Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For The Quarterly Period Ended June 30, 2014

OR

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

For the transition period from to

Commission File 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)
351 East Evelyn Avenue **Mountain View, California**	**94041**
(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 ☒ No ☐

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 ☒ No ☐

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 ☒	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
(Do not check if a smaller reporting company)	

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). ☐ Yes ☒ No

At July 23, 2014, 103,460,015 shares of common stock, par value $.001 per share, were outstanding.

Table of Contents

VIVUS, INC.

Quarterly Report on Form 10-Q

INDEX

PART I: FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

VIVUS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

	June 30, 2014 (Unaudited)	December 31, 2013 Note 1
ASSETS		
Current assets:		
Cash and cash equivalents	$ 96,262	$ 103,262
Available-for-sale securities	227,922	240,024
Accounts receivable, net	13,284	12,214
Inventories	43,822	48,503
Prepaid expenses and other assets	12,269	19,938
Total current assets	393,559	423,941
Property and equipment, net	1,725	1,954
Non-current assets	5,390	5,901
Total assets	$ 400,674	$ 431,796
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9,715	$ 10,759
Accrued and other liabilities	23,532	23,993
Deferred revenue	19,407	17,255
Total current liabilities	52,654	52,007
Long-term debt, net of current portion	216,841	213,106
Deferred revenue, net of current portion	9,994	10,360
Non-current accrued and other liabilities	2,388	2,954
Total liabilities	281,877	278,427
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; 103,390 and 103,161 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	103	103
Additional paid-in capital	820,573	813,802
Accumulated other comprehensive income	98	66
Accumulated deficit	(701,977)	(660,602)
Total stockholders' equity	118,797	153,369
Total liabilities and stockholders' equity	$ 400,674	$ 431,796

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Revenue:				
Net product revenue	$ 10,983	$ 5,534	$ 20,121	$ 9,646
License and milestone revenue	4,181	—	23,544	—
Supply revenue	5,666	—	13,036	—
Royalty revenue	1,051	—	1,871	—
Total revenue	21,881	5,534	58,572	9,646
Operating expenses:				
Cost of goods sold	7,015	572	16,548	962
Inventory impairment and commitment fee	—	4,448	—	10,225
Research and development	4,086	9,232	8,509	16,278
Selling, general and administrative	28,266	39,509	56,875	83,499
Non-recurring charges	—	3,218	2,054	3,924
Total operating expenses	39,367	56,979	83,986	114,888
Loss from operations	(17,486)	(51,445)	(25,414)	(105,242)
Total interest expense and other expense (income), net	8,341	4,183	16,399	4,148
Loss from continuing operations before income taxes	(25,827)	(55,628)	(41,813)	(109,390)
Provision for (benefit from) income taxes	(2)	7	(438)	13
Loss from continuing operations	(25,825)	(55,635)	(41,375)	(109,403)
Income from discontinued operations, net of tax	—	123	—	315
Net loss	$ (25,825)	$ (55,512)	$ (41,375)	$ (109,088)
Basic and diluted net loss per share:				
Continuing operations	$ (0.25)	$ (0.55)	$ (0.40)	$ (1.08)
Discontinued operations	—	—	—	—
Net loss per share	$ (0.25)	$ (0.55)	$ (0.40)	$ (1.08)
Shares used in per share computation:				
Basic and diluted	103,350	100,739	103,320	100,700

See accompanying notes to unaudited condensed consolidated financial statements.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net loss	$ (25,825)	$ (55,512)	$ (41,375)	$ (109,088)
Other comprehensive loss:				
Unrealized gain (loss) on securities, net of taxes	(11)	(40)	32	(59)
Comprehensive loss	$ (25,836)	$ (55,552)	$ (41,343)	$ (109,147)

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2014	2013
Cash flows from operating activities:		
Net loss from continuing operations	$ (41,375)	$ (109,403)
Adjustments to reconcile net loss to net cash used for operating activities from operations:		
Depreciation	424	419
Amortization of debt issuance costs and discounts	7,806	1,659
Amortization of discount or premium on available-for-sale securities	1,917	998
Share-based compensation expense	5,692	11,961
Inventory impairment	—	7,525
Other non-cash adjustments, net	(235)	105
Changes in assets and liabilities:		
Accounts receivable	(1,070)	(2,307)
Inventories	4,681	(16,022)
Prepaid expenses and other assets	8,042	821
Accounts payable	(1,044)	(8,762)
Accrued and other liabilities	(4,479)	1,390
Deferred revenue	1,786	1,696
Net cash used for operating activities from continuing operations	(17,855)	(109,920)
Net cash used for operating activities from discontinued operations	—	(410)
Net cash used for operating activities	(17,855)	(110,330)
Cash flows from investing activities:		
Property and equipment purchases	(195)	(1,845)
Purchases of available-for-sale securities	(118,783)	(209,118)
Proceeds from sales and maturities of available-for-sale securities	129,000	130,500
Non-current assets	(246)	(228)
Net cash provided by (used for) investing activities	9,776	(80,691)
Cash flows from financing activities:		
Net proceeds from debt issuances	—	290,247
Payments for capped call transactions	—	(34,709)
Proceeds from exercise of stock options and sale of common stock through employee stock purchase plan	1,079	1,591
Net cash provided by financing activities	1,079	257,129
Net change in cash and cash equivalents	(7,000)	66,108
Cash and cash equivalents:		
Beginning of period	103,262	58,605
End of period	$ 96,262	$ 124,713

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2014

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 and six months ended June 30, 2014, are not necessarily indicative of the results that may be expected for the year ending December 31, 2014. Management has evaluated all events and transactions that occurred after June 30, 2014, through the date these unaudited condensed consolidated financial statements were filed. There were no events or transactions during this period that require recognition or disclosure in these unaudited condensed consolidated financial statements. 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, 2013 as filed on February 28, 2014 and as amended by the Form 10-K/A filed on April 30, 2014, with the Securities and Exchange Commission, or SEC. The unaudited condensed consolidated financial statements include the accounts of VIVUS, Inc. 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 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, debt instruments, 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.

Fair Value Measurements

Financial instruments include cash equivalents, available-for-sale securities, accounts receivable, accounts payable and accrued liabilities. Available-for-sale securities are carried at estimated fair value. The carrying value of cash equivalents, accounts payable and accrued liabilities approximate their estimated fair value due to the relatively short-term nature of these instruments.

Debt instruments are initially recorded at fair value, with coupon interest and amortization of debt issuance discounts recognized in the statement of operations as interest expense at each period end while such instruments are outstanding. If the Company issues shares to discharge the liability, the debt obligation is derecognized and common stock and additional paid-in capital are recognized on the issuance of those shares.

