THERAVANCE INC
Form 10-Q
May 05, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2010

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	**94-3265960**
(State or Other Jurisdiction of Incorporation or Organization)	(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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company 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 April 30, 2010 was 63,761,505.

The number of shares of registrant s Class A common stock outstanding on April 30, 2010 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)

	March 31, 2010 (Unaudited)	December 31, 2009 *
Assets		
Current assets:		
Cash and cash equivalents	$ 109,923	$ 47,544
Marketable securities	115,525	107,846
Receivable from related party	16	274
Notes receivable	448	144
Prepaid and other current assets	6,237	6,234
Total current assets	232,149	162,042
Restricted cash	1,310	1,310
Property and equipment, net	11,881	12,927
Notes receivable	630	947
Other long-term assets	3,960	4,167
Total assets	$ 249,930	$ 181,393
Liabilities and stockholders net capital deficiency		
Current liabilities:		
Accounts payable	$ 1,999	$ 1,792
Accrued personnel-related expenses	4,133	6,314
Accrued clinical and development expenses	2,449	1,805
Other accrued liabilities	4,003	5,129
Current portion of note payable and capital lease	191	184
Current portion of deferred revenue	22,801	23,722
Total current liabilities	35,576	38,946
Convertible subordinated notes	172,500	172,500
Deferred rent	709	851
Notes payable and capital lease	213	275
Deferred revenue	153,647	157,426
Other long-term liabilities	314	389
Commitments and contingencies		
Stockholders net capital deficiency:		
Common stock, $0.01 par value; 200,000 shares authorized; 63,655 and 54,830 shares issued and outstanding at March 31, 2010 and December 31, 2009, respectively	637	549

Class A Common Stock, $0.01 par value, 30,000 shares authorized, 9,402 issued and outstanding at March 31, 2010 and December 31, 2009		94		94
Additional paid-in capital		1,025,548		927,082
Accumulated other comprehensive (loss) income		(18)		35
Accumulated deficit		(1,139,290)		(1,116,754)
Total stockholders net capital deficiency		(113,029)		(188,994)
Total liabilities and stockholders net capital deficiency	$	249,930	$	181,393

* Condensed consolidated balance sheet at December 31, 2009 has been derived from audited consolidated financial statements.

See accompanying notes to condensed consolidated financial statements.

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THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended March 31,	
	2010	**2009**
Revenue (1)	$ 5,714	$ 9,544
Operating expenses:		
Research and development	20,351	19,557
General and administrative	6,476	7,052
Restructuring charges		1,283
Total operating expenses	26,827	27,892
Loss from operations	(21,113)	(18,348)
Interest and other income	94	647
Interest expense	(1,517)	(1,516)
Net loss	$ (22,536)	$ (19,217)
Basic and diluted net loss per share	$ (0.35)	$ (0.31)
Shares used in computing basic and diluted net loss per share	64,921	62,288

(1) Revenue includes amounts from GSK, a related party, of $2,457 and $6,948 for the three months ended March 31, 2010 and 2009, respectively.

See accompanying notes to condensed consolidated financial statements.

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THERAVANCE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2010	2009
Cash flows from operating activities		
Net loss	$ (22,536)	$ (19,217)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,515	1,205
Stock-based compensation	4,497	5,113
Notes receivable	3	(26)
Changes in operating assets and liabilities:		
Receivables, prepaid and other current assets	36	(1,749)
Accounts payable and accrued liabilities	(56)	(2,731)
Accrued personnel-related expenses	(2,181)	(1,380)
Deferred rent	(142)	(120)
Deferred revenue	(4,700)	(8,544)
Other long-term liabilities	(75)	620
Net cash used in operating activities	(23,639)	(26,829)
Cash flows from investing activities		
Purchases of property and equipment		(2)
Purchases of marketable securities	(51,994)	(25,204)
Maturities of marketable securities	44,000	27,500
Payments received on notes receivable	10	238
Net cash provided by (used in) investing activities	(7,984)	2,532
Cash flows from financing activities		
Payments on notes payable and capital lease	(55)	(29)
Proceeds from issuances of common stock	94,057	4,964
Net cash provided by financing activities	94,002	4,935
Net increase (decrease) in cash and cash equivalents	62,379	(19,362)
Cash and cash equivalents at beginning of period	47,544	92,280
Cash and cash equivalents at end of period	$ 109,923	$ 72,918

See accompanying notes to condensed consolidated financial statements.

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Theravance, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

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 notes required by GAAP 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 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, results of operations and cash flows. The interim results are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2010 or any other period.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2009 filed with the Securities and Exchange Commission (SEC) on February 26, 2010.

Use of Management s Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

Inventory

Inventory is stated at the lower of cost or market and is included with prepaid and other current assets. Inventory consisted of $3.5 million and $3.4 million of VIBATIV finished goods, active pharmaceutical ingredient, or other commercial launch supplies as of March 31, 2010 and December 31, 2009, respectively. If Astellas decides not to purchase any of the remaining VIBATIV inventory, the Company will be required to expense a portion of or the entire remaining capitalized inventory.

