

THERAVANCE INC  
Form 10-K/A  
March 10, 2006

**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K/A**

**(Amendment No. 1)**

(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, 2005

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: **NONE**

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

**COMMON STOCK \$0.01 PAR VALUE**

(Title of Class)

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

## Edgar Filing: THERAVANCE INC - Form 10-K/A

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.

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 stock and non-voting stock (consisting of Common Stock, \$.01 par value and Class A Common Stock, \$.01 par value) held by non-affiliates of the registrant based upon the closing price of the Common Stock on the NASDAQ National Market on June 30, 2005 was \$637,388,786. 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, 2005 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, 2006 there were 49,858,332 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 2006 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2005, 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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**Explanatory Note**

This amendment does not reflect events occurring after the original filing of our Annual Report on Form 10-K for the fiscal year ended December 31, 2005 (the Form 10-K ) or modify or update those disclosures, except to reflect the correction of one misprint in the table under Our Programs in Item 1 and to correct typographical errors in (i) the Report of Independent Registered Public Accounting Firm on Consolidated Financial Statements in Item 8 and (ii) Part III.

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THERAVANCE, INC.

2005 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 (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, for development in each therapeutic program. In total, our research and development expenses incurred for all of our

therapeutic programs in 2005, 2004 and 2003 were \$134.7 million, \$87.0 million and \$61.7 million, respectively.

Telavancin, the lead product candidate in our bacterial infections program, is a rapidly bactericidal, injectable antibiotic. Telavancin is currently in Phase 3 clinical studies 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 methicillin-resistant *Staphylococcus aureus* (MRSA) in both complicated skin and skin structure infections (cSSSI) and hospital-acquired pneumonia (HAP). Our goal is for telavancin to become first line therapy in treating these very serious infections.

In November 2005, we entered into a collaboration arrangement with Astellas for the development and commercialization of telavancin worldwide, except Japan. We received a \$65 million upfront payment from Astellas in December 2005, and we are eligible to receive up to an additional \$156 million in 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 is in pre-clinical development.

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 \$5.5 billion of sales reported by GSK in 2005. Each company contributed four LABA product candidates to the collaboration and five product candidates either have completed or are in Phase 2a clinical studies.

We entered into a strategic alliance agreement with GSK in March 2004. Under this alliance GSK received an option to license product candidates from all of our current and future 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. 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.

In our gastrointestinal (GI) motility dysfunction program, TD-2749, our lead compound, and TD-5108, our second compound in this program, are in Phase 1 clinical programs to assess safety and tolerability in healthy subjects.

In October 2005 we discontinued our overactive bladder program based upon the results of our Phase 1 studies with compound TD-6301.

GSK currently owns all of our Class A common stock, which represents approximately 15.9% of our outstanding stock as of February 15, 2006. Under the terms of the strategic alliance, GSK's ownership of

our stock could increase to approximately 58% 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 in this Annual Report 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 in this Annual Report 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 discovery programs initiated by us 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 worldwide, except Japan. We received a \$65 million upfront payment from Astellas in December 2005, and we are eligible to receive up to an additional \$156 million in clinical and regulatory milestone payments, which include up to \$136 million for completion of clinical studies and filing and approval of new drug applications for cSSSI and HAP, and up to \$20 million if the Phase 3 data demonstrates telavancin's superiority over vancomycin for 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 is in pre-clinical development.

#### **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 five product candidates either have completed or are in Phase 2a clinical studies.

In connection with this collaboration, in 2002 we received from GSK an upfront payment of \$10 million and sold to GSK shares of our Series E preferred stock for an aggregate purchase price of \$40 million. In addition, we were eligible to receive up to \$495 million in milestones and royalties on the sales of any product resulting from this collaboration. Through December 31, 2005, we have received \$45 million in milestone payments related to the clinical progress of our product candidates. In the event that a LABA product candidate discovered by us is successfully developed and commercially launched in multiple regions of the world, these future milestone payments to us could total up to an additional \$450 million, allocated as follows: up to \$80 million related to the achievement of certain clinical milestones, up to \$220 million related to approval and launch of our product candidate in multiple regions in the world, and up to \$150 million related to the product candidate, whether discovered by Theravance



or GSK, reaching certain sales thresholds. In the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple locations of the world, we will be obligated to make payments to GSK of up to \$220 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 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 current and future 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 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 discovery programs. Upon entering into the strategic alliance with GSK, we received from GSK a payment of \$20 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.

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 million to \$162 million for programs with single-agent medicines and up to \$252 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 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 58% through the concurrent issuance to GSK of the number of shares of stock that we redeem. 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 programs initiated prior to September 1, 2012; otherwise, this exclusive option does not apply to programs initiated after September 1, 2007.

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 an additional 433,757 shares of Class A common stock. GSK's ownership position of our outstanding stock was approximately 15.9% as of February 15, 2006.

## **Development Programs**

### ***Bacterial Infections***

Telavancin, the lead product candidate in our bacterial infections program, is a rapidly bactericidal, injectable antibiotic. Telavancin is currently in Phase 3 clinical studies 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 in both cSSSI and HAP. Our goal is for telavancin to become first line therapy in treating these very serious infections.

#### *Telavancin Status*

We currently have two Phase 3 programs, one for cSSSI and one for HAP, each consisting of two studies targeting approximately 750 patients per study for a total of approximately 1,500 patients per program. Our goal in the design and execution of both programs is to demonstrate non-inferiority compared to standard therapy in the treatment of Gram-positive infections and to obtain a sufficient subpopulation of MRSA patients to be able to demonstrate superiority over vancomycin in those patients infected by MRSA, if superiority in fact exists. With this superiority endpoint in mind, we recently decided to increase the size of the cSSSI program, and enrollment in this program has surpassed 1,500 patients.

Our goal is to complete enrollment for the cSSSI program in the first half of 2006 and for the HAP program in the second half of 2006.

Currently we are using the proceeds of our 2004 initial public offering to fund the Phase 3 clinical studies for telavancin.

### ***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 \$5.5 billion reported by GSK in 2005.

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. Three of these Phase 2 compounds, GSK159797 ( 797), GSK542444 ( 444) and GSK159802 ( 802) are receiving the majority of development resources. We anticipate that GSK will initiate a Phase 2b program with 797 in the first half of 2006. This Phase 2b program is designed to evaluate the safety and efficacy of 797 in multi-day administration to mild-to-moderate asthmatics and to assess potential commercial dosing. Compound 444 is currently in multi-dose Phase 2a studies and 802 is currently in single-dose Phase 2a 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*

TD-5742, our lead compound in this program, has completed Phase 1 studies. The initial results from this study suggest that TD-5742 is less potent than we expected and as a result, the joint steering committee comprised of representatives of GSK and our Company has decided to terminate further development of this compound. We have recently delivered to GSK a second, structurally different, product candidate for this program pursuant to the terms of the strategic alliance.

***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 as a muscarinic antagonist and 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*

GSK recently initiated a Phase 1 study with our lead compound in this program, GSK961081. We have delivered to GSK a second, structurally different, product candidate for this program pursuant to the terms of the strategic alliance.

***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), opioid-induced constipation, functional dyspepsia and diabetic gastroparesis.

*GI Status*

In late December 2005, we announced the results from recently completed Phase 1 single-dose and multiple-dose studies in healthy volunteers with TD-2749, a selective 5-HT<sub>4</sub> agonist and the lead compound in our GI motility dysfunction program. In the single dose study, TD-2749 demonstrated a dose-dependent prokinetic effect with rapid onset at the highest doses and was generally well tolerated. In the multiple-dose study, TD-2749 demonstrated modest prokinetic activity and was generally well tolerated. Two subjects on TD-2749 and one subject on placebo demonstrated reversible elevations in liver enzymes in the multiple dose study.

In December 2005, we also enrolled the first healthy volunteers in a Phase 1 clinical study designed to assess the safety, tolerability and pharmacokinetics of a second, structurally distinct, investigational GI prokinetic, TD-5108. In 2006, we are continuing to evaluate TD-2749 and intend to complete the initial Phase 1 program for TD-5108. We will then make a decision regarding future clinical development of these compounds based on our evaluation of the data.

**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.

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**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-party manufacturers and our collaborative partner, GSK, to produce our compounds for clinical purposes and expect to do so for substantially all commercial production of any product candidates that are approved for marketing. Manufacturing of our Beyond Advair, LAMA and MABA program candidates will be 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 worldwide clinical studies for cSSSI and HAP, 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 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 humans 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, 2005, we had 63 issued United States patents and have received notices of allowance for 13 other United States patent applications. As of that date, we had 84 pending patent applications in the United States and 203 granted foreign patents. We also have 32 Patent Cooperation Treaty applications that permit us to pursue patents outside of the United States and 517 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 10 issued United States patents that expire between 2019 and 2023, 4 allowed United States patent applications and 10 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 4 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. 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. We do not anticipate the royalty, milestone or other payments that may be made to Janssen under the terms of the License Agreement to be material to our financial results.

### **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. These include but are not limited to daptomycin (marketed by Cubist Pharmaceuticals), linezolid (marketed by Pfizer Inc) and tigecycline (marketed by Wyeth). In addition, dalbavancin (a Pfizer product currently under review by the FDA) 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 Inc). In addition, indacaterol (being developed by Novartis) is in late stage clinical studies and represents 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, 2005, we had 270 full-time employees, over 218 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**

**Any failure or delay in commencing or completing clinical studies for our product candidates, such as a failure or delay in GSK's commencement of the planned Phase 2b program in the Beyond Advair collaboration, 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. To date we have not completed the clinical studies of any product candidate. The commencement and completion of clinical studies for our product candidates may be delayed by many factors, including:

- 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;

- delays in patient enrollment, which we have experienced, and variability in the number and types of patients available for clinical studies;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- 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;
- 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 fourth quarter of 2005, we announced that the Phase 2b program with 797, the lead investigational compound in the Beyond Advair collaboration with GSK, would not occur by the end of 2005 due to potential issues associated with the formulation of the compound. While we anticipate that GSK will commence this program during the first half of 2006, there can be no assurance that the Phase 2b program will occur in this time period. Failure to commence the Phase 2b program in the first half of 2006 would likely cause our stock price to decline.

It is possible that none of our product candidates will complete clinical studies in any of the markets in which we, our collaborators or licensees intend to sell those product candidates. Accordingly, we, our collaborators or licensees may not receive the regulatory approvals needed to market our product candidates. Any failure or delay in commencing or completing clinical studies or obtaining regulatory approvals for our product candidates would delay commercialization of our product candidates and severely harm our business and financial condition.

