million for completion of clinical studies and filing and approval of new drug applications for cSSSI and HAP, and \$10.0 million if the Phase 3 data demonstrates telavancin's superiority over vancomycin for HAP patients infected with methicillin-resistant *Staphylococcus aureus* (MRSA). We recorded the payments as

deferred revenue to be amortized ratably over our estimated period of performance (development and commercialization period). We recognized \$6.5 million and \$0.4 million in revenue under this agreement in 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 also received an option to further develop and commercialize TD-1792, our heterodimer antibiotic compound that entered Phase 2 clinical studies in December 2006.

*2002 Beyond Advair Collaboration with GSK*

In November 2002, we entered into our Beyond Advair collaboration with GSK to develop and commercialize long-acting beta2 agonist (LABA) product candidates for the treatment of asthma and chronic obstructive pulmonary disease (COPD). Each company contributed four LABA product candidates to the collaboration and two product candidates are in Phase 2b clinical programs. In connection with this collaboration, 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 collaboration. As of December 31, 2006, we have received a total of \$50.0 million in development milestones and have up to \$445.0 million in remaining milestones allocated as follows: up to \$75.0 million related to the achievement of certain clinical milestones by a Theravance-discovered LABA compound, up to \$220.0 million related to approval and launch of a product containing a Theravance-discovered LABA in multiple regions in the world, and up to \$150.0 million related to the achievement of certain sales thresholds, whether the LABA compound was discovered by Theravance or 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 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 Beyond Advair collaboration, 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 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 \$7.8 million, \$7.6 million and \$7.0 million in 2006, 2005 and 2004, respectively. Subsequent development milestones are expected to be recorded as deferred revenue when received and amortized over the remaining period of performance during the development period. Additionally, we accrued reimbursements of \$0.3 million and \$0.4 million in 2005 and 2004, respectively, compared to none in 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, we entered into our strategic alliance with GSK for the development and commercialization of product candidates in a variety of therapeutic areas. In connection with the strategic alliance with GSK, we received a \$20.0 million payment in May 2004. This payment is being amortized over the initial 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, \$2.7 million and \$1.7 million in revenue in 2006, 2005 and 2004, respectively. In addition, in May 2004, GSK, through an affiliate, purchased approximately 6.4 million shares of our Class A common stock for an aggregate purchase price of \$108.9 million.

The alliance provides GSK with an option to license product candidates from all of our full drug discovery and development programs initiated prior to September 1, 2007 on pre-determined terms and on an exclusive, world-wide basis. Upon licensing a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. 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 based on performance and royalties on any sales of medicines developed from these programs. The royalty structure for a product containing one of our compounds as a single active ingredient in the programs licensed to date by GSK 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 we receive, the total upfront and milestone payments that we could receive in any given program that GSK licenses range from up to \$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 exercise its right to license a development 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: LABA and MABA.

In August 2004, GSK exercised its right to license our long-acting muscarinic antagonist (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, 2006, 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 \$0.2 million in revenue related to the LAMA program in 2006, 2005 and 2004, respectively. Additionally, we accrued reimbursements of \$0.4 million, \$0.5 million and \$2.1 million in 2006, 2005 and 2004, 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 muscarinic antagonist-beta2 agonist (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, 2006, 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 \$0.9 million and \$0.5 million in revenue related to the MABA program in 2006 and 2005, respectively. Additionally, we accrued reimbursements of zero and \$2.9 million in 2006 and 2005, respectively, as an offset to research and development expense for certain costs related to the MABA program that were reimbursable by GSK.

GSK may increase its ownership of our outstanding stock up to approximately 59.4% through the issuance by us to GSK of the number of shares of our common stock that we may be required to redeem from our stockholders as described below. In July 2007, GSK has the right to require us to redeem ( call ), and upon notice of such redemption, each stockholder (including GSK, to the extent GSK holds common

stock) will automatically be deemed to have submitted for redemption, 50% of our common stock held by such stockholder at \$54.25 per share. If GSK does not exercise this right, our stockholders (including GSK, to the extent GSK holds common stock) have the right to require us to redeem (put) up to 50% of their common stock at \$19.375 per share in August 2007. In either case, GSK is contractually obligated to pay to us the funds necessary for us to redeem the shares of common stock from our stockholders; however, GSK's maximum obligation for the shares subject to the put is capped at \$525.0 million. We are under no obligation to redeem our shares under the call or the put until we receive from GSK funds to redeem the shares. Alternatively, if our stockholders exercise the put, GSK may elect to purchase the shares of common stock that are put directly from our stockholders. In connection with those arrangements, we have agreed not to issue new equity securities if it would cause more than approximately 54.2 million shares of common stock subject to the put (including securities vested and exercisable or convertible into shares of common stock) to be outstanding as of the put date. If GSK's ownership increases to more than 50% in 2007 as a result of the call or put, it will receive an extension of its option to license our full drug discovery programs initiated prior to September 1, 2012; otherwise, this exclusive option does not apply to programs initiated after September 1, 2007.

The effect of the redemption of our common stock pursuant to the call or the put would not cause a decrease to our cash balances, total assets, or total stockholders' equity. Accordingly, we have classified our common stock within stockholders' equity.

### Results of Operations

**Revenue.** We recognized revenue of \$19.6 million, \$12.1 million and \$8.9 million in 2006, 2005 and 2004, respectively, from the amortization of upfront and milestone payments from GSK related to our Beyond Advair collaboration and strategic alliance agreements and from Astellas related to our telavancin collaboration. Following are the upfront and milestone payments received from GSK under the Beyond Advair collaboration and strategic alliance agreements, from Astellas under the telavancin collaboration and from AstraZeneca under our license agreement through December 31, 2006 (in millions).

Agreements/Programs	Signed Agreement/Licensed Program	Upfront and Milestone Payments
<i>GSK Collaborations</i>		
Beyond Advair collaboration	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	101.0
<i>AstraZeneca License agreement execution</i>	2006	1.0
Total		\$ 198.0

Upfront fees and milestone payments received have been deferred and are being amortized ratably into revenue over the applicable estimated performance periods with end dates ranging between 2007 and 2019. Revenue in 2007 is expected to be comprised of the ongoing amortization of deferred revenue that relates to the \$198.0 million of upfront and milestone payments received through December 31, 2006, under our agreements with GSK, Astellas and AstraZeneca and to any additional upfront or milestone payments earned under current or new agreements with GSK, Astellas, AstraZeneca or other partners. We periodically review the estimated performance periods of our contracts and as such, during the fourth quarter of 2006, we revised performance periods for certain agreements based on the progress of our programs. We do not expect that this will have a material impact on future revenue recognized under these contracts.

**Research & Development**

Research and development expenses (in millions):

	Year Ended December 31,		
	2006	2005	2004
External research and development	\$ 94.0	\$ 78.7	\$ 34.9
Employee-related	37.5	35.6	32.6
Stock-based compensation	12.6	3.3	4.6
Facilities, depreciation and other allocated	22.5	20.3	19.5
Total research and development expenses	\$ 166.6	\$ 137.9	\$ 91.6

Research and development expenses increased \$28.7 million in 2006 compared to 2005. This increase was primarily the 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 Phase 2 clinical studies for TD-5108 (our GI motility dysfunction candidate) and other various development and discovery programs.

Employee-related research and development expenses increased \$1.9 million in 2006 compared to 2005. This increase was due to higher salary and benefits costs in 2006 partially offset by lower recruiting and relocation costs. Facilities, depreciation and other allocated expenses increased \$2.2 million in 2006 compared to 2005. This increase was due primarily to higher supplies and materials costs used to support our clinical programs, as well as higher facilities-related expenses.

Total research and development stock-based compensation expense for 2006 was \$12.6 million, consisting 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. Stock-based compensation expense recognized for 2005 was \$3.3 million, consisting 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 prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R).

Research and development expenses increased 51.0% in 2005, compared to 2004. This increase was primarily the result of higher external research and development expenses and increased employee costs. The higher external development costs were primarily related to preclinical and clinical services and contract manufacturing activities supporting Phase 3 clinical programs for telavancin as well as Phase 1 clinical studies for TD-2749 and TD-5108 (our GI motility dysfunction candidates) and TD-6301 (our candidate for our overactive bladder program which was terminated in October 2005) and external research and development expenses for the other development and discovery programs, which increased by \$41.1 million compared to 2004.

Employee-related research and development expenses increased by \$3.0 million in 2005 compared to 2004. This increase was due to higher salary and benefits costs in 2005 partially offset by the forgiveness of an executive loan of \$1.0 million and related employee income and employment taxes of \$0.7 million in June 2004. Facilities, depreciation and other allocated expenses were relatively unchanged in 2005 compared to 2004.

Research and development expenses for 2007 will be driven largely by clinical study enrollment, particularly for our HAP telavancin Phase 3 studies and Phase 2 clinical studies for our GI program and for our heterodimer compound. Should enrollment occur more quickly than forecast or should we begin

various studies sooner than anticipated, it is possible that these expenses will increase. Under our agreement with Astellas, we are responsible for completion of the HAP telavancin Phase 3 program, publication of the results of these studies, preparation and submission of a new drug application (NDA) to the United States Food and Drug Administration (FDA) for the HAP indication, and manufacture of sufficient quantities of active pharmaceutical ingredient (API) and drug product for the launch of telavancin for the first approved indication. 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 these responsibilities will be completed, we anticipate that our aggregate external costs associated with the telavancin Phase 3 programs will be towards the upper end of the range of \$125.0 million to \$150.0 million.