The Company's Convertible Notes, as described in Note 13. Long-Term Debt, contain a conversion option that is classified as equity. The Company determined the fair value of the liability component of the debt instrument and allocated the excess amount from the initial proceeds to the conversion option. The fair value of the debt component was determined by estimating a risk adjusted interest rate, or market yield, at the time of issuance for similar notes that do not include the conversion feature, or equity component. This excess is reported as a debt discount and is amortized as non-cash interest expense, using the interest method, over the expected life of the Convertible Notes.

Issuance costs related to the equity component of the Convertible Notes were charged to additional paid-in capital. The remaining portion related to the debt component is being amortized and recorded as additional interest expense over the expected life of the Convertible Notes. In connection with the issuance of the Convertible Notes, the Company entered into capped call transactions with certain counterparties affiliated with the underwriters. The fair value of the purchased capped calls was recorded to stockholders' equity.

Revenue from Multiple-Element Arrangements

The Company accounts for multiple-element arrangements, such as license and commercialization agreements in which a customer may purchase several deliverables, in accordance with ASC Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements*, or ASC 605-25. The Company evaluates if the deliverables in the arrangement represent separate units of accounting. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have value to its customers on a stand-alone basis. Factors considered in this determination include whether the deliverable is proprietary to the Company, whether the customer can use the license or other deliverables for their intended purpose without the receipt of the remaining elements, whether the value of the deliverable is dependent on the undelivered items, and whether there are other vendors that can provide the undelivered items. Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting.

When deliverables are separable, the Company allocates non-contingent consideration to each separate unit of accounting based upon the relative selling price of each element. When applying the relative selling price method, the Company determines the selling price for each deliverable using vendor-specific objective evidence, or VSOE, of selling price, if it exists, or third-party evidence, or TPE, of selling price, if it exists. If neither VSOE nor TPE of selling price exists for a deliverable, the Company uses best estimated selling price, or BESP, for that deliverable. Significant management judgment may be required to determine the relative selling price of each element. Revenue allocated to each element is then recognized based on when the following four basic revenue recognition criteria are met for each element: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the price is fixed or determinable; and (iv) collectability is reasonably assured.

Determining whether and when some of these criteria have been satisfied often involves assumptions and judgments that can have a significant impact on the timing and amount of revenue the Company reports. Changes in assumptions or judgments, or changes to the elements in an arrangement, could cause a material increase or decrease in the amount of revenue reported in a particular period.

ASC Topic 605-28, *Revenue Recognition—Milestone Method* (ASC 605-28), established the milestone method as an acceptable method of revenue recognition for certain contingent, event-based payments under research and development arrangements. Under the milestone method, a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event: (i) that can be achieved based in whole or in part on either the Company's performance or on the occurrence of a specific outcome resulting from the Company's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the Company. The determination that a milestone is substantive requires judgment and is made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone is: (i) commensurate with either the Company's performance to achieve the milestone or the enhancement of value of the item delivered as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (ii) relates solely to past performance, and (iii) is reasonable relative to all deliverables and payment terms in the arrangement.

Other contingent, event-based payments received for which payment is either contingent solely upon the passage of time or the results of a collaborative partner's performance are not considered milestones under ASC 605-28. In accordance with ASC 605-25, such payments will be recognized as revenue when all of the four basic revenue recognition criteria are met.

Revenues recognized for royalty payments are recognized as net sales are reported in accordance with the terms of the license and commercialization agreements.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued ASU No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09). The standard provides companies with a single model for use in accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific revenue guidance. The core principle of the model is to recognize revenue when control of the goods or services transfers to the customer, as opposed to recognizing revenue when the risks and rewards transfer to the customer under the existing revenue guidance. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early adoption is not permitted. The guidance permits companies to either apply the requirements retrospectively to all prior periods presented, or apply the requirements in the year of adoption, through a cumulative adjustment. The Company is in the process of evaluating the impact of adoption on its consolidated financial statements.

2. SHARE-BASED COMPENSATION

The Company accounts for share-based compensation arrangements in accordance with the 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 June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Cost of goods sold	$ 29	$ —	$ 63	$ —
Research and development	313	944	587	1,879
Selling, general and administrative	2,502	4,960	4,699	10,082
Non-recurring charges	—	—	343	—
Total share-based compensation expense	$ 2,844	$ 5,904	$ 5,692	$ 11,961

There was no share-based compensation cost capitalized as part of the cost of inventory for the three and six months ended June 30, 2014 as compared to $187,000 and $367,000 for the three and six months ended June 30, 2013, respectively.

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 June 30, 2014 and December 31, 2013, are presented in the tables that follow.

	As of June 30, 2014 (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	$ 96,262	$ —	$ —	$ 96,262
U.S. Treasury securities	227,824	100	(2)	227,922
Total	324,086	100	(2)	324,184
Less amounts classified as cash and cash equivalents	(96,262)	—	—	(96,262)
Classified as available-for-sale securities	$ 227,824	$ 100	$ (2)	$ 227,922

	As of December 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	$ 103,262	$ —	$ —	$ 103,262
U.S. Treasury securities	239,959	69	(4)	240,024
Total	343,221	69	(4)	343,286
Less amounts classified as cash and cash equivalents	(103,262)	—	—	(103,262)
Classified as available-for-sale securities	$ 239,959	$ 69	$ (4)	$ 240,024

As of June 30, 2014, all of the Company's available-for-sale securities have original contractual maturities up to 24 months. However, the Company may or may not hold securities with stated maturities greater than 12 months until maturity. In response to changes in the availability of and the yield on alternative investments as well as liquidity requirements, the Company may sell these securities prior to their stated maturities. As these securities are viewed by the Company as available to support current operations, securities with maturities beyond 12 months are classified as current assets. Due to their short-term maturities, the Company believes that the fair value of its bank deposits approximate their carrying value.

Fair Value Measurements

As of June 30, 2014 and December 31, 2013, 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 measured on a recurring basis where Level 2 or Level 3 valuation techniques were used.

4. ACCOUNTS RECEIVABLE

Accounts receivable consist of (in thousands):

	Balance as of	
	June 30, 2014	**December 31, 2013**
Qsymia	$ 8,189	$ 6,777
STENDRA/SPEDRA	5,259	5,571
	13,448	12,348
Qsymia allowance for cash discounts	(164)	(134)
Net	$ 13,284	$ 12,214

5. INVENTORIES

Inventories consist of (in thousands):

	Balance as of	
	June 30, 2014	December 31, 2013
Raw materials	$ 30,704	$ 28,557
Finished goods	9,106	14,793
Deferred costs	4,012	5,153
Total	$ 43,822	$ 48,503

As of June 30, 2014 and December 31, 2013, raw materials inventories consist primarily of the active pharmaceutical ingredients, or API, for the commercialization of Qsymia (phentermine and topiramate extended release) capsules CIV and finished goods and deferred costs inventories consist of both Qsymia and STENDRA (avanafil). The Qsymia deferred costs represents Qsymia product shipped to the Company's wholesalers, certified retail pharmacies and certified home delivery pharmacy services networks, but not yet dispensed to patients through prescriptions, net of prompt payment discounts, and for which recognition of revenue has been deferred. The STENDRA deferred costs represent certain initial orders of STENDRA or SPEDRA product with the right of return or credit, which did not meet the required specifications of one of the Company's partners, and for which recognition of revenue has been deferred.