**If our product candidates, in particular telavancin, which is currently in Phase 3 clinical studies, are determined to be unsafe or ineffective in humans, our business will be adversely affected.**

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 all of 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 and preclinical studies and limited clinical studies. We currently expect to complete the first of our Phase 3 clinical studies for telavancin in 2006. There is no assurance that this study or other studies will demonstrate that telavancin is safe or effective. Any adverse development or result, or perceived adverse development or result, with respect to our telavancin Phase 3 studies will harm our business and cause our stock price to decline. In addition, a number of other compounds remain in the lead identification, lead optimization, preclinical testing stages and early clinical testing. 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.

**If the 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 Food and Drug Administration (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 New Drug Application (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. We have not yet filed an NDA with the FDA or made a comparable filing in any foreign country for any of our product candidates.

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.

**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 and increasing 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 sales revenue to date. We may never generate revenue from selling medicines or achieve profitability. As of December 31, 2005, we had an accumulated deficit of approximately \$611.8 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 and increasing 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 products 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 of the world, we are obligated to pay GSK milestone payments of up to an aggregate of \$220 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. 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 will be 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 pursuing research and development efforts. 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 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, 2006, GSK beneficially owned approximately 15.9% of our outstanding capital stock, and will have the right in July 2007 to increase its ownership of our stock up to approximately 58% 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 current and future 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, collaborators or consultants 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. 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 GSK and Astellas. 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 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 compound manufacturers and active pharmaceutical ingredient formulators. 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 formulators 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 compounds 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 or timely manner;
- some of the manufacturing processes for our compounds have not been tested in 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 formulated drug product to complete all of the currently planned clinical studies of telavancin, our lead product candidate in our bacterial infections program. In 2006 and early 2007 we plan to manufacture additional bulk drug substance 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 the commercial introduction of telavancin, if approved, would be adversely affected. For our development compounds in our gastrointestinal motility dysfunction program, we are using single sources to manufacture each of the bulk

drug substance and drug product. We have adequate supplies for the currently planned development activities for these compounds, but if the supplier fails to continue to produce them at acceptable quantity or quality levels, our future clinical and preclinical studies could be delayed.

**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 pre-clinical and clinical studies for our product candidates. We rely heavily on these parties for execution of our pre-clinical 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. 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 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 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 or Astellas, 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 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. Telavancin will compete with vancomycin, a relatively inexpensive generic drug that is manufactured by a variety of companies, a number of existing anti-infective drugs manufactured and marketed by major pharmaceutical companies and others, and potentially against new anti-infective drugs 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 due to antibiotic resistance concerns. 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.

**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 loss of Dr. Vagelos, Mr. Winningham, Dr. Humphrey or Dr. Kitt could impair our ability to discover, develop and market new medicines.

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

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

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

#### **Risks Related to 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, 2006, GSK beneficially owned approximately 15.9% of our outstanding capital stock. In addition, GSK has certain rights to maintain its percentage ownership of our capital stock in the future, and in 2007 GSK may exercise its call right to acquire additional shares and thereby increase its ownership up to approximately 58% 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 current and future 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 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. 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 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, 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 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 1, 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 1, 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. However, the status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of December 31, 2005, we had 63 issued United States patents and have received notices of allowance for 13 other United States patent applications. As of that date, we had 84 pending patent applications in the United States and 203 granted foreign patents. We also have 32 Patent Cooperation Treaty applications that permit us to pursue patents outside of the United States, and 517 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 could 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 could 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.

**Uncertainty regarding the effects of recent health care reform measures, trends in the managed health care and health insurance industries, and the likelihood of further legislative reform of the healthcare system could adversely affect our ability to sell our potential medicines profitably.**

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 certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. In the United States recently there have been federal and state government initiatives directed at lowering the total cost of health care, and we anticipate that

Congress and state legislatures will continue to focus on health care reform, the cost of prescription drugs and the reform of the Medicare and Medicaid systems. For example, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the MMA ) provides a new Medicare prescription drug benefit and mandates additional reforms. It is possible that the new Medicare prescription drug benefit, which will be managed by private health insurers and other managed care organizations, will 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.

**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**

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

As of February 15, 2006, GSK beneficially owned approximately 15.9% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 14.2% of our outstanding capital stock. These stockholders could substantially control the outcome of actions taken by us that require stockholder approval. In addition, pursuant to our governance agreement with GSK, GSK currently has the right to nominate a director and following September 2007 will have the right to nominate a certain number of directors depending on GSK's ownership percentage of 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.

**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:

- the extent to which GSK advances (or does not advance) our product candidates through development into commercialization, in particular any delay in the commencement of the planned Phase 2b program in the Beyond Advair collaboration;

- any adverse developments or results or perceived adverse developments or results with respect to our telavancin Phase 3 clinical studies;
- any adverse developments or results or perceived adverse developments or results with respect to any product candidates in the Beyond Advair collaboration;
- GSK's call right in 2007 for 50% of our common stock at \$54.25 per share;
- the put right and the expiration of the put right in 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.

**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**



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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 \$5.9 million, subject to annual increases. We may require additional space as our business expands.

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**ITEM 3. LEGAL PROCEEDINGS**

Currently, we are not a party to any material legal proceedings. 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.

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**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 National Market under the symbol THRX 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 National Market:

Calendar Quarter	High	Low
<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
<b>2004</b>		
Fourth Quarter	\$ 18.46	\$ 15.40

As of February 15, 2006, there were 527 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 2005.

*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.

*Use of Proceeds from Registered Securities.*

We effected the initial public offering of our common stock pursuant to Registration Statements on Form S-1 (File No. 333-116384 and File No. 333-119527) that were declared effective by the Securities and Exchange Commission on October 4, 2004 and October 5, 2004, respectively. The net offering proceeds to us from the initial public offering of our common stock in October of 2004, after deducting underwriting discounts and commissions and offering expenses, were approximately \$102.1 million. Except as otherwise disclosed in this Annual Report on Form 10-K, no offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. From October 4, 2004, the effective date of the registration statement for our initial public offering, to December 31, 2005, we estimate approximately \$63 million, consisting primarily of third party expenses, of the net offering proceeds were used to fund our Phase 3 clinical programs of telavancin. Such payments were not paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any of our affiliates.

*Equity Compensation Plans*

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2005:

	<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 stockholders	10,095,599	\$ 9.82	2,728,847
Equity compensation plans not approved by stockholders			
<b>Total</b>	<b>10,095,599</b>	<b>\$ 9.82</b>	<b>2,728,847 *</b>

\* Includes 459,262 shares of common stock issuable under our Employee Stock Purchase Plan.

**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.

	<b>Year Ended December 31,</b>				
	<b>2005</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>
	<b>(in thousands, except per share data)</b>				
<b>CONSOLIDATED STATEMENT OF OPERATIONS DATA:</b>					
Revenue	\$ 12,054	\$ 8,940	\$ 3,605	\$ 156	\$
Operating expenses:					
Research and development(1)	134,677	86,996	61,704	66,481	53,773
General and administrative	21,310	19,818	12,153	11,817	10,506
Stock-based compensation(2)	5,623	8,521	2,214	4,941	10,134
Total operating expenses	161,610	115,335	76,071	83,239	74,413
Loss from operations	(149,556 )	(106,395 )	(72,466 )	(83,083 )	(74,413 )
Interest and other income	6,969	4,564	3,373	4,990	11,530
Interest expense	(577 )	(823 )	(1,490 )	(1,134 )	(1,962 )
Net loss	\$ (143,164 )	\$ (102,654 )	\$ (70,583 )	\$ (79,227 )	\$ (64,845 )
Basic and diluted net loss per common share	\$ (2.69 )	\$ (3.08 )	\$ (10.37 )	\$ (12.50 )	\$ (11.73 )
Shares used in computing net loss per common share(3),(4),(5),	53,270	33,283	6,809	6,336	5,526
<b>CONSOLIDATED BALANCE SHEET DATA:</b>					
Cash, cash equivalents and marketable securities	\$ 200,009	\$ 257,141	\$ 89,152	\$ 148,550	\$ 152,976
Working capital	118,645	230,530	71,085	112,720	142,649
Total assets	224,835	286,022	125,449	192,715	188,749
Long-term liabilities	117,078	61,717	37,494	18,187	7,916
Convertible preferred stock			367,358	367,358	327,107
Accumulated deficit	(611,768 )	(468,604 )	(365,950 )	(295,367 )	(216,140 )
Total stockholders' equity (deficit)	59,584	190,367	(299,566 )	(231,934 )	(157,752 )

(1) Research and development expenses in 2001 includes a charge of \$0.7 million for acquired in-process research and development, impairment of intangible assets and other charges related to an acquisition in 1999.

(2) Stock-based compensation, consisting of amortization of deferred stock-based compensation and the value of options issued to non-employees for services rendered, is allocated as follows:

Research and development	\$ 3,259	\$ 4,631	\$ 1,300	\$ 3,398	\$ 6,574
General and administrative	2,364	3,890	914	1,543	3,560
Total non-cash stock-based compensation	\$ 5,623	\$ 8,521	\$ 2,214	\$ 4,941	\$ 10,134

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

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

(5) On October 5, 2004, the Company completed its initial public offering with the sale of 7,072,500 shares of common stock. Net proceeds, after underwriters' commissions and offering expenses, totaled \$102.1 million. Contemporaneously with the closing of its initial public offering, the Company sold 433,757 shares of its Class A common stock to an affiliate of GSK in a private transaction for total proceeds of \$6.9 million.

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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, 2005, we had an accumulated deficit of \$611.8 million. 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.

The net loss for the year ended December 31, 2005 was \$143.2 million compared to \$102.7 million in 2004, an increase of \$40.5 million. This increase was primarily due to higher research and development costs. Research and development spending for the year ended December 31, 2005 increased to \$134.7 million compared to \$87.0 million in 2004. This increase was primarily driven by higher external research and development costs associated with Phase 3 telavancin clinical programs, Phase 1 clinical studies for our gastrointestinal (GI) motility dysfunction program and Phase 1 clinical studies for our overactive bladder program, which was discontinued in October 2005. Cash, cash equivalents, and short-term investments totaled \$200.0 million at December 31, 2005, an increase of \$27.7 million during the fourth quarter 2005 and a decrease of \$57.1 million since December 31, 2004. This increase during the fourth quarter of 2005 includes a \$65.0 million payment received in December in connection with our collaboration with Astellas.

