THERAVANCE INC Form 10-Q November 07, 2007

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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| | | |
| | | |
| | | |

(Mark One)

| X | QUARTERLY REPORT PURSUANT TO SECTION 13 OR $15(d)$ OF THE SECURITIES |
|-------------------|--|
| EXCHANGE A | CT OF 1934 |

For the quarterly period ended September 30, 2007

OR

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

For the transition period from

to

Commission File Number: 0-30319

THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware (State or Other Jurisdiction of

Incorporation or Organization)

94-3265960

(I.R.S. Employer Identification No.)

901 Gateway Boulevard

South San Francisco, CA 94080

(Address of Principal Executive Offices including Zip Code)

(650) 808-6000

(Registrant s Telephone Number, Including Area Code)

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 x No o

Indicate by check mark whether the 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 x Accelerated Filer o Non-Accelerated Filer o

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

Yes o No x

The number of shares of registrant s common stock outstanding on October 31, 2007 was 51,505,987.

The number of shares of registrant s Class A common stock outstanding on October 31, 2007 was 9,401,499.

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PART I FINANCIAL INFORMATION

ITEM 1. Financial Statements

THERAVANCE, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

| | September 30, 2007 (Unaudited) | December 31, 2006 * |
|--|--------------------------------------|---------------------------|
| Assets | , , | |
| Current assets: | | |
| Cash and cash equivalents | \$ 78,860 | \$ 72,388 |
| Marketable securities | 58,678 | 128,692 |
| Receivable from related party | 98 | 608 |
| Notes receivable | 437 | 1,142 |
| Prepaid and other current assets | 6,363 | 4,361 |
| Total current assets | 144,436 | 207,191 |
| Marketable securities | 28,983 | 34,490 |
| Restricted cash and cash equivalents | 3,810 | 3,860 |
| Property and equipment, net | 19,847 | 15,101 |
| Notes receivable | 1,547 | 1,782 |
| Total assets | \$ 198,623 | \$ 262,424 |
| Liabilities and stockholders equity (deficit) | | |
| Current liabilities: | | |
| Accounts payable | \$ 5,954 | ,- |
| Accrued personnel-related expenses | 10,597 | 8,316 |
| Accrued clinical and development expenses | 14,952 | 13,608 |
| Other accrued liabilities | 2,795 | 2,314 |
| Current portion of notes payable | 98 | 87 |
| Current portion of deferred revenue | 22,740 | 19,273 |
| Total current liabilities | 57,136 | 59,609 |
| Deferred rent | 2,085 | 2,298 |
| Notes payable | 462 | 538 |
| Deferred revenue | 171,544 | 134,383 |
| Other long term liabilities | 8,281 | 2,286 |
| Commitments and contingencies | | |
| Stockholders equity (net capital deficiency): | | |
| Preferred stock, \$0.01 par value, 230 shares authorized, no shares issued and outstanding | | |
| Common stock, \$0.01 par value; 200,000 shares authorized, issuable in series; 51,461 | | |
| and 50,746 shares issued and outstanding at September 30, 2007 and December 31, | | |
| 2006, respectively | 514 | 507 |
| Class A Common Stock, \$0.01 par value, 30,000 shares authorized, 9,402 issued and | | |
| outstanding at September 30, 2007 and December 31, 2006 | 94 | 94 |
| Additional paid-in capital | 863,177 | 840,498 |
| Notes receivable from stockholders | | (3) |
| Accumulated other comprehensive income | 81 | 26 |
| Accumulated deficit | (904,751) | (777,812) |
| Total stockholders equity (net capital deficiency) | (40,885) | 63,310 |
| Total liabilities and stockholders equity (net capital deficiency) | \$ 198,623 | |

* Condensed consolidated balance sheet at December 31, 2006 has been derived from audited consolidated financial statements.

See accompanying notes to condensed consolidated financial statements.

THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data) (Unaudited)

| | Three Mor Septem | | Nine Months E September 3 | | |
|--|---------------------|-------------------|------------------------------|----|-----------|
| | 2007 | 2006 | 2007 | | 2006 |
| Revenue (1) | \$ 5,669 | \$ 5,524 \$ | 16,372 | \$ | 14,657 |
| Operating expenses: | | | | | |
| Research and development | 31,964 | 39,103 | 124,319 | | 128,562 |
| General and administrative | 8,462 | 7,868 | 26,772 | | 24,041 |
| Total operating expenses | 40,426 | 46,971 | 151,091 | | 152,603 |
| | | | | | |
| Loss from operations | (34,757) | (41,447) | (134,719) | | (137,946) |
| | | | | | |
| Interest and other income | 2,438 | 3,875 | 8,059 | | 10,234 |
| Interest and other expense | (45) | (208) | (279) | | (495) |
| Net loss | \$ (32,364) | \$ (37,780) \$ | (126,939) | \$ | (128,207) |
| Basic and diluted net loss per common share | \$ (0.53) | \$ (0.63) \$ | (2.10) | \$ | (2.18) |
| | | | | | |
| Shares used in computing net loss per common | | | | | |
| share | 60,664 | 59,762 | 60,384 | | 58,702 |

⁽¹⁾ Revenue includes amounts from GSK, a related party, of \$2,824 and \$8,473 for the three and nine months ended September 30, 2007, respectively, and \$3,381 and \$9,741 for the three and nine months ended September 30, 2006, respectively.

