VIVUS INC
Form 10-Q
May 08, 2013
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For The Quarterly Period Ended March 31, 2013

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 001-33389

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3136179**
(State or other jurisdiction of incorporation or organization)	(IRS employer identification number)
1172 Castro Street Mountain View, California	**94040**
(Address of principal executive office)	(Zip Code)

(650) 934-5200

(Registrant s telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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 x 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 the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x	Accelerated filer o
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 Act). o Yes x No

At April 23, 2013, 100,665,029 shares of common stock, par value $.001 per share, were outstanding.

Table of Contents

VIVUS, INC.

Quarterly Report on Form 10-Q

INDEX

Table of Contents

PART I: FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

VIVUS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

	March 31, 2013 (Unaudited)	December 31, 2012 Note 1
ASSETS		
Current assets:		
Cash and cash equivalents	$ 90,606	$ 58,605
Available-for-sale securities	59,702	155,981
Accounts receivable, net	4,878	2,778
Inventories	27,564	25,353
Prepaid expenses and other assets	24,324	19,159
Total current assets	207,074	261,876
Property and equipment, net	2,867	1,951
Non-current assets	992	287
Total assets	$ 210,933	$ 264,114
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 18,670	$ 25,375
Accrued and other liabilities	14,656	13,777
Deferred revenue	1,546	1,150
Current liabilities of discontinued operations	506	903
Total current liabilities	35,378	41,205
Commitments and contingencies		
Stockholders equity:		
Preferred stock; $1.00 par value; 5,000 shares authorized; no shares issued and outstanding		
Common stock; $.001 par value; 200,000 shares authorized; 100,660 and 100,659 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively	101	101
Additional paid-in capital	715,162	708,921
Accumulated other comprehensive income	14	33
Accumulated deficit	(539,722)	(486,146)
Total stockholders equity	175,555	222,909
Total liabilities and stockholders equity	$ 210,933	$ 264,114

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended March 31,	
	2013	**2012**
Revenue:		
Net product revenue	$ 4,112	$
Operating expenses:		
Cost of goods sold	390	
Inventory charge	5,777	
Research and development	7,046	6,291
Selling, general and administrative	44,696	12,481
Total operating expenses	57,909	18,772
Loss from operations	(53,797)	(18,772)
Interest and other income, net	35	17
Loss from continuing operations before income taxes	(53,762)	(18,755)
Provision for income taxes	(6)	(7)
Loss from continuing operations	(53,768)	(18,762)
Income (loss) from discontinued operations, net of tax	192	(16)
Net loss	$ (53,576)	$ (18,778)
Basic and diluted net loss per share:		
Continuing operations	$ (0.53)	$ (0.20)
Discontinued operations	0.00	0.00
Net loss per share	$ (0.53)	$ (0.20)
Shares used in per share computation:		
Basic and diluted	100,660	92,267

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended March 31,

	2013	2012
Net loss	$ (53,576)	$ (18,778)
Other comprehensive loss:		
Unrealized loss on securities, net of taxes	(19)	(32)
Comprehensive loss	$ (53,595)	$ (18,810)

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2013	**2012**
Cash flows from operating activities:		
Net loss from continuing operations	$ (53,768)	$ (18,762)
Adjustments to reconcile net loss to net cash used for operating activities from continuing operations:		
Provision for cash discounts	104	
Depreciation	183	22
Amortization of discount or premium on available-for-sale securities	510	763
Share-based compensation expense	6,061	2,718
Inventory charge	5,036	
Changes in assets and liabilities:		
Accounts receivable	(2,204)	
Inventories	(7,071)	210
Prepaid expenses and other assets	(5,165)	(44)
Accounts payable	(6,876)	1,864
Accrued and other liabilities	879	518
Deferred revenue	396	
Net cash used for operating activities from continuing operations	(61,915)	(12,711)
Net cash used for operating activities from discontinued operations	(204)	(316)
Net cash used for operating activities	(62,119)	(13,027)
Cash flows from investing activities:		
Property and equipment purchases	(929)	
Purchases of available-for-sale securities		(48,763)
Other non-current assets	(705)	(287)
Proceeds from maturity of available-for-sale securities	95,750	13,500
Proceeds from sale of available-for-sale securities		9,035
Net cash provided by (used for) investing activities	94,116	(26,515)
Cash flows from financing activities:		
Net proceeds from exercise of common stock options	4	8,665
Net proceeds from issuance of common stock		192,005
Net cash provided by financing activities	4	200,670
Net increase in cash and cash equivalents	32,001	161,128
Cash and cash equivalents:		
Beginning of period	58,605	39,554
End of period	$ 90,606	$ 200,682

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

VIVUS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2013

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, for interim financial information and with 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 U.S. GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013. Management has evaluated all events and transactions that occurred after March 31, 2013 through the date these unaudited condensed consolidated financial statements were filed. There were no events or transactions during this period which require recognition or disclosure in these unaudited condensed consolidated financial statements, except as disclosed in Note 9. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. The unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2012, as filed on February 26, 2013 with the Securities and Exchange Commission, or SEC. The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

When we refer to we, our, us, the Company or VIVUS in this document, we mean the current Delaware corporation, or VIVUS, Inc., and its California predecessor, as well as all of our consolidated subsidiaries.

Reclassifications

Certain prior year amounts in the unaudited condensed consolidated financial statements have been reclassified to conform to the current year presentation.

Use of Estimates

The preparation of these unaudited condensed consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. On an ongoing basis, the Company evaluates its

estimates, including critical accounting policies or estimates related to available-for-sale securities, research and development expenses, income taxes, inventories, revenues, contingencies and litigation and share-based compensation. The Company bases its estimates on historical experience, information received from third-parties and on various market specific and other relevant assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ significantly from those estimates under different assumptions or conditions.

Recent Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements during the three months ended March 31, 2013, as compared to the recent accounting pronouncements described in the Company s Form 10-K for the year ended December 31, 2012, that are of significance, or potential significance to the Company.

Table of Contents

2. SHARE-BASED COMPENSATION

The Company accounts for share-based compensation arrangements in accordance with the Financial Accounting Standards Board, or FASB s, Accounting Standards Codification, or ASC, topic 718, *Compensation Stock Compensation,* or ASC 718, and ASC 505-50, *Equity Equity Based Payments to Non-Employees*.

Total share-based compensation expense for all of the Company s share-based awards is as follows (in thousands):

	Three Months Ended March 31,	
	2013	**2012**
Research and development	$ 940	$ 726
Selling, general and administrative	5,121	1,992
Share-based compensation expense	$ 6,061	$ 2,718

Included in the inventory carrying value as of March 31, 2013 is $176,000 of share-based compensation expense.

3. CASH, CASH EQUIVALENTS AND AVAILABLE-FOR-SALE SECURITIES

The fair value and the amortized cost of cash, cash equivalents, and available-for-sale securities by major security type at March 31, 2013 and December 31, 2012 are presented in the tables that follow.

As of March 31, 2013 (in thousands):

Cash and cash equivalents and available-for-sale securities	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Estimated Fair Value**
Cash and money market funds	$ 90,606	$	$	$ 90,606
U.S. Treasury securities	59,688	14		59,702
Total	150,294	14		150,308
Less amounts classified as cash equivalents	(90,606)			(90,606)
Total available-for-sale securities	$ 59,688	$ 14	$	$ 59,702

As of March 31, 2013, all of the Company s available-for-sale securities have a contractual maturity of less than one year.

As of December 31, 2012 (in thousands):

Cash and cash equivalents and available-for-sale securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and money market funds	$ 58,605	$	$	$ 58,605
U.S. Treasury securities	155,948	33		155,981
Total	214,553	33		214,586
Less amounts classified as cash equivalents	(58,605)			(58,605)
Total available-for-sale securities	$ 155,948	$ 33	$	$ 155,981

Fair Value Measurements

As of March 31, 2013 and December 31, 2012, all of the Company s cash and cash equivalents and available-for-sale securities were measured at fair value on a recurring basis, and classified as Level 1 in the fair value hierarchy. There were no assets or liabilities where Level 2 or Level 3 valuation techniques were used and there were no assets and liabilities measured at fair value on a non-recurring basis.

Table of Contents

4. INVENTORIES

Inventories consist of (in thousands):

	Balance as of	
	March 31, 2013	December 31, 2012
Raw materials	$ 11,229	$ 5,139
Work in process	2,336	2,635
Finished goods	13,895	17,506
Deferred costs	104	73
Total	$ 27,564	$ 25,353

As of March 31, 2013 and December 31, 2012, the raw materials inventories consist primarily of the active pharmaceutical ingredients, or API, for the commercialization of Qsymia® (phentermine and topiramate extended-release) capsules CIV, the finished goods inventory consists of both Qsymia and STENDRATM (avanafil) primarily for commercialization, while the work in process and deferred costs inventories relate exclusively to Qsymia. The deferred costs represent the costs of Qsymia product shipped to customers, but not yet shipped to patients through prescriptions, and for which recognition of revenue has been deferred.

Inventories are stated at the lower of cost or market. Cost is determined using the weighted average method. The Company periodically evaluates the carrying value of inventory on hand for potential excess amount over demand using the same lower of cost or market approach as that used to value the inventory. As a result of this evaluation, during the three months ended March 31, 2013, the Company recognized an inventory charge of $5.8 million, primarily to write off work-in-process and finished goods inventories on hand in excess of demand.

5. PREPAID EXPENSES AND OTHER ASSETS

Prepaid expenses and other assets consist of (in thousands):

	Balance as of	
	March 31, 2013	December 31, 2012
Interest receivable	$ 375	$ 743
Prepaid insurance	5,749	6,979
Prepaid sales and marketing expenses	10,108	5,735
Prepaid medical affairs expenses	5,224	1,782
Manufacturing capacity commitment fees	1,791	2,300
Other prepaid expenses and assets	1,077	1,620
Total	$ 24,324	$ 19,159

The amounts included in prepaid expenses and other assets consist of interest receivable, prepaid insurance, and deposits and prepayments for future services, primarily related to prepaid product commercialization costs for services relating to future periods in support of the sales and marketing of Qsymia in the U.S., prepayments related to medical affairs activities for Qsymia and STENDRA, and manufacturing capacity

commitment fees. These amounts represent probable future economic benefits obtained or controlled by the Company as a result of past transactions or events, which meet the definition of an asset under FASB Concept Statement 6. As such, these costs have been deferred as prepaid expenses and other assets on the consolidated balance sheet and will be either (i) charged to expense accordingly when the related prepaid services are rendered to the Company, or (ii) converted to cash when the receivables are collected by the Company.

6. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities consist of (in thousands):

	Balance as of	
	March 31, 2013	**December 31, 2012**
Accrued research and clinical expenses	$ 1,576	$ 1,372
Accrued employee compensation and benefits	4,575	3,859
Accrued manufacturing costs	4,308	4,135
Accrued sales and marketing expenses	1,903	2,908
Other accrued liabilities	2,294	1,503
Total	$ 14,656	$ 13,777

The amounts included in accrued and other liabilities consist of obligations for past services, primarily related to accrued manufacturing and product commercialization costs for services relating to past periods in support of the commercial launch of Qsymia in the U.S., accrued employee compensation and benefits, and accrued research and clinical expenses.

Table of Contents

7. NET INCOME (LOSS) PER SHARE

The Company computes basic net income (loss) per share applicable to common stockholders based on the weighted average number of common shares outstanding during the period. Diluted net income per share is based on the weighted average number of common and common equivalent shares, which represent shares that may be issued in the future upon the exercise of outstanding stock options. Common share equivalents are excluded from the computation in periods in which they have an anti-dilutive effect. Stock options for which the price exceeds the average market price over the period have an anti-dilutive effect on net income per share and, accordingly, are excluded from the calculation. When there is a net loss, potentially dilutive common equivalent shares are not included in the calculation of net loss per share since their inclusion would be anti-dilutive.

As the Company recognized a net loss for the three months ended March 31, 2013 and 2012 all potential common equivalent shares were excluded for these periods as they were anti-dilutive. For the three months ended March 31, 2013 and 2012, 5,461,000 and 4,546,000 options outstanding, respectively, were not included in the computation of diluted net loss per share for the Company because the effect would be anti-dilutive.

8. LEGAL MATTERS

Securities Related Class Action Lawsuits

The Company and two of its officers were defendants in a putative class action lawsuit captioned *Kovtun v. Vivus, Inc., et al.*, Case No. 4:10-CV-04957-PJH, in the U.S. District Court, Northern District of California. The action, filed in November 2010, alleged violations of Section 10(b) and 20(a) of the federal Securities Exchange Act of 1934 based on allegedly false or misleading statements made by the defendants in connection with the Company s clinical trials and New Drug Application, or NDA, for Qsymia as a treatment for obesity. Defendants filed a motion to dismiss plaintiff s Amended Class Action Complaint, and that motion was granted with leave to amend. On November 9, 2011, plaintiff filed his Second Amended Class Action Complaint, generally alleging that defendants misled investors regarding the prospects for Qsymia s NDA approval, and Qsymia s efficacy and safety. Defendants again filed a motion to dismiss. After briefing and argument, the District Court on September 27, 2012 granted the motion and dismissed the action with prejudice. The District Court entered final judgment for defendants the same day. On October 26, 2012, plaintiff filed a Notice of Appeal to the U.S. Court of Appeals for the Ninth Circuit. Plaintiff filed his opening appellate brief on February 19, 2013, and defendants filed their answering brief on April 11, 2013. Briefing is expected to continue into May 2013, after which the Court of Appeals may request oral argument.

Additionally, certain of the Company s officers and directors are defendants in a shareholder derivative lawsuit captioned *Turberg v. Logan, et al.*, Case No. CV-10-05271-PJH, pending in the same federal court. In the plaintiff s Verified Amended Shareholder Derivative Complaint filed June 3, 2011, the plaintiff largely restated the allegations of the *Kovtun* action and alleged that the directors breached fiduciary duties to the Company by purportedly permitting the Company to violate the federal securities laws as alleged in the *Kovtun* action. The parties had agreed to stay the litigation pending resolution of the appeal. The same individuals are also named defendants in consolidated shareholder derivative suits pending in the California Superior Court, Santa Clara County under the caption *In re VIVUS, Inc. Derivative Litigation,* Master File No. 11 0 CV188439. The allegations in the state court derivative suits are substantially similar to the other lawsuits. The parties have agreed to stay these consolidated actions on the same terms as the federal derivative litigation.

The Company and its directors cannot predict the outcome of the various shareholder lawsuits, but they believe the various shareholder lawsuits are without merit and intend to continue vigorously defending them.

Table of Contents

9. SUBSEQUENT EVENTS

The Company entered into a Purchase and Sale Agreement, or the BioPharma Agreement, effective as of March 25, 2013 between the Company and BioPharma Secured Investments III Holdings Cayman LP, a Cayman Islands exempted limited partnership, or BioPharma, which provides for the purchase of a debt-like instrument. Notwithstanding anything in the BioPharma Agreement to the contrary, the Company intends for the transactions under the BioPharma Agreement to be characterized and treated as debt for all U.S. tax and accounting purposes. Under the BioPharma Agreement, the Company received $50 million less $1.1 million in funding and facility payments, at the initial closing on April 9, 2013. Subject to the terms and conditions of the BioPharma Agreement and at the Company s sole discretion, the Company may also elect prior to December 31, 2013 to receive an additional $60 million, less $600,000 in a funding payment, at the secondary closing, which is subject to customary closing conditions and which closing shall occur, if at all, no later than January 15, 2014. The Company shall be responsible for all reasonable and documented out-of-pocket legal costs and fees incurred by BioPharma related to the BioPharma Agreement, subject to a cap of $300,000.