*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; 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 continue to increase in 2006 due, in particular, to our telavancin Phase 3 clinical programs. Also we may experience higher spending on other programs to the extent that we enter later-stage clinical studies for our product candidates currently in Phase 1, and as we advance the development of our other product candidates. Depending on the timing and structure of any corporate collaborations, increases in spending may be partially offset by reimbursements or assumption of development costs by corporate partners.

We currently expect to continue to use the total net proceeds of our initial public offering and our other cash resources to fund our telavancin Phase 3 clinical programs.

#### *General and Administrative Expenses*

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

#### **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 worldwide, except Japan. We received a \$65.0 million upfront payment from Astellas in December 2005, and we are eligible to receive up to an additional \$156.0 million in clinical and regulatory milestone payments, which include up to \$136.0 million for completion of clinical studies and filing and approval of new drug applications for complicated skin and skin structure infections (cSSSI) and hospital-acquired pneumonia (HAP), and up to \$20.0 million if the Phase 3 data demonstrates telavancin's superiority over vancomycin for patients infected with methicillin-resistant *Staphylococcus aureus* (MRSA). We recorded the initial cash payment of \$65.0 million as deferred revenue to be amortized ratably over our estimated period of performance (development and commercialization period), which we currently estimate to be thirteen years from the effective date of the agreement. The Company recognized \$0.4 million in revenue under this agreement in 2005.

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 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 is in pre-clinical development.

##### *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 five product candidates either have completed or are in Phase 2a clinical studies. In connection with this collaboration, in 2002 we received from GSK an upfront payment of \$10 million. In addition, we were eligible to receive up to \$495 million in milestones and royalties on the sales of any product resulting from this collaboration. Through December 31, 2005, we received milestone payments from GSK of \$45.0 million related to clinical progress of our candidates.



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), which we currently estimate to be eight years from the collaboration's inception. Collaboration revenue from GSK was \$7.6 million, \$7.0 million and \$3.6 million in 2005, 2004 and 2003, 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, \$0.4 million and \$3.1 million in 2005, 2004 and 2003, respectively, as an offset to research and development expense for certain costs related to the collaboration that were reimbursable by GSK.

In the event that a LABA product candidate discovered by us is successfully developed and commercially launched in multiple regions of the world, milestone payments to us could total up to \$450.0 million, allocated as follows: up to \$80 million related to the achievement of certain clinical milestones, up to \$220 million related to approval and launch of our product candidate in multiple regions in the world, and up to \$150.0 million related to the product candidate, whether discovered by Theravance or GSK, reaching certain sales thresholds. In the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple locations of the world, we will be obligated to make milestone payments to GSK of up to \$220.0 million. Based on available information, we do not estimate that any 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 GSK. The royalty structure is downward tiering and would result in an average percentage royalty rate in the low to mid-teens at annual net sales of up to approximately \$4.0 billion, and the average royalty rate would decline to single digits at annual net sales of more than \$6.0 billion. Sales of single agent LABA medicines and combination LABA/inhaled corticosteroid (ICS) medicines would be combined for the purposes of this royalty calculation.

#### *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 alliance agreement, 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 is currently estimated to be approximately seven and one-half years. In connection with the strategic alliance, we recognized \$2.7 million and \$1.7 million in revenue in 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 a purchase price of approximately \$108.9 million.

The alliance provides GSK with an option to license product candidates from all of our current and future 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 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.

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, 2005, we received an additional 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), which is currently estimated to be approximately seven and one-half years from the date GSK acquired the license. The Company recognized \$0.9 million and \$0.2 million in revenue related to the LAMA program in 2005 and 2004, respectively. Additionally, we accrued reimbursements of \$0.5 million and \$2.1 million in 2005 and 2004 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 the our MABA program. This payment is being amortized ratably over the estimated period of performance (the product development period), which is currently estimated to be approximately eight years from the date GSK acquired the license. We recognized \$0.5 million in revenue related to the MABA program for the year ended December 31, 2005. Additionally, we accrued reimbursements of \$2.9 million in 2005 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 58% 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 (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 programs initiated prior to September 1, 2012; otherwise, this exclusive option does not apply to programs initiated after September 1, 2007.

**Results of Operations**

**Revenue.** We recognized revenue of \$12.1 million, \$8.9 million and \$3.6 million in 2005, 2004 and 2003, 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, and from Astellas under the telavancin collaboration through December 31, 2005 (in millions).

Agreements/Programs	Signed Agreement/Licensed Program	End of Estimated Performance Period	Upfront and Milestone Payments
<i>GSK Collaborations</i>			
Beyond Advair collaboration	2002	2010	\$ 55.0
Strategic alliance execution	2004	2011	20.0
Strategic alliance LAMA	2004	2011	8.0
Strategic alliance MABA	2005	2013	5.0
<i>Astellas Collaboration execution</i>			
Total	2005	2019	\$ 153.0

Revenue in 2006 is expected to be comprised of the ongoing amortization of deferred revenue that relates to the \$153.0 million of upfront and milestone payments received, as of the year ended December 31, 2005, under our agreements with GSK and Astellas and to any additional upfront or milestone payments earned under current or new agreements with GSK, Astellas or other partners.

**Research & Development**

Research and development expenses (in millions):

	Year Ended December 31,		
	2005	2004	2003
External research and development	\$ 78.7	\$ 34.9	\$ 15.8
Employee-related	35.7	32.6	26.2
Facilities, depreciation and other allocated	20.3	19.5	19.7
Total research and development expenses	\$ 134.7	\$ 87.0	\$ 61.7

Research and development expenses increased 54.8% 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 studies for telavancin (our lead antibiotic candidate) as well as Phase 1 clinical studies for TD-2749 and TD-5108 (our gastrointestinal (GI) motility dysfunction candidates) and TD-6301 (our candidate for our overactive bladder program that 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 \$3.1 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 increased 41% in 2004, compared to 2003. This increase was primarily the result of higher external research and development expenses and increased employee costs.



The higher external development costs were primarily driven by increased spending on telavancin and our former overactive bladder program totaling \$15.1 million, related to further progress in clinical studies. In addition, external research and development expenses for the other development and discovery programs increased by \$4.0 million compared to 2003. Employee-related expenses were higher in 2004 due to the forgiveness of an executive loan in June 2004 of \$1.0 million and related employee income and employment taxes of \$0.7 million, and higher salary and benefits costs compared to 2003. Facilities, depreciation and other allocated expenses were relatively unchanged in 2004 compared to 2003.

We anticipate that research and development expenses will continue to increase in 2006 driven primarily by our Phase 3 clinical programs for telavancin. Other external research and development expenses will be driven by our ongoing development efforts in our GI program and expenses associated with our additional early-stage drug discovery programs. However, actual expenses may vary considerably based upon 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.

**General and administrative.** General and administrative expenses increased to \$21.3 million in 2005, from \$19.8 million in 2004. The net increase of \$1.5 million was due to higher employee and facilities related expenses of approximately \$3.8 million, telavancin pre-launch marketing costs of approximately \$0.6 million and higher audit and consulting costs related to Sarbanes Oxley of approximately \$1.2 million for 2005 compared with 2004. 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. General and administrative expenses increased to \$19.8 million in 2004 from \$12.2 million in 2003. This increase was primarily related to the forgiveness of an executive loan in June 2004 of \$3.0 million, which was net of forgiveness expense recorded in prior periods, related employee income and employment taxes of \$2.9 million, an increase in consulting and business development expenses, and expenses related to the GSK strategic alliance in 2004.

We anticipate general and administrative expenses will increase in 2006 and subsequent years to support our discovery and development efforts, commercial development activities and expanded operational infrastructure.

**Stock-based compensation.** Stock-based compensation expense decreased to \$5.6 million in 2005 from \$8.5 million in 2004. These amounts reflect the amortization of deferred stock-based compensation, much of which was recorded in 2004 and 2003. In 2005 we recorded deferred stock-based compensation of \$0.9 million related to the grant of restricted stock of which \$0.2 million was amortized in 2005. We anticipate that these amounts will increase significantly in 2006 and beyond due to the impact of expensing stock options in accordance with FASB Statement No. 123 (revised 2004) Share-Based Payment (see further discussion under Recent Accounting Pronouncements below), which is effective beginning in the first quarter of 2006. It is likely that we will adopt the modified prospective application method and the Black Scholes valuation model to determine the fair value of our stock as provided by the provisions of SFAS 123(R). In 2004 we recorded deferred stock-based compensation of \$17.4 million for stock options granted in 2004 at prices below the deemed fair value of our common stock on the option grant dates. Stock-based compensation expense increased to \$8.5 million in 2004 from \$2.2 million in 2003. These amounts reflect the amortization of deferred stock-based compensation, much of which was recorded in 2004 and 2003.

**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 \$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 income increased to \$4.6 million in 2004 from \$3.4 million in

2003, due to higher cash balances following the closing of the GSK strategic alliance in May 2004 and the closing of our initial public offering in October 2004. This increase was partially offset by a lower rate of return in 2004 compared to 2003.

**Interest expense.** Interest expense includes interest expense on capital lease and debt arrangements. Interest expense decreased to \$0.6 million in 2005 from \$0.8 million in 2004 and to \$0.8 million in 2004 from \$1.5 million in 2003, in both cases due to declining capital lease and debt balances.

#### **Income Taxes**

At December 31, 2005, we had net operating loss carryforwards for federal income taxes of \$381.6 million and federal research and development tax credit carryforwards of \$9.5 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 the deferred tax assets because realization of these benefits is uncertain.

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

As of December 31, 2005 and December 31, 2004, we had \$200.0 million and \$257.1 million in cash, cash equivalents and marketable securities, respectively, excluding \$3.9 million and \$4.5 million in restricted cash and cash equivalents that was pledged as collateral for certain of our leased facilities and equipment. In addition, in February 2006, we raised proceeds, net of estimated issuance costs, of approximately \$139.8 million, 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, or 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, including the proceeds of approximately \$139.8 million, net of estimated issuance costs, from our February 2006 public offering will be sufficient to meet our anticipated operating needs for at least the 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 may need to raise additional funds more quickly 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 \$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. Net cash used in operating activities was \$47.8 million and \$31.7 million in 2004 and 2003, respectively. The increase in cash used in operations of \$16.1 million was primarily due to an increase of \$28.0 million in research and development and general and administrative expenses, partially offset by an increase of \$10.0 million in cash payments from GSK related to the 2004 strategic alliance.

