THERAVANCE INC
Form S-3ASR
January 30, 2006

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As filed with the Securities and Exchange Commission on January 30, 2006

Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

THERAVANCE, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**94-3265960**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)

901 Gateway Blvd.
South San Francisco, CA 94080
(650) 808-6000

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Rick E Winningham
Chief Executive Officer
Theravance, Inc.
901 Gateway Blvd.
South San Francisco, CA 94080
(650) 808-6000

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

The Commission is requested to send copies of all communications to:

David T. Young, Esq.
Christopher C. Dillon, Esq.
John F. Dietz, Esq.
Gunderson Dettmer Stough
Villeneuve Franklin & Hachigian, LLP
155 Constitution Drive
Menlo Park, California 94025
(650) 321-2400

Approximate date of commencement of proposed sale to the public: From time to time after this Registration Statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. ý

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ý

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

CALCULATION OF REGISTRATION FEE

Title of each class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Unit	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, par value $0.01	5,200,000 shares	(1)	(1)	(1)

(1) In accordance with Rule 456(b) and 457(r) of the Securities Act of 1933, the registrant is deferring payment of all of the registration fee.

Subject To Completion
Preliminary Prospectus Dated January 30, 2006

The information in this prospectus is not complete and may be changed. This prospectus is not an offer to sell securities and it is not soliciting an offer to buy securities in any state where the offer or sale is not permitted.

P R O S P E C T U S

4,600,000 Shares

Common Stock

We are offering 4,600,000 shares of our common stock.

Our common stock is traded on The Nasdaq National Market under the symbol "THRX." The last reported sale price of our common stock on The Nasdaq National Market on January 26, 2006 was $26.99 per share.

Investing in our common stock involves risks. See "Risk Factors" on page 12 of this prospectus.

	Per Share	Total
Public offering price	$	$
Underwriting discount	$	$
Proceeds, before expenses, to us	$	$

The underwriters may also purchase up to an additional 600,000 shares of common stock from us at the public offering price, less the underwriting discounts, within 30 days from the date of this prospectus to cover overallotments.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about February , 2006.

Merrill Lynch & Co.

HSBC

Thomas Weisel Partners LLC

The date of this prospectus is February , 2006.

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You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized anyone to provide you with information that is different. The information contained or incorporated by reference in this prospectus is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus or of any sale of common stock. Our business, financial condition, results of operations and prospects may have changed since those dates. It is important for you to read and consider all information contained in this prospectus, including the documents incorporated by reference herein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you under the caption "Where You Can Find More Information" in this prospectus.

We are offering to sell, and are seeking offers to buy, the common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus must inform themselves about and observe any restrictions relating to the offering of the common stock and the distribution of this prospectus outside the United States. This prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Some of the documents referred to herein have been filed as exhibits to the registration statement of which this prospectus is a part, while others are incorporated by reference from our previously filed periodic reports or our Registration Statement on Form 8-A (Commission File No. 000-30319), filed on September 27, 2004, and amendments thereto, including their exhibits, and you may obtain copies of these documents as described below under "Where You Can Find More Information."

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere or incorporated by reference in this prospectus. This summary may not contain all the information that you should consider before investing in our common stock. You should read the entire prospectus carefully, including "Risk Factors" and the financial statements incorporated by reference in this prospectus, before making an investment decision. Unless the context otherwise requires, any reference to "Theravance," "we," "our" and "us" in this prospectus refers to Theravance, Inc., a Delaware corporation, and its subsidiaries.

Theravance, Inc.

Overview

We are 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 disorders. Of our five programs in development, two are in late stage our telavancin program focusing on treating serious Gram-positive 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. None of our products have been approved for marketing and sale to patients and we have not received any product revenue to date.

Our Programs

The following table 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.

Telavancin and our Relationship 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 $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). If telavancin is commercialized, we will be entitled to receive royalties on global sales of telavancin by Astellas that, on a percentage basis, increase 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.

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 vancomycin 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. However, we may increase the size of the cSSSI program to greater than 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. 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.

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 beta$_2$ 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 $4.0 billion of sales reported by GSK for the first nine months of 2005. Each company contributed four LABA product candidates to the collaboration, and five product candidates have either completed or are in Phase 2a clinical studies.