In return, the Company is obligated to make scheduled quarterly payments to BioPharma, as further described in the BioPharma Agreement and below, until the total amount due under the BioPharma Agreement is paid. Below is a summary of the scheduled quarterly payments:

Each Calendar Quarter Occurring	**Scheduled Quarterly Amount**	**Total Scheduled Annual Amount**
in 2014	$ 3,000,000	$ 12,000,000
in 2015	$ 5,000,000	20,000,000
in 2016	$ 5,000,000	20,000,000
in 2017	$ 5,000,000	20,000,000
in the first calendar quarter of 2018	$ 1,700,000	1,700,000
Total		**$ 73,700,000**

The scheduled quarterly payments, other than the payment(s) for the first calendar quarter of 2018, are capped at the lower of the scheduled payment amounts or 25% of the net sales of (i) Qsymia (and any derivative or improvement thereof, including Qsiva as it relates to the European Union), or the Product, and (ii) any other obesity agent developed or marketed by the Company or its affiliates or licensees. Accordingly, if 25% of the net sales is less than the scheduled quarterly payment, then the Company can elect to make a payment that is lower than the scheduled payment amount. The final payment, scheduled to be made in the second quarter of 2018, is not subject to this limitation. The final payment will include any unpaid scheduled quarterly payments, plus any accrued and unpaid make-whole premiums. Any quarterly payment less than the scheduled quarterly payment amount will be subject to a make-whole premium equal to the applicable scheduled quarterly payment of the preceding quarter less the actual payment made to BioPharma for the preceding quarter multiplied by 1.03. Regardless, the Company may pay scheduled quarterly payments out of any available funds notwithstanding Product net sales. The Company also has the option to prepay all scheduled quarterly payments as specified in the BioPharma Agreement. Assuming all scheduled quarterly payments are made timely and in full, the annual implied effective interest rate is 12.75% compounded quarterly, or 13.37% per annum.

To secure its obligations in connection with the BioPharma Agreement, the Company granted BioPharma a security interest to (i) the purchased receivables which are defined in the BioPharma Agreement as the scheduled quarterly payments, any underpayments of such payments based on an audit of the Company s records and any interest due on the foregoing amounts, and (ii) the Company s patents, trademarks, copyrights and regulatory filings related to the Product, or the Additional Collateral. For the purposes herein, (i) and (ii) above shall be referred to as the Collateral.

10

Table of Contents

If the Company (i) fails to deliver a payment when due and does not remedy that failure within a cure period, (ii) fails to deliver certain reports when due and does not remedy that failure within a cure period, (iii) fails to use commercially reasonable efforts in the promotion and marketing of the Product after March 25, 2015 and does not remedy that failure within a cure period, (iv) incurs certain forms of indebtedness above specified limits, (v) fails to maintain a first-priority perfected security interest in the Additional Collateral and does not remedy that failure within a cure period or (vi) becomes subject to an event of bankruptcy, then BioPharma may attempt to recover its unpaid scheduled payments, including by exercising its right to sell or otherwise dispose of all or any part of the Collateral.

During the term of the BioPharma Agreement, the Company is required to use commercially reasonable efforts, as defined in the BioPharma Agreement, to undertake certain obligations and activities to develop, market, promote and commercialize the Product and maximize net sales of the Product. Additionally, during the term of the BioPharma Agreement the Company may not (i) pay a dividend or other cash distribution on its capital stock, unless it has cash and cash equivalents in excess of a specified amount, (ii) amend or restate its certificate of incorporation or bylaws unless such amendments or restatements do not affect BioPharma s interests under the BioPharma Agreement, (iii) encumber the Collateral, or (iv) abandon certain patent rights, in each case without the consent of BioPharma. In addition, the Company may incur (i) up to $250 million in unsecured indebtedness with a maturity date after September 30, 2018, and (ii) additional unsecured indebtedness with a maturity date after December 31, 2019 in a principal amount of the lesser of (a) the net sales during the previous 12 months minus $350 million and (b) $250 million. However, the Company s total unsecured indebtedness may not exceed $450 million.

Upon the occurrence of a Company change of control transaction, as defined in the BioPharma Agreement, BioPharma will be entitled to receive an amount equal to the sum of all unpaid scheduled quarterly payments. A permitted partnering agreement and a permitted action, both as defined in the BioPharma Agreement, shall not constitute a change of control transaction under the BioPharma Agreement. A permitted partnering agreement is an agreement for promotional and/or marketing resources for the Product, where (i) the Company continues to receive 25% of the net sales of the Product and (ii) the permitted partner agrees to be subject to the same promotional and marketing covenants that apply to the Company under the BioPharma Agreement. A permitted action allows the Company to take certain actions with respect to a certain subset of the Additional Collateral as specified in the BioPharma Agreement.

On April 16, 2013, the U.S. Food and Drug Administration, or FDA, approved the Company s amendment and modification to the Risk Evaluation and Mitigation Strategy, or REMS, for Qsymia. The amendment, submitted in October 2012, allows Qsymia to be dispensed through certified retail pharmacies, in addition to the existing network of certified mail-order pharmacies. With this modification, the goals, commitments and components of the original Qsymia REMS will remain in place, including a Medication Guide, patient brochure, voluntary healthcare provider training and other educational tools.

On April 26, 2013, the European Medicines Agency s Committee for Medicinal Products for Human Use, or CHMP, adopted a positive opinion recommending the granting of a marketing authorization for avanafil, known by the trade name SPEDRA in the European Union, for the treatment of erectile dysfunction.

Table of Contents

ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management s Discussion and Analysis of Financial Conditions and Results of Operations and other parts of this Form 10-Q contain forward looking statements that involve risks and uncertainties. These statements typically may be identified by the use of forward looking words or phrases such as may, believe, expect, forecast, intend, anticipate, predict, should, planned, likely, opportunity, e the negative use of these words or other similar words. All forward looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor for such forward looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to: (1) our limited commercial experience with Qsymia® in the United States, or U.S.; (2) the timing of initiation and completion of the clinical studies required as part of the approval of Qsymia by the U.S. Food and Drug Administration, or FDA; (3) the response from the FDA to the data that VIVUS will submit relating to post-approval clinical studies; (4) the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy, or REMS, requirements; (5) the impact of distribution of Qsymia through a certified home delivery pharmacy network; (6) our ability to implement the recently FDA approved amendment to the REMS for Qsymia, which, allows dispensing through certified retail pharmacies; (7) that we may be required to provide further analysis of previously submitted clinical trial data; (8) the negative opinion of the European Medicines Agency s, or EMA, Committee for Medicinal Products for Human Use, or CHMP, for the Marketing Authorization Application, or MAA, for Qsymia; (9) whether healthcare providers, payors and public policy makers will recognize the significance of the new AACE guidelines; (10) our ability to successfully commercialize Qsymia or establish partnerships for avanafil; (11) the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand; (12) our history of losses and variable quarterly results; (13) substantial competition; (14) risks related to the failure to protect our intellectual property and litigation in which we may become involved; (15) uncertainties of government or third-party payor reimbursement; (16) our reliance on sole source suppliers; (17) our reliance on third parties and our collaborative partners; (18) our failure to continue to develop innovative investigational drug candidates and drugs; (19) risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; (20) our ability to demonstrate through clinical testing the safety and effectiveness of our investigational drug candidates; (21) the timing of initiation and completion of clinical trials and submissions to foreign authorities; (22) the results of post-marketing studies are not favorable; (23) compliance with post-marketing regulatory standards is not maintained; (24) the volatility and liquidity of the financial markets; (25) our liquidity and capital resources; (26) our expected future revenues, operations and expenditures and (27) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, or the SEC, or the Commission, including those set forth in this filing as Item 1A. Risk Factors.

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the quarter ended March 31, 2013, are not necessarily indicative of the results that may be expected for the full fiscal year or any future period.

OVERVIEW

VIVUS is a pharmaceutical company with two FDA approved therapies, Qsymia and STENDRA . Our drug, Qsymia (phentermine and topiramate extended-release) (formerly known as Qnexa®) was approved by the U.S. Food and Drug Administration, or FDA, on July 17, 2012, as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 or greater (obese), or 27 or greater (overweight) in the presence of at least one weight-related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol (dyslipidemia). Qsymia incorporates a proprietary formulation combining low doses of active ingredients from two previously approved drugs, phentermine and topiramate. Although the exact mechanism of action is unknown, Qsymia is believed to suppress appetite and increase satiety, or the feeling of being full, the two main mechanisms that impact eating behavior. On September 17, 2012, we announced the U.S. market availability of Qsymia. We currently distribute Qsymia through a certified home delivery network, which includes CVS Pharmacy, Express Scripts, Walgreens, Wal-Mart Pharmacy, and, for its members only, Kaiser Permanente.

As part of the approval of Qsymia, we are committed to conducting post-marketing studies. We intend to conduct a study to assess the long-term treatment effect of Qsymia on the incidence of major adverse cardiovascular events in overweight and obese subjects with confirmed cardiovascular disease, studies to assess the safety and efficacy of Qsymia for weight management in obese pediatric and adolescent subjects, studies to assess drug utilization and pregnancy exposure and a study to assess renal function, as well as animal and in vitro studies. We anticipate beginning certain of these studies in 2013.

Table of Contents

On December 17, 2010, we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, to market Qsymia in the European Union, or EU, for the treatment of obesity. The approved trade name for Qsymia in the EU is Qsiva . On October 18, 2012, we received the formal opinion from the EMA s Committee for Medicinal Products for Human Use, or CHMP, recommending against approval of the MAA for Qsiva in the EU due to concerns over the potential cardiovascular and central nervous system effects associated with long-term use, teratogenic potential and use by patients for whom Qsiva would not have been indicated. We appealed this opinion and requested a re-examination of the decision by the CHMP. After re-examination, on February 21, 2013, the CHMP affirmed their earlier opinion. We are currently exploring options to seek approval of Qsiva in the EU, including filing on a country-by-country basis under a decentralized approval process. We also intend to seek approval for Qsymia in other territories outside the United States and EU. We intend to commercialize Qsymia in territories where we obtain approval through collaboration agreements with third-parties.

Our drug, STENDRA, or avanafil, was approved by the FDA on April 27, 2012, for the treatment of erectile dysfunction, or ED, in the United States. As part of the approval of STENDRA, we are committed to conducting post-marketing studies. In March 2012, we filed an MAA with the EMA to market avanafil in the EU for the treatment of ED. The approved trade name for STENDRA in the EU is SPEDRA™. Avanafil is an oral PDE5 inhibitor that we have licensed from Mitsubishi Tanabe Pharma Corporation, or MTPC. Through collaboration arrangements with third-parties, we intend to market and sell STENDRA in the United States and, if approved, SPEDRA in the EU and other territories outside the United States. We are currently in discussions with potential collaboration partners for all stated territories.

Foreign regulatory approvals, including approvals to market Qsiva or SPEDRA in the EU, may not be obtained on a timely basis, or at all, and the failure to receive regulatory approvals in a foreign country would prevent us from marketing our products in that market, which could have a material adverse effect on our business, financial condition and results of operations.

Recent Developments

On March 25, 2013, we entered into the BioPharma Agreement, which provides for the purchase of a debt-like instrument. At the initial closing on April 9, 2013, we received $50 million, less $1.1 million in funding and facility payments. Subject to the terms and conditions of the BioPharma Agreement and at our sole discretion, we may also elect prior to December 31, 2013 to receive an additional $60 million, less $600,000 in a funding payment, at the secondary closing, which is subject to customary closing conditions and which closing shall occur, if at all, no later than January 15, 2014. We will be responsible for all reasonable and documented out-of-pocket legal costs and fees incurred by BioPharma related to the BioPharma Agreement, subject to a cap of $300,000.

On April 16, 2013, the FDA approved an amendment to the REMS that allows for distribution of Qsymia through certified retail pharmacy locations. We intend to certify pharmacies and announce retail availability in the third quarter of 2013.

In April 2013, the CHMP adopted a positive opinion recommending the granting of a marketing authorization for SPEDRA for the treatment of erectile dysfunction in the European Union to the European Commission, or EC. A final decision from the EC regarding the SPEDRA MAA is expected to take approximately two months.

Strategy

Our goal is to build a successful pharmaceutical company through the commercialization and development of innovative proprietary drugs. We intend to achieve this by:

- successfully implementing the certified retail pharmacy distribution channel for Qsymia in the United States;

- continuing to lower out of pocket costs for patients with discount programs, increased third-party payor coverage and changes in public policy;

- establishing medical obesity treatment as a widely accepted category supported by treatment guidelines;

- increasing awareness for Qsymia through direct to consumer advertising;

- expanding our commercialization efforts for Qsymia through working with a major pharmaceutical company;

- entering into and supporting a collaboration agreement for the commercialization of STENDRA for the treatment of ED in the U.S.;

Table of Contents

- obtaining regulatory approval for Qsiva for the treatment of obesity and SPEDRA for the treatment of ED in the EU and other territories worldwide;

- if approved, entering into and supporting collaboration agreements for the commercialization of Qsiva for the treatment of obesity and SPEDRA for the treatment of ED in the EU and other territories worldwide; and

- continuing to identify and develop early to later stage investigational drug candidates for approval in the U.S., the EU and elsewhere, thereby providing a steady pipeline of drugs for eventual sale, partnership or commercialization.

It is our objective to continue as a successful drug development company and to become a successful commercial entity largely through the sales of Qsymia and profits from collaborations for STENDRA, SPEDRA and Qsymia outside of the U.S.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. On an ongoing basis, we evaluate our estimates, including those related to available-for-sale securities, research and development expenses, income taxes, inventories, revenues, contingencies and litigation and share-based compensation. We base our estimates on historical experience, information received from third-parties and on various market specific and other relevant assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates under different assumptions or conditions.

During the first three months of fiscal 2013, there were no significant changes to our critical accounting policies and estimates. Management s Discussion and Analysis of Financial Condition and Results of Operations contained in Part II, Item 7 of our Annual Report on Form 10-K for our fiscal year ended December 31, 2012 provides a more complete discussion of our critical accounting policies and estimates.

Recent Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements during the three months ended March 31, 2013, as compared to the recent accounting pronouncements described in our Form 10-K for the year ended December 31, 2012, that are of significance, or potential significance to the Company.

RESULTS OF OPERATIONS

For the quarter ended March 31, 2013, we reported a net loss of $53.6 million or $0.53 net loss per share, as compared to a net loss of $18.8 million or $0.20 net loss per share during the same period in 2012. The increased net loss in the quarter ended March 31, 2013, as compared to the quarter ended March 31, 2012, is primarily attributable to increased selling, general and administrative expenses related to commercialization activities for Qsymia.

We may have continued losses in future periods, depending on our success in commercializing Qsymia and STENDRA, the timing of our research and development expenditures, and our continued investment in the clinical development of our current research and investigational drug candidates, to bring those potential drugs to market.

Continuing operations

Net product revenue (Unaudited)

Net product revenue was $4.1 million for the three months ended March 31, 2013. As Qsymia was not approved until July 2012, we had no net product revenue from continuing operations for three months ended March 31, 2012. In September 2012, we began distributing Qsymia to the certified home delivery pharmacies in our network. We currently recognize revenue for Qsymia based upon prescription sell-through by our certified home delivery pharmacy services networks to patients as we do not have sufficient historical information to reliably estimate returns.

Table of Contents

At March 31, 2013, we have deferred revenue of $1.5 million, which represents Qsymia product shipped to our certified home delivery pharmacy services networks, but not yet shipped to patients through prescriptions, net of prompt payment discounts.

We expect Qsymia product revenue and prescriptions shipped to patients to increase in 2013 as we continue the commercialization of Qsymia.

Cost of goods sold (Unaudited)

Cost of goods sold is $390,000 for the three months ended March 31, 2013 and relates to our product shipments of Qsymia to patients and includes the inventory costs of APIs, third-party contract manufacturing and packaging and distribution costs, royalties, cargo insurance, freight, shipping, handling and storage costs, and overhead costs of the employees involved with production. The cost of goods sold associated with deferred revenue on Qsymia product shipments is recorded as deferred costs, which are included in inventories in the unaudited condensed consolidated balance sheets, until such time as the deferred revenue is recognized.

We expect cost of goods sold to increase in 2013 as product sales of Qsymia increase.