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. Net cash used in investing activities was \$100.4 million and \$13.6 million in 2004 and 2003, respectively. The increase of cash used in investing activities of \$86.8 million was primarily due to the increase of \$89.2 million in net purchases of marketable securities with cash received from the initial public offering and the GSK strategic alliance, partially offset by a decrease in notes receivable of \$3.7 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. Financing activities provided cash of \$213.9 million and used cash of \$27.8 million in 2004 and 2003, respectively. The increase in cash provided by financing activities of \$241.6 million was primarily due to \$109.0 million in net proceeds received from our initial public offering and concurrent sale of Class A common stock to GSK in October 2004 and GSK's purchase of our Class A common stock for \$108.9 million in May 2004 in connection with the strategic alliance.

**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, 2005, 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	\$ 0.2	\$ 0.2	\$ 0.7
Capital lease obligations	1.2				1.2
Operating leases	6.7	12.5	12.7	8.3	40.2
Purchase obligations	4.9	0.3			5.2
Total	\$ 12.9	\$ 13.0	\$ 12.9	\$ 8.5	\$ 47.3

As security for performance of our obligations under the operating leases for our headquarters, we have issued letters of credit totaling \$3.8 million, collateralized by an equal amount of restricted cash. The terms of these facilities leases require us to maintain an unrestricted cash and marketable securities balance of at least \$50.0 million on the last day of each calendar quarter.

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 locations of 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.

**Critical Accounting Policies**

This discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. 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 upon the terms of underlying agreements, the expected course of development, historical experience and other factors that we believe are reasonable under the circumstances. The results of this evaluation form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 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, stock-based compensation charges and bonus accruals are most critical in fully understanding and evaluating our reported financial results.

*Revenue Recognition*

In connection with our agreements with GSK and Astellas, 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. To date, we have not recorded a material adjustment as a result of changes to our revenue recognition estimates.

We have been reimbursed by GSK for certain external development costs under the Beyond Advair collaboration agreement and the GSK strategic alliance. 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. No material adjustments to preclinical study and clinical study expenses have been recognized.

#### *Stock-based Compensation*

**Deferred stock-based compensation.** Deferred stock-based compensation for stock options granted to employees is recorded when the fair value of our common stock exceeds the exercise price of the stock options on the date of measurement, which is typically the date of grant. Deferred stock-based compensation is amortized using the accelerated method over the vesting periods of the related options, generally four years. The accelerated vesting method provides for vesting of portions of the overall award at interim dates and results in higher expenses in earlier years than straight-line vesting.

The amount of stock-based compensation expense expected to be amortized in future periods may decrease if unvested options for which deferred stock-based compensation has been recorded are subsequently cancelled or may increase if future option grants are made with exercise prices below the deemed fair value of the common stock on the date of measurement.

The Company recorded deferred stock-based compensation of \$0.9 million in 2005 related to a grant of restricted stock. The Company recorded deferred stock-based compensation of \$17.4 million and \$1.5 million in 2004 and 2003, respectively, due to options granted below the deemed fair value on the option grant dates prior to our public offering in October 2004. In addition, a portion of the Company's deferred stock-based compensation was established in 1999 and 2000 due to the Company granting options at exercise prices less than the deemed fair value on the date of grant.

**Other stock-based compensation.** Other stock-based compensation generally consists of the fair value of options granted to non-employees, such as consultants and advisors, calculated using the Black-Scholes method. These options are subject to periodic remeasurement over the vesting period as services are rendered based on changes in the fair value of our common stock. As a result, other stock-based compensation charges in future periods may vary significantly.

### *Bonus Accruals*

The Company has 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 accruals to vary significantly in future periods. To date, we have not recorded a material adjustment as a result of changes to our bonus estimates.

### **Recent Accounting Pronouncements**

In June 2004, the FASB ratified Emerging Issues Task Force Issue No. 03-1 (EITF 03-1), *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. EITF 03-1 includes new guidance for evaluating and recording impairment losses on debt and equity investments, as well as new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the Financial Accounting Standards Board approved the issuance of a FASB Staff Position to delay the recognition and measurement provisions of EITF 03-1. In June 2005, the FASB decided not to provide additional guidance on the meaning of other-than-temporary impairment under EITF 03-1. The FASB directed the staff to issue FASB Staff Position Paper ( FSP ) 115-1, *The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments ( FSP 115-1 )*, superseding EITF 03-1. FSP 115-1 will replace the accounting guidance on the determination of whether an investment is other-than-temporarily impaired as set forth in EITF 03-1 with references to existing other-than-temporary impairment guidance. FSP 115-1 will be effective for other-than-temporary impairment analysis conducted in periods beginning after December 15, 2005. We do not expect our adoption of this new standard to have a material impact on our financial position, results of operations or cash flows.

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004) ( SFAS 123(R) ), *Share-Based Payment*, which is a revision of FASB Statement No. 123 ( SFAS 123 ), *Accounting for Stock-Based Compensation*. SFAS 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS 123(R) is similar to the approach described in SFAS 123. However, SFAS 123(R) *requires* all share-based payments to employees, including grants of employee stock options and employee stock purchase plans, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. On April 14, 2005, the SEC adopted a new rule deferring the required compliance dates for SFAS 123(R). In accordance with the new SEC rule, the accounting provisions of SFAS 123(R) will be effective for us for the annual period beginning January 1, 2006.

We are evaluating the requirements of SFAS 123(R) and we expect that the adoption of SFAS 123(R) will have a material impact on our consolidated results of operations and net loss per share, although it will have no impact on our overall financial position. It is likely that we will adopt the modified prospective application method and the Black Scholes valuation model to determine the fair value of our stock as provided by the provisions of SFAS 123(R). The impact of adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted Statement 123(R) in prior periods, we believe the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net loss and net loss per share in Note 1 of our notes to our consolidated financial statements included in Item 8, *Financial Statements and Supplementary Data* in this Annual Report on Form 10-K.

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. We do not expect our adoption of this new standard to have a material impact on our financial position, results of operations or cash flows.

**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 clinical and safety studies, and manufacture some active pharmaceutical product with vendors located outside the United States. Some of these expenses are paid in U.S. dollars, and some are paid in the local foreign currency. If the exchange rate undergoes a change of 10%, we do not believe that it would have a material impact on our results of operations or cash flows.

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

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

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 49,787	\$ 101,411
Marketable securities	112,138	155,730
Receivable from related party	990	2,124
Prepaid and other current assets	3,903	5,203
Total current assets	166,818	264,468
Marketable securities	38,084	
Restricted cash and cash equivalents	3,860	4,537
Property and equipment, net	13,180	13,242
Deferred sublease costs	297	545
Notes receivable	2,496	2,989
Notes receivable from related parties		64
Other assets	100	177
Total assets	\$ 224,835	\$ 286,022
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 8,118	\$ 5,925
Accrued personnel-related expenses	6,041	6,516
Accrued clinical and development expenses	13,779	5,579
Other accrued liabilities	1,997	2,338
Current portion of notes payable	75	262
Current portion of capital lease obligations	1,169	2,359
Current portion of deferred revenue	16,994	10,959
Total current liabilities	48,173	33,938
Deferred rent	2,538	2,500
Notes payable	631	706
Capital lease obligations		1,073
Deferred revenue	111,251	56,339
Other long term liabilities	2,658	1,099
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; 44,475 and 43,522 shares issued and outstanding at December 31, 2005 and December 31, 2004, respectively.	444	435
Class A Common Stock, \$0.01 par value, 30,000 shares authorized, 9,402 issued and outstanding at December 31, 2005 and December 31, 2004.	94	94
Additional paid-in capital	676,299	669,698
Notes receivable from stockholders	(17 )	(495 )
Deferred stock-based compensation	(4,965 )	(10,079 )
Accumulated other comprehensive loss	(503 )	(682 )
Accumulated deficit	(611,768 )	(468,604 )
Total stockholders equity	59,584	190,367
Total liabilities and stockholders equity	\$ 224,835	\$ 286,022

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

	Year Ended December 31,		
	2005	2004	2003
Revenue (includes amounts from GSK, a related party, of (\$11,685, \$8,940 and \$3,605 in 2005, 2004 and 2003, respectively)	\$ 12,054	\$ 8,940	\$ 3,605
Operating expenses:			
Research and development	134,677	86,996	61,704
General and administrative	21,310	19,818	12,153
Stock-based compensation*	5,623	8,521	2,214
Total operating expenses	161,610	115,335	76,071
Loss from operations	(149,556 )	(106,395 )	(72,466 )
Interest and other income	6,969	4,564	3,373
Interest expense	(577 )	(823 )	(1,490 )
Net loss	\$ (143,164 )	\$ (102,654 )	\$ (70,583 )
Basic and diluted net loss per common share	\$ (2.69 )	\$ (3.08 )	\$ (10.37 )
Shares used in computing net loss per common share	53,270	33,283	6,809

\* Stock-based compensation, consisting of amortization of deferred stock-based compensation and the value of options issued to non-employees for services rendered, is allocated as follows:

	Year Ended December 31,		
	2005	2004	2003
Research and development	\$ 3,259	\$ 4,631	\$ 1,300
General and administrative	2,364	3,890	914
Total non-cash stock-based compensation	\$ 5,623	\$ 8,521	\$ 2,214

**THERAVANCE, INC.****Consolidated Statements 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, 2002</i>	47,644	\$ 367,358	7,201	\$ 72		\$ 67,702	\$ (1,765)	\$ (2,797 )	\$ 221	\$ (295,367)	\$ (231,934)
Stock option exercises at prices ranging from \$1.32 to \$8.53, net of repurchases and net of unvested stock options exercised early			29			100					100
Forgiveness and repayments of notes receivable							837				837
Stock-based compensation related to grants of stock options to nonemployees						262					262
Reversal of deferred stock-based compensation related to employee terminations						(862 )		220			(642 )
Deferred stock-based compensation						1,535		(1,535 )			
Amortization of deferred stock-based compensation								2,594			2,594
Comprehensive loss:											
Net loss										(70,583 )	(70,583 )
Net unrealized loss on marketable securities									(200 )		(200 )
Total comprehensive loss											(70,783 )
<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									

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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 )
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		945	9			6,067					6,076



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exercised early											
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 )
Balance at December 31, 2005	\$	44,475	\$ 444	9,402	\$ 94	\$ 676,299	\$ (17 )	\$ (4,965 )	\$ (503 )	\$ (611,768)	\$ 59,584

See accompanying notes to consolidated financial statements.