In connection with this collaboration, we were eligible to receive up to $495.0 million in milestones and royalties on the sales of any product resulting from this collaboration. Through September 30, 2005, we received $45.0 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 could total up to an additional $450.0 million, of which $150.0 million would be attributable to the product candidates reaching certain sales thresholds. In the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple regions of the world, we will be obligated to make payments to GSK of up to $220.0 million. Based on available information, we do not estimate that a significant portion of these potential milestone payments to GSK are likely to be made in the next three years. In addition, we are entitled to receive the same royalties on product sales of medicines from the Beyond Advair collaboration, regardless of whether the product candidate originated with us or with GSK. The royalty structure is downward tiering and would result in an average percentage royalty rates in the low to mid-teens at annual net sales up to approximately $4.0 billion and the average royalty rate would decline to single digits at annual net sales of more than $6.0 billion. Sales of single agent LABA medicines and combination LABA/ICS medicines would be combined for the purposes of this royalty calculation.

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.

2004 GSK Strategic Alliance. We entered into our strategic alliance 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, pursuant to the terms of the strategic alliance, GSK exercised its right to license our long-acting muscarinic antagonist (LAMA) program, and in March 2005, GSK exercised its right to license our bifunctional muscarinic antagonist beta2agonist (MABA) program.

COPD Programs

Long Acting Muscarinic Antagonist (LAMA)

Among the most frequently used bronchodilators for COPD are the inhaled muscarinic antagonists. 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.

In August 2004, GSK exercised its right to license our LAMA program under the strategic alliance. Accordingly, GSK is funding 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. A joint steering committee comprised of representatives of GSK and our Company is analyzing the data from these initial results and, once this analysis is complete, will provide a recommendation regarding whether or not to continue 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 Beta$_2$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 both a muscarinic antagonist and a beta$_2$ 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.

In March 2005, GSK licensed our MABA program under the strategic alliance. Accordingly, GSK is funding all development, manufacturing and commercialization activities for product candidates in this program.

MABA Status

Our lead compound in this program, GSK961081, is currently in preclinical studies. 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.

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 disorders 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.

GI Status

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.

GSK Share Ownership and Put/Call Rights

GSK currently owns all of our Class A common stock, which represented approximately 17.4% of our outstanding stock as of December 31, 2005. Under the terms of the 2004 strategic alliance, GSK's ownership of our stock could increase to approximately 60% 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 prospectus 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 prospectus 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. We are under no obligation to redeem our shares under the call or the put until we receive the necessary funds from GSK. Alternatively, if our stockholders exercise the put, GSK may choose to purchase the shares of common stock put directly from our stockholders. 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 call and put arrangements with GSK are described in detail in the "Description of Capital Stock" section of this prospectus.

Financial Update

While we are still in the process of determining final results for the fourth quarter of 2005, as of November 30, 2005, we had cash, cash equivalents and marketable securities totaling $148.1 million and in December 2005 we received a $65.0 million upfront payment from Astellas in connection with our collaboration arrangement. In addition, and consistent with previous guidance, we expect that our operating expenses, particularly research and development expense, will be significantly higher over the next several quarters than in prior periods as we move toward completion of our Phase 3 clinical studies of telavancin. We expect that our cash, cash equivalents and marketable securities, together with the proceeds of this offering, will be sufficient to meet our capital needs for at least the next 18 months.

Corporate Information

We were incorporated on November 19, 1996 under the name Advanced Medicine, Inc. In April 2002, we changed our name to Theravance, Inc. Our principal executive offices are located at 901 Gateway Boulevard, South San Francisco, California 94080, and our telephone number is (650) 808-6000. Theravance and the Theravance logo are registered trademarks of Theravance, Inc. Trademarks, tradenames or service marks of other companies appearing in this prospectus are the property of their respective owner. Our web site is www.theravance.com. Information contained on our web site does not constitute a part of this prospectus.

THE OFFERING

Common stock we are offering	4,600,000 shares
Common stock to be outstanding after this offering	49,137,694 shares
Class A common stock to be outstanding after this offering	9,401,498 shares
Use of proceeds	We intend to use the net proceeds from this offering for general corporate purposes, which may include clinical and preclinical development of existing product candidates, drug research activities and manufacture of pre-clinical, clinical and commercial drug supplies, capital expenditures and working capital. See "Use of Proceeds."
Nasdaq National Market symbol	THRX

The number of shares of our common stock and Class A common stock to be outstanding immediately after this offering is based on the number of shares outstanding as of December 31, 2005, plus the 4,600,000 shares of common stock to be issued in this offering. GSK owns all of our outstanding Class A common stock. Our Class A common stock has rights and obligations substantially the same as our common stock except that (i) our Class A common stock is not subject to the call and the put, and (ii) depending on GSK's ownership of our Class A common stock, the Class A common stock has the right to designate 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. See "Description of Capital Stock Common Stock Call and Put Arrangements with GSK Voting Rights for the Election of Directors/Board of Directors Composition."