Other external research and development expenses will be driven by our ongoing development efforts in our GI program and our heterodimer compound, as well as expenses associated with our additional early-stage drug discovery programs. However, actual expenses 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 increased to \$32.2 million in 2006, from \$23.7 million in 2005. The net increase of \$8.5 million was 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 2006 was \$9.2 million, consisting of stock-based compensation expense related to employee stock options, to employee stock purchases, the value of options issued to non-employees for services rendered and to 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 and the value of stock options granted to non-employees. In accordance with the modified-prospective transition method, the general and administrative expenses for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R).

General and administrative expenses were relatively unchanged at \$23.7 million for both 2005 and 2004. Expenses increased in 2005 due to higher employee and facilities related expenses of approximately \$3.8 million, higher audit and consulting costs related to Sarbanes Oxley of approximately \$1.2 million and telavancin pre-launch marketing costs of approximately \$0.6 million. Included in the higher employee expenses for 2005 was a bonus paid to an executive of \$1.1 million. These increases were partially offset by the forgiveness of an executive loan in June 2004 of \$3.0 million and related employee income and employment taxes of \$2.9 million and decreased stock-based compensation expense in 2005 compared to 2004.

We anticipate general and administrative expenses will increase in 2007 and subsequent years to support our discovery and development efforts, commercial development activities and expanded operational infrastructure. In addition, general and administrative expenses may increase in the first half of 2007 as a result of a potential non-recurring stock-based compensation charge up to a maximum amount of \$0.8 million related to the modification of a former executive's stock options in conjunction with his termination.



**Interest and other income.** Interest and other income include interest income earned on cash and marketable securities, net realized gains on marketable securities and net sublease income on facilities. Interest income increased to \$13.6 million in 2006 from \$7.0 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 include interest income earned on cash and marketable securities, net realized gains on marketable securities and net sublease income on facilities. Interest income increased to \$7.0 million in 2005 from \$4.6 million in 2004 due to relatively higher average cash balances in 2005 following the closing of our initial public offering in October 2004 and lower rates of return in 2004 compared to 2005.

**Interest expense.** Interest expense includes interest expense on capital lease and debt arrangements. Interest expense decreased to \$0.5 million in 2006 from \$0.6 million in 2005 and to \$0.6 million in 2005 from \$0.8 million in 2004, in both cases due to declining capital lease and debt balances.

### **Income Taxes**

At December 31, 2006, we had net operating loss carryforwards for federal income taxes of \$525.5 million and federal research and development tax credit carryforwards of \$12.5 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.

### **Liquidity and Capital Resources**

As of December 31, 2006 and December 31, 2005, we had \$235.6 million and \$200.0 million in cash, cash equivalents and marketable securities, respectively, in each case excluding \$3.9 million in restricted cash and cash equivalents that was pledged as collateral for certain of our leased facilities and equipment. 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.

Our governance agreement with GSK limits the number of shares of capital stock that we may issue and the amount of debt that we may incur. Prior to the termination of the call and put arrangements with GSK in 2007, without the prior written consent of GSK, we may not issue any equity securities if it would cause more than approximately 54.2 million shares of common stock subject to the put (including securities that are vested and exercisable or convertible into shares of common stock) to be outstanding as of the put date. After our sale of 5.2 million shares of common stock in February 2006, we are contractually prohibited from selling significant additional equity securities to raise capital until the expiration of the call and put arrangements with GSK. In addition:

- If, on or immediately after the termination of the call and put arrangements with GSK in 2007, GSK directly or indirectly controls more than 35.1% of our outstanding capital stock, then without the prior written consent of GSK, we may not issue more than an aggregate of approximately 16.1 million shares of our capital stock after September 1, 2007 through August 2012; and
- Prior to the termination of the call and put arrangements with GSK in 2007, we may not borrow money or otherwise incur indebtedness of more than \$100.0 million or if such indebtedness would cause our consolidated debt to exceed our cash and cash equivalents and marketable securities.

These limits on issuing equity and debt could leave us without adequate financial resources to fund our discovery and development efforts in the event that GSK does not license development programs pursuant to our alliance agreement and no other third parties enter into collaborations with us for these programs. This could result in a reduction of our discovery and development efforts and our ability to

commercialize product candidates and generate revenues and may cause us to enter into collaborations with third parties on less favorable terms.

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 also expect expenditures to increase as we invest in administrative infrastructure to support our expanded operations.

We believe that our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next eighteen months based upon current operating and spending assumptions. However, 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. We also expect expenditures to increase as we invest in administrative infrastructure to support our expanded operations. As a result, we will likely raise additional funds in advance of actual cash needs or if we choose to expand more rapidly than we presently anticipate, or if our operating costs exceed our expectations. Pursuant to the restrictions in our agreements with GSK, we cannot sell significant additional equity until expiration of the call and put arrangements in 2007, but we may sell debt securities or incur indebtedness, subject to limitations under one or more credit facilities and our agreements with GSK. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. 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 \$104.8 million and \$58.6 million in 2006 and 2005, respectively. The 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 payments of \$36.0 million from Astellas. Net cash used in operating activities was \$58.6 million and \$47.8 million in 2005 and 2004, respectively. The increase in cash used in operations of \$10.8 million was primarily due to an increase in research and development and general and administrative expenses and a decrease in cash payments received from GSK related to the 2004 strategic alliance, partially offset by a cash payment of \$65.0 million from Astellas in late 2005.

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. Investing activities provided cash of \$3.3 million and used cash of \$100.4 million in 2005 and 2004, respectively. The increase in 2005 primarily results from an increase in proceeds from net sales and maturities of marketable securities, partially offset by an increase in capital expenditures.

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 from which we received net proceeds of \$139.9 million. Financing activities provided cash of \$3.7 million and \$213.9 million in 2005 and 2004, respectively. The decrease in cash provided by financing activities was primarily due to GSK's purchase of our Class A common stock for \$108.9 million in connection with the 2004 strategic alliance in May 2004 and \$109.0 million in net proceeds received from our initial public offering and concurrent sale of Class A common stock to a GSK affiliate in October 2004.

### **Contractual Obligations and Commitments**

Our major outstanding contractual obligations relate to our notes payable, capital leases from equipment financings, operating leases and fixed purchase commitments under contract research,

development and clinical supply agreements. These contractual obligations as of December 31, 2006, are as follows (in millions):

	Less than 1 year	1-3 years	4-5 years	After 5 years	Total
Notes payable	\$ 0.1	\$ 0.2	\$ 0.3	\$	\$ 0.6
Operating leases	6.3	12.4	13.0	1.7	33.4
Purchase obligations	2.6				2.6
Total	\$ 9.0	\$ 12.6	\$ 13.3	\$ 1.7	\$ 36.6

As security for our performance of certain obligations including the operating leases of our headquarters, we have issued letters of credit totaling \$3.9 million, collateralized by an equal amount of restricted cash.

Pursuant to our Beyond Advair 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. Based on available information, we do not estimate that any significant portion of these potential milestone payments to GSK are likely to be made in the next three years.

### Effect of Recent Accounting Pronouncements

In June 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement 109 (FIN 48). FIN 48 provides measurement and recognition guidance related to accounting for uncertainty in income taxes by prescribing a recognition threshold for tax positions. FIN 48 also requires extensive disclosures about uncertainties in the income tax positions taken. The Company will adopt FIN 48, as required on January 1, 2007. The Company has not performed the calculations related to this implementation and therefore the impact of FIN 48 on its financial statements is unknown at this time.

On June 1, 2005 the FASB issued SFAS 154, Accounting Changes and Error Corrections, which replaces APB 20, Accounting Changes, and SFAS 3, Reporting Accounting Changes in Interim Financial Statements. SFAS 154 applies to all voluntary changes in accounting principle, and changes the requirements for accounting for and reporting of a change in accounting principle. SFAS 154 requires retrospective application to prior periods financial statements of a voluntary change in accounting principle unless it is impracticable. APB 20 previously required that most voluntary changes in accounting principle be recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. SFAS 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005. Earlier application is permitted for accounting changes made in fiscal years beginning after June 1, 2005. The Company adopted SFAS 154 on January 1, 2006. The adoption of this new standard did not have a material impact on the Company's financial position, results of operations or cash flows.

In September 2006, 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. The provisions of SFAS 157 are effective for the Company beginning in the first quarter of fiscal year 2009. The Company is currently evaluating the impact of the provisions of SFAS 157 on its financial position, results of operations and cash flows and does not believe the impact of the adoption will be material.

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

Our exposure to market risk is confined to our cash, cash equivalents, restricted cash and marketable securities. We invest in high-quality financial instruments, primarily money market funds, federal agency notes, asset backed securities, corporate debt securities and U.S. treasury notes. 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 capital lease obligations and notes payable are all at fixed interest rates, and therefore, have minimal exposure to changes in interest rates.