Inventory charge (Unaudited)

Inventories are stated at the lower of cost or market. Cost is determined using the weighted average method. We periodically evaluate the carrying value of inventory on hand for potential excess amount over demand using the same lower of cost or market approach as that used to value the inventory. As a result of this evaluation, during the three months ended March 31, 2013, we recognized an inventory charge of $5.8 million, primarily to write off work-in-process and finished goods inventories on hand in excess of demand. A substantial portion of the excess amount relates to the initial production of Qsymia, which has a shelf life of 24 months. With additional stability data to support a longer shelf life, we have submitted an application to the FDA to extend the shelf life to 36 months for current and future production. We will continue to evaluate our inventories on a periodic basis and we may incur additional inventory write-downs in future periods if actual events differ materially from our current assumptions.

Research and development expenses (Unaudited)

	Three Months Ended March 31,		
Drug Indication/Description	**2013**	**2012**	**2013 vs. 2012 Increase/(Decrease)**
	(In thousands, except percentages)		
Qsymia for obesity	$ 605	$ 2,703	(78)%
STENDRA for ED	2,938	639	360%
Other projects	186	405	(54)%

Share-based compensation	790	726	9%
Overhead costs*	2,527	1,818	39%
Total research and development expenses	$ 7,046	$ 6,291	12%

*Overhead costs include compensation and related expenses, consulting, legal and other professional services fees relating to research and development activities, which we do not allocate to specific projects.

The increase in research and development expenses for the three months ended March 31, 2013, as compared to the same period in 2012, is primarily due to start-up and enrollment costs associated with the post-approval studies for STENDRA, including a corresponding increase in headcount to support these projects.

We anticipate that our research and development expenses for the remainder of 2013 will increase as compared to 2012 as we continue the planning phase of a post-approval cardiovascular outcomes study for Qsymia, known as ACQLAIM. The details of ACQLAIM have not yet been agreed with the FDA. This study could cost between $150 and $250 million and take as long as five to six years to complete. There are likely to be additional research and development expenses for other post-approval studies related to STENDRA and Qsymia, and for our investigational drug candidates under development. Our research and development expenses may fluctuate from period to period due to the timing and scope of our development activities and the results of clinical and pre-clinical studies.

Table of Contents

Selling, general and administrative expenses (Unaudited)

	Three Months Ended March 31,		
	2013	2012	2013 vs. 2012 Increase
	(In thousands, except percentages)		
Selling, general and administrative expenses	$ 44,696	$ 12,481	258%

The increase in selling, general and administrative expenses for the three months ended March 31, 2013 is primarily due to increased spending for Qsymia commercialization activities of $23.0 million, including expenses related to the contract sales organization, marketing programs, market research and analytics, and additional headcount; increased medical affairs-related expenses of $2.2 million primarily related to additional headcount; incremental increases in other corporate expenses totaling $3.8 million; and increased share-based compensation expense (a non-cash expense) of $3.1 million, as compared to the quarter ended March 31, 2012.

We anticipate our selling, general and administrative expenses to be significantly higher for the remainder of 2013 as compared to 2012, primarily due to the additional efforts involved in the commercialization and marketing activities for Qsymia related to the FDA approval of our amendment to the REMS program, allowing for the distribution of Qsymia through certified retail pharmacy locations.

Income (loss) from discontinued operations

Income from discontinued operations of $192,000 in the three months ended March 31, 2013 relates primarily to adjustments to our sales reserves for accrued product returns related to the MUSE product. The net loss from discontinued operations in the three months ended March 31, 2012 was $16,000.

LIQUIDITY AND CAPITAL RESOURCES

Continuing Operations

Cash. Cash, cash equivalents and available-for-sale securities (cash) totaled $150.3 million at March 31, 2013, as compared to $214.6 million at December 31, 2012. The decrease of $64.3 million is primarily due to cash used for operating activities.

Since inception, we have financed operations primarily from the issuance of equity securities. Through March 31, 2013, we have raised $661.0 million from financing activities, received $150 million from the sale of Evamist, and had an accumulated deficit of $539.7 million at March 31, 2013. Additionally, in April 2013, we received a net amount of $48.9 million through the sale of a debt-like instrument to BioPharma.

At March 31, 2013, we had $90.6 million in cash and cash equivalents and $59.7 million in available-for-sale securities. We invest our excess cash balances in money market and marketable securities, primarily U.S. Treasury securities and debt securities of U.S. government agencies, corporate debt securities and asset-backed securities, in accordance with our investment policy. At March 31, 2013, all of our cash equivalents and available-for-sale securities were invested in either U.S. government securities or money market funds that invest only in U.S. Treasury securities. The investment policy has the primary investment objectives of preservation of principal; however, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy. If those securities are downgraded or impaired, we would experience realized or unrealized losses in the value of our portfolio, which would have an adverse effect on our results of operations, liquidity and financial condition.

Investment securities are exposed to various risks, such as interest rate, market and credit. Due to the level of risk associated with certain investment securities and the level of uncertainty related to changes in the value of investment securities, it is possible that changes in these risk factors in the near term could have an adverse material impact on our results of operations or stockholders equity.

Liabilities. Total liabilities were $35.4 million at March 31, 2013, which is $5.8 million lower than at December 31, 2012.

Operating Activities. Our operating activities used $62.1 million and $13.0 million in cash during the three months ended March 31, 2013 and 2012, respectively. During the three months ended March 31, 2013, the use of cash from our net operating loss from continuing operations of $53.8 million was offset by $6.1 million in non-cash share-based compensation expense due to increased headcount and $5.0 million due to the inventory write-off for Qsymia. Additional cash used in operating activities resulted from changes in assets and liabilities during the quarter including a $5.2 million net increase in prepaid expenses and other assets, which is primarily comprised of medical affairs, sales and marketing activities for Qsymia. In addition, there was a net $7.1 million increase in

Table of Contents

inventories, primarily for Qsymia. Accounts receivable increased approximately $2.2 million as a result of increased shipments of Qsymia to pharmacies in support of growing demand for Qsymia. Accounts payable decreased by $6.9 million during the first quarter of 2013 due to the timing of vendor payments.

During the three months ended March 31, 2012, our net operating loss of $18.8 million was offset by $2.7 million in non-cash share-based compensation expense and a $1.9 million increase in accounts payable, primarily due to the timing of invoices and payments and increased activities related to Qsymia pre-commercialization activity.

We anticipate cash used in operations in 2013 will be higher than cash used in operations in 2012, primarily due to ongoing commercialization activities for Qsymia.

Investing Activities. Our investing activities provided $94.1 million and used $26.5 million in cash during the three months ended March 31, 2013 and 2012, respectively. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturity of investment securities.

Financing Activities. Financing activities were not material during the first quarter of 2013 as compared to cash provided by financing activities of $200.7 million during the first quarter of 2012. In the first three months of 2012, cash provided by financing activities included $8.7 million in proceeds from the exercise of stock options and $192.0 million in net proceeds from an underwritten public offering of our common stock.

On March 25, 2013, we entered into the BioPharma Agreement, which provides for the purchase of a debt-like instrument. Under the BioPharma Agreement, we received $50 million, less $1.1 million in funding and facility payments, at the initial closing, which occurred on April 9, 2013. Subject to the terms and conditions of the BioPharma Agreement and at our sole discretion, we may also elect prior to December 31, 2013 to receive an additional $60 million, less $600,000 in a funding payment, at the secondary closing, which is subject to customary closing conditions and which closing shall occur, if at all, no later than January 15, 2014. We will be responsible for all reasonable and documented out-of-pocket legal costs and fees incurred by BioPharma related to the BioPharma Agreement, subject to a cap of $300,000.

The funding necessary to execute our business strategies is subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. Commercialization of Qsymia and STENDRA may be more costly than we planned. In addition, completion of clinical trials and approval by the FDA of investigational drug candidates may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of an investigational drug candidate. It is also important to note that if an investigational drug candidate is identified, the further development of that candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, lack of efficacy or safety or change in market demand.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs at least through the first quarter of 2014. However, we anticipate that we may require additional funding to continue our commercialization of Qsymia, to conduct post-approval clinical studies for both Qsymia and STENDRA, to conduct non-clinical and clinical research and development work to support regulatory submissions and applications for our current and future investigational drug candidates, to finance the costs involved in filing and prosecuting patent applications and enforcing or defending our patent claims, if any, to fund operating expenses, to establish additional or new manufacturing and marketing capabilities, to manufacture quantities of our drugs and investigational drug candidates

and to make payments under our existing license agreements for Qsymia and STENDRA.

While some of our anticipated costs are unknown at the current time, we may need to raise additional capital to continue the funding of our commercialization efforts, product development programs and our research and development plans in future periods beyond the first quarter of 2014. If we require additional capital, we may seek any required additional funding through collaborations, public and private equity or debt financings, capital lease transactions or other available financing sources. Additional financing may not be available on acceptable terms, or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing stockholders may result. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our commercialization or development programs or obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop on our own.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet financing arrangements and have not established any special purpose entities. We have not guaranteed any debt or commitments of other entities or entered into any options on non-financial assets.

Table of Contents

Contractual Obligations

On March 25, 2013, we entered into the BioPharma Agreement, which provides for the purchase of a debt-like instrument. At the initial closing on April 9, 2013, we received $50 million less $1.1 million in funding and facility payments. Subject to the terms and conditions of the BioPharma Agreement and at our sole discretion, we may also elect prior to December 31, 2013 to receive an additional $60 million, less $600,000 in a funding payment, at the secondary closing, which is subject to customary closing conditions and which closing shall occur, if at all, no later than January 15, 2014. We will be responsible for all reasonable and documented out-of-pocket legal costs and fees incurred by BioPharma related to the BioPharma Agreement, subject to a cap of $300,000.

In return, we are obligated to make scheduled quarterly payments to BioPharma, as further described in the BioPharma Agreement and below, until the total amount due under the BioPharma Agreement is paid. Below is a summary of the scheduled quarterly payments:

Year	Scheduled Quarterly Amount	Total Scheduled Annual Amount
2014	$ 3,000,000	$ 12,000,000
2015	$ 5,000,000	20,000,000
2016	$ 5,000,000	20,000,000
2017	$ 5,000,000	20,000,000
First calendar quarter of 2018	$ 1,700,000	1,700,000
Total	**$**	**73,700,000**

The scheduled quarterly payments, other than the payment(s) for the first calendar quarter of 2018, are capped at the lower of the scheduled payment amounts or 25% of the net sales of (i) Qsymia (and any derivative or improvement thereof, including Qsiva as it relates to the European Union), or the Product, and (ii) any other obesity agent developed or marketed by the Company or its affiliates or licensees. Accordingly, if 25% of the net sales is less than the scheduled quarterly payment, then we can elect to make a payment that is lower than the scheduled payment amount. The final payment, scheduled to be made in the second quarter of 2018, is not subject to this limitation. The final payment will include any unpaid scheduled quarterly payments, plus any accrued and unpaid make-whole premiums. Any quarterly payment less than the scheduled quarterly payment amount will be subject to a make-whole premium equal to the applicable scheduled quarterly payment of the preceding quarter less the actual payment made to BioPharma for the preceding quarter multiplied by 1.03. Regardless, we may pay scheduled quarterly payments out of any available funds notwithstanding Product net sales. We also have the option to prepay all scheduled quarterly payments as specified in the BioPharma Agreement. Assuming all scheduled quarterly payments are made timely and in full, the annual implied effective interest rate is 12.75% compounded quarterly, or 13.37% per annum.

To secure our obligations in connection with the BioPharma Agreement, we granted BioPharma a security interest to certain of our assets, agreed to certain payments upon the occurrence of a change of control transaction and agreed to certain covenants.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Securities and Exchange Commission s rule related to market risk disclosure requires that we describe and quantify our potential losses from market risk sensitive instruments attributable to reasonably possible market changes. Market risk sensitive instruments include all financial or commodity instruments and other financial instruments that are sensitive to future changes in interest rates, currency exchange rates, commodity

prices or other market factors.

Table of Contents

Market and Interest Rate Risk

Our cash, cash equivalents and available-for-sale securities as of March 31, 2013 consisted primarily of money market funds and U.S. Treasury securities. Our cash is invested in accordance with an investment policy approved by our Board of Directors that specifies the categories (money market funds, U.S. Treasury securities and debt securities of U.S. government agencies, corporate bonds, asset-backed securities, and other securities), allocations, and ratings of securities we may consider for investment. Currently, we have focused on investing in U.S. Treasuries until market conditions improve.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable debt securities. The primary objective of our investment activities is to preserve principal. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment may decline. A hypothetical 100 basis point increase in interest rates would reduce the fair value of our available-for-sale securities at March 31, 2013 by approximately $112,000. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

ITEM 4. CONTROLS AND PROCEDURES

(a.) Evaluation of disclosure controls and procedures. We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the rules and forms of the Securities and Exchange Commission, or SEC, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of VIVUS disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

(b.) Changes in internal controls. There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Securities Related Class Action Lawsuits

The Company and two of its officers were defendants in a putative class action lawsuit captioned *Kovtun v. Vivus, Inc., et al.*, Case No. 4:10-CV-04957-PJH, in the U.S. District Court, Northern District of California. The action, filed in November 2010, alleged violations of Section 10(b) and 20(a) of the federal Securities Exchange Act of 1934 based on allegedly false or misleading statements made by the defendants in connection with the Company s clinical trials and New Drug Application, or NDA, for Qsymia as a treatment for obesity. Defendants filed a motion to dismiss plaintiff s Amended Class Action Complaint, and that motion was granted with leave to amend. On November 9, 2011, plaintiff filed his Second Amended Class Action Complaint, generally alleging that defendants misled investors regarding the prospects for Qsymia s NDA approval, and Qsymia s efficacy and safety. Defendants again filed a motion to dismiss. After briefing and argument, the District Court on September 27, 2012 granted the motion and dismissed the action with prejudice. The District Court entered final judgment for defendants the same day. On October 26, 2012, plaintiff filed a Notice of Appeal to the U.S. Court of Appeals for the Ninth Circuit. Plaintiff filed his opening appellate brief on February 19, 2013, and defendants filed their answering brief on April 11, 2013. Briefing is expected to continue into May 2013, after which the Court of Appeals may request oral argument.

Additionally, certain of the Company s officers and directors are defendants in a shareholder derivative lawsuit captioned *Turberg v. Logan, et al.*, Case No. CV-10-05271-PJH, pending in the same federal court. In the plaintiff s Verified Amended Shareholder Derivative Complaint filed June 3, 2011, the plaintiff largely restated the allegations of the *Kovtun* action and alleged that the directors breached fiduciary duties to the Company by purportedly permitting the Company to violate the federal securities laws as alleged in the *Kovtun* action. The parties had agreed to stay the litigation pending resolution of the appeal. The same individuals are also named defendants in consolidated shareholder derivative suits pending in the California Superior Court, Santa Clara County under the caption *In re VIVUS, Inc. Derivative Litigation,* Master File No. 11 0 CV188439. The allegations in the state court derivative suits are substantially similar to the other lawsuits. The parties have agreed to stay these consolidated actions on the same terms as the federal derivative litigation.

Table of Contents

The Company and its directors cannot predict the outcome of the various shareholder lawsuits, but they believe the various shareholder lawsuits are without merit and intend to continue vigorously defending them.

ITEM 1A. RISK FACTORS

Set forth below and elsewhere in this Form 10-Q and in other documents we file with the SEC, are risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this Quarterly Report on Form 10-Q. These are not the only risks and uncertainties facing VIVUS. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Relating to our Business

Our success will depend on our ability to effectively and profitably commercialize Qsymia®.