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories, which are valued using a weighted average cost method calculated for each production batch. 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, no charges were recorded in the three and six months ended June 30, 2014.

6. PREPAID EXPENSES AND OTHER ASSETS

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

	Balance as of	
	June 30, 2014	December 31, 2013
Prepaid insurance	$ 1,230	$ 3,617
Prepaid sales and marketing expenses	5,625	5,187
Withholding tax receivable	—	5,560
Debt issuance costs	1,255	1,247
Prepaid expenses and other assets	4,159	4,327
Total	$ 12,269	$ 19,938

The amounts included in prepaid expenses and other assets consist primarily of interest income receivable, deposits and prepayments for future services.

7. NON-CURRENT ASSETS

Non-current assets consist of (in thousands):

	Balance as of	
	June 30, 2014	December 31, 2013
Debt issuance costs	$ 3,993	$ 4,620
Other non-current assets	1,397	1,281
Total	$ 5,390	$ 5,901

The amounts included in non-current assets consist of debt issuance costs relating to the Convertible Notes and the Senior Secured Notes (see Note 13. Long-Term Debt), which primarily consist of investment banker, legal and other professional fees, and other assets which are not expected to be realized in the next 12 months.

8. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities consist of (in thousands):

	Balance as of	
	June 30, 2014	December 31, 2013
Accrued interest expense	$ 5,540	$ 5,541
Non-recurring charges (see Note 10)	3,974	4,577
Current portion of long-term debt	3,452	—
Accrued employee compensation and benefits	3,048	3,408
Accrued manufacturing costs	815	4,071
Other accrued liabilities	6,703	6,396
Total	$ 23,532	$ 23,993

The amounts included in other accrued liabilities consist of obligations primarily related to research and clinical expense, sales, marketing and corporate expense and royalties.

9. NON-CURRENT ACCRUED AND OTHER LIABILITIES

Non-current accrued and other liabilities at June 30, 2014 and December 31, 2013, of $2.4 million and $3.0 million, respectively, consist of employee severance and benefits related to a cost reduction plan and lease exit costs that will be paid in periods beyond the next 12 months (see Note 10. Non-Recurring Charges).

10. NON-RECURRING CHARGES

The following table sets forth activities for the Company's cost reduction plan obligations during the three and six months ended June 30, 2014 (in thousands):

	Severance obligations	Facilities-related obligations	Total
Balance of accrued costs at December 31, 2013	$ 6,509	$ 1,022	$ 7,531
Charges	1,711[1]	—	1,711
Payments	(1,659)	(180)	(1,839)
Balance of accrued costs at March 31, 2014	6,561	842	7,403
Payments	(1,086)	(219)	(1,305)
Balance of accrued costs at June 30, 2014	$ 5,475	$ 623	$ 6,098

[1] In addition to the above non-recurring charges, as previously disclosed, the Company incurred non-cash share-based compensation expense of $0.3 million in the six months ended June 30, 2014, for aggregate non-recurring charges of $2.1 million in the six months ended June 30, 2014. There were no such charges in the three months ended June 30, 2014.

The accrued facilities-related costs at June 30, 2014 represent estimated losses, net of expected subleases, on space vacated as part of the Company's cost reduction plan. The noncancelable operating leases and scheduled payments against the amounts accrued extend through May 2020, unless the Company is able to negotiate earlier terminations.

Of the total accrued employee severance and facilities-related costs in the Company's unaudited condensed consolidated balance sheet at June 30, 2014, $4.0 million is included under current liabilities in "Accrued and other liabilities" and $2.1 million is included in "Non-current accrued and other liabilities."

The balance of the accrued employee severance and facilities-related costs at June 30, 2014 is anticipated to be paid out as follows (in thousands):

2014 *(remaining six months)*	$	2,255
2015		3,215
2016		260
2017		341
2018		11
Thereafter		16
	$	6,098

11. DEFERRED REVENUE

Qsymia Deferred Revenue

At June 30, 2014, the Company had $15.2 million in current deferred revenue, which represents Qsymia product shipped to the Company's wholesalers, certified retail pharmacies and certified home delivery pharmacy services networks, but not yet dispensed to patients through prescriptions, net of prompt payment discounts.

STENDRA or SPEDRA Deferred Revenue

At June 30, 2014, the Company had $0.7 million and $10.0 million in current and noncurrent deferred revenue, respectively, relating to prepayment for future royalties on sales of SPEDRA. Additionally, the Company supplied certain initial orders of STENDRA or SPEDRA product with a right of return or credit, which did not meet the required specifications of one of the Company's partners and for which the Company had $3.5 million in current deferred revenue related to STENDRA or SPEDRA product supply at June 30, 2014.

12. LICENSE, COMMERCIALIZATION AND SUPPLY AGREEMENTS

During 2013, the Company entered into license and commercialization agreements and commercial supply agreements with the Menarini Group, through its subsidiary Berlin-Chemie AG, or Menarini, Auxilium Pharmaceuticals, Inc., or Auxilium, and Sanofi and its affiliate, or Sanofi, to commercialize and promote STENDRA or SPEDRA in their respective territories. Menarini's territory is comprised of over 40 European countries, including the EU, plus Australia and New Zealand. Auxilium's territory is comprised of the United States and Canada and their respective territories. Sanofi's territory is comprised of Africa, the Middle East, Turkey and Eurasia.

For the three and six months ended June 30, 2014, the Company recognized $4.2 million and $23.5 million, respectively, in license and milestone revenue primarily due to product launches in certain EU countries. During the same periods, the Company recognized $5.7 million and $13.0 million, respectively, in supply revenue relating to STENDRA or SPEDRA delivered under the various commercial supply agreements with Menarini, Auxilium and Sanofi. Additionally, for the three and six months ended June 30, 2014, the Company recognized $1.1 million and $1.9 million, respectively, in royalty revenue based on net sales reported by Menarini and Auxilium.