See accompanying notes to condensed consolidated financial statements.

THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands) (Unaudited)

| | Nine Months Ended Sep 2007 | otember 30, 2006 | | |
|---|-------------------------------|---------------------|--|--|
| Cash flows used in operating activities | | | | |
| Net loss | \$ (126,939) \$ | (128,207) | | |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Depreciation and amortization | 2,525 | 2,695 | | |
| Stock-based compensation | 17,167 | 16,484 | | |
| Forgiveness (net cancellation) of notes receivable | (6) | 42 | | |
| Other | (562) | 476 | | |
| Changes in operating assets and liabilities: | | | | |
| Receivables, prepaid and other current assets | 1,817 | 586 | | |
| Accounts payable and accrued liabilities | (11,213) | 1,740 | | |
| Accrued personnel-related expenses | 2,281 | 521 | | |
| Deferred rent | (213) | 34 | | |
| Deferred revenue | 40,628 | 30,342 | | |
| Other long-term liabilities | 6,011 | 1,290 | | |
| Net cash used in operating activities | (68,504) | (73,997) | | |
| Cash flows provided by (used in) investing activities | | | | |
| Purchases of property and equipment | (7,565) | (4,157) | | |
| Purchases of marketable securities | (78,732) | (181,545) | | |
| Maturities of marketable securities | 100,945 | 105,924 | | |
| Sales of marketable securities | 53,888 | 45,377 | | |
| Release of restricted cash | 50 | | | |
| Additions to notes receivable | (250) | (850) | | |
| Payments received on notes receivable | 1,165 | 392 | | |
| Net cash provided by (used in) investing activities | 69,501 | (34,859) | | |
| Cash flows provided by financing activities | | | | |
| Payments on notes payable and capital leases | (65) | (766) | | |
| Net proceeds from issuances of common stock | 5,540 | 145,565 | | |
| Net cash provided by financing activities | 5,475 | 144,799 | | |
| Net increase in cash and cash equivalents | 6,472 | 35,943 | | |
| Cash and cash equivalents at beginning of period | 72,388 | 49,787 | | |
| Cash and cash equivalents at end of period | \$ 78,860 \$ | 85,730 | | |
| Supplemental disclosures of cash flow information | | | | |
| Non-cash financing activity: | | | | |
| Removal of deferred stock-based compensation | \$ \$ | (4,965) | | |

See accompanying notes to condensed consolidated financial statements.

Theravance, Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2007

(Unaudited)

1. Basis of Presentation and Significant Accounting Policies

Unaudited Interim Financial Statements

The accompanying unaudited condensed consolidated financial statements of Theravance, Inc. (the Company) have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of the Company s management, the unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary for the fair presentation of the Company s financial position at September 30, 2007, the results of operations for the three and nine months ended September 30, 2007 and 2006 and the cash flows for the nine months ended September 30, 2007 and 2006. The results for the three and nine months ended September 30, 2007 are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2007 or any other period.

The condensed consolidated balance sheet at December 31, 2006 has been derived from audited consolidated financial statements, which are contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2006 filed with the Securities and Exchange Commission (SEC) on March 1, 2007 (2006 10-K). The accompanying condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the 2006 10-K.

Use of Management s Estimates

The preparation of condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates based upon current assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual conditions may differ materially from the Company s current assumptions. This may result in the Company s estimates being incorrect and may require it to record adjustments to its financial position, results of operations or cash flows.

Segment Reporting

The Company has determined that it operates in only one segment, which is the research and development of human therapeutics. Revenues are primarily generated from collaborations with the Company s partners located in the United Kingdom and Japan. All long-lived assets are maintained in the United States.

Inventory

Inventory is stated at the lower of cost or market and is included with prepaid and other current assets. Inventory consists of \$3.8 million of commercial launch supplies of the Company s product candidate telavancin which is currently awaiting regulatory approval. Under the Company s 2005 License, Development and Commercialization Agreement with Astellas Pharma Inc. (Astellas), the Company is responsible to deliver to Astellas approximately six months of first commercial sale stock (as defined) in anticipation of the regulatory approval and commercialization of telavancin. If the Company s product candidate is approved by the J.S. Food and Drug Administration (FDA), the inventory costs would be reimbursed through a milestone payment required under the agreement.