Other-than-Temporary Impairment Assessment

The Company reviews its investment portfolio to identify and evaluate investments that have indications of possible impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, credit quality and the Company s conclusion that it does not intend to sell an impaired investment and is not more likely than not to be required to sell the security before it recovers its amortized cost basis. If the Company determines that the impairment of an investment is other-than-temporary, the investment is written down with a charge recorded in interest and other income.

Research and Development Costs

Research and development costs are expensed in the period that services are rendered or goods are received. Research and development costs consist of salaries and benefits, laboratory supplies and facility costs, as well as fees paid to third parties that conduct certain research and development activities on behalf of the Company, net of certain external development costs reimbursed by GlaxoSmithKline plc (GSK) and Astellas.

Fair Value of Stock-based Compensation Awards

The Company uses the fair value method of accounting for stock-based compensation arrangements. Stock-based compensation arrangements currently include stock options granted, restricted shares issued, restricted stock unit awards (RSUs) granted and performance-contingent RSUs granted under the 2004 Equity Incentive Plan and the 2008 New Employee Equity Incentive Plan 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

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options, restricted shares and RSUs is expensed on a straight-line basis over the expected term of the grant and the fair value of performance-contingent RSUs is expensed during the term of the award when the Company determines that it is probable that certain performance milestones 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.

Stock-based compensation expense for stock options and RSUs has been reduced for estimated forfeitures so that compensation expense is based on options and RSUs ultimately expected to vest. The Company s estimated annual forfeiture rates for stock options and RSUs are based on its historical forfeiture experience.

Recent Accounting Pronouncements

In January 2010, the Financial Accounting Standards Board issued guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. The guidance requires new disclosures on the transfers of assets and liabilities between Level 1 (quoted prices in active market for identical instruments) and Level 2 (significant other observable inputs) of the fair value measurement hierarchy, including the reasons and the timing of the transfers. Additionally, the guidance requires a roll forward of activities on purchases, sales, issuance, and settlements of the assets and liabilities measured using significant unobservable inputs (Level 3 fair value measurements). The guidance became effective for the Company with the reporting period beginning January 1, 2010, except for the disclosure on the roll forward activities for Level 3 fair value measurements, which will become effective for the Company with the reporting period beginning July 1, 2011. Adoption of this new guidance did not have a material impact on the Company s condensed consolidated financial statements.

2. Net Loss per Share

Basic net loss per share (basic EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding during the period, less shares subject to repurchase. Diluted net loss per share (diluted EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding during the period, less shares subject to repurchase, plus dilutive potential common shares. 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.

Potential common shares that were excluded from the calculation of net loss per share are as follows:

	Three Months Ended March 31,	
(in thousands)	**2010**	**2009**
Shares issuable upon the exercise of stock options	1,345	2,205
Shares issuable under restricted stock unit awards	153	277
Shares issuable upon the conversion of convertible debt	6,668	6,668

The calculation of basic and diluted EPS is as follows:

(in thousands, except for per share amounts)	Three Months Ended March 31, 2010	2009
Net loss	$ (22,536)	$ (19,217)
Weighted average shares of common stock outstanding	64,978	62,364
Less: unvested restricted shares	(57)	(76)
Weighted average shares used in computing basic and diluted net loss per share	64,921	62,288
Basic and diluted net loss per share	$ (0.35)	$ (0.31)

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3. Comprehensive Loss

Comprehensive loss is comprised of net loss and changes in other comprehensive (loss) income, which consists of unrealized gains and losses on the Company s marketable securities. Comprehensive loss is as follows:

	Three Months Ended March 31,	
(in thousands)	**2010**	**2009**
Net loss	$ (22,536)	$ (19,217)
Other comprehensive loss:		
Net unrealized loss on available-for-sale securities	(53)	(174)
Comprehensive loss	$ (22,589)	$ (19,391)

4. Restructuring Charges

In response to the completion of its Phase 3 development activities and to reduce its overall cash burn rate, the Company announced a plan to reduce its workforce by approximately 40% through layoffs from all departments throughout the organization in April 2008.

In February 2009, the Company entered into a sublease agreement with a third party to sublease excess space in a portion of one of its South San Francisco, CA buildings. The sublease has a 37 month term that began March 2009. For the three months ended March 31, 2009, the Company recorded a restructuring charge of $1.3 million of which $1.1 million represents the fair value of the Company s lease payments and expenses less sublease income through March 2012.

The following table summarizes the accrual balance and utilization by cost type for the restructuring for the three months ended March 31, 2010:

(in thousands)	**Employee Severance and Benefits**	**Excess Facilities**
Balance as of December 31, 2009	$ 116	$ 694
Cash payments	(116)	(74)*
Balance as of March 31, 2010	$	$ 620

* Includes fair value of cash payments less sublease payments received

To date, the Company has incurred cumulative restructuring charges of $6.9 million relating to the actions taken in April 2008 and February 2009.