13. LONG-TERM DEBT

Convertible Senior Notes Due 2020

On May 21, 2013, the Company closed an offering of $220.0 million in 4.5% Convertible Senior Notes due May 1, 2020, or the Convertible Notes. The Convertible Notes are governed by an indenture, dated as of May 21, 2013, between the Company and Deutsche Bank National Trust Company, as trustee. On May 29, 2013, the Company closed on an additional $30.0 million of Convertible Notes upon exercise of an option by the initial purchasers of the Convertible Notes. Total net proceeds from the Convertible Notes were approximately $241.8 million. For the three and six months ended June 30, 2014, total interest expense was $8.2 million and $16.2 million, respectively, which includes amortization of $3.6 million and $7.2 million of the debt discount and

$192,000 and $381,000 of deferred financing costs, respectively. The remaining expected life of the Convertible Notes at June 30, 2014 is 4.4 years. As of June 30, 2014, the Convertible Notes were not convertible and the if-converted value did not exceed their principal amount.

Senior Secured Notes Due 2018

On March 25, 2013, the Company entered into the Purchase and Sale Agreement between the Company and BioPharma Secured Investments III Holdings Cayman LP, a Cayman Islands exempted limited partnership, providing for the purchase of a debt-like instrument, or the Senior Secured Notes. Under the agreement, the Company received $50 million, less $500,000 in funding and facility payments, at the initial closing on April 9, 2013. The Company had the option, but elected not to exercise it, to receive an additional $60 million, less $600,000 in a funding payment, at a secondary closing no later than January 15, 2014. For the three and six months ended June 30, 2014, the imputed interest expense for the Senior Secured Notes was $1.9 million and $3.8 million, respectively. This includes amortization of deferred financing costs amounting to $119,000 and $238,000 for the three and six months ended June 30, 2014, respectively.

The following table summarizes information on the debt (in thousands):

	June 30, 2014
Convertible Senior Notes due 2020:	
Fair value of the liability component at issuance date	$ 154,737
Accumulated accretion of discount	15,556
Net carrying value	$ 170,293
Senior Secured Notes due 2018:	
Carrying value	$ 50,000[1]
Total Notes:	
Fair value of the liability component at issuance date	$ 204,737
Accumulated accretion of discount	15,556
Net carrying amount	$ 220,293

[1] Approximately $3.5 million is classified as current and included in accrued and other current liabilities in the Condensed Consolidated Balance Sheet as of June 30, 2014.

14. 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 or upon a net share settlement of the Company's Convertible Notes. 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. The triggering conversion conditions that allow holders of the Convertible Notes to convert have not been met. If such conditions are met and the note holders opt to convert, the Company may choose to pay in cash, common stock, or a combination thereof; however, if this occurs, the Company has the intent and ability to net share settle this debt security; thus the Company uses the treasury stock method for earnings per share purposes. Due to the effect of the capped call instrument purchased in relation to the Convertible Notes, there would be no net shares issued until the market value of the Company's stock exceeds $20 per share, and thus no impact on diluted net income per share. Further, 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 and six months ended June 30, 2014 and 2013, all potential common equivalent shares were excluded for these periods as they were anti-dilutive. For the three and six months ended June 30, 2014 and

2013, awards and options outstanding of 8,779,000 and 8,191,000, and 6,122,000 and 5,789,000, respectively, were not included in the computation of diluted net loss per share for the Company because the effect would be anti-dilutive.

15. INCOME TAXES

For the three and six months ended June 30, 2014, the Company recorded a tax benefit of $2,000 and $438,000, respectively. For the three and six months ended June 30, 2013, the Company recorded provisions for income taxes of $7,000 and $13,000, respectively. The tax benefit for the three and six months ended June 30, 2014 relates to tax liabilities in certain states, offset by a tax refund received from the state of New Jersey, as a result of a settlement of an audit and acceptance of a refund claim for the tax year ended December 31, 2007. The tax provision for the three and six months ended June 30, 2013 related to state tax liabilities.

The Company assesses the likelihood that it will be able to recover its deferred tax assets on a quarterly basis. The Company considers all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is not more likely than not that the Company will recover its deferred tax assets, the Company will increase its provision for taxes by recording a valuation allowance against the deferred tax assets that the Company estimates will not ultimately be recoverable. As a result of the Company's analysis of all available evidence, both positive and negative, as of December 31, 2013, it was considered more likely than not that the Company's deferred tax assets would not be realized. However, should there be a change in the Company's ability to recover its deferred tax assets, the Company would recognize a benefit to its tax provision in the period in which the Company determines that it is more likely than not that it will recover its deferred tax assets.

There were no material changes to the Company's unrecognized tax benefits in the three months ended June 30, 2014, and we do not expect to have any significant changes to unrecognized tax benefits through the end of the fiscal year. Because of our history of tax losses, certain tax years remain open to tax audit.

16. LEGAL MATTERS

Securities Related Class Action and Shareholder Derivative Lawsuits

The Company, a current officer and a former officer were defendants in a putative class action 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. The Court granted defendants' motions to dismiss both plaintiff's Amended Class Action Complaint and Second Amended Class Action Complaint; by order dated September 27, 2012, the latter dismissal was with prejudice and final judgment was entered 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. Briefing of the appeal is complete, and the parties are awaiting word on whether the Court of Appeals wishes to entertain oral argument.

Additionally, certain of the Company's former officers and directors and a current director 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 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 Company is named as a nominal defendant in these actions, neither of which seeks any recovery from the Company. The parties have agreed to stay the derivative lawsuits pending the outcome of the appeal of the securities class action.

On July 12, 2013, various current and former officers and directors of the Company were named as defendants in a separate shareholder derivative lawsuit filed in the California Superior Court, Santa Clara County, and captioned *Ira J. Gaines IRA, et al. v. Leland F. Wilson, et al.,* Case No.1-13-CV-249436. The lawsuit generally alleged breaches of the fiduciary duty of care in connection with the launch of Qsymia, breaches of the duty of loyalty and insider trading by some defendants for selling Company stock while purportedly being aware that the Qsymia launch would be less successful than predicted and corporate waste. On March 14, 2014, the Court sustained a demurrer and dismissed the complaint with leave to amend. An order memorializing the Court's ruling was entered March 21, 2014. On April 21, 2014, derivative plaintiffs filed an Amended Shareholder Derivative Complaint alleging substantially similar breaches of duty. On May 21, 2014, the Company filed a demurrer to the Amended Complaint. With that demurrer pending, derivative plaintiffs asked the Court in July 2014 to dismiss the action with prejudice as to the named plaintiffs and otherwise without prejudice. The Court did so by order entered July 17, 2014, and the matter is now concluded.