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.

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

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**THERAVANCE, INC.**  
**Consolidated Balance Sheets**  
(in thousands, except per share amounts)

	December 31, 2006	2005
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 72,388	\$ 49,787
Marketable securities	128,692	112,138
Receivable from related party	608	990
Notes receivable	1,118	32
Prepaid and other current assets	4,361	3,903
Total current assets	207,167	166,850
Marketable securities	34,490	38,084
Restricted cash and cash equivalents	3,860	3,860
Property and equipment, net	15,101	13,180
Deferred sublease costs		297
Notes receivable	1,782	2,464
Other assets	24	100
Total assets	\$ 262,424	\$ 224,835
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 16,011	\$ 8,118
Accrued personnel-related expenses	8,316	6,041
Accrued clinical and development expenses	13,608	13,779
Other accrued liabilities	2,314	1,997
Current portion of notes payable	87	75
Current portion of capital lease obligations		1,169
Current portion of deferred revenue	19,273	16,994
Total current liabilities	59,609	48,173
Deferred rent	2,298	2,538
Notes payable	538	631
Deferred revenue	134,383	111,251
Other long term liabilities	2,286	2,658
Commitments and Contingencies (Notes 3, 7 and 8)		
Stockholders' equity:		
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; 50,746 and 44,475 shares issued and outstanding at December 31, 2006 and December 31, 2005, respectively.	507	444
Class A Common Stock, \$0.01 par value, 30,000 shares authorized, 9,402 issued and outstanding at December 31, 2006 and December 31, 2005.	94	94
Additional paid-in capital	840,498	676,299
Notes receivable from stockholders	(3)	(17)
Deferred stock-based compensation		(4,965)
Accumulated other comprehensive income (loss)	26	(503)
Accumulated deficit	(777,812)	(611,768)
Total stockholders' equity	63,310	59,584
Total liabilities and stockholders' equity	\$ 262,424	\$ 224,835

See accompanying notes to consolidated financial statements.

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

	<b>Year Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Revenue (includes amounts from GSK, a related party, of \$12,565, \$11,685 and \$8,940 in 2006, 2005 and 2004, respectively)	\$ 19,587	\$ 12,054	\$ 8,940
Operating expenses:			
Research and development	166,564	137,936	91,627
General and administrative	32,193	23,674	23,708
Total operating expenses	198,757	161,610	115,335
Loss from operations	(179,170 )	(149,556 )	(106,395 )
Interest and other income	13,649	6,969	4,564
Interest expense	(523 )	(577 )	(823 )
Net loss	\$ (166,044 )	\$ (143,164 )	\$ (102,654 )
Basic and diluted net loss per common share	\$ (2.81 )	\$ (2.69 )	\$ (3.08 )
Shares used in computing net loss per common share	59,013	53,270	33,283

See accompanying notes to consolidated financial statements.

## THERAVANCE, INC.

## Consolidated Statements Convertible Preferred Stock and of Stockholders Equity (Deficit)

(in thousands)

	Convertible Preferred Stock		Common Stock		Class A Common Stock		Additional Paid-In Capital	Notes Receivable from Stockholders	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income (Loss) Deficit	Total Stockholders Equity (Deficit)	
	Shares	Amount	Shares	Amount	Shares	Amount						
<i>Balance at December 31, 2003</i>	47,644	\$ 367,358	7,230	\$ 72			\$ 68,737	\$ (928)	\$ (1,518 )	\$ 21	\$ (365,950)	\$ (299,566)
Stock option exercises at prices ranging from \$0.78 to \$9.69, net of repurchases and net of unvested stock options exercised early			329	3			1,728					1,731
Exercise of warrants to purchase 20,000 shares of Series C preferred stock	20	170										
Exercise of warrants to purchase 4,000 shares of Series A preferred stock	4	5										
Conversion of Series A through D-1 convertible preferred stock into common stock	(43,668)	(327,596 )	28,890	289			327,307					327,596
Conversion of Series E preferred stock into common stock	(4,000 )	(39,937 )	2,580	26			39,911					39,937
Exchange of common stock for Class A common stock			(2,580 )	(26 )	2,580	26						
Issuance of common stock for cash in initial public offering, net of offering expenses of \$3.2 million			7,073	71			101,997					102,068
Issuance of Class A common stock, net of issuance costs of \$2.8 million					6,388	64	105,999					106,063
Issuance of Class A common stock for cash concurrent to our initial public offering					434	4	6,936					6,940
Forgiveness and repayments of notes receivable								433				433
Stock-based compensation related to grants of stock options to nonemployees							830					830
Reversal of deferred stock-based compensation related to employee terminations							(1,155 )	815				(340 )
Amortization of deferred stock-based compensation								8,032				8,032
Deferred stock-based compensation							17,408	(17,408 )				
Comprehensive loss:												
Net loss											(102,654 )	(102,654 )
Net unrealized loss on marketable securities									(703 )			(703 )



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Total comprehensive loss											(103,357 )
<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 at prices ranging from \$1.32 to \$14.75, net of repurchases 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
Common stock issuances from employee stock option and purchase plans at prices ranging from \$1.32 to \$21.89, net of repurchases and net of unvested stock options exercised early		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						(4,965 )	4,965				

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compensation												
Comprehensive loss:												
Net loss										(166,044 )	(166,044 )	
Net unrealized gain on marketable securities										529	529	
Total comprehensive loss											(165,515 )	
<i>Balance at</i>												
<i>December 31, 2006</i>	\$	50,746	\$ 507	9,402	\$ 94	\$ 840,498	\$ (3 )	\$	\$ 26	\$ (777,812)	\$ 63,310	

See accompanying notes to consolidated financial statements.

**THERAVANCE, INC.**  
**Consolidated Statements of Cash Flows**  
**(in thousands)**

	<b>Year Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>Cash flows provided by (used in) operating activities</b>			
Net loss	\$ (166,044 )	\$ (143,164 )	\$ (102,654 )
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	4,198	4,107	4,812
Stock-based compensation	21,831	5,623	8,521
Forgiveness of notes receivables	53	179	4,308
Other non-cash operating activities	709	403	(226 )
Changes in operating assets and liabilities:			
Receivables, prepaid and other assets	12	2,374	(3,772 )
Accounts payable and accrued liabilities	7,203	9,664	6,681
Accrued personnel-related expenses	2,275	(475 )	2,075
Deferred rent	(240 )	138	273
Deferred revenue	25,411	60,947	31,060
Other liabilities	(199 )	1,559	1,099
Net cash used in operating activities	(104,791 )	(58,645 )	(47,823 )
<b>Cash flows provided by (used in) investing activities</b>			
Purchases of property and equipment	(5,708 )	(3,443 )	(2,085 )
Purchases of marketable securities	(190,974 )	(152,260 )	(170,713 )
Maturities of marketable securities	124,715	89,330	38,232
Sales of marketable securities	53,828	68,617	29,452
Restricted cash and cash equivalents		677	1,587
Additions to notes receivable	(850 )	(160 )	(708 )
Decrease in notes receivable	407	578	3,867
Net cash provided by (used in) investing activities	(18,582 )	3,339	(100,368 )
<b>Cash flows provided by (used in) financing activities</b>			
Payments on notes payables and capital leases	(1,250 )	(2,525 )	(3,470 )
Net proceeds from issuances of convertible preferred stock			175
Net proceeds from issuances of common stock	147,224	6,207	217,149
Net cash provided by (used in) financing activities	145,974	3,682	213,854
Net increase (decrease) in cash and cash equivalents	22,601	(51,624 )	65,663
Cash and cash equivalents at beginning of period	49,787	101,411	35,748
Cash and cash equivalents at end of period	\$ 72,388	\$ 49,787	\$ 101,411
<b>Supplemental Disclosures of Cash Flow Information</b>			
Cash paid for interest	\$ 193	\$ 309	\$ 575
Non-cash investing and financing activities:			
Conversion of convertible preferred stock to common stock	\$	\$	\$ 367,533
Repurchases/issuances of common stock for notes receivable	\$	\$	\$ (3 )
Addition to (reversal of) deferred stock-based compensation	\$ (4,965 )	\$ 896	\$ 17,408

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 five programs in development, two are in late stage - its telavancin program focusing on treating serious Gram-positive bacterial infections with Astellas Pharma Inc. (Astellas) and the Beyond Advair collaboration with GlaxoSmithKline plc (GSK). By leveraging the Company's proprietary insight of multivalency to drug discovery focused on validated targets, Theravance is pursuing a next generation drug discovery strategy designed to discover superior medicines in large markets. 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). None of the Company's products 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 \$3.9 million of restricted cash and cash equivalents related to such agreements at December 31, 2006 and 2005.

*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 and included in accumulated other comprehensive income (loss). 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.

#### *Fair Value of Financial Instruments*

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

#### *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 fourth quarter of 2006, the Company revised the performance periods for certain agreements. The Company expects that the revision of the performance periods under these contracts 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 and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, ranging from three to seven years. Leasehold improvements and assets under capital leases are amortized over the shorter of their estimated useful lives or the related lease term ranging from 3 to 12 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.