If the regulatory approval of the Company s product candidate is significantly delayed or denied by the necessary regulatory bodies, or if new information becomes available that suggests that the inventory will not be realisable, the Company may be required to expense a portion or all of the capitalized inventory costs. The amount that may be expensed may be partially offset by reimbursement through alternative arrangements with Astellas under terms of the Company s collaboration agreement. During the three months ended September 30, 2007, the Company expensed approximately \$0.9 million of its previously capitalized inventory as it was determined to not be realisable for commercial launch supplies. This inventory, however, may be used to support future clinical trial activity.

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Bonus Accruals

The Company has short-and long-term bonus programs for certain eligible employees. Bonuses are determined based on various criteria, including the achievement of corporate, departmental and individual goals. Bonus accruals are estimated based on various factors, including target bonus percentages per level of employee and probability of achieving the goals upon which bonuses are based. The Company s management periodically reviews the progress made towards the goals under the bonus programs. As bonus accruals are dependent upon management s judgments of the likelihood of achieving the various goals, in some cases over a period of time in excess of twelve months, it is possible for bonus expense to vary significantly in future periods if changes occur in those management estimates. During the nine months ended September 30, 2007, the Company recorded an increase in bonus expense and related accrual for non-officer employees of \$8.5 million related to the achievement of the last clinical milestone under a long-term bonus plan established in 2004, which included the effect of a change in estimate of \$7.1 million. As of September 30, 2007, the Company had fully accrued its bonus liability of approximately \$12.4 million relating to its long-term bonus program, which ended in September 2007. The amounts accrued are scheduled to be paid to the employees in December of 2007, 2008 and 2009.

Fair Value of Share-based Payment Awards

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

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

Recent Accounting Pronouncements

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

In February 2007, the Financial Accounting Standards Board (FASB) issued Statement on Financial Accounting Standards No. 159, The Fair Value Option for Financial Assets and Financial Liabilities (SFAS 159). SFAS 159 permits companies to make a one-time election to carry eligible types of financial assets and liabilities at fair value, even if fair value measurement is not required under U.S. GAAP. SFAS 159 is effective for the Company beginning in the first quarter of fiscal year 2008. The Company is currently evaluating the impact of the provisions of SFAS 159 on its financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and

expands disclosures about fair value measurements. SFAS 157 is effective for the Company beginning in the first quarter of fiscal year 2008. The Company is currently evaluating the impact of the provisions of SFAS 157 on its financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

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

Reclassification of Prior Year Amounts

Certain prior year amounts related to the classification of marketable securities in the condensed consolidated statement of cash flows and accrued interest related to notes receivable have been reclassified to conform to the current period s presentation. These reclassifications had no impact on previously reported results of operations or stockholders equity.

2. Net Loss per Share

Basic net loss per common share (Basic EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding, less shares subject to repurchase. Diluted net loss per common share (Diluted EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding, less shares subject to repurchase, plus dilutive potential common shares and shares subject to repurchase. At September 30, 2007, potential common shares consist of approximately 11,450,000 shares issuable upon the exercise of stock options, approximately 2,000,000 shares issuable under performance-contingent restricted stock unit awards and 18,000 shares issuable upon the exercise of a warrant. (The outstanding warrant was not exercised as of its expiration date of October 5, 2007 and therefore no stock was or will be issued under the warrant.) At September 30, 2006, potential common shares consist of approximately 10,620,000 shares issuable upon the exercise of stock options and 18,000 shares issuable upon the exercise of a warrant. Diluted EPS is identical to Basic EPS for all periods presented since potential common shares are excluded from the calculation, as their effect is anti-dilutive.

| | Three Mo Septen | | Nine Mon Septem | | |
|---|--------------------|-------------------|--------------------|----|-----------|
| (in thousands, except for per share amounts) | 2007 | 2006 | 2007 | | 2006 |
| Basic and diluted: | | | | | |
| Net loss | \$ (32,364) | \$ (37,780) \$ | (126,939) | \$ | (128,207) |
| | | | | | |
| Weighted average shares of common stock outstanding | 60,724 | 59,927 | 60,468 | | 58,883 |
| Less: weighted average shares subject to repurchase | (60) | (165) | (84) | | (181) |
| Weighted average shares used in computing basic and | | | | | |
| diluted net loss per common share | 60,664 | 59,762 | 60,384 | | 58,702 |
| Basic and diluted net loss per common share | \$ (0.53) | \$ (0.63)\$ | (2.10) | \$ | (2.18) |

3. Collaboration and Licensing Agreements

2002 Beyond Advair Collaboration with GSK

In November 2002, the Company entered into its Beyond Advair collaboration agreement with GlaxoSmithKline plc (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.