On March 27, 2014, Mary Jane and Thomas Jasin, who purport to be purchasers of VIVUS common stock, filed an Amended Complaint alleging securities fraud against the Company and three of its former officers and directors. Plaintiffs served the defendants a few days after filing the Amended Complaint. The Amended Complaint in the action, styled *Jasin v. VIVUS, Inc.,* Case No. 114-cv-261427 pending in the California Superior Court, Santa Clara County, asserts claims for violation of California Corporations Code Sections 25400 and 25401 and Business and Professions Code Section 17200. Plaintiffs allege generally that defendants misrepresented the prospects for the Company's success, including with the launch of Qsymia, while purportedly selling VIVUS stock for personal profit. The factual allegations include substantial overlap with the allegations in the *Gaines* action. Plaintiffs allege losses of "at least" $2.8 million, and their prayer seeks damages plus attorney's and expert witness fees, among other relief. On June 5, 2014, the Company and the other defendants filed a demurrer to the Amended Complaint seeking its dismissal. That motion is scheduled for a hearing in September 2014. VIVUS cannot predict the outcome of the motion or of the case generally. With the demurrer pending, however, on July 18, 2014, the same plaintiffs filed a complaint in the United States District Court for the Northern District of California, styled *Jasin v. VIVUS, Inc.,* Case No. 5:14-cv-03263. The Jasins' federal complaint alleges violations of Sections 10(b) and 20A of the Securities Exchange Act of 1934, based on substantially similar underlying facts as are alleged in their state court action. As the federal action has not been served, no schedule exists for defendants' response to the complaint or for other proceedings, and we cannot predict the course or outcome of any federal court proceedings. The Company maintains directors' and officers' liability insurance that it believes affords coverage for much of the anticipated cost of both *Jasin* actions, subject to payment of the Company's self-insured retention and the policies' terms and conditions.

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.

Qsymia ANDA Litigation

On May 7, 2014, the Company received a Paragraph IV certification notice from Actavis Laboratories FL indicating that it filed an abbreviated new drug application, or ANDA, with the U.S. Food and Drug Administration, or FDA, requesting approval to market a generic version of Qsymia and contending that all 6 patents listed for Qsymia in the FDA Orange Book (U.S. Patents 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, and 8,580,299 (collectively "patents-in-suit")) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Qsymia as described in their ANDA. On June 12, 2014, the Company filed a lawsuit in the U.S District Court for the District of New Jersey against Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as Actavis. The lawsuit (Case No. 14-3786 (FSH)(MAH)) was filed on the basis that Actavis' submission of their ANDA to obtain approval to manufacture, use, sell or offer for sale generic versions of Qsymia prior to the expiration of the patents-in-suit constitutes infringement of one or more claims of those patents.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Actavis, FDA approval of Actavis' ANDA will be stayed until the earlier of (i) November 7, 2016 which is 30 months from the Company's May 7, 2014 receipt of Actavis' Paragraph IV certification notice or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. The Company intends to vigorously enforce its intellectual property rights relating to Qsymia, but the Company cannot predict the outcome of this matter.

17. SEGMENT INFORMATION

The Company operates in one reportable segment—the development and commercialization of novel therapeutic products. The Company has identified its Chief Executive Officer as the Chief Operating Decision Maker, or CODM, who manages the Company's operations on a consolidated basis for purposes of allocating resources. When evaluating financial performance, the CODM reviews product information, while other financial information is reviewed on a consolidated basis. Therefore, results of operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Disclosures about revenues by product and by geographic area are presented below.

Geographic Information

Outside the United States, or ROW, the Company sells products through a commercialization licensee principally in the EU. The geographic classification of product sales was based on the location of the customer. The geographic classification of supply, license and milestone revenue was based on the domicile of the entity from which the revenue was earned.

Net product revenue by geographic region was as follows (in thousands):

	Three Months Ended June 30,					
	2014			2013		
	U.S.	ROW	Total	U.S.	ROW	Total
Qsymia—Net product revenue	$ 10,983	$ —	$ 10,983	$ 5,534	$ —	$ 5,534
STENDRA/SPEDRA—License and milestone revenue	—	4,181[1]	4,181	—	—	—
STENDRA/SPEDRA—Supply revenue	857	4,809	5,666	—	—	—
STENDRA/SPEDRA —Royalty revenue	430	621	1,051	—	—	—
Total revenue	$ 12,270	$ 9,611	$ 21,881	$ 5,534	$ —	$ 5,534

	Six Months Ended June 30,					
	2014			2013		
	U.S.	ROW	Total	U.S.	ROW	Total
Qsymia—Net product revenue	$ 20,121	$ —	$ 20,121	$ 9,646	$ —	$ 9,646
STENDRA/SPEDRA—License and milestone revenue	406	23,138[1]	23,544	—	—	—
STENDRA/SPEDRA—Supply revenue	5,406	7,630	13,036	—	—	—
STENDRA/SPEDRA —Royalty revenue	1,250	621	1,871	—	—	—
Total revenue	$ 27,183	$ 31,389	$ 58,572	$ 9,646	$ —	$ 9,646

[1] $4.2 million and $20.7 million of which are attributable to Germany for the three and six months ended June 30, 2014.

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

This Management's Discussion and Analysis of Financial Condition 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," "estimated," and "potential," 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 we 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 requirements; (5) our ability to continue to certify and add to the Qsymia retail pharmacy network and sell Qsymia through this network; (6) whether the Qsymia retail pharmacy network will simplify and reduce the prescribing burden for physicians, improve access and reduce waiting times for patients seeking to initiate therapy with Qsymia; (7) that we may be required to provide further analysis of previously submitted clinical trial data; (8) our assessment of the European Medicines Agency's Scientific Advice relating to our cardiovascular outcomes trial, or CVOT, and the resubmission of an application for the grant of a marketing authorization to the European Medicines Agency, or EMA, the timing of such resubmission, if any, the results of the CVOT, assessment by the EMA of the application for marketing authorization, and their agreement with the data from the CVOT; (9) our ability to successfully seek approval for Qsymia in other territories outside the U.S. and European Union, or EU; (10) whether healthcare providers, payors and public policy makers will recognize the significance of the American Medical Association officially recognizing obesity as a disease, or the new American Association of Clinical Endocrinologists guidelines; (11) our ability to successfully commercialize Qsymia including risks and uncertainties related to expansion to retail distribution, the broadening of payor reimbursement, the expansion of Qsymia's primary