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

	<b>Year Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
<b>Cash flows (used in) provided by operating activities</b>			
Net loss	\$ (143,164 )	\$ (102,654 )	\$ (70,583 )
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	4,107	4,812	5,209
Stock-based compensation	5,623	8,521	2,214
Forgiveness of notes receivables	179	4,308	1,342
Other non-cash operating activities	403	(226 )	503
Changes in operating assets and liabilities:			
Receivables, prepaid and other current assets	2,374	(3,772 )	1,092
Accounts payable and accrued liabilities	9,664	6,681	1,283
Accrued personnel-related expenses	(475 )	2,075	465
Deferred rent	138	273	405
Deferred revenue	60,947	31,060	26,394
Other long-term liabilities	1,559	1,099	
Net cash used in operating activities	(58,645 )	(47,823 )	(31,676 )
<b>Cash flows (used in) provided by investing activities</b>			
Purchases of property and equipment	(3,443 )	(2,085 )	(763 )
Purchases of marketable securities	(152,260 )	(170,713 )	(65,114 )
Sales and maturities of marketable securities	157,947	67,684	51,264
Restricted cash and cash equivalents	677	1,587	1,629
Deferred sublease costs			(38 )
Additions to notes receivable	(160 )	(708 )	(784 )
Decrease in notes receivable	578	3,867	197
Net cash (used in) provide by investing activities	3,339	(100,368 )	(13,609 )
<b>Cash flows provided by (used in) financing activities</b>			
Proceeds from line of credit			75,000
Payments on line of credit			(3,181 )
Payments on notes payables and capital leases	(2,525 )	(3,470 )	(100,000 )
Net proceeds from issuances of convertible preferred stock		175	
Net proceeds from issuances of common stock	6,207	217,149	418
Net cash provided by (used in) financing activities	3,682	213,854	(27,763 )
Net increase (decrease) in cash and cash equivalents	(51,624 )	65,663	(73,048 )
Cash and cash equivalents at beginning of period	101,411	35,748	108,796
Cash and cash equivalents at end of period	\$ 49,787	\$ 101,411	\$ 35,748
<b>Supplemental Disclosures of Cash Flow Information</b>			
Cash paid for interest	\$ 309	\$ 575	\$ 920
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 )	\$ 26
Deferred financing costs	\$	\$	\$
Deferred stock-based compensation	\$ 896	\$ 17,408	\$ 1,535

**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 its 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 (GSK). By leveraging its 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. None of the Company's products have been approved for marketing and sale to patients 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 and \$4.5 million of restricted cash and cash equivalents related to such agreements at December 31, 2005 and 2004, respectively.

*Marketable Securities*

The Company classifies its marketable securities as available-for-sale. 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, accounts payable and notes payable. Marketable securities are carried at fair value. Cash and cash equivalents, receivable from related party, accounts payable and notes payable are carried at cost and we believe 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). 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 period. The Company has been reimbursed by GSK for certain external development costs under the Beyond Advair collaboration with GSK and the strategic alliance with GSK. 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, \$2.8 million and \$0.1 million for the years ended December 31, 2005, 2004 and 2003.

*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 \$25,000, \$0.2 million and \$1.0 million at December 31, 2005, 2004 and December 31, 2003, 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 January 2006 through 2014.

On July 1, 2002, the Company extended a loan to Mr. Winningham, the Company's Chief Executive Officer, in the principal amount of \$3.8 million pursuant to the terms of his employment offer letter. The proceeds from the loan were used by Mr. Winningham to purchase his principal residence. The note was interest free, with principal due on July 1, 2012, subject to acceleration upon borrower's cessation of employment under certain circumstances and certain other events. The loan provided that 50% of the principal of such loan was to be forgiven on his fifth anniversary of employment with the Company and an additional 16% of the original principal was to be forgiven on his seventh anniversary with the Company.

The loan was secured by a second deed of trust on the residence and a pledge of 774,192 shares of stock issuable upon exercise of his options. The largest aggregate amount of indebtedness outstanding under this loan during 2004 was \$3.8 million.

On June 4, 2004, the Company entered into an agreement with its Chief Executive Officer, Mr. Wunningham pursuant to which they agreed to forgive Mr. Wunningham's housing loan in the amount of \$3.8 million, thereby extinguishing his debt in full, in recognition of Mr. Wunningham entering into a lock-up agreement with the Company and GSK pursuant to which he has agreed not to sell or transfer 50% of the shares purchasable under all of his options prior to September 2007 and agreed not to put a portion of the shares purchasable under his options to purchase common stock in 2007 pursuant to the call and put arrangements with GSK. Also, Mr. Wunningham agreed to deposit an additional 129,032 shares of common stock purchasable under an option into escrow if he exercises the option prior to September 7, 2007. On December 31, 2005, 25% of these shares would have been released from escrow if Mr. Wunningham had exercised this option. As Mr. Wunningham had not exercised this option as of December 31, 2005, there were no shares to release from escrow on that date; however, should Mr. Wunningham exercise this option prior to September 7, 2007, he will have to deposit 96,774 shares into escrow. Should Mr. Wunningham leave the Company's employ due to voluntary resignation or a termination by the Company for cause, then he will forfeit any of these shares deposited into escrow. Subject to continued employment, the Company will release any shares from escrow over the following periods: 33.3% on December 31, 2006 and the balance on September 7, 2007. The Company will release the shares from escrow immediately should Mr. Wunningham die or leave the Company's employ due to disability. The net balance of the loan, \$3.0 million, representing the original principal amount of \$3.8 million, less a reserve of approximately \$0.8 million for forgiveness under the original terms of the loan that was recorded in periods prior to 2004, plus \$2.9 million of related income and employment taxes, was recorded as general and administrative expense in 2004.

On February 27, 2002, the Company extended a loan to Dr. Humphrey, the Company's Executive Vice President, Research, in the principal amount of \$1.0 million pursuant to the terms of his employment offer letter. The proceeds from the loan were used by Dr. Humphrey to purchase his principal residence. The note was interest free, with principal due on February 27, 2012, subject to acceleration upon borrower's cessation of employment under certain circumstances and certain other events. The loan was secured by a deed of trust on the residence and a pledge of 387,096 shares of stock issuable upon exercise of his options. The largest aggregate amount of indebtedness outstanding under this loan during 2004 was \$1.0 million.

On June 4, 2004, the Company entered into an agreement with Dr. Humphrey pursuant to which the Company agreed to forgive Dr. Humphrey's housing loan in the amount of \$1.0 million, thereby extinguishing his debt in full, in recognition of Dr. Humphrey entering into a lock-up agreement with the Company and GSK pursuant to which he has agreed not to sell or transfer 50% of the shares purchasable under all of his options prior to September 2007 and agreed not to put a portion of the shares purchasable under his options to purchase common stock in 2007 pursuant to the call and put arrangements with GSK. Also, Dr. Humphrey agreed to deposit an additional 62,696 shares of common stock purchasable under options into escrow if he exercises the options prior to September 7, 2007. On December 31, 2005, 25% of these shares would have been released from escrow if Dr. Humphrey had exercised these options. As none of Dr. Humphrey's options had been exercised as of December 31, 2005, there were no shares to release from escrow on that date; however, should Dr. Humphrey exercise some or all of these options prior to September 7, 2007, he will have to deposit 47,022 shares into escrow. Should Dr. Humphrey leave the Company's employ due to voluntary resignation or a termination by the Company for cause, then he will forfeit any of these shares deposited into escrow. Subject to continued employment, the Company will release any shares from escrow over the following periods: 33.3% on December 31, 2006, and the balance on September 7, 2007. The Company will release the shares from escrow immediately should

Dr. Humphrey die or leave our employ due to disability. The full amount of this loan, plus related income and employment taxes of \$0.7 million, was recorded as research and development expense in 2004.

#### *Bonus Programs*

The Company has bonus programs covering substantially all employees. Bonuses are determined based on the achievement of corporate goals and other performance measures approved by the Board of Directors. 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 periodically reviews the progress made towards the goals, some of which extend beyond twelve months, under the bonus programs. Bonus expense was \$6.6 million, \$5.9 million and \$3.2 million for the years ended December 31, 2005, 2004 and 2003, respectively.

#### *Deferred Rent*

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. 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.

#### *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. 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. No material adjustments to preclinical study and clinical study expenses have been recognized.

#### *Deferred stock-based compensation*

The Company accounts 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 . 25 ), Financial Accounting Standards Board Interpretation ( FIN ) No. 44, Accounting for Certain Transactions Involving Stock Compensation, an interpretation of APB No. 25, and related to interpretations and has adopted the disclosure-only provisions of SFAS No. 123, Accounting for Stock-Based Compensation ( SFAS 123 ).

The option valuation models used to value the options under SFAS 123 were developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In

addition, option valuation models require the input of highly subjective assumptions, including the expected price volatility. Because the employee stock options have characteristics significantly different from those of traded options and because changes in the subjective input can materially affect the fair value estimate, in the Company's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of the Company's employee stock options.

The information regarding pro forma net loss and net loss per common share as required by SFAS 123 has been determined as if the Company had accounted for its employee stock options under the fair value method of that Statement. The resulting effect on net loss pursuant to SFAS 123 is not likely to be representative of the effects on net loss pursuant to SFAS 123 in future years, since future years are likely to include additional grants and the irregular effect of future years' vesting.

Deferred stock-based compensation for stock options granted to employees is recorded when the fair value of the Company's common stock exceeds the exercise price of the stock options on the date of measurement, which is typically the date of grant. Deferred stock-based compensation is amortized using the accelerated method over the vesting periods of the related options, generally four years. The accelerated vesting method provides for vesting of portions of the overall award at interim dates and results in higher expense in earlier years than straight-line vesting.

*Other stock-based compensation*

Other stock-based compensation generally consists of the fair value of options granted to non-employees, such as consultants and advisors, calculated using the Black-Scholes method. The Company accounts for options granted to non-employees in accordance with EITF No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. These options are subject to periodic remeasurement over the period services are rendered based on changes in the value of the Company's common stock. As a result, other stock-based compensation charges in future periods may vary significantly.