Our success will depend on our ability to effectively and profitably commercialize Qsymia, formerly known as Qnexa®, which will include our ability to:

- implement and certify thousands of retail pharmacies nationwide in a timely manner;
- expand our commercialization efforts for Qsymia through working with a major pharmaceutical company;
- lower out of pocket costs to patients with discount programs, improve third-party payor coverage and change public policy;
- create market demand for Qsymia through direct-to-consumer advertising, patient and physician education, marketing and sales activities;
- achieve market acceptance and generate product sales;

- comply with the post-marketing requirements established by the U.S. Food and Drug Administration, or FDA, including the Risk Evaluation and Mitigation Strategy, or REMS, and any other requirements established by the FDA in the future;

- conduct the post-marketing studies required by the FDA;

- comply with other healthcare regulatory requirements;

- maintain and defend our patents, if challenged;

- ensure that the APIs for Qsymia and the finished product are manufactured in sufficient quantities and in compliance with requirements of the FDA and similar foreign regulatory agencies and with an acceptable quality and pricing level in order to meet commercial demand; and

- ensure that the entire supply chain for Qsymia, from APIs to finished product, efficiently and consistently delivers Qsymia to our customers.

Table of Contents

Prior to the commercialization of Qsymia, we have not had any commercial products since the divestiture of MUSE in November 2010. While our management and key personnel have significant experience developing, launching and commercializing drugs at VIVUS and at other companies, we have only recently begun to work together to commercialize Qsymia and we cannot be certain that we will be successful. If we are unable to successfully commercialize Qsymia, our ability to generate product sales will be severely limited, which will have a material adverse impact on our business, financial condition, and results of operations.

We intend to market and sell STENDRATM (avanafil) in the U.S. under a collaboration arrangement with a third party. We also intend to market and sell SPEDRATM (avanafil) outside the U.S., if approved, under collaboration arrangements with third parties. These arrangements might subject us to a number of risks.

We intend to enter into collaborative arrangements or strategic alliances with pharmaceutical partners or others to commercialize STENDRA in the U.S. and, if approved, to commercialize SPEDRA outside the U.S.

We may be unable to enter into agreements with third parties for these arrangements on favorable terms or at all, which could delay or impair our ability to commercialize STENDRA and SPEDRA in the relevant territories. Additionally, dependence on collaborative arrangements or strategic alliances will subject us to a number of risks, including the following:

- we may not be able to control the commercialization of our drug products in the relevant territories, including amount, timing and quality of resources that our collaborators may devote to our drug products;

- our collaborators may experience financial, regulatory or operational difficulties, which may impair their ability to commercialize our drug products;

- our collaborators may be required under the laws of the relevant territory to disclose our confidential information or may fail to protect our confidential information;

- as a requirement of the collaborative arrangement, we may be required to relinquish important rights with respect to our drug products, such as marketing and distribution rights;

- business combinations or significant changes in a collaborator s business strategy may adversely affect a collaborator s willingness or ability to satisfactorily complete its commercialization or other obligations under any collaborative arrangement;

- legal disputes or disagreements may occur with one or more of our collaborators;

- a collaborator could independently move forward with a competing investigational drug candidate developed either independently or in collaboration with others, including with one of our competitors; and

- a collaborator could terminate the collaborative arrangement, which could negatively impact the continued commercialization of our drug products.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.

We intend to market and sell SPEDRA, if approved, in the European Union, or EU, and in other territories outside the U.S. through collaboration arrangements with third parties. In order to market products in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. In March 2012, we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, to market SPEDRA in the EU for the treatment of ED and a final decision from the EC regarding the SPEDRA MAA is expected to take approximately two months. We have had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional testing. 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. For example, Qsymia was approved in the U.S. by the FDA; however, we were denied an MAA for the same product in the EU. Foreign regulatory approvals may not be obtained on a timely basis, or at all, for any of our products and the failure to receive regulatory approvals in a foreign country would prevent us from marketing our products in that country, which could have a material adverse effect on our business, financial condition and results of operations.

Table of Contents

We intend to market SPEDRA outside the U.S., if approved, which will subject us to risks related to conducting business internationally.

We, together with our affiliates and partners, intend to manufacture, market, and distribute SPEDRA, if approved, outside the U.S. We expect that we will be subject to additional risks related to conducting business internationally, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing U.S. and foreign drug import and export rules;
- reduced protection for intellectual property rights in some foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;

- production shortages resulting from events affecting raw material supply or manufacturing capabilities abroad;

- potential liability resulting from development work conducted by these distributors; and

- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

We could be negatively affected as a result of a threatened proxy contest and other actions of dissident stockholders.

First Manhattan Co. and its affiliates, or First Manhattan, have filed a preliminary proxy statement presenting a proposal to (i) nominate six nominees, or First Manhattan Nominees, for election to the Board at the annual meeting of stockholders, or Annual Meeting, (ii) vote against the Company s proposal to approve, on an advisory basis, the compensation of the Company s named executive officers, (iii) ratify the appointment of OUM & Co., LLP as the Company s independent registered public accounting firm for the fiscal year ending December 31, 2013 and (iv) repeal any bylaw amendments in effect at the time of the Annual Meeting that were not included in our bylaws in effect as of April 18, 2012, as amended on February 20, 2013, and is inconsistent with the election of the First Manhattan Nominees at the Annual Meeting. If First Manhattan carries through with its intention and launches a proxy contest, our business and our stock price could be adversely affected because if individuals are elected to the Board with a different agenda, it may adversely affect our ability to effectively and timely implement our strategic plan. There can be no assurance as to the outcome of this situation, the level of distraction it may cause to our management team, the amount of expenses we may incur relating thereto or the impact on our stock price.

We rely in part on a third-party contract sales organization for certain sales and marketing support services for Qsymia.

We rely on PDI, Inc., or PDI, a third-party contract sales organization, to assist with the hiring of sales representatives and the promotion of Qsymia to physicians. Our internal sales and marketing personnel manage and supervise the activities of this sales force. Nevertheless, we face risks in our partial reliance on the third-party contract sales organization including the following:

- PDI may not apply the expected financial resources or required expertise to successfully promote Qsymia;

- PDI may not invest in the continued development of a sales force and the related infrastructure at levels that ensure that sales of Qsymia reach their full potential;

- PDI, or its sales representatives, may not comply with applicable legal or regulatory requirements, including the requirement to promote drugs only for uses for which they have been approved;

- disputes may arise between us and PDI, including between the contract sales representatives, who are PDI employees, and sales management, who are VIVUS employees, that may adversely affect Qsymia sales or profitability; and

- PDI may enter into agreements with other parties that have products that could compete with Qsymia.

We depend on the success of PDI in performing its services, and we cannot be certain PDI will cooperate with us to perform its obligations under the agreement. Although they are contractually obligated, we cannot control the amount of resources that will be devoted by PDI to the promotion of Qsymia. Any failure of PDI to perform its obligations or to continue to allocate resources to the promotion of Qsymia could adversely affect the commercialization of Qsymia and materially harm our business, financial condition and results of operations.

Table of Contents

Our failure to properly implement the REMS modification and make Qsymia available in certified retail pharmacy locations by the expected target date of the third quarter of 2013 would be detrimental to our business.

On April 16, 2013, we received approval of the previously submitted amendment to the Qsymia REMS that allows for distribution through certified retail pharmacy locations. Our failure to implement the terms of the REMS modification and to certify a sufficient number of pharmacies on a timely basis would have a negative impact on our business. The implementation of the REMS amendment poses several risks including:

- our inability to enter into contracts with wholesalers in a timely fashion, on reasonable terms, or at all, to allow for retail pharmacy dispensing of Qsymia;

- our inability to obtain the proper technology (pharmacy software) to implement the REMS modification;

- the failure by pharmacies to complete the training necessary for certification;

- our failure to properly identify and stock the locations of the pharmacies to be certified based on patient needs and current or future prescribing habits;

- our failure to comply with the assessment and requirements for each of these pharmacies set forth in the amendment; and

- our inability to properly assess the individual pharmacy locations.

Our success in commercializing Qsymia will depend on our ability to effectively advertise to consumers.

We will need to increase awareness of Qsymia to be successful in our commercialization of Qsymia. To increase awareness of Qsymia, we intend to advertise directly to consumers. Direct-to-consumer advertising requires significant financial resources, and we will have to rely on external agencies to provide effective advertisements and run successful campaigns. In addition, we are required to submit all print advertisements to the FDA at the time they are first used. There can be no assurance that our advertisements will be acceptable to the FDA, or that the advertisements will be successful in increasing consumer demand. Even if the advertisements are successful, there can be no assurance that increased consumer demand will result in more physicians prescribing Qsymia.

We have significant inventories on hand and, in the first quarter of 2013, we recorded an inventory charge of $5.8 million, primarily to write off excess inventory related to Qsymia.

We maintain significant inventories and evaluate these inventories on a periodic basis for potential excess and obsolescence. In the first quarter of 2013, we recorded an inventory charge of $5.8 million, primarily to write off inventory in excess of demand. These charges were based on our analysis of current Qsymia inventory on hand and remaining shelf life, in relation to our projected demand for the product. The current FDA-approved commercial product shelf life for Qsymia is 24 months and for STENDRA is 36 months. We have submitted a request to the FDA to extend the shelf life of Qsymia to 36 months, and we have submitted a similar application to extend the shelf life of STENDRA to 48 months.

Our allowance for excess and obsolete inventory is subjective and requires accurate forecasting of the future market demand for our products. We will continue to evaluate our inventories on a periodic basis. The value of our inventories could be impacted if actual sales differ significantly from our estimates of future demand, if the FDA does not approve extensions of the shelf lives for Qsymia and STENDRA, or if any significant unanticipated changes in future product demand or market conditions occur. Any of these events, or a combination thereof, could result in additional inventory write-downs in future periods, which could be material.

Our failure to manage and maintain our distribution network for Qsymia could compromise the commercialization of this product.

We rely on Cardinal Health PTS, LLC, or Cardinal Health, a third-party distribution and supply-chain management company, to warehouse Qsymia and distribute it to the certified home delivery pharmacies that then distribute Qsymia directly to patients. Cardinal Health provides billing, collection and returns services. We also have entered into agreements with select certified pharmacies, including CVS Pharmacy, Express Scripts, Walgreens, Wal-Mart Pharmacy and Kaiser Permanente, to distribute Qsymia to eligible patients through their certified home delivery networks and intend to enter into agreements to establish a certified retail pharmacy distribution network. Patients and physicians have experienced delays in processing prescriptions in the home delivery network. In addition to providing services to support the distribution and use of Qsymia, each of the pharmacies has agreed to comply with the REMS program certified pharmacy requirements and will provide us with the necessary patient and prescribing physician

Table of Contents

data. We have contracted with a third-party data warehouse to collect this patient and prescribing physician data from the certified pharmacy home delivery network and report it to us. We rely on this third-party data in order to recognize revenue and comply with the REMS requirements for Qsymia, such as data analysis. This distribution and data collection network requires significant coordination with our sales and marketing, finance, regulatory and medical affairs teams, in light of the REMS requirements applicable to Qsymia.

Cardinal Health is our exclusive supplier of distribution logistics services, and accordingly we depend on Cardinal Health to satisfactorily perform its obligations under our agreement with them. Pursuant to the REMS program applicable to Qsymia, our distribution network is through a small number of certified home delivery pharmacies, and we rely on these pharmacies to implement a number of safety procedures and report certain information to the third-party data warehouse. Failure to maintain our contracts with Cardinal Health, with the select certified home delivery pharmacies, or with the third-party data warehouse, or the inability or failure of any of them to adequately perform under the contracts, could negatively impact the distribution of Qsymia, or adversely affect our ability to comply with the REMS applicable to Qsymia. Failure to comply with a requirement of an approved REMS can result in, among other things, civil penalties, operating restrictions and criminal prosecution. Failure to coordinate financial systems could also negatively impact our ability to accurately report and forecast product revenue. If we are unable to effectively manage the distribution and data collection process, sales of Qsymia could be severely compromised and our business, financial condition and results of operations would be harmed.

If we are unable to enter into agreements with suppliers or our suppliers fail to supply us with the APIs for our products or if we rely on sole source suppliers, we may experience delays in commercializing our products.

We currently do not have supply agreements for extended-release topiramate or phentermine, which are the APIs used in Qsymia. We cannot guarantee that we will be successful in entering into supply agreements on reasonable terms or at all or that we will be able to obtain or maintain the necessary regulatory approvals for these suppliers in a timely manner or at all.

We anticipate that we will continue to rely on single source suppliers for phentermine and extended-release topiramate for the foreseeable future. Any production shortfall on the part of our suppliers that impairs the supply of phentermine or extended-release topiramate could have a material adverse effect on our business, financial condition and results of operations. If we are unable to obtain a sufficient quantity of these compounds, there could be a substantial delay in successfully developing a second source supplier. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could adversely affect our ability to satisfy demand for Qsymia, which could adversely affect our product sales and operating results materially, which could significantly harm our business.

The API and the tablets for STENDRA are currently manufactured by Mitsubishi Tanabe Pharma Corporation, or MTPC. MTPC has arrangements for the three main starting materials necessary for the manufacturing of avanafil API. The MTPC manufacturing sites for the API (avanafil) and STENDRA tablets have been inspected by the U.S. authorities. We do not believe the results of those inspections will have an impact on MTPC s ability to supply STENDRA, or the approval, or the timing of approval, of SPEDRA in the EU. However, if MTPC is unable to receive approval from foreign regulators and maintain ongoing FDA or foreign regulatory compliance, or manufacture STENDRA s API or tablets in sufficient quantities to meet projected demand, the EU approval, the U.S. commercial launch, and future sales of STENDRA and SPEDRA will be adversely effected, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration for the commercialization of STENDRA and SPEDRA, if approved.

In August 2012, we entered into an amendment to our agreement with MTPC that permits us to manufacture the API and tablets for STENDRA ourselves or through third-party suppliers at any time, and we are required under the amendment to transition away from MTPC supply on or before June 2015. In February 2013, we entered into a technology transfer agreement with the manufacturing division of a global pharmaceutical company that can become the contract manufacturer, or CMO, for avanafil. Enabling this CMO to manufacture commercial supply in the future is a critical step in establishing a high quality, reliable supply chain. If this CMO is unable to effectively establish the supply chain, the commercialization of avanafil and any potential commercial agreements will be severely compromised. We currently do not have any manufacturing facilities and intend to continue to rely on third parties for the supply of the starting materials, API and tablets. However, we cannot be certain that we will be successful in entering into such agreements with other suppliers or that we will be able to obtain the necessary regulatory approvals for these suppliers in a timely manner or at all.

Table of Contents

We have in-licensed all or a portion of the rights to Qsymia and STENDRA from third parties. If we default on any of our material obligations under those licenses, we could lose rights to these drugs.

We have in-licensed and otherwise contracted for rights to Qsymia and STENDRA, and we may enter into similar licenses in the future. Under the relevant agreements, we are subject to commercialization, development, supply, sublicensing, royalty, insurance and other obligations. If we fail to comply with any of these requirements, or otherwise breach these license agreements, the licensor may have the right to terminate the license in whole or to terminate the exclusive nature of the license. Loss of any of these licenses or the exclusive rights provided therein could harm our financial condition and operating results.

In particular, we license the rights to avanafil from MTPC, and we have certain obligations to MTPC in connection with that license. For example, we are obligated to use our best commercial efforts to market STENDRA in the U.S. by December 31, 2013. Failure to launch STENDRA in the U.S. before this date may result in us losing our license to STENDRA in the U.S. and could adversely impact the commercial future of STENDRA outside of the U.S. In addition, we license the rights to Qsymia from Dr. Najarian. We believe we are in compliance with the material terms of our license agreements with MPTC and Dr. Najarian. However, there can be no assurance that this compliance will continue or that the licensors will not have a differing interpretation of the material terms of the agreements. If the license agreements were terminated early or if the terms of the licenses were contested for any reason, it would have a material adverse impact on our ability to commercialize products subject to these agreements, our ability to raise funds to finance our operations, our stock price and our overall financial condition. The monetary and disruption costs of any disputes involving our agreements could be significant despite rulings in our favor.

Our ability to gain market acceptance and generate revenues will be subject to a variety of risks, many of which are out of our control.