The restructuring accrual related to excess facilities is recorded within other accrued liabilities and other long-term liabilities on the Company s condensed consolidated balance sheets.

5. Collaboration and Licensing Agreements

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, Japan was added to the collaboration, thereby giving Astellas worldwide rights to this medicine. Through March 31, 2010, the Company has received $191.0 million in upfront, milestone and other fees from Astellas. The Company is eligible to receive up to an additional $30.0 million in remaining milestone payments related to regulatory approvals in various regions of the world. The Company records these payments as deferred revenue and is amortizing them ratably over its estimated period of performance (development and commercialization period). The Company recognized $3.2 million and $2.6 million in revenue under this agreement in the three months ended March 31, 2010 and 2009, respectively.

Under this arrangement, the Company is responsible for substantially all costs to develop and obtain U.S. regulatory approval for telavancin for complicated skin and skin structure infections (cSSSI) and nosocomial pneumonia (NP) and Astellas is responsible for substantially all other costs associated with commercialization and further development of telavancin. The Company is entitled to receive royalties on global net sales of VIBATIV by Astellas that, on a percentage basis, range from the high teens to the upper twenties depending on sales volume. As a result of the initial wholesaler stocking in the three months ended December 31, 2009, the Company recognized minimal royalties in the three months ended March 31, 2010.

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RELOVAIRTM Program with GSK

In November 2002, the Company entered into its long-acting beta2 agonist (LABA) collaboration with GSK to develop and commercialize a LABA product candidate both as a single-agent new medicine for the treatment of chronic obstructive pulmonary disease (COPD) and as part of a new combination medicine with an inhaled corticosteroid (ICS) for the treatment of asthma and/or a long-acting muscarinic antagonist (LAMA) for COPD.

In connection with the RELOVAIR program, in 2002 the Company received from GSK an upfront payment of $10.0 million and sold to an affiliate of GSK shares of the Company s Series E Preferred Stock for an aggregate purchase price of $40.0 million. In addition, the Company was eligible to receive up to $495.0 million in development, approval, launch and sales milestones and royalties on the sales of any product resulting from this program. Through March 31, 2010, the Company has received a total of $60.0 million in upfront and development milestone payments. GSK has determined to focus the collaboration s resources on the development of the lead LABA, GW642444, a GSK-discovered compound, together with GSK s ICS, fluticasone furoate. Accordingly, the Company does not expect to receive any further milestone payments from the RELOVAIR program. In the event that a LABA product candidate discovered by GSK is successfully developed and commercialized, the Company would be obligated to make milestone payments to GSK which could total as much as $220.0 million if both a single-agent and a combination product were launched in multiple regions of the world. 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 two years. Moreover, the Company is entitled to receive the same royalties on sales of medicines from the RELOVAIR program, regardless of whether the product candidate originated with Theravance or with GSK. The Company is entitled to receive royalties of 15% on the first $3.0 billion of annual global net sales, and 5% on annual global net sales above $3.0 billion, for approved single-agent LABA and combination LABA-ICS medicines. Sales of single-agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the RELOVAIR program, such as a combination LABA/LAMA medicine, which are launched after a LABA/ICS combination medicine, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS combination product at the time that the first other LABA combination is launched, then the royalties described above for the LABA/ICS combination medicine are applicable.

The Company recorded the initial cash payment and subsequent milestone payments as deferred revenue and is amortizing them ratably over its estimated period of performance (the product development period). Collaboration revenue from GSK under this agreement was $1.3 million for each of the three months ended March 31, 2010 and 2009.

2004 Strategic Alliance with GSK

In March 2004, the Company entered into its strategic alliance with GSK. Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from all of the Company s full drug discovery programs initiated prior to September 1, 2007, on pre-determined terms and on an exclusive, worldwide basis. Under the terms of the strategic alliance, GSK has only one opportunity to license each of the Company s programs. Upon GSK s decision to license a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. In addition, GSK is obligated to use diligent efforts to develop and commercialize product candidates from any program that it licenses. Consistent with the Company s strategy, it 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 and royalties on any sales of medicines developed from these programs. For product candidates licensed to date under this agreement, the royalty structure for a product containing one of its compounds as a single active ingredient would result in an average percentage royalty rate in the low double digits. If a product is successfully commercialized, in addition to any royalty revenue that the Company receives, the total upfront and milestone payments that it could receive in any given program that GSK licenses range from $130.0 million to

$162.0 million for programs with single-agent medicines and up to $252.0 million for programs with both a single-agent and a combination medicine. If GSK chooses not to license a program, the Company retains all rights to the program and may continue the program alone or with a third party. To date, GSK has licensed the Company s two COPD programs: long-acting muscarinic antagonist (LAMA) and bifunctional muscarinic antagonist-beta2 agonist (MABA). The Company received $5.0 million payments from GSK in connection with its license of each of the Company s LAMA and MABA programs in August 2004 and March 2005, respectively. GSK has chosen not to license the Company s bacterial infections program, anesthesia program or 5-HT4 program.