*Fair value of employee stock options*

For purposes of disclosures pursuant to SFAS 123, as amended by SFAS No. 148, the estimated fair value of options is amortized to expense over the vesting period of the options. 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):

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Net loss, as reported	\$ (143,164 )	\$ (102,654 )	\$ (70,583 )
Add: Employee stock-based compensation calculated using the intrinsic value method	4,455	7,691	1,952
Less: Total employee stock compensation calculated using the fair value method	(16,296 )	(13,089 )	(7,291 )
Pro forma net loss	\$ (155,055 )	\$ (108,052 )	\$ (75,922 )
Net loss per common share, as reported	\$ (2.69 )	\$ (3.08 )	\$ (10.37 )
Pro forma net loss per common share	\$ (2.91 )	\$ (3.25 )	\$ (11.15 )

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 Black-Scholes method. As the Company's common stock has only recently



become publicly traded, 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, the volatility estimate of 70% is significantly higher than the Company's actual stock price volatility, which is approximately 30% since the Company's October 2004 initial public offering. As a result, it is likely that this valuation input will be revised downward in 2006 as more historical data on stock price volatility becomes available. This revision would have the impact of reducing the value of the stock options. The Company will continue to evaluate its assumptions as additional historical data regarding volatility of the Company's stock and expected lives of its employee stock options becomes available. The weighted-average assumptions used to value employee stock based compensation for stock options granted and employee stock purchase plan issuances during the periods were as follows:

	Years Ended December 31,		
	2005	2004	2003
Risk-free interest rate	3.54% - 4.43 %	2.53% - 3.17 %	2.08 %
Expected life (in years)	2 - 4	3 - 5	4 - 5
Volatility	0.7	0.7	0.7
Weighted average estimated fair value of stock options granted	\$8.84	\$10.16	\$2.33
<b>Employee stock purchase plan issuances</b>			
Risk-free interest rate	2.58% - 4.42 %		
Expected life (in years)	2		
Volatility	0.7		
Weighted average estimated fair value of ESPP issuances	\$9.05		

The Company currently does not 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. In addition, all revenues are generated from United States entities, and 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 2004, the Financial Accounting Standards Board (FASB) ratified Emerging Issues Task Force Issue No. 03-1 (EITF 03-1), *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. EITF 03-1 includes new guidance for evaluating and recording impairment losses on debt and equity investments, as well as new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the Financial Accounting Standards Board approved the issuance of a FASB Staff Position to delay the recognition and measurement provisions of EITF 03-1. In June 2005, the FASB decided not to provide additional guidance on the meaning of other-than-temporary impairment under EITF 03-1. The FASB directed the staff to issue FASB Staff Position Paper ( FSP ) 115-1, *The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments ( FSP 115-1 )*, superseding EITF 03-1. FSP 115-1 will replace the accounting guidance on the determination of whether an investment is other-than-temporarily impaired as set forth in EITF 03-1 with references to existing other-than-temporary impairment guidance. FSP 115-1 will be effective for other-than-temporary impairment analysis conducted in periods beginning after December 15, 2005. The Company does not expect the adoption of this new standard to have a material impact on the Company's financial position, results of operations or cash flows.

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004) ( SFAS 123(R) ), *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS 123(R) is similar to the approach described in SFAS 123. However, SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options and employee stock purchase plans, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. On April 14, 2005, the SEC adopted a new rule deferring the required compliance dates for SFAS 123(R). In accordance with the new SEC rule, the accounting provisions of SFAS 123(R) will be effective for the Company for the annual period beginning January 1, 2006.

The Company is evaluating the requirements of SFAS 123(R) and expects that the adoption of SFAS 123(R) will have a material impact on the Company's consolidated results of operations and net loss per share, although it will have no impact on its overall financial position. It is likely that the Company will adopt the modified prospective application method and the Black Scholes valuation model to determine the fair value of the Company's stock, as provided by the provisions of SFAS 123(R). The impact of adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted Statement 123(R) in prior periods, the Company believes the impact of that standard would have approximated the impact of Statement 123 as described earlier, in the disclosure of pro forma net loss and net loss per share.

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 does not expect the adoption of this new standard to have a material impact on the Company's financial position, results of operations or cash flows.

*Reclassification of Prior Year Amounts*

\$1.1 million related to bonus programs that was classified as Accrued personnel-related expenses in 2004, has been reclassified to Other long-term liabilities to conform to the current period's presentation. This reclassification 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, 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. At December 31, 2003, potential common shares consist of 394,000 shares subject to repurchase and 6,395,000 shares issuable upon the exercise of stock options. For the year ended December 31, 2003 there were no outstanding warrants to purchase shares of the Company's common stock. Diluted EPS is identical to Basic EPS for the two years ended December 31, 2004 and 2003, since potential common shares are excluded from the calculation as their effect is anti-dilutive.

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
	<b>(In thousands, except for per share amounts)</b>		
<b>Basic and diluted:</b>			
Net loss	\$ (143,164 )	\$ (102,654 )	\$ (70,583 )
Weighted average shares of common stock outstanding	53,512	33,605	7,327
Less: weighted average shares subject to repurchase	(242 )	(322 )	(518 )
Weighted average shares used in computing basic and diluted net loss per common share	53,270	33,283	6,809
Basic and diluted net loss per common share	\$ (2.69 )	\$ (3.08 )	\$ (10.37 )

For the years ended December 31, 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 five product candidates either have completed or are in Phase 2a clinical studies. GSK is responsible for all development and commercialization costs associated with these eight product candidates and is obligated to make payments to the Company based upon its product candidates reaching clinical, regulatory and commercial milestones. The Company received an upfront cash payment from GSK of \$10.0 million in December 2002 and received milestone payments totaling \$30.0 million in 2003 and \$15.0 million in 2004, related to clinical progress of the Company's product candidates.

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), which it currently estimates to be eight years from the collaboration's inception. Collaboration revenue from GSK was \$7.6 million, \$7.0 million and \$3.6 million for the years ended December 31, 2005, 2004 and 2003, 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, \$0.4 million and \$3.1 million for the years ended December 31, 2005, 2004 and 2003, respectively, as an offset to research and development expense for certain costs related to the collaboration that were reimbursable by GSK.

In the event that a LABA product candidate discovered by the Company is successfully developed and commercially launched in multiple regions of the world, milestone payments to us could total up to an additional \$450.0 million, allocated as follows: up to \$80 million related to the achievement of certain clinical milestones, up to \$220 million related to approval and launch of our product candidate in multiple regions in the world, and up to \$150.0 million related to the product candidate, whether discovered by the Company or GSK, reaching certain sales thresholds. In the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple locations of the world, the Company will be obligated to make milestone payments to GSK of up to \$220.0 million. In addition, the Company is entitled to the same royalties from product sales of medicines from the Beyond Advair collaboration, regardless of whether the product candidate originated with the Company or with GSK. The royalty structure is downward tiering and would result in an average percentage royalty rate in the low to mid-teens at annual net sales of up to approximately \$4.0 billion, and the average royalty rate would decline to single digits at annual net sales of more than \$6.0 billion. Sales of single agent LABA medicines and combination LABA/inhaled corticosteroid medicines would be combined for the purposes of this royalty calculation.

#### *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. The alliance provides GSK with an option to license product candidates from all of the Company's current and future 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 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 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. To date, GSK has licensed the Company's two COPD programs.

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 period during which GSK may exercise its right to license certain of our programs under the agreement, which is currently estimated to be approximately seven and one-half years. The Company recognized \$2.7 million and \$1.7 million in revenue for the years

ended December 31, 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 our initial public offering in October 2004, GSK purchased an additional 433,757 shares of Class A common stock for \$6.9 million.

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, 2005, we received an additional milestone payment from GSK of \$3.0 million related to clinical progress of our candidate. These payments will be amortized ratably over the estimated period of performance (the product development period), which is currently estimated to be approximately seven and one-half years. The Company recognized \$0.9 million and \$0.2 million in revenue for the years ended December 31, 2005 and 2004, respectively. Additionally, the Company accrued reimbursements of \$0.5 million and \$2.1 million for the years ended December 31, 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. This payment is being amortized ratably over the estimated period of performance (the product development period), which is currently estimated to be approximately eight years from the date GSK acquired the license. The Company recognized \$0.5 million in revenue related to the MABA program for the year ended December 31, 2005. Additionally, the Company accrued reimbursements of \$2.9 million for the year ended December 31, 2005 as an offset to research and development expense for certain costs related to the MABA program that were reimbursable by GSK.

*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 worldwide, except Japan. The Company received a \$65.0 million upfront payment from Astellas in December 2005, and the Company is eligible to receive up to an additional \$156.0 million in clinical and regulatory milestone payments. The Company recorded the initial cash payment of \$65.0 million as deferred revenue, to be amortized ratably over the estimated period of performance (development and commercialization period), which we currently estimate to be thirteen years from the effective date. The Company recognized \$0.4 million in revenue in 2005.

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 is in pre-clinical development.

#### 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, 2005 and December 31, 2004 (in thousands):

	December 31, 2005				December 31, 2004			
	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	\$ 61,182	\$ 10	\$ (372 )	\$ 60,820	\$ 57,641	\$	\$ (266 )	\$ 57,375
U.S. corporate notes	47,159	2	(38 )	47,123	53,271	1	(111 )	53,161
U.S. commercial paper	44,098			44,098	95,257			95,257
Asset-backed securities	40,885	4	(109 )	40,780	47,300		(306 )	46,994
Certificates of deposit	1,611			1,611	110			110
Money market funds	9,437			9,437	8,781			8,781
<b>Total</b>	<b>204,372</b>	<b>16</b>	<b>(519 )</b>	<b>203,869</b>	<b>262,360</b>	<b>1</b>	<b>(683 )</b>	<b>261,678</b>
Less amounts classified as cash and cash equivalents	(49,787 )			(49,787 )	(101,411 )			(101,411 )
Less amounts classified as restricted cash	(3,860 )			(3,860 )	(4,537 )			(4,537 )
Amounts classified as marketable securities	\$ 150,725	\$ 16	\$ (519 )	\$ (150,222 )	\$ 156,412	\$ 1	\$ (683 )	\$ 155,730

The estimated fair value amounts have been determined by the Company using available market information. At December 31, 2005, approximately 55% of marketable securities (excluding asset-backed securities) mature within twelve months, and 25% of marketable securities mature between twelve and twenty-four months. The remaining 20% are asset-backed securities with effective maturities beyond 24 months. Average duration of available-for-sale securities was approximately eight months at December 31, 2005.