Qsymia and STENDRA may not gain market acceptance among physicians, patients, healthcare payors or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from such drugs will depend on a number of factors, including:

- our ability to expand our distribution system for Qsymia from a certified home delivery pharmacy network to certified retail pharmacy locations;

- contraindications for Qsymia and STENDRA;

- competition and timing of market introduction of competitive drugs;

- efficacy and safety in the approved setting;

- prevalence and severity of any side effects, including those of the generic components of our drugs;
- emergence of previously unknown side effects, including those of the generic components of our drugs;
- results of any post-approval studies;
- potential or perceived advantages or disadvantages over alternative treatments including generics;
- the relative convenience and ease of administration and dosing schedule;
- the convenience and ease of purchasing the drug, as perceived by potential patients;
- strength of sales, marketing and distribution support;
- price both in absolute terms and relative to alternative treatments;
- the effectiveness of our or any future collaborators sales and marketing strategies;
- the effect of current and future healthcare laws;
- availability of coverage and reimbursement from government and other third-party payors;

Table of Contents

- the level of mandatory discounts required under federal and state healthcare programs and the volume of sales subject to those discounts;

- recommendations for prescribing physicians to complete certain educational programs for prescribing drugs;

- the willingness of patients to pay out of pocket in the absence of government or third-party coverage; and

- product labeling or product insert requirements of the FDA or other regulatory authorities.

Our drugs may fail to achieve market acceptance or generate significant revenue to achieve or sustain profitability. In addition, our efforts to educate the medical community and third-party payors on the safety and benefits of our drugs may require significant resources and may not be successful.

We are required to complete post-approval studies mandated by the FDA for both Qsymia and STENDRA, and such studies are expected to be costly and time consuming. If the results of these studies reveal unacceptable safety risks, Qsymia or STENDRA may be required to be withdrawn from the market.

As part of the approval for STENDRA, the FDA is requiring us to perform two post-approval clinical studies. The first is a randomized, double-blind, placebo-controlled, parallel group multicenter clinical trial on the effect of STENDRA on spermatogenesis in healthy adult males and males with mild erectile dysfunction, or ED. The other study is a double-blind, randomized, placebo-controlled, single-dose clinical trial to assess the effects of STENDRA on multiple parameters of vision, including, but not limited to, visual acuity, intraocular pressure, pupillometry, and color vision discrimination in healthy male subjects. If we are unable to complete these studies or the results of these studies reveal unacceptable safety risks, we could be required to perform additional tests and regulatory approval could even be withdrawn.

As part of the approval of Qsymia, we are required to conduct several post-marketing studies, including a study to assess the long-term treatment effect of Qsymia on the incidence of major adverse cardiovascular events in overweight and obese subjects with confirmed cardiovascular disease, studies to assess the safety and efficacy of Qsymia for weight management in obese pediatric and adolescent subjects, studies to assess drug utilization and pregnancy exposure and a study to assess renal function. The details of the cardiovascular outcomes study, known as ACQLAIM, have not yet been agreed upon with the FDA. This study could cost between $150.0 and $250.0 million and take as long as five to six years to complete. Enrollment in ACQLAIM is expected to begin in the fourth quarter of 2013. There can be no assurance that the FDA will not request or require us to provide additional information or undertake additional prospective studies or retrospective observational studies or that we will be able to agree with the FDA on the details of ACQLAIM.

In addition, at the FDA s request, we initiated a retrospective observational study utilizing existing electronic medical claims healthcare databases to review fetal outcomes, including the incidence of congenital malformations and oral cleft, in the offspring of women who received treatment with topiramate, for any condition or at any dose, or FORTRESS. We announced preliminary results from FORTRESS in December 2011. The

results of the study are considered to be preliminary until the results are validated, which we expect to complete in the second half of 2013. If the results of this study reveal unacceptable safety risks for topiramate, we could be required to perform additional studies and regulatory approval could even be withdrawn.

In addition to these studies, the FDA may also require us to commit to perform other lengthy post-approval studies, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results, financial condition and stock price. Failure to comply with the applicable regulatory requirements can result in, among other things, civil penalties, suspensions of regulatory approvals, operating restrictions and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition, results of operations and stock price.

We depend upon consultants and outside contractors extensively in important roles within our company.

We outsource many key functions of our business and therefore rely on a substantial number of consultants, and we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials or other development activities may be extended, delayed or terminated, and we may not be able to complete our post-approval clinical trials for Qsymia and STENDRA, obtain regulatory approval for our current and future investigational drug candidates, successfully commercialize our approved drugs or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on commercially reasonable terms, or at all.

Table of Contents

Qsymia is a combination of two active ingredient drug products approved individually by the FDA that are commercially available and marketed by other companies, although the specific dose strengths and formulation (extended-release vs. immediate-release) would differ. As a result, Qsymia may be subject to substitution by prescribing physicians with individual drugs contained in the Qsymia formulation, which would adversely affect our business.

Although Qsymia is a once-a-day, proprietary extended-release formulation, each of the approved APIs (phentermine and topiramate extended-release) that is combined to produce Qsymia is commercially available as drug products at prices that together are lower than the price at which we sell Qsymia. In addition, the distribution and sale of these drug products is not limited under a REMS program, as is the case with Qsymia. Further, the individual drugs contained in the Qsymia formulation are available in retail pharmacies and neither has a Pregnancy Category X, which is used to indicate that the risks involved in the use of the drug in pregnant women clearly outweigh potential benefits, as is the case with Qsymia. We cannot be sure that physicians will view Qsymia as sufficiently superior to a treatment regimen of Qsymia s individual APIs to justify the significantly higher cost for Qsymia, and they may prescribe the individual generic drugs already approved and marketed by other companies instead of our combination drug. Although our U.S. and European patents contain composition, product formulation and method-of-use claims that we believe protect Qsymia, these patents may be ineffective or impractical to prevent physicians from prescribing the individual generic constituents marketed by other companies instead of our combination drug. Phentermine and topiramate are currently available in generic form, although the doses used in Qsymia are currently not available and no extended-release formulation of topiramate is currently available. In addition, topiramate is not approved for obesity treatment, and phentermine is only approved for short-term treatment of obesity. However, because the price of Qsymia is significantly higher than the prices of the individual components as marketed by other companies, physicians may have a greater incentive to write prescriptions for the individual components outside of their approved indication, instead of for our combination drug, and this may limit how we price or market Qsymia. Similar concerns could also limit the reimbursement amounts private health insurers or government agencies in the U.S. are prepared to pay for Qsymia, which could also limit market and patient acceptance of our drug and could negatively impact our revenues.

In many regions and countries where we may plan to market Qsymia, the pricing of reimbursed prescription drugs is controlled by the government or regulatory agencies. The government or regulatory agencies in these countries could determine that the pricing for Qsymia should be based on prices for its APIs when sold separately, rather than allowing us to market Qsymia at a premium as a new drug.

If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage.

Qsymia and STENDRA, like all pharmaceutical products, are subject to heightened risk for product liability claims due to inherent potential side effects. For example, because topiramate, a component of Qsymia, may increase the risk of congenital malformation in infants exposed to topiramate during the first trimester of pregnancy and also may increase the risk of suicidal thoughts and behavior, such risks may be associated with Qsymia as well. Other potential risks involving Qsymia may include, but are not limited to, an increase in resting heart rate, acute angle closure glaucoma, cognitive and psychiatric adverse events, metabolic acidosis, an increase in serum creatinine, hypoglycemia in patients with type 2 diabetes, kidney stone formation, decreased sweating and hypokalemia, or lower-than-normal amount of potassium in the blood.

Although we have obtained product liability insurance coverage for Qsymia, we may be unable to maintain this product liability coverage for Qsymia or any other of our approved drugs in amounts or scope sufficient to provide us with adequate coverage against all potential risks. A product liability claim in excess of, or excluded from, our insurance coverage would have to be paid out of cash reserves and could have a material adverse effect upon our business, financial condition and results of operations. Product liability insurance is expensive, difficult to maintain, and current or increased coverage may not be available on acceptable terms, if at all.

In addition, we develop, test, and manufacture through third parties, approved drugs and future investigational drug candidates that are used by humans. We face an inherent risk of product liability exposure related to the testing of our approved drugs and investigational drug candidates in clinical trials. An individual may bring a liability claim against us if one of our approved drugs or future investigational drug candidates causes, or merely appears to have caused, an injury.

Table of Contents

If we cannot successfully defend ourselves against a product liability claim, whether involving Qsymia, STENDRA or a future investigational drug candidate, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- injury to our reputation;
- withdrawal of clinical trial patients;
- costs of defending the claim and/or related litigation;
- cost of any potential adverse verdict;
- substantial monetary awards to patients or other claimants; and
- the inability to commercialize our drugs.

Damages awarded in a product liability action could be substantial and could have a negative impact on our financial condition. Whether or not we were ultimately successful in product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources, and might result in adverse publicity, all of which would impair our business. In addition, product liability claims could result in an FDA investigation of the safety or efficacy of our product, our third-party manufacturing processes and facilities, or our marketing programs. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension or withdrawal of approval.

The markets in which we operate are highly competitive and we may be unable to compete successfully against new entrants or established companies.

Competition in the pharmaceutical and medical products industries is intense and is characterized by costly and extensive research efforts and rapid technological progress. We are aware of several pharmaceutical companies also actively engaged in the development of therapies for the treatment of obesity, diabetes and sexual health and medical device companies for the treatment of sleep apnea. Many of these companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. Some of the drugs which may compete with Qsymia may not have a REMS requirement and the accompanying complexities such a requirement presents. Our competitors may develop technologies and products that are more effective than those we are currently marketing or researching and developing. Such developments could render Qsymia and STENDRA less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience.

Qsymia for the treatment of chronic weight management competes with several approved anti-obesity drugs including, Belviq® (lorcaserin), Arena Pharmaceutical s approved anti-obesity compound to be marketed by Eisai Inc., Eisai Co., Ltd. s U.S. subsidiary; Xenical (orlistat), marketed by Roche; alli®, the over-the-counter version of orlistat, marketed by GlaxoSmithKline; and Suprenza (phentermine hydrochloride), marketed by Akrimax Pharmaceuticals, LCL. In addition, Orexigen Therapeutics, Inc., or Orexigen, has an investigational drug in late stage testing, Contrave®, which, according to Orexigen, could be approved and on the market in 2014. Contrave would be marketed by Takeda Pharmaceutical Company Limited.

There are also several drugs in development for obesity including an investigational drug candidate, liraglutide, in Phase 3 clinical trials being developed by Novo Nordisk A/S. Victoza® (liraglutide) is approved by the FDA for the treatment of type 2 diabetes and also is being developed for the treatment of obesity. In addition, there are several other investigational drug candidates in Phase 2 clinical trials. There are also a number of generic pharmaceutical drugs that are prescribed for obesity, predominantly phentermine. Phentermine is sold at much lower prices than we charge for Qsymia and is available in retail pharmacies. The availability of branded prescription drugs, generic drugs and over-the-counter drugs could limit the demand for, and the price we are able to charge for, Qsymia.

We also may face competition from the off-label use of the generic components in our drugs. In particular, it is possible that patients will seek to acquire phentermine and topiramate, the generic components of Qsymia. Neither of these generic components has a REMS program and both are available at retail pharmacies. Although the dose strength of these generic components has not been approved by the FDA for use in the treatment of obesity, the off-label use of the generic components in the U.S. or the importation of the generic components from foreign markets could adversely affect the commercial potential for our drugs and adversely affect our overall business, financial conditions and results of operations.

There are also surgical approaches to treat severe obesity that are becoming increasingly accepted. Two of the most well established surgical procedures are gastric bypass surgery and adjustable gastric banding, or lap bands. In February 2011, the FDA approved the use of a lap band in patients with a BMI of 30 (reduced from 35) with comorbidities. The lowering of the BMI requirement will make more obese patients eligible for lap band surgery. In addition, other potential approaches that utilize various implantable devices or surgical tools are in development. Some of these approaches are in late stage development and may be approved for marketing.

Table of Contents

We anticipate that STENDRA (avanafil) for the treatment of erectile dysfunction will compete with PDE5 inhibitors in the form of oral medications including Viagra® (sildenafil citrate), marketed by Pfizer, Inc.; Cialis® (tadalafil), marketed by Eli Lilly and Company; Levitra® (vardenafil), co-marketed by GlaxoSmithKline plc and Schering-Plough Corporation in the U.S.; and STAXYN (vardenafil in an oral disintegrating tablet, or ODT), co-marketed by GlaxoSmithKline plc and Merck & Co., Inc.

As patents for the three major PDE5 inhibitors, sildenafil citrate, tadalafil and vardenafil, expire beginning in 2017, we anticipate that generic PDE5 inhibitors will enter the market. Generic PDE5 inhibitors would likely be sold at lower prices and may reduce the demand for STENDRA especially at the prices we would be required to charge for STENDRA to cover our manufacturing and other costs. In addition, PDE5 inhibitors are in various stages of development by other companies. Warner-Chilcott plc has licensed the U.S. rights to udenafil, a PDE5 inhibitor from Dong-A Pharmaceutical. Warner-Chilcott continues Phase 3 development of this compound. Other treatments for ED exist, such as needle injection therapies, vacuum constriction devices and penile implants, and the manufacturers of these products will most likely continue to develop or improve these therapies.

Qsymia and STENDRA may also face challenges and competition from newly developed generic products. Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, newly approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act stimulates competition by providing incentives to generic pharmaceutical manufacturers to introduce non-infringing forms of patented pharmaceutical products and to challenge patents on branded pharmaceutical products. If we are unsuccessful at challenging an Abbreviated New Drug Application, or ANDA, filed pursuant to the Hatch-Waxman Act, a generic version of Qsymia or STENDRA may be launched, which would harm our business.

New developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical and medical technology industries at a rapid pace. These developments may render our drugs and future investigational drug candidates obsolete or noncompetitive. Compared to us, many of our potential competitors have substantially greater:

- research and development resources, including personnel and technology;
- regulatory experience;
- investigational drug candidate development and clinical trial experience;
- experience and expertise in exploitation of intellectual property rights; and
- access to strategic partners and capital resources.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our investigational drug candidates. Our competitors may also develop drugs or surgical approaches that are more effective, more useful and less costly than ours and may also be more successful in manufacturing and marketing their products. In addition, our competitors may be more effective in commercializing their products. We currently outsource our manufacturing and therefore rely on third parties for that competitive expertise. There can be no assurance that we will be able to develop or contract for these capabilities on acceptable economic terms, or at all.

We may participate in new partnerships and other strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we consider strategic transactions, such as out-licensing or in-licensing of compounds or technologies, acquisitions of companies and asset purchases. Additional potential transactions we may consider include a variety of different business arrangements, including strategic partnerships, joint ventures, spin-offs, restructurings, divestitures, business combinations and investments. In addition, another entity may pursue us as an acquisition target. Any such transactions may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges, require additional expertise or disrupt our management or business, any of which could harm our operations and financial results.

As part of an effort to enter into significant transactions, we conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the expected benefits of the transaction. If we fail to realize the expected benefits from any transaction we may consummate, whether as a result of unidentified risks, integration difficulties, regulatory setbacks or other events, our business, results of operations and financial condition could be adversely affected.

Table of Contents

Our failure to successfully acquire, develop and market additional investigational drug candidates or approved drugs would impair our ability to grow.

As part of our growth strategy, we may acquire, in-license, develop and/or market additional products and investigational drug candidates. We have not in-licensed any new product candidates in several years. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical investigational drug candidates and products.

The process of proposing, negotiating and implementing a license or acquisition of an investigational drug candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of investigational drug candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional investigational drug candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management s time and attention to develop acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition, integration and maintenance costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;

- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and

- inability to retain key employees of any acquired businesses.

Further, any investigational drug candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and obtaining approval by the FDA and applicable foreign regulatory authorities. All investigational drug candidates are prone to certain failures that are relatively common in the field of drug development, including the possibility that an investigational drug candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot be certain that any drugs that we develop or approved products that we may acquire will be commercialized profitably or achieve market acceptance.