As of September 30, 2007, the Company has received upfront and milestone payments from GSK of \$60.0 million related to the clinical progress of its candidates, and could receive up to \$445.0 million in remaining milestones allocated as follows: up to \$75.0 million related to the achievement of certain clinical milestones by a Theravance-discovered LABA, up to \$220.0 million related to approval and launch of a product containing a Theravance-discovered LABA in multiple regions in the world, and up to \$150.0 million related to the achievement of certain sales

thresholds by a Theravance-discovered LABA. In the event that a LABA product candidate discovered by GSK is successfully developed and commercially launched in multiple locations of the world, the Company will be obligated to make payments to GSK of up to \$220.0 million. Based on available information, the Company does 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, the Company is entitled to receive the same royalties on product sales of medicines from the Beyond Advair collaboration, regardless of whether the product candidate originated with Theravance or with GSK. The royalty structure is downward tiering and would result in an average percentage royalty rate in the low- to mid-teens at annual net sales of up to approximately \$4.0 billion and the average royalty rate would decline to single digits at annual net sales of more than \$6.0 billion. Sales of single-agent LABA medicines and combination LABA/ICS medicines would be combined for the purposes of this royalty calculation.

The Company recorded the upfront and milestone payments as deferred revenue and they are being amortized ratably over the Company s estimated period of performance (the product development period). Collaboration revenue was \$1.7 million and \$2.2 million for the three months ended September 30, 2007 and 2006, respectively, and \$5.1 million and \$6.2 million for the nine months ended September 30, 2007 and 2006, respectively. Subsequent development milestones will be recorded as deferred revenue when received and amortized over the remaining period of performance during the development period. Additionally, certain costs related to the collaboration are reimbursable by GSK as an offset to research and development expense. For each of the three and nine months ended September 30, 2007 and 2006, reimbursable costs related to the collaboration were not material.

2004 Strategic Alliance with GSK

In March 2004, the Company entered into its strategic alliance with GSK for the development and commercialization of product candidates in a variety of therapeutic areas. In connection with the strategic alliance, the Company received a \$20.0 million payment from GSK in May 2004. This payment is being amortized over the initial period during which GSK may exercise its right to license certain of its programs under the agreement, which the Company currently estimates to be through September 2011. In addition, in May 2004, an affiliate of GSK purchased approximately 6.4 million shares of the Company s Class A common stock for \$108.9 million. Pursuant to a partial exercise of its rights under the agreement, upon the closing of the Company s initial public offering in October 2004, GSK purchased an additional 433,757 shares of Class A common stock for \$6.9 million.

The alliance provides GSK with an option to license product candidates from the Company s full drug discovery programs initiated prior to September 1, 2007 on pre-determined terms and on an exclusive, worldwide basis. Upon licensing a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. Consistent with the Company s strategy, the Company is obligated at its sole cost to discover two structurally different product candidates for any programs that are licensed by GSK under the alliance. If these programs are successfully advanced through development by GSK, the Company is entitled to receive clinical, regulatory and commercial milestone payments based on performance and royalties on any sales of medicines developed from these programs. The royalty structure for a product containing one of the Company s compounds as a single active ingredient in the programs licensed to date by GSK would result in an average percentage royalty rate in the low double digits. If a product is successfully commercialized, in addition to any royalty revenue the Company receives, the total upfront and milestone payments that the Company could receive in any given program that GSK licenses range from \$130.0 million to \$162.0 million for programs with single-agent medicines and up to \$252.0 million for programs with both a single-agent and a combination medicine. To date, GSK has licensed the Company s two COPD programs: LAMA and MABA.

In August 2004, GSK exercised its right to license the Company s long-acting muscarinic antagonist program (LAMA) pursuant to the terms of the strategic alliance. The Company received a \$5.0 million payment from GSK in connection with the licensing of this program. Through September 30, 2007, the Company received a milestone payment of \$3.0 million from GSK related to clinical progress of its candidate. These payments are amortized ratably over the estimated period of performance (the product development period). The Company recognized \$0.2 million and \$0.3 million for the three months ended September 30, 2007 and 2006, respectively, and \$0.6 million and \$0.9 million for the nine months ended September 30, 2007 and 2006, respectively, in revenue related to the LAMA program. Additionally, the Company is reimbursed by GSK for certain costs related to the LAMA program as an offset to research and development expense. For the three and nine months ended September 30, 2007 and 2006, reimbursable costs were not material.

In March 2005, GSK exercised its right to license the Company s muscarinic antagonist-beta2 agonist (MABA) program pursuant to the terms of the strategic alliance. The Company received a \$5.0 million payment from GSK in connection with the license of the Company s MABA program. Through September 30, 2007, the Company received a milestone payment of \$3.0 million from GSK related to clinical progress of its candidate. This payment is being amortized

ratably over the estimated period of performance (the product development period). Collaboration revenue related to the MABA program was \$0.3 million for each of the three months ended September 30, 2007 and 2006, respectively, and \$0.8 million and \$0.7 million for the nine months ended September 30, 2007 and 2006, respectively. Additionally, the Company is reimbursed by GSK for certain costs related to the MABA program as an offset to research and development expense. Reimbursements for the three and nine months ended September 30, 2007 and 2006 were not material.

In September 2007, the Company announced that it retained full ownership rights of its GI Motility Dysfunction program as a result of GSK s decision not to exercise its right to license the program under the strategic alliance. The Company is currently reviewing plans for the future development of this program.