*Deferred Sublease Costs*

Deferred sublease costs consist of recoverable leasehold improvements and commissions paid to obtain tenants for leased facilities no longer occupied by the Company. These costs are being amortized over the respective sublease terms.

*Impairment of Long-Lived Assets*

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

*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 dependent on third-party vendors and clinical research organizations for selected manufacturing and service functions related to its drug discovery and development efforts.

The Company is substantially dependent on third-party vendors for clinical studies related to its drug discovery and development efforts. In addition, 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. 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 \$0.5 million, \$0.5 million and \$2.8 million for the years ended December 31, 2006, 2005 and 2004, 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 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 \$24,000, \$25,000 and \$0.2 million at December 31, 2006, 2005 and 2004, respectively, and is included in other assets. The Company accrues interest on the notes at rates ranging up to 8%. The outstanding loans have maturity dates ranging from March 2007 through 2014.

#### *Bonus Programs*

Theravance has short- and long-term bonus programs for certain 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. Bonus expense was \$5.9 million, \$6.6 million and \$5.9 million for the years ended December 31, 2006, 2005 and 2004, 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 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 Employee Stock Options*

On January 1, 2006, the Company adopted the fair value recognition provisions of Financial Accounting Standards Board (FASB), Statement No. 123(R), Share-based Payment (SFAS123(R)), which requires the measurement and recognition of compensation expenses for all share-based payments made to employees and directors including stock options and employee stock purchases under the Company's

2004 Employee Stock Purchase Plan (employee stock purchases) based on estimated fair values. SFAS 123(R) supersedes the Company's previous accounting for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees (APB No. 25), Financial Accounting Standards Board Interpretation (FIN) No. 44, Accounting for Certain Transactions Involving Stock Compensation, an interpretation of APB No. 25, and related interpretations and the disclosure-only provisions of SFAS No. 123, Accounting for Stock-Based Compensation (SFAS 123). In March 2005, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 107 (SAB 107) relating to SFAS 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R).

The Company adopted SFAS 123(R) using the modified-prospective transition method. Under this method, compensation costs recognized during the year ended December 31, 2006 include: a) compensation costs for all share-based payment awards granted prior to, but not yet vested as of January 1, 2006, based on grant-date fair value estimated in accordance with the original provisions of SFAS 123; and b) compensation costs for all share-based payment awards granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R).

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 method of the vesting periods 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 recognized in the Consolidated Statement of Operations for the year ended December 31, 2006 has been reduced for estimated forfeitures so that compensation expense is based on awards 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. In the Company's pro forma information required under SFAS 123 for the periods prior to 2006, the Company accounted for forfeitures as they occurred. In addition, under SFAS 123 (R), the Company elected to continue to use the Black-Scholes valuation model for share-based payment awards granted. For additional information, see Note 10. The Company's determination of the fair value of share-based payment awards on the grant date using option valuation models requires the input of highly subjective assumptions, including the expected price volatility and option life. 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. Instead the Company is required to use the simplified method as described in SAB 107 relating to SFAS 123(R) for expected term and peer company price volatility, both of which have been 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.

In accordance with the modified-prospective transition method, the Company's Consolidated Financial Statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). 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. In addition, as of December 31, 2006, there was \$30.7 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 2.4 years. As a result of adopting FAS 123(R) on January 1, 2006, the Company's net loss for the year ended December 31, 2006 was \$17.4 million higher than if the Company had continued to account for share-based compensation



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under APB No. 25 as it did in the comparable prior year periods. Accordingly, basic and diluted net loss per share for the year ended December 31, 2006 was \$0.29 higher than if the Company had continued to account for share-based compensation under APB No. 25. 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.

The table below details 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, allocated as follows (in thousands):

	Year Ended December 31,		
	2006	2005	2004
Research and development	\$ 12,635	\$ 3,259	\$ 4,631
General and administrative	9,196	2,364	3,890
Total stock-based compensation	\$ 21,831	\$ 5,623	\$ 8,521

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

	Years Ended December 31,		
	2006	2005	2004
<b>Employee stock options</b>			
Risk-free interest rate	4.56% - 5.16 %	3.54% - 4.43 %	2.53% - 3.17 %
Expected life (in years)	5 - 6	2 - 4	3 - 5
Volatility	0.48 - 0.51	0.7	0.7
Weighted average estimated fair value of stock options granted	\$ 15.65	\$ 8.84	\$ 10.16
<b>Employee stock purchase plan issuances</b>			
Risk-free interest rate	4.70% - 5.08 %	2.58% - 4.42 %	
Expected life (in years)	0.5 - 2	2	
Volatility	0.24 - 0.38	0.7	
Weighted average estimated fair value of ESPP issuances	\$ 8.73	\$ 9.05	

*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 had been applied to stock-based employee compensation (in thousands, except per share amounts) for the years ended December 31, 2005 and 2004. For purposes of pro forma disclosures, pursuant to SFAS No. 123 as amended by SFAS No. 148, the 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>	<b>Year Ended December 31, 2004</b>
Net loss, as reported	\$ (143,164 )	\$ (102,654 )
Add: Employee stock-based compensation calculated using the intrinsic value method	4,455	7,691
Less: Total employee stock compensation calculated using the fair value method	(16,296 )	(13,089 )
Pro forma net loss	\$ (155,005 )	\$ (108,052 )
Net loss per common share, as reported	\$ (2.69 )	\$ (3.08 )
Net loss common per share, pro forma	\$ (2.91 )	\$ (3.25 )

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 valuation method. 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 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.

The Company does not currently pay dividends. On May 27, 2004, the Company's board of directors adopted the 2004 Employee Stock Purchase Plan (ESPP) that became effective on October 5, 2004, the date of the Company's 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 Loss*

Comprehensive 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.

*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 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 June 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an Interpretation of FASB Statement 109 (FIN 48). FIN 48 provides measurement and recognition guidance related to accounting for uncertainty in income taxes by prescribing a recognition threshold for tax positions. FIN 48 also requires extensive disclosures about uncertainties in the income tax positions taken. The Company will adopt FIN 48, as required on January 1, 2007. The Company has not performed the calculations related to this implementation and therefore the impact of FIN 48 on its financial statements is unknown at this time.

On June 1, 2005 the FASB issued SFAS 154, *Accounting Changes and Error Corrections*, which replaces APB 20, *Accounting Changes*, and SFAS 3, *Reporting Accounting Changes in Interim Financial Statements*. SFAS 154 applies to all voluntary changes in accounting principle, and changes the requirements for accounting for and reporting of a change in accounting principle. SFAS 154 requires retrospective application to prior periods financial statements of a voluntary change in accounting principle unless it is impracticable. APB 20 previously required that most voluntary changes in accounting principle be recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. SFAS 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005. Earlier application is permitted for accounting changes made in fiscal years beginning after June 1, 2005. The Company adopted SFAS 154 on January 1, 2006. The adoption of this new standard did not have a material impact on the Company's financial position, results of operations or cash flows.

In September 2006, 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. The provisions of SFAS 157 are effective for the Company beginning in the first quarter of fiscal year 2009. The Company is currently evaluating the impact of the provisions of SFAS 157 on its financial position, results of operations and cash flows and does not believe the impact of the adoption will be material.

*Reclassification of Prior Year Amounts*

Certain prior year amounts for stock-based compensation expenses and notes receivable have been reclassified to conform to the current period's presentation. These reclassifications had no impact on previously reported results of operations or stockholders' equity.

## 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, plus dilutive potential common shares. At December 31, 2006, potential common shares consist of 144,000 shares subject to repurchase (including 50,000 shares of restricted stock), 10,389,000 shares issuable upon the exercise of stock options and 18,000 shares issuable upon the exercise of warrants. At December 31, 2005, potential common shares consist of 202,000 shares subject to repurchase (including 50,000 shares of restricted stock), 10,096,000 shares issuable upon the exercise of stock options and 18,000 shares issuable upon the exercise of warrants. At December 31, 2004, potential common shares consist of 250,000 shares subject to repurchase and 9,435,000 shares issuable upon the exercise of stock options and 65,000 shares issuable upon the exercise of warrants. For the years ended December 31, 2006, 2005 and 2004, diluted EPS is identical to Basic EPS since potential common shares are excluded from the calculation as their effect is anti-dilutive.

	Years Ended December 31,		
	2006	2005	2004
	(In thousands, except for per share amounts)		
<b>Basic and diluted:</b>			
Net loss	\$ (166,044 )	\$ (143,164 )	\$ (102,654 )
Weighted average shares of common stock outstanding	59,187	53,512	33,605
Less: weighted average shares subject to repurchase	(174 )	(242 )	(322 )
Weighted average shares used in computing basic and diluted net loss per common share	59,013	53,270	33,283
Basic and diluted net loss per common share	\$ (2.81 )	\$ (2.69 )	\$ (3.08 )

For the years ended December 31, 2006, 2005 and 2004, share and per share amounts reflect the conversion of all of the Company's outstanding preferred stock into common stock or Class A common stock as of May 11, 2004.