If we fail to retain our key personnel and hire, train and retain qualified employees, we may not be able to compete effectively, which could result in reduced revenues or delays in the development of our investigational drug candidates or commercialization of our approved drugs.

Our success is highly dependent upon the skills of a limited number of key management personnel. To reach our business objectives, we will need to retain and hire qualified personnel in the areas of manufacturing, commercial operations, research and development, regulatory and legal affairs, business development, clinical trial design, execution and analysis, and pre-clinical testing. There can be no assurance that we will be able to hire or retain such personnel, as we must compete with other companies, academic institutions, government entities and other agencies. The loss of any of our key personnel or the failure to attract or retain necessary new employees could have an adverse effect on our research programs, investigational drug candidate development, approved drug commercialization efforts and business operations.

Table of Contents

We rely on third parties and collaborative partners to manufacture sufficient quantities of compounds within product specifications as required by regulatory agencies for use in our pre-clinical and clinical trials and commercial operations and an interruption to this service may harm our business.

We do not have the ability to manufacture the materials we use in our pre-clinical and clinical trials and commercial operations. Rather, we rely on various third parties to manufacture these materials and there may be long lead times to obtain materials. There can be no assurance that we will be able to identify, qualify and obtain prior regulatory approval for additional sources of clinical materials. If interruptions in this supply occur for any reason, including a decision by the third parties to discontinue manufacturing, technical difficulties, labor disputes, natural or other disasters, or a failure of the third parties to follow regulations, we may not be able to obtain regulatory approvals for our investigational drug candidates and may not be able to successfully commercialize these investigational drug candidates or our approved drugs.

Our third-party manufacturers and collaborative partners, may encounter delays and problems in manufacturing our investigational drug candidates or approved drugs for a variety of reasons, including accidents during operation, failure of equipment, delays in receiving materials, natural or other disasters, political or governmental changes, or other factors inherent in operating complex manufacturing facilities. Supply chain management is difficult. Commercially available starting materials, reagents, excipients, and other materials may become scarce, more expensive to procure, or not meet quality standards, and we may not be able to obtain favorable terms in agreements with subcontractors. Our third-party manufacturers, may not be able to operate manufacturing facilities in a cost-effective manner or in a time frame that is consistent with our expected future manufacturing needs. If our third-party manufacturers, cease or interrupt production or if our third-party manufacturers and other service providers fail to supply materials, products or services to us for any reason, such interruption could delay progress on our programs, or interrupt the commercial supply, with the potential for additional costs and lost revenues. If this were to occur, we may also need to seek alternative means to fulfill our manufacturing needs.

For example, Catalent Pharma Solutions, LLC, or Catalent, supplied the product for the Phase 3 program for Qsymia and is our sole source of clinical and commercial supplies for Qsymia. Catalent has been successful in validating the commercial manufacturing process for Qsymia at an initial scale, which has been able to support the launch of Qsymia in the U.S. market. While Catalent has significant experience in commercial scale manufacturing, there is no assurance that Catalent will be successful in increasing the scale of the initial Qsymia manufacturing process, should the market demand for Qsymia expand beyond the level supportable by the current validated manufacturing process. Such a failure by Catalent to further scale up the commercial manufacturing process for Qsymia could have a material adverse impact on our ability to realize commercial success with Qsymia in the U.S. market, and have a material adverse impact on our plan, market price of our common stock and financial condition.

In the case of STENDRA, we currently rely on MTPC to supply the API (avanafil) and the tablets for STENDRA. MTPC is responsible for all aspects of manufacture, including obtaining the starting materials for the production of API. If MTPC is unable to manufacture the API for STENDRA or tablets in sufficient quantities to meet projected demand future sales of STENDRA could be adversely effected, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration for the commercialization of STENDRA.

In August 2012, we entered into an amendment to our agreement with MTPC that permits us to manufacture the API and tablets for avanafil ourselves or through third parties. According to the amendment, the transition of manufacturing from MTPC must occur on or before June 2015. The transfer of technology to, and qualification of, a new supplier is expensive, time consuming and logistically complicated. The technology transfer needed for this transition is highly dependent on the cooperation of MTPC and its current suppliers. If MTPC, or its current suppliers, is unable to effectively transfer the technology or supply on commercially reasonable terms, the approvability, partnerability and commercial success of STENDRA could be adversely impacted. In February 2013, we entered into a technology transfer agreement with the manufacturing division of a global pharmaceutical company that can become the contract manufacturer, or CMO, for avanafil. Enabling this CMO to

manufacture commercial supply in the future is a critical step in establishing a high quality, reliable supply chain. If this CMO is unable to effectively establish the supply chain, the commercialization of avanafil and any potential commercial agreements will be severely compromised. Any future manufacturing sites would need to be inspected by the U.S. and EU authorities, and any failure of such manufacturing sites to receive approval from FDA or foreign authorities, obtain and maintain ongoing FDA or foreign regulatory compliance, or manufacture avanafil API or STENDRA tablets in expected quantities, could adversely affect future sales of STENDRA, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration for the commercialization of STENDRA.

Table of Contents

We rely on third parties to maintain appropriate levels of confidentiality of the data compiled during clinical, pre-clinical and retrospective observational studies and trials.

We seek to maintain the confidential nature of our confidential information through contractual provisions in our agreements with third parties, including our agreements with clinical research organizations, or CROs, that manage our clinical studies for our investigational drug candidates. These CROs may fail to comply with their obligations of confidentiality or may be required as a matter of law to disclose our confidential information. As the success of our clinical studies depends in large part on our confidential information remaining confidential prior to, during and after a clinical study, any disclosure could have a material adverse effect on the outcome of a clinical study, our business, financial condition and results of operations.

If we fail to comply with applicable healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse are and will be applicable to our business. The regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Law, which prohibits, among other things, knowingly or willingly offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care items or service reimbursable under federal healthcare programs such as Medicare and Medicaid. Further, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations of our products may be subject to scrutiny if they do not qualify for an exemption or safe harbor. We seek to comply with the exemptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability;

- the federal False Claims Laws, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the False Claims Act for a variety of alleged improper marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company s products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government healthcare programs. In addition, in recent years the government has pursued False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved, and thus non-reimbursable, uses. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs;

- numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who prescribe our product and from whom we obtain patient health information are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. We are not a HIPAA covered entity and we do not operate as a business associate to any covered entities. Therefore, these privacy and security requirements do not apply to us. However, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA. We are unable to predict whether our actions could be subject to prosecution in the event of an impermissible disclosure of health information to us. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including

Table of Contents

recently enacted laws in a majority of states requiring security breach notification. These laws could create liability for us or increase our cost of doing business;

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the payor. Some state laws also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states prohibit providing meals to prescribers or other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes of conduct. Additional states are considering or recently have considered similar proposals. Foreign governments often have similar regulations which we also will be subject to in those countries where we market and sell products; and

- the federal Physician Payment Sunshine Act will require extensive tracking of physician and teaching hospital payments, maintenance of a payments database, and public reporting of the payment data. Centers for Medicare and Medicaid Services, or CMS, recently issued a final rule implementing the Physician Payment Sunshine Act provisions and clarified the scope of the reporting obligations, as well as that manufacturers must begin tracking on August 1, 2013 and must report payment data to CMS by March 31, 2014.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare programs, like Medicare and Medicaid, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Marketing activities for our approved drugs are subject to continued governmental regulation.

The FDA has the authority to impose significant restrictions, including REMS requirements, on approved products through regulations on advertising, promotional and distribution activities. After approval, if products are marketed in contradiction with FDA laws and regulations, the FDA may issue warning letters that require specific remedial measures to be taken, as well as an immediate cessation of the impermissible conduct resulting in adverse publicity. The FDA may also require that all future promotional materials receive prior agency review and approval before use. We intend to begin print direct-to-consumer advertising for Qsymia in the fourth quarter of 2013. In the second quarter of 2013, we plan to submit the print advertisements for review by the FDA. There can be no assurance that the FDA will find our print advertisements acceptable as submitted. Certain states have also adopted regulations and reporting requirements surrounding the promotion of pharmaceuticals. Qsymia and STENDRA are subject to these regulations. Failure to comply with state requirements may affect our ability to promote or sell pharmaceuticals drugs in certain states. This in turn could have a material adverse impact on our financial results and financial condition and could subject us to significant liability, including civil and administrative remedies as well as criminal sanctions.

We are subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our drugs.

We are required to comply with extensive regulations for drug manufacturing, labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion and record keeping in connection with the marketing of Qsymia and STENDRA. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the investigational drug candidates or to whom and how we may distribute our products. Even after FDA approval is obtained, the FDA may still impose significant restrictions on a drug s indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. For example, the labeling approved for Qsymia includes restrictions on use, including recommendations for pregnancy testing, level of obesity and duration of treatment. We are subject to ongoing regulatory obligations and restrictions which may result in significant expense and limit our ability to commercialize Qsymia. The FDA has also required the distribution of a Medication Guide to patients outlining the increased risk of teratogenicity with fetal exposure and the possibility of suicidal thinking or behavior. In addition, the FDA has required a REMS that may act to limit access to the drug, reduce our revenues and/or increase our costs. The FDA may modify the Qsymia REMS in the future to be more or less restrictive.

Even if we receive FDA and other regulatory approvals, if we or others identify adverse side effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our products, additional clinical trials, changes in labeling and additional marketing applications may be required, any of which could harm our business and cause our stock price to decline.

Table of Contents

We and our contract manufacturers are subject to significant regulation with respect to manufacturing of our products.

All of those involved in the preparation of a therapeutic drug for clinical trials or commercial sale, including our existing supply contract manufacturers, and clinical trial investigators, are subject to extensive regulation. Components of a finished drug product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with current Good Manufacturing Practices, or cGMP. These regulations govern quality control of the manufacturing processes and documentation policies and procedures, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of our third-party contractors must be inspected routinely for compliance. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulation occurs independent of such an inspection or audit, we or the FDA may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the issuance of a warning letter, temporary or permanent suspension of a clinical trial or commercial sales, recalls, market withdrawals, seizures, or the temporary or permanent closure of a facility. Any such remedial measures would be imposed upon us or third parties with whom we contract until satisfactory cGMP compliance is achieved. The FDA could also impose civil penalties. We must also comply with similar regulatory requirements of foreign regulatory agencies.

We obtain the necessary raw materials and components for the manufacture of Qsymia and STENDRA as well as certain services, such as analytical testing packaging and labeling, from third parties. In particular, we rely on Catalent Pharma Solutions, LLC to supply Qsymia capsules and Packaging Coordinators, Inc., or PCI, for Qsymia packaging services. We and these suppliers and service providers are required to follow cGMP requirements and are subject to routine and unannounced inspections by the FDA and by state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Upon inspection of these facilities, the FDA or foreign regulatory agencies may find the manufacturing process or facilities are not in compliance with cGMP requirements and other regulations. Because manufacturing processes are highly complex and are subject to a lengthy regulatory approval process, alternative qualified supply may not be available on a timely basis or at all. Difficulties, problems or delays in our suppliers and service providers manufacturing and supply of raw materials, components and services could delay our clinical trials, increase our costs, damage our reputation and cause us to lose revenue or market share if we are unable to timely meet market demands.

In addition, we have an agreement with MTPC to supply the API and the tablets for STENDRA. The MTPC manufacturing sites have been inspected by the U.S. authorities. We do not believe the results of those inspections will have an impact on MTPC s ability to supply STENDRA, or the approval, or the timing of approval, of SPEDRA in the EU. However, if MTPC is unable to receive approval from foreign authorities, and maintain ongoing FDA or foreign regulatory compliance, or manufacture avanafil API or STENDRA tablets in sufficient quantities to meet projected demand, the EU approval, the U.S. commercial launch, and future sales of STENDRA will be adversely effected, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration for the commercialization of STENDRA. In August 2012, we entered into an amendment to our agreement with MTPC that permits us to manufacture the API and STENDRA tablets for avanafil ourselves or through third parties. According to the amendment, the transition of manufacturing from MTPC must occur on or before June 2015. The technology transfer needed for this transition is highly dependent on the cooperation of MTPC and its current suppliers. If MTPC, or its current suppliers, is unable to effectively transfer the technology or supply on commercially reasonable terms, the approvability, partnerability and commercial success of STENDRA could be adversely impacted. In February 2013, we entered into a technology transfer agreement with the manufacturing division of a global pharmaceutical company that can become the contract manufacturer, or CMO, for avanafil. The identification of this CMO is a critical step in establishing a high quality, reliable supply chain. If this CMO is unable to effectively establish the supply chain, the commercialization of avanafil and any potential commercial agreements will be severely compromised. Any future manufacturing sites would need to be inspected by the U.S. and EU authorities, and any failure of such manufacturing sites to receive approval from FDA or foreign authorities, obtain and maintain ongoing FDA or foreign regulatory compliance, or manufacture avanafil API or tablets in expected quantities, could adversely affect future sales of STENDRA, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration for the commercialization of STENDRA.

Any adverse changes in reimbursement procedures by government and other third-party payors may limit our ability to market and sell our approved drugs, or any future drugs, if approved or limit our product revenues and delay profitability.

In the U.S. and abroad, sales of pharmaceutical drugs are dependent, in part, on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. Some third-party payor benefit packages restrict reimbursement, charge co-pays to patients, or do not provide coverage for specific drugs or drug classes.

Table of Contents

In addition, certain healthcare providers are moving towards a managed care system in which such providers contract to provide comprehensive healthcare services, including prescription drugs, for a fixed cost per person. We are unable to predict the reimbursement policies employed by third-party healthcare payors.

The healthcare industry in the U.S. and abroad is undergoing fundamental changes that are the result of political, economic and regulatory influences. The levels of revenue and profitability of pharmaceutical companies may be affected by the continuing efforts of governmental and third-party payors to contain or reduce healthcare costs through various means. Reforms that have been and may be considered include mandated basic healthcare benefits, controls on healthcare spending through limitations on the increase in private health insurance premiums and the types of drugs eligible for reimbursement and Medicare and Medicaid spending, the creation of large insurance purchasing groups and fundamental changes to the healthcare delivery system. These proposals include measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide. These changes could impact our ability to maximize revenues in the federal marketplace.

The Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers, and could have a material adverse effect on our future business, cash flows, financial condition and results of operations, including by operation of the following provisions:

- Effective March 23, 2010, drug rebates are due on the utilization of Medicaid managed care organizations. This expanded eligibility affects rebate liability for that utilization.

- Effective January 1, 2011, pharmaceutical companies must provide a 50% discount on branded prescription drugs dispensed to beneficiaries within the Medicare Part D coverage gap or donut hole, which is a funding gap that currently exists in the Medicare Part D prescription drug program. We currently do not anticipate coverage under Medicare Part D, but this could change in the future.

- Effective January 1, 2011, the U.S. Federal government must allocate an annual branded prescription drug fee among pharmaceutical manufacturers of branded prescription drugs based on the dollar value of their branded prescription drug sales to certain federal health care programs identified in the law. The Affordable Care Act determines an individual manufacturer s market share as the ratio of its aggregate sales of branded prescription drugs during the preceding calendar year as a percentage of the aggregate branded prescription drug sales for all covered manufacturers. Each individual pharmaceutical manufacturer will pay a prorated share of the branded prescription drug fee of $2.8 billion in 2013 (and set to increase in ensuing years) based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law.