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

2005 License, Development and Commercialization Agreement with Astellas

In November 2005, the Company entered into a collaboration arrangement with Astellas for the development and commercialization of telavancin. In July 2006, the Company and Astellas agreed to add Japan to their telavancin collaboration, thereby giving Astellas worldwide rights to this potential medicine. Through September 30, 2007, the Company had received \$158.0 million in upfront, milestone and other fees from Astellas, which are being amortized ratably over the estimated period of performance (the estimated development and commercialization period). The Company recognized \$2.8 million and \$1.9 million in revenue for the three months ended September 30, 2007 and 2006, respectively, and \$7.5 million and \$4.6 million for the nine months ended September 30, 2007 and 2006, respectively. As of September 30, 2007, the Company was eligible to receive up to \$70.0 million in remaining clinical and regulatory milestone payments, which includes up to \$60.0 million related to regulatory filings and approvals in various regions of the world and \$10.0 million if the FDA determines telavancin s superiority over vancomycin for hospital-acquired pneumonia (HAP) patients infected with methicillin-resistant *Staphylococcus aureus* (MRSA).

In August 2007, the Company received a \$25.0 million milestone payment from Astellas after the last clinical visit (test of cure) by the last patient in the HAP Phase 3 program.

If telavancin is commercialized, the Company will be entitled to receive royalties on global sales of telavancin by Astellas that, on a percentage basis, range from the high teens to the upper twenties depending on sales volume. Under this arrangement, the Company will be responsible for substantially all costs to develop and obtain U.S. regulatory approval for telavancin for complicated skin and skin structure infections (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 had an option to license TD-1792, the Company s investigational antibiotic, for further development and commercialization on substantially the same terms under which Astellas licensed telavancin. In September 2007, the Company announced that it retained full ownership rights of TD-1792 as a result of Astellas decision not to exercise its right to license the compound. The Company is currently reviewing plans for the future development of TD-1792.

2006 License Agreement with AstraZeneca AB

In May 2006, the Company entered into a license agreement with AstraZeneca AB (AstraZeneca) pursuant to which it granted an exclusive, worldwide license to AstraZeneca to develop and commercialize the Company s intravenous anesthetic compound TD-4756 for which the Company received a \$1.0 million upfront payment. In addition, the Company is eligible to receive milestone payments and royalties on global sales. Through September 30, 2007, the Company had fully recognized the upfront payment as revenue (\$0.4 million and \$0.6 million in 2007 and 2006, respectively), due to the completion of its performance obligations under the contract.

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4. Marketable Securities

The Company invests in a variety of highly liquid investment-grade securities. The following is a summary of the Company s available-for-sale securities at September 30, 2007:

| | Amortized | | | | oer 30, 2007 Gross Unrealized | Estimated |
|--|-----------|----------|----|------|-------------------------------------|--------------|
| (in thousands) | | Cost | G | ains | Losses | Fair Value |
| U.S. government agencies | \$ | 32,197 | \$ | 48 | \$ | \$ 32,245 |
| U.S. corporate notes | | 28,489 | | 19 | (6) | 28,502 |
| U.S. commercial paper | | 67,456 | | | | 67,456 |
| Asset-backed securities | | 26,894 | | 29 | (9) | 26,914 |
| Certificates of deposit | | 60 | | | | 60 |
| Money market funds | | 15,154 | | | | 15,154 |
| Total | | 170,250 | | 96 | (15) | 170,331 |
| | | | | | | |
| Less amounts classified as cash and cash equivalents | | (78,860) | | | | (78,860) |
| Less amounts classified as restricted cash | | (3,810) | | | | (3,810) |
| Amounts classified as marketable securities | \$ | 87,580 | \$ | 96 | \$ (15) | \$ 87,661 |

The estimated fair value amounts have been determined by the Company using available market information. At September 30, 2007, approximately 63% of marketable securities have contractual maturities within twelve months, 13% of marketable securities have contractual maturities between twelve and twenty-four months and the remaining 24% have contractual maturities beyond twenty-four months. Average duration of available-for-sale securities was approximately 6 months at September 30, 2007. The Company has determined that the gross unrealized losses on its marketable securities at September 30, 2007 were temporary in nature.

5. Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income, which consists of net unrealized gains and losses on the Company s available-for-sale securities. The components of comprehensive loss are as follows:

| | Three Months Ended September 30, | | | Nine Month Septembe | ed | | |
|--|-------------------------------------|----------|----|------------------------|-----------|----|-----------|
| (in thousands) | | 2007 | | 2006 | 2007 | | 2006 |
| Net loss | \$ | (32,364) | \$ | (37,780) \$ | (126,939) | \$ | (128,207) |
| Other comprehensive income: | | | | | | | |
| Net unrealized gain on available-for-sale securities | | 47 | | 455 | 55 | | 466 |
| Comprehensive loss | \$ | (32,317) | \$ | (37,325) \$ | (126,884) | \$ | (127,741) |

6. Commitments

Guarantees and Indemnifications

The Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recognized any liabilities relating to these agreements as of September 30, 2007.