The number of shares of our common stock and Class A common stock to be outstanding immediately after this offering does not include:

- an aggregate of 10,032,967 shares of common stock subject to outstanding options as of December 31, 2005, under our 2004 Equity Incentive Plan, 1997 Stock Plan and the Long-term Stock Option Plan, at a weighted average exercise price of $9.86 per share;
- an additional 2,728,847 shares of common stock reserved for future stock option grants or purchases as of December 31, 2005 under our 2004 Equity Incentive Plan and our Amended and Restated 2004 Employee Stock Purchase Plan; and
- 18,064 shares of common stock issuable upon exercise of outstanding warrants with a weighted average exercise price of $1.94 per share.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables present our summary consolidated statements of operations data for our fiscal years 2002 through 2004 and the nine months ended September 30, 2004 and 2005, and our summary consolidated balance sheet data as of September 30, 2005. You should read this information in conjunction with our consolidated financial statements, including the related notes, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2004 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2005. The summary consolidated balance sheet data is presented on an actual basis and as adjusted to reflect the sale of 4,600,000 shares of common stock offered by us in this offering at an assumed public offering price of $26.99 per share after deducting estimated underwriting discounts and commissions and offering expenses.

	Years Ended December 31,			Nine Months Ended September 30,	
	2002	2003	2004	2004	2005
	(in thousands, except per share amounts)				
				(unaudited)	
Consolidated Statements of Operations Data					
Revenue from related party	$ 156	$ 3,605	$ 8,940	$ 6,200	$ 8,676
Operating expenses:					
Research and development	66,481	61,704	86,996	59,694	93,654
General and administrative	11,817	12,153	19,818	15,959	16,732
Stock-based compensation(1)	4,941	2,214	8,521	6,160	3,934
Total operating expenses	83,239	76,071	115,335	81,813	114,320
Loss from operations	(83,083)	(72,466)	(106,395)	(75,613)	(105,644)
Interest and other income	4,990	3,373	4,564	2,762	5,153
Interest and other expense	(1,134)	(1,490)	(823)	(632)	(462)
Net loss	$ (79,227)	$ (70,583)	$ (102,654)	$ (73,483)	$ (100,953)
Basic and diluted net loss per share(2)	$ (12.50)	$ (10.37)	$ (3.08)	$ (2.71)	$ (1.90)
Shares used in per share calculations(2)	6,336	6,809	33,283	27,097	53,155

(1) 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	$ 3,398	$ 1,300	$ 4,631	$ 3,180	$ 2,466
General and administrative	1,543	914	3,890	2,980	1,468
Total non-cash stock-based compensation	$ 4,941	$ 2,214	$ 8,521	$ 6,160	$ 3,934

(2) Share and per share amounts for all periods reflect the effect of a one for 1.55 reverse stock split effected September 27, 2004; and, for the year ended December 31, 2004, the nine months ended September 30, 2004 and the nine months ended September 30, 2005, the conversion of all of our outstanding preferred stock into common stock as of May 11, 2004.

	As of September 30, 2005	
	Actual	As Adjusted
	(unaudited)	
Consolidated Balance Sheet Data		
Cash, cash equivalents and marketable securities	$ 172,323	$ 289,149
Working capital	136,584	253,410
Total assets	196,988	313,814
Long-term liabilities	58,384	58,384
Accumulated deficit	(569,557)	(569,557)
Total stockholders' equity (deficit)	98,177	215,003

A $1.00 increase (decrease) in the assumed public offering price of $26.99 per share would increase (decrease) the net proceeds to us from this offering by $4.3 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriter discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

You should carefully consider the risks described below before making an investment decision. You should also refer to the other information in this prospectus, including our financial statements and the related notes incorporated by reference in this prospectus. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, results of operations and financial condition could suffer. In that event the trading price of our common stock could decline, and you may lose all or part of your investment in our common stock. The risks discussed below also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements.

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 pre-clinical 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 our 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 September 30, 2005, we had an accumulated deficit of approximately $569.6 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 together with the proceeds of this offering will be sufficient to meet our anticipated operating needs for at least the next 18 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 $220.0 million under our Beyond Advair collaboration. We may also need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate. 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, after this offering

and 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 December 31, 2005, GSK beneficially owned approximately 17.4% of our outstanding capital stock, and will have the right in July 2007 to acquire up to approximately 60% of our common stock 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. 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 December 31, 2005, GSK beneficially owned approximately 17.4% 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 60% 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 realiz