

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 ☐

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

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

Large Accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

The aggregate market value of the voting 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.

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.

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-HT₄ 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.

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. 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.

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
2005		
First Quarter	\$ 18.86	\$ 16.53
Second Quarter	\$ 18.31	\$ 16.55
Third Quarter	\$ 21.57	\$ 16.98
Fourth Quarter	\$ 23.50	\$ 20.86
2004		
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:

	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by stockholders	10,095,599	\$ 9.82	2,728,847
Equity compensation plans not approved by stockholders			
Total	10,095,599	\$ 9.82	2,728,847 *

* 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.

	Year Ended December 31,				
	2005	2004	2003	2002	2001
	(in thousands, except per share data)				
CONSOLIDATED STATEMENT OF OPERATIONS DATA:					
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
CONSOLIDATED BALANCE SHEET DATA:					
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.

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>	2005	2019	65.0
Total			\$ 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

<u>Consolidated Balance Sheets at December 31, 2005 and December 31, 2004</u>	48
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THERAVANCE, INC.
Consolidated Balance Sheets
(in thousands, except per share amounts)

	December 31, 2005	2004
Assets		
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
Liabilities and stockholders' equity		
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)	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount						
Balance at December 31, 2002	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)
Balance at December 31, 2003	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					