## 3. Collaboration Agreements

### *2002 Beyond Advair Collaboration with GSK*

In November 2002, the Company entered into the Beyond Advair collaboration with GSK to develop and commercialize long acting beta2 agonist (LABA) product candidates for the treatment of asthma and chronic obstructive pulmonary disease (COPD). Each company contributed four LABA product candidates to the collaboration and two product candidates are in Phase 2b clinical programs. In connection with this collaboration, 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 was 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 collaboration. As of December 31, 2006, the Company has received a total of \$50.0 million in development milestones and has up to \$445.0 million in remaining milestones allocated as follows: up to \$75.0 million related to the achievement of certain clinical milestones by a Theravance-discovered LABA compound, up to \$220.0 million related to approval and launch of a product containing a Theravance-discovered LABA in multiple regions in the world, and up to \$150.0 million related to the achievement of certain sales thresholds, whether the LABA compound was discovered by Theravance or GSK. 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 will be obligated to make 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 Beyond Advair collaboration, 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 billion. Sales of single agent LABA medicines and combination LABA/ICS medicines would be combined for the purposes of this royalty calculation.

The Company recorded the initial cash payment and subsequent milestone payments as deferred revenue, to be amortized ratably over the Company's estimated period of performance (the product development period). Collaboration revenue from GSK was \$7.8 million, \$7.6 million and \$7.0 million for the years ended December 31, 2006, 2005 and 2004, respectively. Subsequent development milestones are expected to be recorded as deferred revenue when received and amortized over the remaining period of performance during the development period. Additionally, the Company accrued reimbursements of \$0.3 million and \$0.4 million for the years ended December 31, 2005 and 2004, respectively, compared to none for the year ended December 31, 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 for the development and commercialization of product candidates in a variety of therapeutic areas. In connection with the strategic alliance, the Company received a \$20.0 million payment from GSK in May 2004. This payment is being amortized over the initial period during which GSK may exercise its right to license certain of its programs under the agreement, which we currently estimate to be through September 2011. The Company recognized \$2.7 million, \$2.7 million and \$1.7 million in revenue for the years ended December 31, 2006, 2005 and 2004, respectively. In addition in May 2004, GSK through an affiliate, purchased approximately 6.4 million shares of the Company's Class A common stock for \$108.9 million. Pursuant to a partial exercise of its rights under the agreement, upon the closing of its initial public offering in October 2004, GSK purchased an additional 433,757 shares of Class A common stock for \$6.9 million.

The alliance provides GSK with an option to license product candidates from the Company's full drug discovery programs initiated prior to September 1, 2007, on pre-determined terms and on an exclusive, worldwide basis. Upon licensing a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. Consistent with the Company's strategy, the Company is obligated at its 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, the Company is entitled to receive clinical, regulatory and commercial milestone payments based on performance and royalties on any sales of medicines developed from these programs. The royalty structure for a product containing one of the Company's compounds as a single active ingredient in the programs licensed to date by GSK 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 the Company receives, the total upfront and milestone payments that the Company 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. To date, GSK has licensed the Company's two COPD programs: LABA and MABA.

In August 2004, GSK exercised its right to license the Company's long-acting muscarinic antagonist program (LAMA) pursuant to the terms of the strategic alliance. The Company received a \$5.0 million payment from GSK in connection with the licensing of this program. Through December 31, 2006, the Company received a milestone payment of \$3.0 million from GSK related to clinical progress of its

candidate. These payments will be amortized ratably over the estimated period of performance (the product development period). The Company recognized \$1.0 million, \$0.9 million and \$0.2 million in revenue for the years ended December 31, 2006, 2005 and 2004, respectively. Additionally, the Company accrued reimbursements of \$0.4 million, \$0.5 million and \$2.1 million for the years ended December 31, 2006, 2005 and 2004, 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 muscarinic antagonist-beta2 agonist (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, 2006, the Company received a milestone payment of \$3.0 million from GSK related to clinical progress of its candidate. This payment is being amortized ratably over the estimated period of performance (the product development period). The Company recognized \$0.9 million and \$0.5 million in revenue related to the MABA program for the years ended December 31, 2006 and 2005, respectively. Additionally, the Company accrued reimbursements \$2.9 million for the year ended December 31, 2005, compared to none for the year ended December 31, 2006, as an offset to research and development expense for certain costs related to the MABA program that were reimbursable by GSK.

GSK may increase its ownership of the Company's outstanding stock up to approximately 59.4% through the issuance by the Company to GSK of the number of shares of its common stock that the Company may be required to redeem from its stockholders as described below. In July 2007, GSK has the right to require the Company to redeem (call), and upon notice of such redemption, each stockholder (including GSK, to the extent GSK holds common stock) will automatically be deemed to have submitted for redemption, 50% of the Company's common stock held by such stockholder at \$54.25 per share. If GSK does not exercise this right, the Company's stockholders (including GSK, to the extent GSK holds common stock) has the right to require the Company to redeem (put) up to 50% of their common stock at \$19.375 per share in August 2007. In either case, GSK is contractually obligated to pay to the Company the funds necessary for it to redeem the shares of common stock from its stockholders; however, GSK's maximum obligation for the shares subject to the put is capped at \$525.0 million. The Company is under no obligation to redeem its shares under the call or the put until it receives funds from GSK to redeem the shares. Alternatively, if the Company's stockholders exercise the put, GSK may elect to purchase the shares of common stock that are put directly from its stockholders. In connection with those arrangements, the Company has agreed not to issue new equity securities if it would cause more than approximately 54.2 million shares of common stock subject to the put (including securities vested and exercisable or convertible into shares of common stock) to be outstanding as of the put date. If GSK's ownership increases to more than 50% in 2007 as a result of the call or put, GSK will receive an extension of its option to license the Company's full drug discovery programs initiated prior to September 1, 2012; otherwise, this exclusive option does not apply to programs initiated after September 1, 2007.

The effect of the redemption of the Company's common stock pursuant to the call or the put would not cause a decrease to its cash balances, total assets, or total stockholders' equity. Accordingly, the Company has classified its common stock within stockholders' equity.

#### *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, the Company and Astellas agreed to add Japan to their telavancin collaboration, thereby giving Astellas worldwide rights to this potential medicine. Through December 31, 2006, the Company received \$101.0 million in upfront and milestone payments from Astellas which included \$76.0 million in upfront payments and \$25.0 million in milestone payments. The Company recorded these payments as deferred revenue, to be amortized ratably over the estimated period of performance (development and commercialization period). The Company recognized

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\$6.5 million and \$0.4 million in revenue in 2006 and 2005, respectively. The Company is eligible to receive \$126.0 million in remaining clinical and regulatory milestone payments, which includes up to \$116.0 million for completion of clinical studies and filing and approval of new drug applications for cSSSI and HAP, and \$10.0 million if the Phase 3 data demonstrates telavancin's superiority over vancomycin for HAP patients infected with methicillin-resistant *Staphylococcus aureus* (MRSA).

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 costs associated with commercialization and further development of telavancin. In addition to the license rights to telavancin, Astellas also received an option to further develop and commercialize TD-1792, the Company's heterodimer antibiotic compound that entered Phase 2 clinical studies in December 2006.

#### 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, 2006 and December 31, 2005 (in thousands):

	December 31, 2006				December 31, 2005			
	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	\$ 70,060	\$ 38	\$ (60 )	\$ 70,038	\$ 61,182	\$ 10	\$ (372 )	\$ 60,820
U.S. corporate notes	49,219	10	(5 )	49,224	47,159	2	(38 )	47,123
U.S. commercial paper	66,343			66,343	44,098			44,098
Asset-backed securities	42,077	66	(23 )	42,120	40,885	4	(109 )	40,780
Certificates of deposit	1,910			1,910	1,611			1,611
Money market funds	9,795			9,795	9,437			9,437
<b>Total</b>	<b>239,404</b>	<b>114</b>	<b>(88 )</b>	<b>239,430</b>	<b>204,372</b>	<b>16</b>	<b>(519 )</b>	<b>203,869</b>
Less amounts classified as cash and cash equivalents	(72,388 )			(72,388 )	(49,787 )			(49,787 )
Less amounts classified as restricted cash	(3,860 )			(3,860 )	(3,860 )			(3,860 )
Amounts classified as marketable securities	\$ 163,156	\$ 114	\$ (88 )	\$ 163,182	\$ 150,725	\$ 16	\$ (519 )	\$ (150,222 )

The estimated fair value amounts have been determined by the Company using available market information. At December 31, 2006, approximately 59% of marketable securities mature within twelve months and 20% of marketable securities mature between twelve and twenty-four months. The remaining 21% are asset-backed securities with effective maturities beyond 24 months. Average duration of available-for-sale securities was approximately six months at December 31, 2006.

Gross realized losses on available-for-sale securities were \$14,000, \$0.1 million and \$0.1 million for the years ended December 31, 2006, 2005 and 2004, respectively.