Purchase Obligations

At September 30, 2007, the Company had outstanding purchase obligations, primarily for services from contract research and manufacturing organizations, totaling \$3.5 million.

7. Stockholders Equity

Determining Fair Value of Stock-Based Compensation

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

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

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|--|-------------------------------------|----|------------|------------------------------------|------------|--|
| | 2007 | | 2006 | 2007 | 2006 | |
| Employee stock options | | | | | | |
| Risk-free interest rate | 4.20-4.74% | | 4.67-4.98% | 4.20-5.03% | 4.57-5.16% | |
| Expected life (in years) | 5.52-6.08 | | 6.08-6.10 | 5.29-6.08 | 5.55-6.17 | |
| Volatility | 0.46-0.48 | | 0.51 | 0.46-0.48 | 0.51 | |
| Dividend yield | c, | 6 | % | % | % | |
| Weighted average fair value of stock options granted | \$ 14.98 | \$ | 13.39 \$ | 16.85 \$ | 15.61 | |
| | | | | | | |
| Employee stock purchase plan issuances | | | | | | |
| Risk-free interest rate | 4.95-4.98% | | 4.97-5.00% | 4.95-4.98% | 2.58-5.00% | |
| Expected life (in years) | 0.50-2.00 | | 0.50-2.00 | 0.50-2.00 | 0.50-2.11 | |
| Volatility | 0.26-0.30 | | 0.30-0.38 | 0.26-0.30 | 0.30-0.70 | |
| Dividend yield | c, | 6 | % | % | % | |
| Weighted average fair value of ESPP issuances | \$ 9.96 | \$ | 8.07 \$ | 9.96 \$ | 9.01 | |

As of September 30, 2007, there was \$45.2 million of total unrecognized compensation cost related to unvested stock options. This cost is expected to be recognized over a weighted-average period of approximately 2.85 years. The Company has not recognized, and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation costs as a result of the full valuation allowance on the Company s net deferred tax assets including deferred tax assets related to its net operating loss carryforwards.

Stock-based compensation expense consists of the compensation cost for employee share-based awards, including restricted stock, and the value of options issued to non-employees for services rendered. The following table discloses the allocation of stock-based compensation expense included in the unaudited condensed consolidated statements of operations:

| | Three Months E September 30 | Nine Months Ended September 30, | | | |
|----------------------------|--------------------------------|------------------------------------|--------|----|--------|
| (in thousands) | 2007 | 2006 | 2007 | | 2006 |
| Research and development | \$ 3,514 \$ | 3,042 \$ | 10,078 | \$ | 9,378 |
| General and administrative | 2,359 | 1,674 | 7,089 | | 7,106 |
| Total | \$ 5,873 \$ | 4,716 \$ | 17,167 | \$ | 16,484 |

Stock Option Plans

During the nine months ended September 30, 2007, the Company granted stock options to purchase 1,954,456 shares at an average exercise price of \$32.71 per share and granted 2,015,827 performance-contingent restricted stock unit awards (RSUs) whose weighted-average fair value was \$32.63 per share, under the 2004 Equity Incentive Plan, as amended (the Plan). On April 25, 2007, an amendment to the Plan which, among other things, increased the number of shares authorized for issuance under the Plan from 3,700,000 to 7,200,000 shares, was approved by the Company s stockholders. As of September 30, 2007, total shares remaining available for issuance under the Plan were 796,358.

The RSUs granted to date have dual triggers of vesting based upon the successful achievement of certain clinical development milestones during 2008 and 2009, as well as a requirement for continued employment through 2009 and 2010. The issuance of shares underlying the RSUs would occur, if at all, during 2009 and 2010. Expense associated with RSUs would be recognized, if at all, during 2007 through 2009, depending on the probability of meeting the

performance conditions. The maximum potential expense associated with the RSUs could be up to approximately \$66.0 million (allocated as \$39.0 million for research and development expense and \$27.0 million for general and administrative expense) if all of the milestones are successfully achieved on time. As of September 30, 2007, the Company had determined that none of the requisite performance conditions were probable and as a result, no compensation expense has been recognized. As vesting of the RSUs is dependent upon the successful achievement of the performance conditions, the expense associated with the RSUs may vary significantly from period to period.