care presence, and the outcomes of our discussions with pharmaceutical companies and our strategic and franchise-specific pathways for Qsymia; (12) our ability to focus our promotional efforts on health-care providers and on patient education that, along with increased access to Qsymia and ongoing improvements in reimbursement, will result in the accelerated adoption of Qsymia; (13) our ability to eliminate expenses that are not essential to expanding the use of Qsymia and fully realize the anticipated benefits from a cost reduction plan, including the timing thereof; (14) the impact of lower annual net cost savings than currently expected; (15) the impact of the cost reduction plan on our business and unanticipated charges not currently contemplated that may occur as a result of the cost reduction plan; (16) our ability to ensure that the entire supply chain for Qsymia efficiently and consistently delivers Qsymia to our customers; (17) risks and uncertainties related to the timing, strategy, tactics and success of the launches and commercialization of STENDRA® (avanafil) or SPEDRA™ (avanafil) by our sublicensees in the United States, Canada, the EU, Australia, New Zealand, Africa, the Middle East, Turkey, and the Commonwealth of Independent States, including Russia; (18) our ability to successfully complete on acceptable terms, and on a timely basis, avanafil partnering discussions for other territories under our license with Mitsubishi Tanabe Pharma Corporation, or MTPC, in which we do not have a commercial collaboration; (19) the timing of the qualification and subsequent approval by regulatory authorities of Sanofi Chimie and Sanofi Winthrop Industrie as a qualified supplier of STENDRA/SPEDRA, Sanofi Chimie's ability to undertake worldwide manufacturing of the avanafil active pharmaceutical ingredient and Sanofi Winthrop Industrie's ability to undertake worldwide manufacturing of the tablets for avanafil; (20) whether the FDA will approve the amendment for the new prescribing information we have submitted, and whether the European Commission, following an opinion by the EMA, will approve the new prescribing information we intend to submit, to include the recently announced clinical study results showing avanafil is effective for sexual activity within 15 minutes in men with erectile dysfunction, or ED; (21) the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand; (22) our ability to accurately forecast Qsymia demand; (23) our ability to increase Qsymia sales in 2014 through growth in certified retail pharmacies, expansion of reimbursement coverage and the use of a more focused selling message; (24) the number of Qsymia prescriptions dispensed through the mail order system and through certified retail pharmacies; (25) the impact of promotional programs for Qsymia on our net product revenue and net income (loss) in future periods; (26) our history of losses and variable quarterly results; (27) substantial competition; (28) risks related to the failure to protect our intellectual property and litigation in which we are involved or may become involved; (29) uncertainties of government or third-party payor reimbursement; (30) our reliance on sole-source suppliers; (31) our reliance on third parties and our collaborative partners; (32) our failure to continue to develop innovative investigational drug candidates and drugs; (33) risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; (34) our ability to demonstrate through clinical testing the quality, safety, and efficacy of our investigational drug candidates; (35) the timing of initiation and completion of clinical trials and submissions to foreign authorities; (36) the results of post-marketing studies are not favorable; (37) compliance with post-marketing regulatory standards, post-marketing obligations or pharmacovigilance rules is not maintained; (38) the volatility and liquidity of the financial markets; (39) our liquidity and capital resources; (40) our expected future revenues, operations and expenditures; (41) potential change in our business strategy to enhance long-term stockholder value; (42) the impact, if any, of the expansion of our Board of Directors to include predominantly new members, the recent appointment of a new Chief Executive Officer and an interim Chief Financial Officer, the resignation of our President, the decision of our Chief Financial Officer to exercise his right to terminate his employment for Good Reason (as defined in his Amended and Restated Change of Control and Severance Agreement with the Company, effective as of July 1, 2013) and the assumption of the Chief Commercial Officer's duties and responsibilities by our Chief Executive Officer; and (43) 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."

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.

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the quarter ended June 30, 2014 are not necessarily indicative of the results that may be expected for the full fiscal year or any future period.

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our audited Consolidated Financial Statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2013 as filed on February 28, 2014 and as amended by the Form 10-K/A filed on April 30, 2014, and other disclosures (including the disclosures under "Part II. Item 1A. Risk Factors") included in this Quarterly Report on Form 10-Q. Our Condensed Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles and are presented in U.S. dollars.

OVERVIEW

VIVUS is a biopharmaceutical company with two therapies approved by the FDA: Qsymia for chronic weight management and STENDRA for erectile dysfunction. STENDRA is also approved by the European Commission, or EC, under a trade name, SPEDRA, for the treatment of erectile dysfunction in the EU.

Our drug Qsymia (phentermine and topiramate extended-release) was approved by the FDA in July 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. In September 2012, we announced the initial U.S. market availability of Qsymia through a limited number of certified home delivery networks. In July 2013, we announced initial retail availability of Qsymia through approximately 8,000 Walgreens, Costco and Duane Reade pharmacies nationwide. As of the date of this report, Qsymia is available in over 40,000 certified retail pharmacies nationwide, including all of the major pharmacy chains in the country. We intend to continue to certify and add new pharmacies to the Qsymia retail pharmacy network, including national and regional chains as well as independent pharmacies.

We commercialize Qsymia in the U.S. primarily through a dedicated contract sales force, supported by an internal commercial team consisting of sales management, marketing and managed care professionals. Our efforts to expand the appropriate use of Qsymia include scientific publications, participation and presentations at medical conferences and development and implementation of patient-directed support programs.

In October 2012, we received the negative opinion from the EMA Committee for Medicinal Products for Human Use, or CHMP, recommending refusal of the marketing authorization in the EU for the medicinal product Qsiva™ (the approved trade name for Qsymia 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 requested that this opinion be re-examined by the CHMP. After re-examination, on February 21, 2013, the CHMP adopted a final opinion that reaffirmed the Committee's earlier negative opinion. On May 15, 2013, the European Commission issued a decision refusing the grant of marketing authorization for Qsiva in the EU. On September 20, 2013, we submitted a request to the EMA for Scientific Advice, a procedure similar to the U.S. Special Protocol Assessment process, regarding use of a pre-specified interim analysis from the 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, or AQCLAIM, to support the resubmission of an application for a marketing authorization for Qsiva for treatment of obesity in accordance with the EU centralized procedure. We received feedback earlier this year from European Union regulatory officials regarding the AQCLAIM CVOT protocol, and we have recently received feedback from the FDA regarding the amended protocol. As a part of addressing the FDA comments, we are working to ensure that the planned interim analysis will not jeopardize the overall integrity of the study and will support other objectives in both the EU and U.S. 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 commercial collaboration agreements with third parties.

Our drug STENDRA, or avanafil, is an oral phosphodiesterase type 5, or PDE5, inhibitor that we have licensed from MTPC. STENDRA was approved by the FDA in April 2012 for the treatment of ED in the United States. In June 2013, the EC adopted the implementing decision granting marketing authorization for SPEDRA (the approved trade name for avanafil in the EU) for the treatment of ED in the EU. In July 2013, we entered into an agreement with the Menarini Group, through its subsidiary Berlin-Chemie AG, or Menarini, under which Menarini received an exclusive license to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, including the EU, plus Australia and New Zealand. Menarini commenced its commercialization launch of the product in France, Germany, Italy, and the United Kingdom in March 2014 and Poland and Spain in April 2014, and as of the date of this filing, SPEDRA is commercially available in 20 countries within the Menarini territory.