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The following table provides the breakdown of the marketable securities with unrealized losses at December 31, 2006 (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. government agencies	\$ 24,053	\$ (20 )	\$ 20,205	\$ (40 )	\$ 44,258	\$ (60 )
U.S. corporate notes	5,295	(2 )	4,000	(3 )	9,295	(5 )
Asset-backed securities	9,113	(9 )	4,210	(14 )	13,323	(23 )
Total	\$ 38,461	\$ (31 )	\$ 28,415	\$ (57 )	\$ 66,876	\$ (88 )

The gross unrealized losses related to marketable securities are primarily due to a decrease in the fair value of debt securities as a result of an increase in interest rates during fiscal 2006. The Company has determined that the gross unrealized losses on its marketable securities at December 31, 2006 are temporary in nature. 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 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. Marketable securities in an unrealized loss position with effective maturities greater than one year have been classified as marketable securities in non-current assets.

### 5. Property and Equipment

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

	December 31,	
	2006	2005
Computer equipment	\$ 2,664	\$ 4,046
Software	3,503	2,371
Furniture and fixtures	3,407	3,384
Laboratory equipment	21,254	18,382
Leasehold improvements	13,636	13,082
	44,464	41,265
Less accumulated depreciation and amortization	(29,363 )	(28,085 )
Property and equipment, net	\$ 15,101	\$ 13,180

Depreciation expense was \$4.2 million, \$4.1 million and \$4.8 million for the years ended December 31, 2006, 2005 and 2004, respectively. The change in accumulated depreciation is net of asset retirements.

### 6. Long-Term Obligations

#### *Capital Lease Arrangements*

At December 31, 2006, the Company had no amounts outstanding under its capital lease agreements compared to \$1.2 million at December 31, 2005.

Laboratory and computer equipment, furniture and fixtures and leasehold improvements financed under capital lease arrangements are included in property and equipment and the related amortization is included in depreciation expense in the consolidated statements of operations and cash flows. The



underlying assets secured the capital lease obligations. During 2006, upon the end of the lease terms, the Company exercised its option to purchase the assets for fair value. There were no assets financed under capital leases at December 31, 2006 compared to \$4.3 million at December 31, 2005. The related accumulated amortization was \$12.4 million and \$11.6 million at December 31, 2006 and 2005, respectively.

*Notes Payable*

Note payable as follows (in thousands):

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Note payable to lessor	\$ 624	\$ 706
	\$ 624	\$ 706

In June 2002, the Company received approximately \$1.1 million under a tenant improvement loan from G.E. Capital, which was payable in monthly installments through June 2005 and bore interest at 10.4% per annum. As of December 31, 2006, no amounts were due under this note. Additionally, 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 five years and thereafter are as follows: \$0.1 million in 2007, \$0.1 million in 2008, \$0.1 million in 2009, \$0.1 million in 2010, \$0.2 million in 2011 and \$42,000 thereafter.

**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 \$3.9 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 \$5.8 million, subject to annual increases.

In addition, the Company has subleased its previously occupied facilities in Cranbury, New Jersey for periods approximating the Company's remaining lease terms.

At December 31, 2006, the Company's future minimum commitments under noncancelable operating leases, net of sublease income, are as follows (in thousands):

	<b>Minimum Lease Commitments</b>	<b>Sublease Income</b>	<b>Net Lease Commitments</b>
Year ending December 31:			
2007	\$ 6,340	\$ (508 )	\$ 5,832
2008	6,133		6,133
2009	6,285		6,285
2010	6,442		6,442
2011	6,603		6,603
Thereafter	1,661		1,661
	\$ 33,464	\$ (508 )	\$ 32,956

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

	Years Ended December 31,		
	2006	2005	2004
Rent expense	\$ 6.7	\$ 6.8	\$ 7.1
Sublease income, net	(0.3 )	(0.4 )	(0.9 )

## 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, 2006.

### *Purchase Obligations*

At December 31, 2006, the Company had outstanding purchase obligations that are committed through 2007, under commercially reasonable terms, primarily for services from contract research organizations, totaling \$2.6 million.

### *Legal Proceedings*

The Company has received a letter dated February 8, 2007 from the United States Environmental Protection Agency ( EPA ) indicating that the EPA is considering an administrative action against the Company for alleged violations of certain laws and regulations regarding organic effluent levels in liquid waste generated by the Company. The EPA has invited the Company to submit further information that it believes the EPA should consider before making a decision to proceed with the proposed administrative action. The Company is in the process of gathering this information and intends to have discussions with the EPA in the near future concerning this matter. While the Company believes it has information to show it has been in compliance and therefore no penalty should be assessed, if the Company is unable to convince the EPA that it should not proceed, the Company may be required to pay monetary penalties to the EPA.

In the future, the Company may become involved in litigation from time to time in the ordinary course of its business.

## 9. Convertible Preferred Stock

In connection with the closing of the GSK alliance agreement on May 11, 2004, all shares of the Company's convertible preferred stock converted to common stock on a one-for-one basis, except for Series D convertible preferred stock, which converted on a basis of 12/3 shares of common stock for each share of Series D convertible preferred stock.

The Company classified the convertible preferred stock prior to May 11, 2004 outside of stockholders' equity (deficit). An acquisition of the Company whereby 50% or more of the outstanding voting power of the Company would have triggered a liquidation event that entitled the preferred stockholders to their liquidation preference. This provision applied to all series of the Company's convertible preferred stock. Since a majority of the outstanding stock of the Company is controlled by outside investors, a hostile takeover or other sale could have occurred outside the control of the Company and thereby triggered a change in control, which would have been a liquidation event.

## 10. Stockholders' Equity

### *Common Stock*

In connection with the strategic alliance agreement with GSK (see Note 3), the Company restated its Certificate of Incorporation to authorize additional common stock, Class A common stock and undesignated preferred stock. The common stockholders and Class A common stockholders are entitled to one vote per share and are entitled to share equally in any dividends as declared by the Company's board of directors. Upon the liquidation, the Company's assets shall be distributed among the holders of the common stock and Class A common stock on a pro rata basis, subject to the prior rights of holders of any classes of stock.

In July 2007, GSK has the right to require the Company to redeem (call), and upon notice of such redemption, each stockholder (including GSK, to the extent GSK holds common stock) will automatically be deemed to have submitted for redemption, 50% of the Company's common stock held by such stockholder at \$54.25 per share. If GSK does not exercise this right, the Company's stockholders (including GSK, to the extent GSK holds common stock) have the right to require the Company to redeem (put) up to 50% of their common stock at \$19.375 per share in August 2007. In either case, GSK is contractually obligated to pay to the Company the funds necessary for it to redeem the shares of common stock from its stockholders; however, GSK's maximum obligation for the shares subject to the put is capped at \$525.0 million. The Company is under no obligation to redeem its shares under the call or the put until it receives the funds from GSK to redeem the shares. Alternatively, if the Company's stockholders exercise the put, GSK may elect to purchase the shares of common stock that are put directly from the Company's stockholders. In connection with those arrangements, the Company has agreed not to issue new equity securities if it would cause more than approximately 54.2 million shares of common stock subject to the put (including securities vested and exercisable or convertible into shares of common stock) to be outstanding as of the put date. If GSK's ownership increases to more than 50% in 2007 as a result of the call or put, it will receive an extension of its option to license the Company's full drug discovery programs initiated prior to September 1, 2012; otherwise, this exclusive option does not apply to programs initiated after September 1, 2007.

The effect of the redemption of the Company's common stock pursuant to the call or the put would not cause a decrease to its cash balances, total assets, or total stockholders' equity. Accordingly, the Company has classified its common stock within stockholders' equity. The Class A common stock has certain rights to nominate members of the Company's board of directors, and is not subject to the call and put. GSK may convert each share of Class A common stock into one share of common stock after (i) the date that the call occurs, or (ii) the end of the put period, as applicable.

### *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. The ESPP allows employees to contribute up to 15% of their gross salary, through payroll deductions, towards the semi-annual purchase of shares of common stock of the Company. The Company's officers are currently excluded from participating in the ESPP. The price of each share will not be less than the lower of 85% of the fair market value of the Company's common stock on the last trading day prior to the commencement of the offering period or 85% of the fair market value of the Company's common stock on the last trading day of the purchase period. 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 2004 Employee Stock Purchase Plan increasing the aggregate number of shares of common stock authorized for issuance under the plan by 300,000 shares.

As of December 31, 2006, the Company issued 331,048 shares under the ESPP at an average price of \$13.92 (165,738 shares at an average price of \$13.64 as of December 31, 2005). The total number of

remaining shares available for issuance under the plan was 293,952. For the year ended December 31, 2006, the total stock-based compensation expense recognized related to the ESPP under SFAS 123(R) was \$1.6 million.