- Changes made by the Affordable Care Act are expected to result in the coverage of 32 million uninsured individuals through an expansion of the Medicaid program, and private sector coverage either through their employer or the new state-based Health Insurance Exchanges effective in 2014. In 2012, the Supreme Court of the United States heard challenges to the constitutionality of the individual mandate and the viability of certain provisions of the Affordable Care Act. The Supreme Court s decision upheld most of the Affordable Care Act and determined that requiring individuals to maintain minimum essential health insurance coverage or pay a penalty to the Internal Revenue Service was within Congress s constitutional taxing authority. However, the Supreme Court struck down a provision in the Affordable Act that penalized states that choose not to expand their Medicaid programs through an increase in the Medicaid eligibility income limit from a state s current eligibility levels to 133% of the federal poverty limit. As a result of the Supreme Court s ruling, it is unclear whether states will expand their Medicaid programs by raising the income limit to 133% of the federal poverty level and whether there will be more uninsured patients in 2014

than anticipated when Congress passed the Affordable Care Act. For each state that does not choose to expand its Medicaid program, there will be fewer insured patients overall, which could impact our sales, business and financial condition. We expect any Medicaid expansion to impact the number of adults in Medicaid more than children because many states have already set their eligibility criteria for children at or above the level designated in the Affordable Care Act. An increase in the proportion of patients who receive our drugs and who are covered by Medicaid could adversely affect our net sales.

Presently, uncertainty exists as many of the specific determinations necessary to implement the Affordable Care Act have yet to be decided and communicated to industry participants. At this time, we cannot predict the full impact of the Affordable Care Act, or the timing and impact of any future rules or regulations promulgated to implement the Affordable Care Act.

There can be no assurance that future healthcare legislation or other changes in the administration or interpretation of government healthcare or third-party reimbursement programs will not have a material adverse effect on us. Healthcare reform is also under consideration in other countries where we intend to market Qsymia.

Table of Contents

We expect to experience pricing and reimbursement pressures in connection with the sale of Qsymia, STENDRA and our investigational drug candidates, if approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. In addition, we may confront limitations in insurance coverage for Qsymia, STENDRA and our investigational drug candidates. For example, the Medicare program generally does not provide coverage for drugs used to treat erectile dysfunction or drugs used to treat obesity. Similarly, other insurers may determine that such products are not covered under their programs. If we fail to successfully secure and maintain reimbursement coverage for our investigational drug candidates or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our investigational drug candidates and our business will be harmed. Congress has enacted healthcare reform and may enact further reform, which could adversely affect the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business.

Both of the active pharmaceutical ingredients in Qsymia, phentermine and topiramate, are available as generics and do not have a REMS requirement. The exact doses of the active ingredients in Qsymia are different than those currently available for the generic components. State pharmacy laws prohibit pharmacists from substituting drugs with differing doses and formulations. The safety and efficacy of Qsymia is dependent on the titration, dosing and formulation, which we believe could not be easily duplicated, if at all, with the use of generic substitutes. However, there can be no assurance that we will be able to provide for optimal reimbursement of Qsymia as a treatment for obesity or any other indication, if approved, from third-party payors or the U.S. government. Furthermore, there can be no assurance that healthcare providers would not actively seek to provide patients with generic versions of the active ingredients in Qsymia in order to treat obesity at a potential lower cost and outside of the REMS requirements.

Setbacks and consolidation in the pharmaceutical and biotechnology industries, and our or our collaborators inability to obtain third-party coverage and adequate reimbursement, could make partnering more difficult and diminish our revenues.

Setbacks in the pharmaceutical and biotechnology industries, such as those caused by safety concerns relating to high-profile drugs like Avandia, Vioxx and Celebrex, or investigational drug candidates, as well as competition from generic drugs, litigation, and industry consolidation, may have an adverse effect on us. For example, pharmaceutical companies may be less willing to enter into new collaborations or continue existing collaborations if they are integrating a new operation as a result of a merger or acquisition or if their therapeutic areas of focus change following a merger. Moreover, our and our collaborators ability to commercialize any of our approved drugs or future investigational drug candidates will depend in part on government regulation and the availability of coverage and adequate reimbursement from third-party payors, including private health insurers and government payors, such as the Medicaid and Medicare programs, increases in government-run, single-payor health insurance plans and compulsory licenses of drugs. Government and third-party payors are increasingly attempting to contain healthcare costs by limiting coverage and reimbursement levels for new drugs. Given the continuing discussion regarding the cost of healthcare, managed care, universal healthcare coverage and other healthcare issues, we cannot predict with certainty what additional healthcare initiatives, if any, will be implemented or the effect any future legislation or regulation will have on our business. These efforts may limit our commercial opportunities by reducing the amount a potential collaborator is willing to pay to license our programs or investigational drug candidates in the future due to a reduction in the potential revenues from drug sales. Adoption of legislation and regulations could limit pricing approvals for, and reimbursement of, drugs. A government or third-party payor decision not to approve pricing for, or provide adequate coverage and reimbursements of, our drugs could limit market acceptance of these drugs.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our contract sales organization, or CSO, CROs, safety monitoring company and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, accidents, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material

disruption of our investigational drug candidate development programs and drug manufacturing operations. For example, the loss of clinical trial data from completed or ongoing clinical trials for our investigational drug candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our investigational drug candidates, or commercialization of our approved drugs, could be delayed. If we are unable to restore our information systems in the event of a systems failure, our communications, daily operations and the ability to develop our investigational drug candidates and approved drug commercialization efforts would be severely affected.

Table of Contents

Natural disasters or resource shortages could disrupt our investigational drug candidate development and approved drug commercialization efforts and adversely affect results.

Our ongoing or planned clinical trials and approved drug commercialization efforts could be delayed or disrupted indefinitely upon the occurrence of a natural disaster. For example, Hurricane Sandy in October 2012 has hindered our Qsymia sales efforts, the nature and extent of which is not yet known. In 2005, our clinical trials in the New Orleans area were interrupted by Hurricane Katrina. In addition, our offices are located in the San Francisco Bay Area near known earthquake fault zones and are therefore vulnerable to damage from earthquakes. In October 1989, a major earthquake in our area caused significant property damage and a number of fatalities. Our supplier of STENDRA is located in Japan near known earthquake fault zones and is vulnerable to damage from earthquakes and tsunamis. We are also vulnerable to damage from other disasters, such as power loss, fire, floods and similar events. If a significant disaster occurs, our ability to continue our operations could be seriously impaired and we may not have adequate insurance to cover any resulting losses. Any significant unrecoverable losses could seriously impair our operations and financial conditions.

Risks Relating to our Intellectual Property

Obtaining intellectual property rights is a complex process, and we may be unable to adequately protect our proprietary technologies.

We hold various patents and patent applications in the U.S. and abroad targeting obesity and morbidities related to obesity, including sleep apnea and diabetes, and sexual health, among other indications. The procedures for obtaining a patent in the U.S. and in most foreign countries are complex. These procedures require an analysis of the scientific technology related to the invention and many sophisticated legal issues. Consequently, the process for having our pending patent applications issue as patents will be difficult, complex and time consuming. We do not know when, or if, we will obtain additional patents for our technologies, or if the scope of the patents obtained will be sufficient to protect our investigational drug candidates or products, or be considered sufficient by parties reviewing our patent positions pursuant to a potential licensing or financing transaction.

In addition, even if our patent applications issue as patents, we cannot make assurances as to how much protection, if any, will be provided by these patents. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Others may independently develop similar or alternative technologies or design around our patented technologies or products. These companies would then be able to develop, manufacture and sell products that compete directly with our products. In that case, our revenues and operating results could decline.

Other entities may also challenge the validity or enforceability of our patents and patent applications in litigation or administrative proceedings. The sponsor of a generic application seeking to rely on one of our approved drug products as the reference listed drug must make one of several certifications regarding each listed patent. A Paragraph III certification is the sponsor s statement that it will wait for the patent to expire before obtaining approval for its product. A Paragraph IV certification is a challenge to the patent; it is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product. Once the FDA accepts for filing a generic application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the reference listed drug, or RLD, NDA holder and patent owner that the application with patent challenge has been submitted, and provide the factual and legal basis for the applicant s assertion that the patent is invalid or not infringed. If the NDA holder or patent owner file suit against the generic applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the generic application for a period of 30 months from the date of receipt of the notice. If the RLD has new chemical entity exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the 30-month stay does not begin until five years after the

RLD approval. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation. If a competitor or a generic pharmaceutical provider successfully challenges our patents, the protection provided by these patents could be reduced or eliminated and our ability to commercialize any approved drugs would be at risk. In addition, if a competitor or generic manufacturer were to receive approval to sell a generic or follow-on version of one of our products, our approved product would become subject to increased competition and our revenues for that product would be adversely affected.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The U.S. Patent Office has recently developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act have only recently become effective. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We also may rely on trade secrets and other unpatented confidential information to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We seek to protect our trade secrets and other confidential information by entering into confidentiality agreements with employees, collaborators, vendors

Table of Contents

(including CROs and our CSO), consultants and, at times, with potential investors. Nevertheless, employees, collaborators, vendors, consultants or potential investors may still disclose or misuse our trade secrets and other confidential information, and we may not be able to meaningfully protect our trade secrets. In addition, others may independently develop substantially equivalent information or techniques or otherwise gain access to our trade secrets. Disclosure or misuse of our confidential information would harm our competitive position and could cause our revenues and operating results to decline.

If we believe that others have infringed or misappropriated our proprietary rights, we may need to institute legal action to protect our intellectual property rights. Such legal action may be expensive, and we may not be able to afford the costs of enforcing or defending our intellectual property rights against others.

We may be sued for infringing the intellectual property rights of others, which could be costly and result in delays or termination of our future research, development, manufacturing and sales activities.

Our commercial success also depends, in part, upon our ability to develop future investigational drug candidates, market and sell approved drugs and conduct our other research, development and commercialization activities without infringing or misappropriating the patents and other proprietary rights of others. There are many patents and patent applications owned by others that could be relevant to our business. For example, there are numerous U.S. and foreign issued patents and pending patent applications owned by others that are related to the therapeutic areas in which we have approved drugs or future investigational drug candidates as well as the therapeutic targets to which these drugs and candidates are directed. There are also numerous issued patents and patent applications covering chemical compounds or synthetic processes that may be necessary or useful to use in our research, development, manufacturing or commercialization activities. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our approved drugs, future investigational drug candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our approved drugs, investigational drug candidates or technologies may infringe. Further, it is not always clear to industry participants, including us, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. We cannot assure you that others holding any of these patents or patent applications will not assert infringement claims against us for damages or seek to enjoin our activities. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, and we may not be able to do this.

There can be no assurance that approved drugs or future investigational drug candidates do not or will not infringe on the patents or proprietary rights of others. In addition, third parties may already own or may obtain patents in the future and claim that use of our technologies infringes these patents.

If a person or entity files a legal action or administrative action against us, or our collaborators, claiming that our drug discovery, development, manufacturing or commercialization activities infringes a patent owned by the person or entity, we could incur substantial costs and diversion of the time and attention of management and technical personnel in defending ourselves against any such claims. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief that could effectively block our ability to further develop, commercialize and sell any current or future approved drugs, and such claims could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, if at all. In that case, we could encounter delays in product introductions while we attempt to develop alternative investigational drug candidates or be required to cease commercializing any affected current or future approved drugs and our operating results would be harmed.

Furthermore, because of the substantial amount of pre-trial document and witness discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

We may face additional competition outside of the U.S. as a result of a lack of patent coverage in some territories and differences in patent prosecution and enforcement laws in foreign counties.

Filing, prosecuting, defending and enforcing patents on all of our drug discovery technologies and all of our approved drugs and potential investigational drug candidates throughout the world would be prohibitively expensive. While we have filed patent applications in many countries outside the U.S., and have obtained some patent coverage for approved drugs in certain foreign countries, we do not currently have widespread patent protection for these drugs outside the U.S. and have no protection in many foreign jurisdictions. Competitors may use our technologies to develop their own drugs in jurisdictions where we have not obtained patent protection. These drugs may compete with our approved drugs or future investigational drug candidates and may not be covered by any of our patent claims or other intellectual property rights.

Table of Contents

Even if international patent applications ultimately issue or receive approval, it is likely that the scope of protection provided by such patents will be different from, and possibly less than, the scope provided by our corresponding U.S. patents. The success of our international market opportunity is dependent upon the enforcement of patent rights in various other countries. A number of countries in which we have filed or intend to file patent applications have a history of weak enforcement and/or compulsory licensing of intellectual property rights. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which makes it difficult for us to stop the infringement of our patents. Even if we have patents issued in these jurisdictions, there can be no assurance that our patent rights will be sufficient to prevent generic competition or unauthorized use.

Attempting to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Our failure to successfully acquire, develop and market additional investigational drug candidates or approved drugs would impair our ability to grow.

As part of our growth strategy, we may acquire, in-license, develop and/or market additional products and investigational drug candidates. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical investigational drug candidates and products.

The process of proposing, negotiating and implementing a license or acquisition of an investigational drug candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of investigational drug candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional investigational drug candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management s time and attention to develop acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;

- higher than expected acquisition, integration and maintenance costs;

- increased amortization expenses;

- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;

- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and

- inability to retain key employees of any acquired businesses.

Further, any investigational drug candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All investigational drug candidates are prone to risks of failure typical of pharmaceutical investigational drug candidate development, including the possibility that an investigational drug candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any drugs that we develop or approved products that we may acquire will be commercialized profitably or achieve market acceptance.

Table of Contents

Risks Relating to our Financial Position and Need for Financing

We may require additional capital for our future operating plans, and we may not be able to secure the requisite additional funding on acceptable terms, or at all, which would force us to delay, reduce or eliminate commercialization efforts.

We expect that our existing capital resources combined with future anticipated cash flows will be sufficient to support our operating activities at least through the first quarter of 2014. Should product sales be significantly less than internal expectations, we would need to raise additional capital to support operating activities through 2014 and beyond. However, we anticipate that we will be required to obtain additional financing to fund our commercialization efforts, additional clinical studies for approved products and the development of our research and development pipeline in future periods. Our future capital requirements will depend upon numerous factors, including:

- the cost required to maintain the certified home delivery pharmacy network and REMS program for Qsymia, including a substantial cost to expand into certified retail pharmacy locations;

- our ability to successfully commercialize Qsymia in the U.S. on a timely basis;

- our ability to successfully commercialize through marketing partnerships for STENDRA in the U.S. and SPEDRA, if approved, in our territories outside the U.S.;

- the cost, timing and outcome of the post-approval clinical studies the FDA has required us to perform as part of the approval for STENDRA and Qsymia;

- the progress and costs of our research and development programs;

- the scope, timing, costs and results of pre-clinical, clinical and retrospective observational studies and trials;

- the cost of access to electronic records and databases that allow for retrospective observational studies;

- patient recruitment and enrollment in future clinical trials;

- the costs involved in seeking regulatory approvals for future drug candidates;
- the costs involved in filing and pursuing patent applications, defending and enforcing patent claims;
- the establishment of collaborations, sublicenses and strategic alliances and the related costs, including milestone payments;
- the costs involved in establishing a commercial operation and in launching a product without a partner;
- the cost of manufacturing and commercialization activities and arrangements;
- the level of resources devoted to our future sales and marketing capabilities;
- the cost, timing and outcome of litigation, if any;
- the impact of healthcare reform, if any, imposed by the federal government;
- the activities of competitors; and
- maintaining compliance to our agreement with BioPharma and maintaining our ability to receive an additional $60 million at a secondary closing.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies. We currently have no commitments or agreements relating to any of these types of transactions.

Table of Contents

To obtain additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of equity or debt securities, corporate alliances, joint ventures and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all. We are continually evaluating our existing portfolio and we may choose to divest, sell or spin-off one or more of our drugs and/or investigational drug candidates at any time. We cannot assure you that our drugs will generate revenues sufficient to enable us to earn a profit. If we are unable to obtain additional capital, management may be required to explore alternatives to reduce cash used by operating activities, including the termination of research and development efforts that may appear to be promising to us, the sale of certain assets and the reduction in overall operating activities. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts.

Raising additional funds by issuing securities will cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, our existing stockholders ownership will be diluted. We have financed our operations, and we expect to continue to finance our operations, primarily by issuing and selling our common stock. For example, in March 2012, we sold 9,000,000 shares of our common stock resulting in net proceeds to us of approximately $192.0 million. Moreover, any issuances by us of equity securities may be at or below the prevailing market price of our common stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our common stock to decline. To raise additional capital, we may choose to issue additional securities at any time and at any price.