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

| | Number of Shares Available for Grant (In | Number of Shares Subject to Outstanding Options and Other Awards thousands, except p | Weighted-Average Exercise Price of Outstanding Options and Fair Value of Other Awards per Share | |
|-----------------------------------|--|--|---|-------|
| Balance at December 31, 2006 | 1,070 | 10,390 | \$ | 12.92 |
| Options granted | (828) | 828 | \$ | 34.05 |
| Options exercised | | (118) | \$ | 5.44 |
| Options forfeited | 39 | (39) | \$ | 21.68 |
| Balance at March 31, 2007 | 281 | 11,061 | \$ | 14.55 |
| Additional shares authorized | 3,500 | | \$ | |
| Options granted | (647) | 647 | \$ | 33.63 |
| RSUs granted | (1,842) | 1,842 | \$ | 33.25 |
| Options exercised | | (336) | \$ | 6.22 |
| Options and RSUs forfeited | 105 | (105) | \$ | 26.51 |
| Balance at June 30, 2007 | 1,397 | 13,109 | \$ | 18.24 |
| Options granted | (479) | 479 | \$ | 29.15 |
| RSUs and restricted stock awarded | (224) | 174 | \$ | 26.10 |
| Options exercised | | (210) | \$ | 7.65 |
| Options and RSUs forfeited | 102 | (102) | \$ | 23.65 |
| Balance at September 30, 2007 | 796 | 13,450 | \$ | 18.85 |

No options were granted with exercise prices less than fair value of common stock on the date of grant during the nine months ended September 30, 2007 or the year ended December 31, 2006.

The total intrinsic value of the options exercised during the three months ended September 30, 2007 and 2006 was \$4.5 million and \$2.8 million, respectively, and the total fair value of options vested was \$26.8 million and \$0.7 million for the three months ended September 30, 2007 and 2006, respectively. The total intrinsic value of the options exercised during the nine months ended September 30, 2007 and 2006 was \$16.6 million and \$15.4 million, respectively, and the total fair value of options vested was \$28.0 million and \$4.3 million for the nine months ended September 30, 2007 and 2006, respectively. For the three and nine months ended September 30, 2007, the fair value of options vested was significantly higher when compared to the 2006 periods due to the unusual number of options that vested at the expiration of the put period in September of 2007.

As of September 30, 2007, all outstanding options to purchase common stock of the Company are summarized in the following table (in thousands, except years and per share data):

| | | | Options Ou | tstanding | | (| Option | ns Exercisabl | e |
|----------------------|---------|---|--|--|-------------------------------|------------------------------------|--------|--------------------------------|--|
| rcise Price Share | | Number of Shares Subject to Outstanding Options | Weighted- Average Remaining Contractual Life | Number of Shares Subject to Options Unvested | ggregate ntrinsic Value | Number of Shares Exercisable | | ggregate Intrinsic Value | Weighted- Average Remaining Contractual Life |
| \$ 1.32 | | 46 | 2.17 | | | 46 | | | 2.17 |
| \$ 3.10 | | 1,253 | 5.67 | 71 | | 1,252 | | | 5.63 |
| \$ 8.53 | | 2,685 | 4.06 | | | 2,685 | | | 4.06 |
| \$ 9.69 | | 1,905 | 6.11 | 973 | | 940 | | | 5.84 |
| \$ 12.40 | \$18.25 | 1,231 | 7.09 | 533 | | 765 | | | 7.04 |
| \$ 18.26 | \$21.70 | 932 | 7.45 | 380 | | 553 | | | 7.36 |
| \$ 21.71 | \$29.65 | 1,683 | 8.48 | 1,079 | | 604 | | | 8.00 |
| \$ 29.66 | \$35.46 | 1,715 | 9.42 | 1,534 | | 180 | | | 9.22 |
| | | 11,450 | 6.62 | 4,570 | \$ 127,259 | 7,025 | \$ | 104,261 | 5.61 |

Employee Stock Purchase Plan

Through September 30, 2007, the Company issued 392,317 shares under the 2004 Employee Stock Purchase Plan (ESPP) at an average price of \$15.50 per share. The total number of remaining shares available for issuance under the plan at September 30, 2007 was 232,683. The total stock-based compensation expense recognized related to the ESPP under SFAS 123(R) for the three and nine months ended September 30, 2007 was \$0.3 million and \$1.1 million, respectively, and \$0.3 million and \$1.2 million for the three and nine months ended September 30, 2006, respectively.

Reserved Shares

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

| | September 30, 2007 |
|---|-----------------------|
| Subject to outstanding warrant | 18 |
| Stock option plans: | |
| Subject to outstanding options and RSUs | 13,450 |
| Available for future grants | 796 |
| Available for future ESPP purchases | 233 |
| Total | 14,497 |

The outstanding warrant at September 30, 2007 was not exercised as of its expiration date of October 5, 2007 and therefore no stock was or will be issued under the warrant.

Restricted Stock

During the three months ended September 30, 2007, the Compensation Committee of the Company s Board of Directors approved an award of 50,000 shares of restricted common stock to a member of the Company s senior management. These restricted shares of stock vest based on continued service, with 33.3% of the shares vesting on July 30, 2010 and 33.3% of the shares vesting upon each of the next two anniversaries of such date. The Company valued the award at \$1.3 million and will amortize that amount over the service period. The value of the restricted common stock award was based on the closing market price of the Company s common stock of \$26.10 on the date of award. Stock-based compensation expense related to this award for the three months ended September 30, 2007 was \$43,000.