#### *Stock Option Plans*

The Company issues stock options under the 2004 Equity Incentive Plan, which was adopted on May 27, 2004 by the Company's board of directors and became effective as of the date of the Company's initial public offering on October 5, 2004. The aggregate number of shares that may be awarded under the 2004 Equity Incentive Plan was 3,700,000 shares which were reserved for issuance under the 2004 Equity Incentive Plan plus 9,334,745 shares remaining available for issuance under the 1997 Stock Option Plan and the Long-Term Stock Option Plan as of the date the 2004 Equity Incentive Plan became effective. No further option grants will be made under the 1997 Stock Plan and the Long-Term Stock Option Plan. The 2004 Equity Incentive Plan provides for the granting of incentive and nonstatutory stock options to employees, officers, directors and consultants of the Company. Incentive stock options and nonstatutory 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, 2006, 2005 and 2004, the Company granted stock options to purchase 1,645,699, 1,715,534 and 3,758,807 shares at average stock prices of \$28.74, \$18.67 and \$9.86, respectively, under the 2004 Equity Incentive Plan. As of December 31, 2006, total shares remaining available for issuance under the 2004 Equity Incentive Plan were 1,070,241.

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). As of December 31, 2006, 87,095 shares were subject to repurchase under these outstanding note agreements.

In 2004, the Company entered into a modification agreement with a former executive which included extended vesting and exercise periods for his option grants. As of December 31, 2006, the Company recognized \$0.1 million of stock-based compensation expense related to this agreement. In addition, there are remaining option grants relating to this modification agreement for which no expense has yet been recognized.

Options granted and employee stock purchases prior to January 1, 2006 are valued in accordance with SFAS 123. The Company used the Black-Scholes option valuation model and the accelerated method for expense attribution over the vesting periods. The volatility and expected life used to estimate the fair value of the options was based on considering the volatility and expected life assumptions used by similar entities within the Company's industry. The Company recognized option forfeitures as they occurred as allowed by SFAS 123.

Options granted and employee stock purchases after January 1, 2006 are valued in accordance with SFAS 123(R). The Company uses the Black-Scholes option valuation model and the straight-line method single-option method for expense attribution. The expected term of the options granted is derived from the simplified method as described in SAB 107 relating to SFAS 123(R). The expected volatility used is based on historical volatilities of similar entities within the Company's industry which were commensurate with the Company's expected term assumption and also on the Company's historical volatility for certain expected term periods, where applicable, when valuing employee stock purchases. The Company estimated forfeitures and only recognized expense for those shares expected to vest. For the year ended December 31, 2006, the Company determined its estimated annual forfeiture rate to be 3.6%, based on its historical forfeiture experience.

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As a result of adopting FAS 123(R) on January 1, 2006, the Company's net loss for the year ended December 31, 2006 was \$17.4 million higher than if the Company had continued to account for share-based compensation under APB No. 25 as it did in the comparable prior year periods. Accordingly, basic and diluted net loss per share for the year ended December 31, 2006 was \$0.29 higher than if the Company had continued to account for share-based compensation under APB No. 25. In conjunction with this adoption, the Company elected to use the short-cut method (as defined under SFAS 123(R)) to calculate its windfall pool of tax benefits. The Company has not recognized, and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation cost as a result of the full valuation allowance on its net deferred tax assets and net operating loss carryforwards.

For the year ended December 31, 2006, under SFAS 123(R), in connection with the grant of certain stock options to employees under the 2004 Equity Incentive Plan, 1997 Stock Option Plan, and the Long-Term Stock Option Plan, the Company recorded stock-based compensation expense of \$18.0 million.

There are options to purchase shares of the Company's common stock held by consultants with exercise prices ranging from \$0.78 to \$9.69 per share. As of December 31, 2006, options to acquire 87,616 shares are subject to remeasurement of fair value using a Black-Scholes model over their remaining contractual terms. The following assumptions were used for the years ended December 31, 2006, 2005 and 2004: a volatility factor ranging from 0.29 to 0.48 for 2006 and 0.7 for 2005 and 2004; risk-free interest rates ranging from 4.6% to 5.0%, 2.8% to 4.4% and 1.04% to 3.26%, respectively; no dividend yield; and a life of the option equal to the full term, generally up to ten years from the date of grant. In accordance with SFAS 123, the Company recognized expense of \$2.0 million, \$0.9 million and \$0.8 million for the years ended December 31, 2006, 2005 and 2004, respectively.

The following table summarizes option activity under the Company's stock option plans, and related information:

	Number of Shares Available for Grant (In thousands, except per share amounts)	Number of Shares Subject to Outstanding Options (per share amounts)	Weighted- Average Exercise Price Per Share
Balance at December 31, 2003	515	6,395	\$ 6.46
Additional shares authorized	6,569		
Options granted	(3,758 )	3,758	\$ 9.86
Options exercised		(339 )	\$ 5.06
Options forfeited	379	(379 )	\$ 5.72
Shares repurchased	6		\$ 1.81
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

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, 2006 and 2005, respectively. The weighted-average fair value of

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options granted with exercise prices less than fair value of common stock on the date of grant during the year ended December 31, 2004 was \$9.79.

The weighted-average fair value of options granted with exercise prices equal to the fair value of common stock on the date of grant for the years ended December 31, 2006, 2005 and 2004 was \$15.65, \$8.84 and \$11.95, respectively.

As of December 31, 2006, there was \$30.7 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 2.4 years. The total intrinsic value of the options exercised for the years ended December 31, 2006, 2005 and 2004 was \$17.7 million, \$9.0 million and \$2.2 million, respectively and the fair value of options vested for the years ended December 31, 2006, 2005 and 2004 was \$5.1 million, \$6.8 million and \$10.0 million, respectively.

As of December 31, 2006, all outstanding options to purchase common stock of the Company are summarized in the following table (in thousands, except years and per share amounts):

Exercise Price Per Share	December 31, 2006				December 31, 2005			
	Number of Shares Subject to Outstanding Options (in thousands)	Number of Shares Exercisable	Number of Shares Subject to Options Unvested	Weighted- Average Remaining Contractual Life	Number of Shares Subject to Outstanding Options (in thousands)	Number of Shares Exercisable	Number of Shares Subject to Options Unvested	Weighted- Average Remaining Contractual Life
\$0.20	19	19		0.7	19	19		1.7
\$1.32	70	70		3.0	118	118		4.0
\$3.10	1,531	1,531	251	6.4	2,015	2,015	838	7.4
\$8.14					48	48		4.2
\$8.53	2,975	2,975	3	4.8	3,359	3,359	125	5.8
\$9.69	1,935	30	1,643	7.3	2,037	35	1,770	8.2
\$12.40 \$18.25	1,267	201	1,069	8.0	1,327	216	1,166	9.0
\$18.26 \$21.70	1,016		947	8.3	1,173		1,173	9.1
\$21.71 \$29.65	1,499		1,439	9.2				
\$29.66 \$31.48	78		78	9.9				
	10,390	4,826	5,430	6.9	10,096	5,810	5,072	7.4

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.

### *Restricted Stock*

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 following the expiration of the period during which the Company's stockholders may exercise their put to GSK in accordance with the Company's Certificate of Incorporation and 25% of the shares vesting upon each of the next two anniversaries of such date. The Company recorded the \$0.9 million value of this restricted stock grant as deferred compensation, a component of stockholders' equity in March 2005, prior to the adoption of SFAS 123(R). 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 \$0.3 million and \$0.2 million related to this award for the years ended December 31, 2006 and 2005, respectively.

### *Stock Subject to Repurchase*

At December 31, 2006, there were 94,290 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.

#### *Reserved Shares*

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

	<b>December 31, 2006</b>	<b>December 31, 2005</b>
Subject to outstanding warrant	18	18
Stock option plans:		
Subject to outstanding options	10,390	10,096
Available for future grants	1,070	2,269
Available for future ESPP grants	294	459
Total	11,772	12,842

#### *Director Compensation Program*

On April 28, 2004, the Compensation Committee of the board of directors approved a 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. In addition, each outside director was granted an option to purchase 25,806 shares of common stock with an exercise price equal to the then fair market value of the Company's common stock. Also, under this director compensation program, at each annual stockholder meeting beginning in 2005, each outside director is entitled to be granted an option to purchase 12,903 shares of common stock. On April 26, 2006, pursuant to the director compensation program previously approved by the Compensation Committee of the board of directors, each of the Company's nine outside directors was granted an option to purchase 12,903 shares of common stock with an exercise price of \$27.56, which was the then fair market value of the Company's common stock. Also on April 26, 2006, the Company's Chairman of the Board was granted 86,694 shares of common stock with an exercise price of \$27.56, 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 \$22,000 and \$0.2 million in the consolidated balance sheets relating to 7,195 and 62,632 options granted that were exercised and unvested at December 31, 2006 and 2005, respectively. Furthermore, these shares are not presented as outstanding on the consolidated balance sheets, but are disclosed as outstanding options.

#### **Warrants**

At December 31, 2006, there was an outstanding and exercisable warrant to purchase 18,064 shares of the Company's common stock at a weighted average exercise price of \$1.94 per share that expires in October 2007.

## 11. Income Taxes

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

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):

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Deferred tax assets:		
Net operating loss carryforwards	\$ 176,000	\$ 130,600
Deferred revenues	61,000	51,100
Capitalized research and development expenditures	28,000	20,400
Research and development tax credit carryforwards	21,000	15,800
Depreciation	6,000	5,800
Deferred compensation	6,000	1,800
Reserves and accruals	2,000	4,600
Valuation allowance	(300,000 )	(230,100 )
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 \$69.9 million, \$61.2 million and \$41.9 million for the years ended December 31, 2006, 2005 and 2004, respectively.