We may also raise additional capital through the incurrence of debt, and the holders of any debt we may issue would have rights superior to our stockholders rights in the event we are not successful and are forced to seek the protection of bankruptcy laws. In addition, debt financing typically contains covenants that restrict operating activities. For example, on March 25, 2013, we entered into the Purchase and Sale Agreement with BioPharma, which provides for the purchase of a debt-like instrument. Under the BioPharma Agreement, we received $50 million, less $1.1 million in funding and facility payments, on April 9, 2013. To secure our obligations in connection with the BioPharma Agreement, we granted BioPharma a security interest to certain of our assets. During the term of the BioPharma Agreement, we are required to use commercially reasonable efforts to undertake certain obligations and activities to develop, market, promote and commercialize Qsymia and maximize net sales of Qsymia. Additionally, during the term of the BioPharma Agreement we may not (i) incur indebtedness greater than a specified amount, (ii) pay a dividend or other cash distribution on our capital stock, unless we have cash and cash equivalents in excess of a specified amount, (iii) amend or restate our certificate of incorporation or bylaws unless such amendments or restatements do not affect BioPharma s interests under the BioPharma Agreement, (iv) encumber the collateral, or (v) abandon certain patent rights, in each case without the consent of BioPharma. Any future debt financing we enter into may involve similar or more onerous covenants that restrict our operations.

If we raise additional capital through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our drugs or future investigational drug candidates, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the commercialization of one or more of our approved drugs or the development of one or more of our future investigational drug candidates.

The investment of our cash balance and our available-for-sale securities are subject to risks which may cause losses and affect the liquidity of these investments.

At March 31, 2013, we had $90.6 million in cash and cash equivalents and $59.7 million in available-for-sale securities. While at March 31, 2013, our excess cash balances were invested in money market and U.S. Treasury securities, our investment policy as approved by our Board of Directors, also provides for investments in debt securities of U.S. government agencies, corporate debt securities and asset-backed securities. Our investment policy has the primary investment objectives of preservation of principal. However, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy. Although the U.S. Congress was able to resolve the debt ceiling issue in time to avoid default, the major credit rating agencies have expressed their ongoing concern about the high levels of debt that the U.S. government has taken on. Standard & Poor s announced that it had revised its outlook on the long-term credit rating of the U.S. to negative, which could affect the trading market for U.S. government securities. These factors could impact the liquidity or valuation of our available-for-sale securities, all of which were invested in U.S. treasury securities as of March 31, 2013. If those securities are downgraded or impaired we would experience losses in the value of our portfolio which would have an adverse effect on our results of operations, liquidity and financial condition. An investment in money market mutual funds is not insured or guaranteed by the Federal Deposit Insurance Corporation or any other government agency. Although money market mutual funds seek to preserve the value of the investment at $1 per share, it is possible to lose money by investing in money market mutual funds.

Table of Contents

Our involvement in securities related class action litigation could divert our resources and management s attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities related class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their investigational drug candidate development programs, the review of marketing applications by regulatory authorities and the commercial launch of newly approved drugs. We are a defendant in federal and consolidated state shareholder derivative lawsuits. These securities related class action lawsuits generally allege that we and our officers misled the investing public regarding the safety and efficacy of Qsymia and the prospects for the FDA s approval of the Qsymia NDA as a treatment for obesity. Securities related class action litigation often is expensive and diverts management s attention and our financial resources, which could adversely affect our business. For example, following the Court s granting of our prior motion to dismiss with leave to amend, on September 27, 2012, the U.S. District Court for the Northern District of California granted, with prejudice, our motion to dismiss the putative class action lawsuit captioned *Kovtun v. Vivus, Inc., et al.*, Case No. 4:10-CV-04957-PJH. Despite the granting of the prior two motions to dismiss, on October 26, 2012, plaintiff filed a Notice of Appeal to the U.S. Court of Appeals for the Ninth Circuit. Plaintiff filed his opening appellate brief on February 19, 2013, and defendants filed their answering brief on April 11, 2013. Briefing is expected to continue into May 2013, after which the Court of Appeals may request oral argument.

We have an accumulated deficit of $539.7 million as of March 31, 2013, and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of $539.7 million for the period from our inception through March 31, 2013, and we anticipate losses in future years due to continued investment in our research and development programs. There can be no assurance that we will be able to achieve or maintain profitability or that we will be successful in the future.

Our ability to utilize our net operating loss carryforwards and other tax attributes to offset future taxable income may be limited.

As of December 31, 2012, we had approximately $449.0 million and $118.1 million of net operating loss, or NOL, carryforwards with which to offset our future taxable income for federal and state income tax reporting purposes, respectively. We used $121.2 million federal and $32.2 million state NOLs to offset our year ended December 31, 2007 federal and state taxable income, which included the $150.0 million in gain recognized from our sale of Evamist. Utilization of our net operating loss and tax credit carryforwards, or Tax Attributes, may be subject to substantial annual limitations provided by the Internal Revenue Code and similar state provisions to the extent certain ownership changes are deemed to occur. Such an annual limitation could result in the expiration of the Tax Attributes before utilization. The Tax Attributes reflected above have not been reduced by any limitations. To the extent it is determined upon completion of the analysis that such limitations do apply, we will adjust the Tax Attributes accordingly. We face the risk that our ability to use our Tax Attributes will be substantially restricted if we undergo an ownership change as defined in Section 382 of the U.S. Internal Revenue Code, or Section 382. An ownership change under Section 382 would occur if 5-percent shareholders, within the meaning of Section 382, collectively increased their ownership in the Company by more than fifty percentage points over a rolling three-year period. There can be no assurance that a Section 382 ownership change has not occurred or will not occur in the future.

We may have exposure to additional tax liabilities that could negatively impact our income tax provision, net income, and cash flow.

We are subject to income taxes and other taxes in both the U.S. and the foreign jurisdictions in which we currently operate or have historically operated. The determination of our worldwide provision for income taxes and current and deferred tax assets and liabilities requires judgment and estimation. In the ordinary course of our business, there are many transactions and calculations where the ultimate tax determination is uncertain. We are subject to regular review and audit by U.S. tax authorities as well as subject to the prospective and retrospective effects of changing tax regulations and legislation. Although we believe our tax estimates are reasonable, the ultimate tax outcome may materially differ from the tax amounts recorded in our consolidated financial statements and may materially affect our income tax provision, net income, or cash flows in the period or periods for which such determination and settlement is made.

Table of Contents

Risks Relating to an Investment in our Common Stock

Our stock price has been and may continue to be volatile.

The market price of our common stock has been volatile and is likely to continue to be so. The market price of our common stock may fluctuate due to factors including, but not limited to:

- our ability to meet the expectations of investors related to the commercialization of Qsymia and STENDRA;
- the costs, timing and outcome of post-approval clinical studies which the FDA has required us to perform as part of the approval for STENDRA and Qsymia;
- the cost required to maintain the certified home delivery pharmacy network and REMS program for Qsymia, including a substantial cost to expand into certified retail pharmacy locations;
- results within the clinical trial programs for Qsymia and STENDRA or other results or decisions affecting the development of our investigational drug candidates;
- announcements of technological innovations or new products by us or our competitors;
- approval of or announcements of other anti-obesity compounds in development;
- publication of generic drug combination weight loss data by outside individuals or companies;
- actual or anticipated fluctuations in our financial results;
- our ability to obtain needed financing;

- sales by insiders or major stockholders;
- economic conditions in the U.S. and abroad;
- the volatility and liquidity of the financial markets;
- comments by or changes in assessments of us or financial estimates by security analysts;
- negative reports by the media or industry analysts on various aspects of our products, our performance and our future operations;
- adverse regulatory actions or decisions;
- any loss of key management;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- discussions about us or our stock price by the financial and scientific press and in online investor communities;
- investment activities employed by short sellers of our common stock;
- developments or disputes concerning patents or other proprietary rights;
- reports of prescription data by us or from independent third parties for our products;
- licensing, product, patent or securities litigation; and

- public concern as to the safety and efficacy of our drugs or future investigational drug candidates developed by us.

Table of Contents

These factors and fluctuations, as well as political and other market conditions, may adversely affect the market price of our common stock. Securities related class action litigation is often brought against a company and senior officers following periods of volatility in the market price of its securities. We have been a defendant in shareholder lawsuits a securities class action against the Company and several senior officers has been dismissed with prejudice but plaintiff has filed an appeal and we could be the target of similar litigation in the future, particularly if we release news about the Company and its performance that proves to be disappointing to investors. Securities related litigation, whether with or without merit, could result in substantial costs and divert management s attention and financial resources, which could harm our business and financial condition, as well as the market price of our common stock.

Additionally, volatility or a lack of positive performance in our stock price may adversely affect our ability to retain or recruit key employees, all of whom have been or will be granted stock options as an important part of their compensation packages.

Our operating results are unpredictable and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.

Our operating results will likely fluctuate from fiscal quarter to fiscal quarter, and from year to year, and are difficult to predict. Although we have commenced sales of Qsymia, we may never increase these sales or become profitable. In addition, we have not entered into a marketing, sales or promotional arrangement with a pharmaceutical partner to commercialize STENDRA. Our operating expenses are largely independent of sales in any particular period. We believe that our quarterly and annual results of operations may be negatively affected by a variety of factors. These factors include, but are not limited to, the level of patient demand for Qsymia and STENDRA, the ability of our distribution partners to process and ship product on a timely basis, the success of our third-party s manufacturing efforts to meet customer demand, fluctuations in foreign exchange rates, investments in sales and marketing efforts to support the sales of Qsymia and STENDRA, investments in the research and development efforts, and expenditures we may incur to acquire additional products.

Future sales of our common stock may depress our stock price.

Sales of our stock by our executive officers and directors, or the perception that such sales may occur, could adversely affect the market price of our stock. We have also registered all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws. Some of our executive officers have adopted trading plans under SEC Rule 10b5-1 to dispose of a portion of their stock. Any of our executive officers or directors may adopt such trading plans in the future. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

Our charter documents and Delaware law could make an acquisition of our company difficult, even if an acquisition may benefit our stockholders.

Our Board of Directors has adopted a Preferred Shares Rights Plan. The Preferred Shares Rights Plan has the effect of causing substantial dilution to a person or group that attempts to acquire us on terms not approved by our Board of Directors. The existence of the Preferred Shares Rights Plan could limit the price that certain investors might be willing to pay in the future for shares of our common stock and could discourage, delay or prevent a merger or acquisition that a stockholder may consider favorable.

Some provisions of our Amended and Restated Certificate of Incorporation and Bylaws could delay or prevent a change in control of our Company. Some of these provisions:

- authorize the issuance of preferred stock by the Board of Directors without prior stockholder approval, commonly referred to as blank check preferred stock, with rights senior to those of common stock;

- prohibit stockholder actions by written consent;

- specify procedures for director nominations by stockholders and submission of other proposals for consideration at stockholder meetings; and

- eliminate cumulative voting in the election of directors.

In addition, we are governed by the provisions of Section 203 of Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These and other provisions in our charter documents could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

Table of Contents

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. REMOVED AND RESERVED

ITEM 5. OTHER INFORMATION

None.

Table of Contents

ITEM 6. EXHIBITS

The following documents are filed as Exhibits to this report:

EXHIBIT NUMBER	DESCRIPTION
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2	Amended and Restated Bylaws of the Registrant.
3.3	Amendment No. 1 to the Amended and Restated Bylaws of the Registrant
3.4	Amendment No. 2 to the Amended and Restated Bylaws of the Registrant
3.5(2)	Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Registrant.
4.1(3)	Specimen Common Stock Certificate of the Registrant.
4.2(4)	Preferred Stock Rights Agreement dated as of March 27, 2007 between the Registrant and Computershare Investor Services, LLC.
10.1	Purchase and Sale Agreement effective as of March 25, 2013 between the Registrant and BioPharma Secured Investments III Holdings Cayman LP.
10.2	Master Services Agreement dated as of September 12, 2007 between the Registrant and Medpace Inc.
10.3(5)*	Fourth Amendment dated January 25, 2013 to the Employment Agreement dated December 20, 2007 between the Registrant and Leland F. Wilson.
10.4(6)	Third Amendment effective as of February 21, 2013 to the Agreement dated as of December 28, 2000 between the Registrant and Mitsubishi Tanabe Pharma Corporation (formerly Tanabe Seiyaku Co., Ltd).
31.1	Certification of Chief Executive Officer, dated May 8, 2013, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer, dated May 8, 2013, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, formatted in Extensible Business Reporting Language (XBRL), include: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) related notes (furnished herewith).

Confidential treatment granted.

Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

* Indicates management contract or compensatory plan or arrangement.

(1) Incorporated by reference to Exhibit 3.2 filed with the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1996 filed with the Commission on March 28, 1997.

(2) Incorporated by reference to Exhibit 3.3 filed with the Registrant s Registration Statement on Form 8-A filed with the Commission on March 28, 2007.

(3) Incorporated by reference to the same numbered exhibit filed with the Registrant s Annual Report on Form 10-K/A for the fiscal year ended December 31, 1996 filed with the Commission on April 16, 1997.

(4) Incorporated by reference to Exhibit 4.1 filed with the Registrant s Registration Statement on Form 8-A filed with the Commission on March 28, 2007.

(5) Incorporated by reference to Exhibit 10.1 filed with the Registrant s Current Report on Form 8-K filed with the Commission on January 30, 2013.

(6) Incorporated by reference to Exhibit 10.1 filed with the Registrant s Current Report on Form 8-K filed with the Commission on February 25, 2013.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 8, 2013

VIVUS, Inc.

/s/ TIMOTHY E. MORRIS
Timothy E. Morris
Sr. Vice President Finance and Global Corporate Development, Chief Financial Officer

/s/ LELAND F. WILSON
Leland F. Wilson
Chief Executive Officer

Table of Contents

VIVUS, INC.

INDEX TO EXHIBITS

EXHIBIT NUMBER	DESCRIPTION
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2	Amended and Restated Bylaws of the Registrant.
3.3	Amendment No. 1 to the Amended and Restated Bylaws of the Registrant
3.4	Amendment No. 2 to the Amended and Restated Bylaws of the Registrant
3.5(2)	Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Registrant.
4.1(3)	Specimen Common Stock Certificate of the Registrant.
4.2(4)	Preferred Stock Rights Agreement dated as of March 27, 2007 between the Registrant and Computershare Investor Services, LLC.
10.1	Purchase and Sale Agreement effective as of March 25, 2013 between the Registrant and BioPharma Secured Investments III Holdings Cayman LP.
10.2	Master Services Agreement dated as of September 12, 2007 between the Registrant and Medpace Inc.
10.3(5)*	Fourth Amendment dated January 25, 2013 to the Employment Agreement dated December 20, 2007 between the Registrant and Leland F. Wilson.
10.4(6)	Third Amendment effective as of February 21, 2013 to the Agreement dated as of December 28, 2000 between the Registrant and Mitsubishi Tanabe Pharma Corporation (formerly Tanabe Seiyaku Co., Ltd).
31.1	Certification of Chief Executive Officer, dated May 8, 2013, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer, dated May 8, 2013, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, formatted in Extensible Business Reporting Language (XBRL), include: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) related notes (furnished herewith).

Confidential treatment granted.

Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

* Indicates management contract or compensatory plan or arrangement.

(1) Incorporated by reference to Exhibit 3.2 filed with the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1996 filed with the Commission on March 28, 1997.

(2) Incorporated by reference to Exhibit 3.3 filed with the Registrant s Registration Statement on Form 8-A filed with the Commission on March 28, 2007.

(3) Incorporated by reference to the same numbered exhibit filed with the Registrant s Annual Report on Form 10-K/A for the fiscal year ended December 31, 1996 filed with the Commission on April 16, 1997.

(4) Incorporated by reference to Exhibit 4.1 filed with the Registrant s Registration Statement on Form 8-A filed with the Commission on March 28, 2007.

(5) Incorporated by reference to Exhibit 10.1 filed with the Registrant s Current Report on Form 8-K filed with the Commission on January 30, 2013.

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