Gross realized losses on available-for-sale securities were \$0.1 million, \$0.1 million and \$23,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

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The following table provides the breakdown of the marketable securities with unrealized losses at December 31, 2005 (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	\$ 27,970	\$ (205 )	\$ 23,082	\$ (166 )	\$ 51,052	\$ (371 )
U.S. corporate notes	\$ 30,107	(38 )	1,999	(1 )	32,106	(39 )
Asset-backed securities	\$ 27,319	(84 )	4,348	(25 )	31,667	(109 )
Total	\$ 85,396	\$ (327 )	\$ 29,429	\$ (192 )	\$ 114,825	\$ (519 )

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 2005. The Company has determined that the gross unrealized losses on its marketable securities at December 31, 2005 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,	
	2005	2004
Computer equipment	\$ 4,046	\$ 3,322
Software	2,371	2,022
Furniture and fixtures	3,384	3,630
Laboratory equipment	18,382	15,822
Leasehold improvements	13,082	12,453
	41,265	37,249
Less accumulated depreciation and amortization	(28,085 )	(24,007 )
Property and equipment, net	\$ 13,180	\$ 13,242

Depreciation expense was \$4.1 million, \$4.8 million and \$5.2 million for the years ended December 31, 2005, 2004 and 2003, respectively.

## 6. Long-Term Obligations

### Capital Lease Arrangements

At December 31, 2005, the Company's aggregate commitments under capital lease agreements are as follows (in thousands):

Year ending December 31:	
2006	\$ 1,228
Total minimum lease payments	1,228
Less amount representing interest	(59 )
Present value of future payments	1,169
Less current portion	(1,169 )
Long-term portion	\$

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 cost of assets financed under capital leases was \$4.3 million and \$12.6 million at December 31, 2005 and 2004, respectively. The related accumulated amortization was \$11.6 million and \$10.3 million at December 31, 2005 and 2004, respectively. The Company has the option to purchase the assets at the end of the term at the then fair value. The underlying assets secure the capital lease obligations.

The lease arrangement(s) specifies that the Company is required to maintain an unrestricted cash and marketable securities balance of at least \$50.0 million on the last day of each calendar quarter and to set aside specified amounts of cash as collateral. At December 31, 2005 the Company had no restricted cash and cash equivalents as collateral and at December 31, 2004, the Company had restricted cash and cash equivalents as collateral of \$0.7 million, respectively (see Note 7).

### Notes Payable

Notes payable are as follows (in thousands):

	December 31,	
	2005	2004
Note payable to G.E. Capital	\$	\$ 197
Note payable to lessor	706	771
	\$ 706	\$ 968

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%. 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 and bears interest at 14.5%. Both notes are secured by the underlying leasehold improvements.

The aggregate maturities of notes payable for each of the five years and thereafter are as follows: \$0.1 million in 2006; \$0.1 million in 2007, \$0.1 million in 2008, \$0.1 million in 2009, \$0.1 million in 2010 and \$0.2 million 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 \$3.8 million, collateralized by an equal amount of restricted cash. If the Company's unrestricted cash and marketable securities balance is less than \$50.0 million during the terms of the leases, then the letters of credit must be increased by an aggregate of \$1.0 million. The current annual rental expense under the combined leases for the Company's headquarters is approximately \$5.9 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, 2005, the Company's future minimum commitments under noncancelable operating leases, net of sublease income, are as follows (in thousands):

	Minimum Lease Commitments	Sublease Income	Net Lease Commitments
Year ending December 31:			
2006	\$ 6,692	\$ (1,184 )	\$ 5,508
2007	6,340	(305 )	6,035
2008	6,133		6,133
2009	6,285		6,285
2010	6,442		6,442
Thereafter	8,264		8,264
	\$ 40,156	\$ (1,489 )	\$ 38,667

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

	Years Ended December 31,		
	2005	2004	2003
Rent expense	\$ 6.8	\$ 7.1	\$ 7.2
Sublease income, net	(0.4 )	(0.9 )	(0.7 )

## 8. Commitments and Contingencies

### *Guarantees and Indemnifications*

In November 2002, the FASB issued interpretation No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees of Indebtedness of Others (FIN No. 45). FIN No. 45 requires that upon issuances of a guarantee, the guarantor must recognize a liability for the fair value of the obligations it assumes under the guarantee.

The Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recognized any liabilities relating to these agreements as of December 31, 2005.

### *Purchase Obligations*

At December 31, 2005, the Company had outstanding purchase obligations, primarily for services from contract research organizations, totaling \$5.2 million.

*Legal Proceedings*

Currently, the Company is not a party to any material legal proceedings. 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 1 $\frac{2}{3}$  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, 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. 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 described in Note 3.

*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%, through payroll deductions, towards the quarterly 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. As the plan is non-compensatory under APB 25, no compensation expense is recorded in connection with the plan. 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.

In 2005, the Company issued 165,738 shares under its 2004 Employee Stock Purchase Plan at an average price of \$13.64. The total number of remaining shares available for issuance under the plan as of December 31, 2005 was 459,262.

*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. No further option grants will be made under the 1997 Stock Plan and the Long-Term Stock Option Plan. The aggregate number of shares that may be awarded under the 2004 Equity Incentive Plan were 3,700,000 shares that 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. 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 to six years. During the year ended December 31, 2005 the Company granted 1,715,534 shares at an average price of \$18.67. At December 31, 2005 total shares remaining available for issuance under the 2004 Equity Incentive Plan were 2,269,585.

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). At December 31, 2005, 89,702 shares were subject to repurchase under these outstanding note agreements.

Through December 31, 2005, in connection with the grant of certain stock options to employees under the 1997 Stock Plan and the Long-Term Stock Option Plan, the Company recorded aggregate deferred stock-based compensation of \$58.1 million and amortized \$45.6 million as non-cash stock-based compensation expense, of which \$4.5 million in stock-based compensation expense was recorded for the year ended December 31, 2005. Deferred stock-based compensation represents the difference between the exercise price and the estimated fair value of the Company's common stock on the date these stock options were granted. The Company recognizes compensation expense for fixed awards in accordance with the accelerated expense attribution method under FIN No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option Award Plans .

The Company has granted options to purchase shares of common stock to nonemployees with exercise prices ranging from \$0.78 to \$9.69 per share. As of December 31, 2005, options to acquire 197,131 shares are periodically subject to remeasurement of fair value using a Black-Scholes model over their remaining vesting terms. The following assumptions were used for 2005, 2004 and 2003: a volatility of 0.7, risk-free interest rates ranging from 2.8% to 4.4%, 1.04% to 3.26% and 3.3% 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 connection with these transactions, the Company recognized expense of \$0.9 million, \$0.8 million and \$0.3 million for the years ended December 31, 2005, 2004 and 2003, respectively.

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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	Weighted- Average Exercise Price Per Share
Balance at December 31, 2002	2,165	4,775	\$ 7.83
Options granted	(1,965 )	1,965	\$ 3.10
Options exercised		(55 )	\$ 2.87
Options forfeited	290	(290 )	\$ 7.84
Shares repurchased	25		\$ 2.82
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

The weighted-average fair value of options granted with exercise prices less than fair value of common stock on the date of grant during the years ended December 31, 2004 and 2003 was \$9.79 and \$4.93, respectively. No options were granted with exercise prices less than fair value of common stock on the date of grant during the year ended December 31, 2005.

The weighted-average fair value of options granted with exercise prices equal to the fair value of common stock on the date of grant during the years ended December 31, 2005, 2004 and 2003 was \$8.84, \$11.95 and \$1.66, respectively.

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At December 31, 2005 and December 31, 2004, all outstanding options to purchase common stock of the Company are summarized in the following table:

Exercise Price Per Share	December 31, 2005		Number of Shares Subject to Options Unvested	Weighted- Average Remaining Contractual Life	December 31, 2004		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 Outstanding Options (in thousands)	Number of Shares Exercisable		
\$0.20	19	19		1.7	19	19		2.7
\$1.32	118	118		4.0	248	248	1	5.1
\$3.10	2,015	2,015	838	7.4	2,366	2,366	1,503	8.4
\$8.14	48	48		4.2	48	48		5.2
\$8.53	3,359	3,359	125	5.8	3,656	3,656	772	6.7
\$9.69	2,037	35	1,770	8.2	2,202	38	1,968	9.3
\$12.40 \$18.25	1,327	216	1,166	9.0	896	257	890	9.7
\$18.26 \$21.70	1,173		1,173	9.1				
	10,096	5,810	5,072	7.4	9,435	6,632	5,134	8.0

*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 and is being amortized over the service period. The value of the restricted stock award was based on the closing market price of the Company's common stock of \$17.91 on the date of award. Stock-based compensation expense related to this award of \$0.2 million was recorded for the year ended December 31, 2005.

*Stock Subject to Repurchase*

At December 31, 2005 and December 31, 2004, there were 152,334 shares and 249,860 shares of the Company's common stock, respectively, 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.

*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 June 30, 2005, pursuant to the director compensation program previously approved by the Compensation Committee of the Board of Directors, each of the Company's eight outside directors was granted an option to purchase 12,903 shares of common stock with an exercise price of \$17.00, which was the then fair market value of the

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Company's common stock. On December 8, 2005, pursuant to the director compensation program, a newly elected outside director was granted an option to purchase 25,806 shares of common stock with an exercise price of \$21.02 which was the then fair market value of the Company's common stock.

### *Reserved Shares*

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

	December 31, 2005	December 31, 2004
Subject to outstanding warrant	18	65
Stock option plans:		
Subject to outstanding options	10,096	9,435
Available for future grants	2,269	3,711
Available for future ESPP grants	459	325
Total	12,842	13,536

### **Stock Options Exercised Early**

The Company generally allows employees to exercise options 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 had a liability of \$0.2 million and \$0.4 million in the consolidated balance sheets relating to 62,632 and 135,814 options granted that were exercised and unvested at December 31, 2005 and 2004, respectively. Furthermore, these shares are not presented as outstanding on the accompanying consolidated statements of stockholders' equity and consolidated balance sheets. Instead, these shares are disclosed as outstanding options.

### **Warrants**

At December 31, 2005, there was an outstanding 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.