As of December 31, 2006, the Company had federal net operating loss carryforwards of approximately \$525.5 million and federal research and development tax credit carryforwards of approximately \$12.5 million, which will expire from 2011 through 2025. The Company also had state net operating loss carryforwards of approximately \$29.1 million expiring in the years 2013 through 2015 and state research tax credits of approximately \$12.9 million, which carry forward indefinitely.

Excess tax benefits from employee stock option exercises are included in the deferred tax asset balances at December 31, 2005 as a component of the Company's net operating loss carryovers. The entire balance is offset by a valuation allowance. As a result of SFAS 123(R), the deferred tax asset balances at December 31, 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.



## 12. 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, 2006. 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.

	March 31	June 30	September 30	December 31
	(in thousands except per share data)			
<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 )
<b>2005:</b>				
Revenue	\$ 2,757	\$ 2,913	\$ 3,006	\$ 3,378
Operating expenses	(35,833 )	(36,104 )	(42,383 )	(47,290 )
Loss from operations	(33,076 )	(33,191 )	(39,377 )	(43,912 )
Net loss	(31,451 )	(31,716 )	(37,786 )	(42,211 )
Net loss per common share:	\$ (0.59 )	\$ (0.60 )	\$ (0.71 )	\$ (0.79 )

## 13. Subsequent Events

On February 20, 2007, the Company announced that the U.S. Food and Drug Administration accepted the New Drug Application (NDA) for the Company's investigational antibiotic telavancin for the treatment of complicated skin and skin structure infections caused by Gram-positive organisms, including methicillin-resistant *Staphylococcus aureus*. The NDA filing triggered a milestone payment of \$31.0 million from the Company's partner, Astellas.

**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, 2006 and 2005, and the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2006. 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, 2006 and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, 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), the effectiveness of Theravance, Inc.'s internal control over financial reporting as of December 31, 2006, 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 27, 2007 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
February 27, 2007

**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, 2006, 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, 2006.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006 has been audited by Ernst & Young LLP, our independent registered public accounting firm, and Ernst & Young LLP also independently assessed the effectiveness of our internal control over financial reporting. Ernst & Young LLP has issued an attestation report concurring with management's assessment, 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, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that Theravance, Inc. (the Company) maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company'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. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of 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, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, 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, management's assessment that Theravance, Inc. maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Theravance, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, 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, 2006 and 2005, and the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2006 of Theravance, Inc. and our report dated February 27, 2007 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
February 27, 2007

**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 can be found on our website at [www.theravance.com](http://www.theravance.com). In February 2007, the Company's board of directors adopted a Stockholder-Director Communications Policy which 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, Compensation Committee Report and Compensation Committee Interlocks and Insider Participation in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

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

For the information required by this Item, see Security Ownership of Certain Beneficial Owners and Management 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.

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

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

1. Financial Statements:

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

<u>Consolidated Balance Sheets at December 31, 2006 and 2005</u>	50
<u>Consolidated Statements of Operations for each of the three years in the period ended December 31, 2006</u>	51
<u>Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) for each of the three years in the period ended December 31, 2006</u>	52
<u>Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2006</u>	53
<u>Notes to Consolidated Financial Statements</u>	54
<u>Report of Independent Registered Public Accounting Firm</u>	76

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
(1)	3.5	Amended and Restated Bylaws
	4.1	Specimen certificate representing the common stock of the registrant
(1)	4.2	Rights Agreement
(1)+	10.1	1997 Stock Plan
(1)+	10.2	Long-Term Stock Option Plan
(1)+	10.3	2004 Equity Incentive Plan
(2)	10.4	Employee Stock Purchase Plan
+	10.5	Amended and Restated Change in Control Severance Plan
(1)	10.8	Amended and Restated Lease Agreement, 951 Gateway Boulevard, between the registrant and HMS Gateway Office L.P., dated January 1, 2001
(1)	10.9	Lease Agreement, 901 Gateway Boulevard, between the registrant and HMS Gateway Office L.P., dated January 1, 2001
(1)*	10.10	Collaboration Agreement between the registrant and Glaxo Group Limited, dated as of November 14, 2002
(1)+	10.11	Form of Indemnification Agreement for directors and officers of the registrant
(1)	10.12	Class A Common Stock Purchase Agreement between the registrant and SmithKline Beecham Corporation, dated as of March 30, 2004

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(1)	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
(1)*	10.15	Strategic Alliance Agreement between the registrant and Glaxo Group Limited, dated as of March 30, 2004
(1)*	10.16	License Agreement between the registrant and Janssen Pharmaceutica, dated as of May 14, 2002
(1)+	10.17	Offer Letter with Rick E Winningham dated August 23, 2001
(1)+	10.18	Full Recourse Note Secured by Deed of Trust and Stock Pledge issued by Rick E Winningham to the registrant, dated as of July 1, 2002
(1)+	10.19	Stock Pledge Agreement between the registrant and Rick E Winningham, dated as of July 1, 2002
(1)+	10.20	Letter Agreement between the registrant and Rick E Winningham, dated as of June 4, 2004
(1)+	10.21	Offer Letter with Patrick P.A. Humphrey dated April 6, 2001
(1)+	10.22	Full Recourse Note Secured by Deed of Trust and Stock Pledge issued by Patrick P.A. Humphrey to the registrant, dated as of February 27, 2002
(1)+	10.23	Stock Pledge Agreement between the registrant and Patrick P.A. Humphrey, dated as of February 27, 2002
(1)+	10.24	Letter Agreement between the registrant and Patrick P.A. Humphrey dated June 4, 2004
(1)+	10.25	Offer Letter with David L. Brinkley dated June 30, 2000
(1)	10.26	Warrant issued to Comdisco, dated as of May 7, 1997
(1)	10.28	Class A Common Stock Purchase Agreement between the registrant and GSK
(3)+	10.29	Offer Letter with Michael W. Aguiar dated as of January 31, 2005
(3)+	10.30	Form of Notice of Grant and Stock Option Agreement under 2004 Equity Incentive Plan
(3)+	10.31	Form of Stock Restriction Agreement under 2004 Equity Incentive Plan
+	10.32	Description of Cash Bonus Program, as amended
(5)*	10.33	License, Development and Commercialization Agreement between the registrant and Astellas Pharma Inc. dated November 7, 2005
(6)+	10.34	Stock Option Agreement between the Company and P. Roy Vagelos dated as of April 26, 2006
(7)*	10.35	TD-6424 Active Pharmaceutical Ingredient Supply Agreement among the Company, ScinoPharm Taiwan, Ltd. and Biddle Sawyer Pharma LLC dated as of May 10, 2002
(7)*	10.36	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
(8)*	10.37	Amendment to License, Development and Commercialization Agreement between the Company and Astellas Pharma Inc. dated as of July 18, 2006
+	10.38	Amended and Restated 2004 Equity Incentive Plan, as amended December 6, 2006
(4)	21.1	List of Subsidiaries
	23.1	Consent of Independent Registered Public Accounting Firm
	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 Registration Statement on Form S-1 (No. 333-116384).
- (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, 2005.
- (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, 2004.
- (4) 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.
- (5) Incorporated herein by reference to the exhibit number 10.1 in the Company's Registration Statement on Form S-3 (No. 333-131359).
- (6) Incorporated herein by reference to the exhibit to the Company's Current Report on Form 8-K filed on May 2, 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 June 30, 2006.
- (8) 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 September 30, 2006.

+ 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.

**SIGNATURES**

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

Date: March 1, 2007

THERAVANCE, INC.  
By:

/s/ RICK E WINNINGHAM  
Rick E Winningham  
*Chief Executive Officer*

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**POWER OF ATTORNEY**

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

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ P. ROY VAGELOS, M.D. P. Roy Vagelos, M.D.	Chairman of the Board and Directors	March 1, 2007
/s/ RICK E WINNINGHAM Rick E Winningham	Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2007
/s/ MICHAEL W. AGUIAR Michael W. Aguiar	Senior Vice President, Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 1, 2007
/s/ JULIAN C. BAKER Julian C. Baker	Director	March 1, 2007
/s/ JEFFREY M. DRAZAN Jeffrey M. Drazan	Director	March 1, 2007
/s/ ROBERT V. GUNDERSON, JR. Robert V. Gunderson, Jr.	Director	March 1, 2007
/s/ ARNOLD J. LEVINE, PH.D Arnold J. Levine, Ph.D	Director	March 1, 2007
/s/ RONN C. LOEWENTHAL Ronn C. Loewenthal	Director	March 1, 2007
/s/ EVE E. SLATER Eve E. Slater	Director	March 1, 2007
/s/ WILLIAM H. WALTRIP William H. Waltrip	Director	March 1, 2007
/s/ GEORGE M. WHITESIDES, PH.D George M. Whitesides, Ph.D	Director	March 1, 2007
/s/ WILLIAM D. YOUNG William D. Young	Director	March 1, 2007

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Exhibits

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(3)+	10.31	Form of Stock Restriction Agreement under 2004 Equity Incentive Plan
+	10.32	Description of Cash Bonus Program, as amended

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