In October 2013, we entered into an agreement with Auxilium Pharmaceuticals, Inc., or Auxilium, under which Auxilium received an exclusive license to commercialize and promote STENDRA in the United States and Canada. On the same date, we also entered into a supply agreement with Auxilium, whereby VIVUS will supply Auxilium with STENDRA drug product for commercialization. Auxilium began commercializing STENDRA in the U.S. market in December 2013.

In December 2013, we entered into an agreement with Sanofi under which Sanofi received an exclusive license to commercialize and promote avanafil for therapeutic use in humans in Africa, the Middle East, Turkey, and the Commonwealth of Independent States, or CIS, including Russia. Sanofi will be responsible for obtaining regulatory approval in its territories. Sanofi intends to market avanafil under the trade name SPEDRA or STENDRA. Effective as of December 11, 2013, we also entered into a supply agreement, or the Sanofi Supply Agreement, with Sanofi Winthrop Industrie, a wholly owned subsidiary of Sanofi.

Under the license agreements with Menarini, Auxilium and Sanofi, avanafil is expected to be commercialized in over 100 countries worldwide. In addition, we are currently in discussions with potential collaboration partners to market and sell STENDRA for our other territories in which we do not currently have a commercial collaboration.

Foreign regulatory approvals, including EC marketing authorization to market Qsiva 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.

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, including revenues from multiple element arrangements, 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.

For the six months ended June 30, 2014, 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, 2013, provides a more complete discussion of our critical accounting policies and estimates.

Revenue from Multiple-Element Arrangements

We account for multiple-element arrangements, such as license and commercialization agreements in which a customer may purchase several deliverables, in accordance with ASC Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements*, or ASC 605-25. We evaluate if the deliverables in the arrangement represent separate units of accounting. In determining the units of accounting, we evaluate certain criteria, including whether the deliverables have value to our customers on a stand-alone basis. Factors considered in this determination include whether the deliverable is proprietary to us, whether the customer can use the license or other deliverables for their intended purpose without the receipt of the remaining elements, whether the value of the deliverable is dependent on the undelivered items, and whether there are other vendors that can provide the undelivered items. Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting.

When deliverables are separable, we allocate non-contingent consideration to each separate unit of accounting based upon the relative selling price of each element. When applying the relative selling price method, we determine the selling price for each deliverable using vendor-specific objective evidence, or VSOE, of selling price, if it exists, or third-party evidence, or TPE, of selling price, if it exists. If neither VSOE nor TPE of selling price exists for a deliverable, we use best estimated selling price, or BESP, for that deliverable. Significant management judgment may be required to determine the relative selling price of each element. Revenue allocated to each element is then recognized based on when the following four basic revenue recognition criteria are met for each element: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the price is fixed or determinable; and (iv) collectability is reasonably assured.

Determining whether and when some of these criteria have been satisfied often involves assumptions and judgments that can have a significant impact on the timing and amount of revenue we report. Changes in assumptions or judgments, or changes to the elements in an arrangement, could cause a material increase or decrease in the amount of revenue that we report in a particular period.

ASC Topic 605-28, *Revenue Recognition—Milestone Method* (ASC 605-28), established the milestone method as an acceptable method of revenue recognition for certain contingent, event-based payments under research and development arrangements. Under the milestone method, a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event: (i) that can be achieved based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to us. The determination that a milestone is substantive requires judgment and is made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone is: (i) commensurate with either our performance to achieve the milestone or the enhancement of value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) relates solely to past performance, and (iii) is reasonable relative to all deliverables and payment terms in the arrangement.

Other contingent, event-based payments received for which payment is either contingent solely upon the passage of time or the results of a collaborative partner's performance are not considered milestones under ASC 605-28. In accordance with ASC 605-25, such payments will be recognized as revenue when all of the four basic revenue recognition criteria are met.

Revenues recognized for royalty payments are recognized as earned in accordance with the terms of the license and commercialization agreements.

Fair Value Measurements

The authoritative literature for fair value measurements established a three-tier fair value hierarchy, which prioritizes the inputs in measuring fair value. These tiers are as follows: Level 1, defined as observable inputs such as quoted market prices in active markets; Level 2, defined as inputs other than the quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as significant unobservable inputs (entity developed assumptions) in which little or no market data exists.

Financial instruments include cash equivalents, available-for-sale securities, accounts receivable, accounts payable and accrued liabilities. Available-for-sale securities are carried at estimated fair value. The carrying value of cash equivalents, accounts payable and accrued liabilities approximate their estimated fair value due to the relatively short nature of these instruments. Our cash and cash equivalents and available-for-sale securities measured at fair value on a recurring basis.

All of our cash and cash equivalents and available-for-sale securities are in cash, money market instruments and U.S. Treasury securities at June 30, 2014 and December 31, 2013, and these are classified as Level 1. The valuation techniques used to measure the fair values of these financial instruments were derived from quoted market prices, as substantially all of these instruments have maturity dates, if any, within one year from the date of purchase and active markets for these instruments exist.

In May 2013, we closed on an offering totaling $250.0 million in Convertible Notes. The fair value of the liability component of the Convertible Notes, excluding the conversion feature, was derived using a binomial lattice model, or Level 3 inputs. To arrive at the appropriate risk adjusted rate, or market yield, for the Convertible Notes, we performed (i) a synthetic credit rating analysis estimating the issuer level credit rating of the Company using a regression model, (ii) research on appropriate market yields using option adjusted spread indications for similar credit ratings, and (iii) considered the market yield implied for the Convertible Notes from a binomial lattice model. Using these inputs, the initial fair value of the liability component of the Convertible Notes was estimated at $154.7 million. The Convertible Notes are described further below and in Note 13. Long-Term Debt to our Condensed Consolidated Financial Statements, included elsewhere in this Quarterly Report on Form 10-Q.

Debt instruments are initially recorded at fair value, with coupon interest and amortization of debt issuance discounts recognized in the statement of operations as interest expense at each period end while such instruments are outstanding. If we issue shares to discharge the liability, the debt obligation is derecognized and common stock and additional paid-in capital are recognized on the issuance of those shares.