In March 2005, the Company s Board of Directors approved the grant of 50,000 shares of restricted stock to a member of the Company s senior management. These restricted shares of stock vest based on continued service, with 50% of the shares vesting following the expiration of stockholders put rights which occurred in September 2007, and 25% of the shares vesting upon each of the next two anniversaries of such date. The value was based on the closing market price of the Company s common stock of \$17.91 on the date of award. The Company recognized stock-based compensation expense of \$51,000 and \$168,000 related to this award for the nine months ended September 30, 2007 and 2006, respectively. In September 2007, upon the vesting of the 25,000 common shares, 16,063 common shares were issued to the officer and the remaining 8,937 common shares were withheld by the Company to satisfy the officer s tax withholding requirements of approximately \$250,000.

8. Related Party Transactions

Related Parties

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

Robert V. Gunderson, Jr. is a director of the Company. The Company has engaged Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, of which Mr. Gunderson is a partner, as its primary legal counsel. Fees totaling \$0.5 million and \$0.4 million were incurred in the ordinary course of business for the nine months ended September 30, 2007 and 2006, respectively.

Notes Receivable

The Company has provided loans to certain of its employees primarily to assist them with the purchase of a primary residence, which collateralizes the resulting loans. Interest receivable was approximately \$27,000 and \$24,000 for the periods ended September 30, 2007 and December 31, 2006, respectively, and is included in prepaid and other current assets. The Company accrues interest on the notes at rates of up to 8.0%. The outstanding loans at September 30, 2007 had maturity dates ranging from October 2007 through July 2012.

9. Income Taxes

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

Under FIN 48, the Company has unrecognized tax benefits of \$26.7 million as of January 1, 2007. If the Company is eventually able to recognize these uncertain positions, \$26.7 million of the unrecognized benefit would reduce its effective tax rate. The Company currently has a full valuation allowance against its net deferred tax asset which would impact the timing of the effective tax rate benefit should any of these uncertain tax positions be favorably settled in the future.

The Company is subject to federal and state examination for years 1996 and forward, by virtue of the tax attributes carrying forward from those years. There are no tax examinations currently in progress.

10. Subsequent Event

On October 22, 2007, the Company announced that the FDA issued an approvable letter for telavancin, a novel bactericidal, once-daily injectable antibiotic discovered by Theravance, for the treatment of cSSSI caused by Gram-positive bacteria, including resistant pathogens such as MRSA. Telavancin is the subject of the Company s collaboration with Astellas (see Note 3 above).

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Statements

The information in this discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements are based upon current expectations that involve risks and uncertainties. Any statements contained herein that are not of historical fact, including, without limitation, statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, goals and objectives, may be forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, projects, 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 may differ significantly from the results discussed in the forward-looking statements we make. Factors that might cause such a discrepancy include, but are not limited to those discussed below in Risk Factors in Item 1A of Part II and in the subsection entitled Liquidity and Capital Resources in this Item 2. All forward-looking statements in this document are based on information available to us as of the date hereof and we assume no obligation to update any such forward-looking statements.

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, four are in late stage our telavancin program focusing on treating serious Gram-positive bacterial infections in collaboration with Astellas Pharma Inc. (Astellas), our Gastrointestinal Motility Dysfunction program, our Beyond Advair collaboration with GlaxoSmithKline plc (GSK) and TD-1792, our investigational antibiotic for the treatment of serious Gram-positive infections. 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 September 30, 2007, we had an accumulated deficit of \$904.8 million. In December 2006, we submitted our first new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for telavancin for the treatment of complicated skin and skin structure infections (cSSSI) and we received an approvable letter from the FDA for the telavancin NDA in October 2007. None of our product candidates have been approved for marketing and sale and we have not received any product revenue to date. Most of our spending to date has been for research and development activities and general and administrative expenses. We expect to incur substantial losses for at least the next several years as we continue to invest in research and development.

Our net loss for the three months ended September 30, 2007 was \$32.4 million compared to \$37.8 million during the same period of 2006, or a 14% decrease. Revenue recognized under our collaboration agreements increased by 3% when compared to the same period of 2006. For the three months ended September 30, 2007, research and development costs decreased by 18% while general and administrative costs increased by 8% when compared to the same period of 2006. Cash, cash equivalents and marketable securities totaled \$166.5 million at September 30, 2007, a decrease of \$69.1 million since December 31, 2006. This decrease was primarily due to the net usage of cash in operations, offset by the receipt of \$57.0 million from Astellas during the nine months ended September 30, 2007.

Following are updates on the progress of our clinical programs as of October 31, 2007:

Bacterial Infections Programs

Telavancin

During October, we announced that the FDA issued an approvable letter for telavancin for the treatment of cSSSI caused by Gram-positive bacteria, including resistant pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA). The FDA letter indicated that the telavancin application is approvable, subject to: resolution