## 12. 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>2005</b>	<b>2004</b>
Deferred tax assets:		
Net operating loss carryforwards	\$ 130,600	\$ 105,900
Deferred revenues	51,100	26,900
Capitalized research and development expenditures	20,400	17,100
Research and development tax credit carryforwards	15,800	9,700
Depreciation	5,800	5,500
Deferred compensation	1,800	2,400
Reserves and accruals	4,600	1,400
Valuation allowance	(230,100 )	(168,900 )
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 \$61.2 million, \$41.9 million and \$27.3 million for the years ended December 31, 2005, 2004 and 2003, respectively.

As of December 31, 2005, the Company had federal net operating loss carryforwards of approximately \$381.6 million and federal research and development tax credit carryforwards of approximately \$9.5 million, which will expire from 2011 through 2025. The Company also had state net operating loss carryforwards of approximately \$14.0 million expiring in the years 2006 through 2015 and state research tax credits of approximately \$9.6 million, which carry forward indefinitely.

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.

### 13. 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, 2005. 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>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 share common:	\$ (0.59 )	\$ (0.60 )	\$ (0.71 )	\$ (0.79 )
<b>2004:</b>				
Revenue	\$ 1,387	\$ 2,176	\$ 2,637	\$ 2,740
Operating expenses	(22,547 )	(33,308 )	(25,958 )	(33,522 )
Loss from operations	(21,160 )	(31,132 )	(23,321 )	(30,782 )
Net loss	(20,711 )	(30,485 )	(22,287 )	(29,171 )
Net loss per share common(1),(2),(3):	\$ (2.97 )	\$ (1.08 )	\$ (0.49 )	\$ (0.56 )

- (1) In May 2004, all shares of convertible preferred stock were converted into common stock.
- (2) In May 2004, GSK, through an affiliate, purchased 6.4 million shares of Class A common stock for \$108.9 million.
- (3) 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.

### 14. Subsequent Event

On February 7, 2006, the Company closed an underwritten public offering of 5.2 million shares of common stock at a price per share of \$28.50, raising proceeds, net of estimated issuance costs, of approximately \$139.8 million. The 5.2 million shares issued in the offering include 600,000 shares issued pursuant to the underwriters' exercise of their over-allotment option.



**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON CONSOLIDATED FINANCIAL STATEMENTS**

The Board of Directors and Stockholders  
Theravance, Inc.

We have audited the accompanying consolidated balance sheets of Theravance, Inc. as of December 31, 2005 and 2004, 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, 2005. 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, 2005 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Theravance, Inc.'s internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 3, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California  
March 3, 2006

**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, 2005, 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, 2005.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 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 controls 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, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM OVER FINANCIAL REPORTING**

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

We have audited management's assessment, included in the accompanying Management Report on Internal Control over Financial Reporting, that Theravance, Inc. (the Company) maintained effective internal control over financial reporting as of December 31, 2005, 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, 2005, 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, 2005, based on the COSO criteria.

We have also 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, 2005 and 2004, 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, 2005 of Theravance, Inc. and our report dated March 3, 2006 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
March 3, 2006

**ITEM 9B. OTHER INFORMATION**

None

**PART III**

**ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

For the information required by this Item, see "Nominees", "Executive Officers", "Section 16(a) Beneficial Ownership Reporting Compliance", "Audit Committee" and "Code of Business Conduct" in the Proxy Statement, which is incorporated herein by reference. The Company's Code of Business Conduct can also be found on our website at [www.theravance.com](http://www.theravance.com).

**ITEM 11. EXECUTIVE COMPENSATION**

For the information required by this Item, see "Compensation of Executive Officers", "Report of the Compensation Committee" and "Compensation Committee Interlocks and Insider Participation" in the Proxy Statement, which is 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, which is incorporated herein by reference.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

For the information required by this Item, see "Compensation of Executive Officers" and "Certain Transactions" in the Proxy Statement, which is 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" in the Proxy Statement, which is incorporated herein by reference.

**PART IV**

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

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

1. Financial Statements:

The following financial statements and schedules of the Registrant are contained in Item 8 of this Annual Report on Form 10-K:  
 Consolidated Balance Sheets at December 31, 2005 and 2004  
 Consolidated Statements of Operations for each of the three years in the period ended December 31, 2005  
 Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) for each of the three years in the period ended December 31, 2005  
 Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2005  
 Notes to Consolidated Financial Statements  
 Report of Independent Registered Public Accounting Firm

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 No	Description
3.3*	Amended and Restated Certificate of Incorporation
3.5*	Amended and Restated Bylaws
4.1*	Specimen certificate representing the common stock of the registrant
4.2*	Rights Agreement
10.1*	1997 Stock Plan
10.2*	Long-Term Stock Option Plan
10.3*	2004 Equity Incentive Plan
10.4**	Employee Stock Purchase Plan
10.5*	Change in Control Severance Plan
10.8*	Amended and Restated Lease Agreement, 951 Gateway Boulevard, between the registrant and HMS Gateway Office L.P., dated January 1, 2001
10.9*	Lease Agreement, 901 Gateway Boulevard, between the registrant and HMS Gateway Office L.P., dated January 1, 2001
10.10*+	Collaboration Agreement between the registrant and Glaxo Group Limited, dated as of November 14, 2002
10.11*	Form of Indemnification Agreement for directors and officers of the registrant
10.12*	Class A Common Stock Purchase Agreement between the registrant and SmithKline Beecham Corporation, dated as of March 30, 2004
10.13*	Amended and Restated Investors' Rights Agreement by and among the registrant and the parties listed therein, dated as of May 11, 2004

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10.14*	Amended and Restated Governance Agreement by and among the registrant, SmithKline Beecham Corporation and GlaxoSmithKline dated as of June 4, 2004
10.15*+	Strategic Alliance Agreement between the registrant and Glaxo Group Limited, dated as of March 30, 2004
10.16*+	License Agreement between the registrant and Janssen Pharmaceutica, dated as of May 14, 2002
10.17*	Offer Letter with Rick E Winningham dated August 23, 2001
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
10.19*	Stock Pledge Agreement between the registrant and Rick E Winningham, dated as of July 1, 2002
10.20*	Letter Agreement between the registrant and Rick E Winningham, dated as of June 4, 2004
10.21*	Offer Letter with Patrick P.A. Humphrey dated April 6, 2001
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
10.23*	Stock Pledge Agreement between the registrant and Patrick P.A. Humphrey, dated as of February 27, 2002
10.24*	Letter Agreement between the registrant and Patrick P.A. Humphrey dated June 4, 2004
10.25*	Offer Letter with David L. Brinkley dated June 30, 2000
10.26*	Warrant issued to Comdisco, dated as of May 7, 1997
10.28*	Class A Common Stock Purchase Agreement between the registrant and GSK
10.29*****	Offer Letter with Michael W. Aguiar dated as of January 31, 2005
10.30*****	Form of Notice of Grant and Stock Option Agreement under 2004 Equity Incentive Plan
10.31*****	Form of Stock Restriction Agreement under 2004 Equity Incentive Plan
10.32*****	Description of Cash Bonus Program
10.33+***	License, Development and Commercialization Agreement between the registrant and Astellas Pharma Inc. dated November 7, 2005
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

\* Incorporated herein by reference to the exhibit of the same number in the Company's Registration Statement on Form S-1 (No. 333-116384).

\*\* 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.

\*\*\* Incorporated herein by reference to the exhibit number 10.1 in the Company's Registration Statement on Form S-3 (No. 333-131359).

\*\*\*\* 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.

\*\*\*\*\* 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.

+ 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 amendment to its Annual Report on Form 10-K/A to be signed on its behalf by the undersigned, thereunto duly authorized on March 10, 2006.

THERAVANCE, INC.

By:

/s/ RICK E WINNINGHAM

Rick E Winningham

*Chief Executive Officer*

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### Exhibits

Exhibit No	Description
3.3*	Amended and Restated Certificate of Incorporation
3.5*	Amended and Restated Bylaws
4.1*	Specimen certificate representing the common stock of the registrant
4.2*	Rights Agreement
10.1*	1997 Stock Plan
10.2*	Long-Term Stock Option Plan
10.3*	2004 Equity Incentive Plan
10.4**	Employee Stock Purchase Plan
10.5*	Change in Control Severance Plan
10.8*	Amended and Restated Lease Agreement, 951 Gateway Boulevard, between the registrant and HMS Gateway Office L.P., dated January 1, 2001
10.9*	Lease Agreement, 901 Gateway Boulevard, between the registrant and HMS Gateway Office L.P., dated January 1, 2001
10.10*+	Collaboration Agreement between the registrant and Glaxo Group Limited, dated as of November 14, 2002
10.11*	Form of Indemnification Agreement for directors and officers of the registrant
10.12*	Class A Common Stock Purchase Agreement between the registrant and SmithKline Beecham Corporation, dated as of March 30, 2004
10.13*	Amended and Restated Investors Rights Agreement by and among the registrant and the parties listed therein, dated as of May 11, 2004
10.14*	Amended and Restated Governance Agreement by and among the registrant, SmithKline Beecham Corporation and GlaxoSmithKline dated as of June 4, 2004
10.15*+	Strategic Alliance Agreement between the registrant and Glaxo Group Limited, dated as of March 30, 2004
10.16*+	License Agreement between the registrant and Janssen Pharmaceutica, dated as of May 14, 2002
10.17*	Offer Letter with Rick E Winningham dated August 23, 2001
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
10.19*	Stock Pledge Agreement between the registrant and Rick E Winningham, dated as of July 1, 2002
10.20*	Letter Agreement between the registrant and Rick E Winningham, dated as of June 4, 2004
10.21*	Offer Letter with Patrick P.A. Humphrey dated April 6, 2001
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
10.23*	Stock Pledge Agreement between the registrant and Patrick P.A. Humphrey, dated as of February 27, 2002
10.24*	Letter Agreement between the registrant and Patrick P.A. Humphrey dated June 4, 2004
10.25*	Offer Letter with David L. Brinkley dated June 30, 2000
10.26*	Warrant issued to Comdisco, dated as of May 7, 1997
10.28*	Class A Common Stock Purchase Agreement between the registrant and GSK
10.29*****	Offer Letter with Michael W. Aguiar dated as of January 31, 2005
10.30*****	Form of Notice of Grant and Stock Option Agreement under 2004 Equity Incentive Plan
10.31*****	Form of Stock Restriction Agreement under 2004 Equity Incentive Plan
10.32*****	Description of Cash Bonus Program
10.33+***	License, Development and Commercialization Agreement between the registrant and Astellas Pharma Inc. dated November 7, 2005
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
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