Our Convertible Notes contain a conversion option that is classified as equity. The fair value of the liability component of the debt instrument was deducted from the initial proceeds to determine the proceeds to be allocated to the conversion option. The excess of the proceeds received from the Convertible Notes over the initial amount allocated to the liability component, is allocated to the equity component. This excess is reported as a debt discount and subsequently amortized as non-cash interest expense, using the interest method, over the expected life of the Convertible Notes. Issuance costs related to the equity component of the Convertible Notes were charged to additional paid-in capital. The remaining portion related to the debt component has been capitalized as a deferred charge and included in non-current assets in the consolidated balance sheets, and is being amortized and recorded as additional interest expense over the expected life of the Convertible Notes. In connection with the issuance of the Convertible Notes, we entered into capped call transactions with certain counterparties affiliated with the underwriters. The fair value of the purchased capped calls was recorded to stockholders' equity.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09). The standard provides companies with a single model for use in accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific revenue guidance. The core principle of the model is to recognize revenue when control of the goods or services transfers to the customer, as opposed to recognizing revenue when the risks and rewards transfer to the customer under the existing revenue guidance. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early adoption is not permitted. The guidance permits companies to either apply the requirements retrospectively to all prior periods presented, or apply the requirements in the year of adoption, through a cumulative adjustment. The Company is in the process of evaluating the impact of adoption on its consolidated financial statements.

RESULTS OF OPERATIONS

For the three and six months ended June 30, 2014, net loss was $25.8 million and $41.4 million or $0.25 and $0.40 net loss per share, respectively, as compared to a net loss of $55.5 million and $109.1 million or $0.55 and $1.08 net loss per share, respectively, during the same periods in 2013. The decreased net loss in the three and six months ended June 30, 2014, as compared to same periods in 2013, is primarily attributable to higher total net revenue and lower selling and marketing expenses related to Qsymia, plus lower spending across other functional areas as a result of the cost reduction plan implemented in the fourth quarter of 2013 and reduced share-based compensation expense.

We may have continued losses in future periods, depending on our success in commercializing, our partners' commercial success with STENDRA or SPEDRA, and the timing of our research and development expenditures, primarily related to the post-marketing study requirements for our approved drugs.

Continuing operations

	Three Months Ended June 30,			Six Months Ended June 30,		
(in thousands, except for percentages)	2014	2013	2014 vs. 2013 Increase/ (Decrease)	2014	2013	2014 vs. 2013 Increase/ (Decrease)
Revenue:						
Net product revenue	$ 10,983	$ 5,534	98%	$ 20,121	$ 9,646	109%
License and milestone revenue	4,181	—	—	23,544	—	—
Supply revenue	5,666	—	—	13,036	—	—
Royalty revenue	1,051	—	—	1,871	—	—
Total revenue	$ 21,881	$ 5,534	295%	$ 58,572	$ 9,646	507%

Net product revenue

For the three and six months ended June 30, 2014, net product revenue from sales of Qsymia was $11.0 million and $20.1 million, respectively, compared to $5.5 million and $9.6 million for same periods in 2013. We began distributing Qsymia to the certified home delivery pharmacies in our network in September 2012, and Qsymia became available in certified retail pharmacies in July 2013. We recognize net product revenue for Qsymia based on prescription sell-through by our certified retail pharmacies and home delivery pharmacy services networks to patients as we do not have sufficient historical information to reliably estimate returns.

For the three and six months ended June 30, 2014, there were approximately 138,000 and 259,000 Qsymia prescriptions dispensed, respectively, compared to 81,000 and 140,000 for the same periods of 2013, respectively. For the three and six months ended June 30, 2014, approximately 61% and 58%, respectively, of our total prescriptions included either a free good or discount offer, with approximately 31,000 and 55,000, respectively, of those prescriptions dispensed as free goods. In comparison, for the three and six months ended June 30, 2013, approximately 45% and 43%, respectively, of our total prescriptions included either a free good or discount offer, with approximately 24,000 and 45,000, respectively, of those prescriptions dispensed as free goods.

As of June 30, 2014, we recorded deferred revenue related to sales of Qsymia of $15.2 million, which represents Qsymia product shipped to wholesalers, certified retail pharmacies and certified home delivery pharmacy services networks, but not yet dispensed to patients through prescriptions, net of prompt-payment discounts.

License and milestone revenue

During 2013, we entered into license and commercialization agreements and commercial supply agreements with the Menarini Group, through its subsidiary Berlin-Chemie AG, or Menarini, Auxilium Pharmaceuticals, Inc., or Auxilium, and Sanofi and its affiliate, or Sanofi, to commercialize and promote STENDRA or SPEDRA in their respective territories. Menarini's territory is comprised of over 40 European countries, including the EU, plus Australia and New Zealand. Auxilium's territory is comprised of the United States and Canada and their respective territories. Sanofi's territory is comprised of Africa, the Middle East, Turkey and

Eurasia. For the three and six months ended June 30, 2014, we recognized $4.2 million and $23.5 million, respectively, in license and milestone revenue primarily due to product launches in certain EU countries.

Supply revenue

For the three and six months ended June 30, 2014, we recognized $5.7 million and $13.0 million, respectively, of STENDRA or SPEDRA supply revenue relating to STENDRA or SPEDRA delivered under the various commercial supply agreements. As of June 30, 2014, $3.5 million of STENDRA or SPEDRA supply revenue remains deferred because not all of the required specifications of one of our partners were met and the related title and risk of loss and damages had not been transferred.

Royalty revenue

For the three and six months ended June 30, 2014, we recognized a total of $1.1 million and $1.9 million, respectively, as royalty revenue based on net sales reported by Menarini and Auxilium.

Cost of goods sold

Cost of goods sold was $7.0 million and $16.5 million for the three and six months ended June 30, 2014, respectively, as compared to $0.6 million and $1.0 million for same periods in 2013. For the three and six months ended June 30, 2014, cost of goods sold relates to product shipments of Qsymia of $1.4 million and $3.2 million, respectively, and STENDRA or SPEDRA product shipments of $5.6 million and $13.3 million, respectively. Cost of goods sold for Qsymia dispensed to patients 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. Cost of goods sold for STENDRA or SPEDRA shipped to Menarini and Auxilium includes the inventory costs of purchased tablets, freight, shipping and handling costs. The cost of goods sold associated with deferred revenue on Qsymia and STENDRA or SPEDRA 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 earned.

Inventory impairment and commitment fee

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories, which are valued using a weighted average cost method calculated for each production batch. 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 and six months ended June 30, 2013, we recognized inventory charges of $4.4 million and $10.2 million, respectively, primarily to write-off work-in-process and finished goods inventories on hand in excess of demand. No charges were required and none were taken for the three and six months ended June 30, 2014. 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 expense

	Three Months Ended June 30,			Six Months Ended June 30,		
Drug Indication/Description	**2014**	**2013**	**2014 vs. 2013 Increase/ (Decrease)**	**2014**	**2013**	**2014 vs. 2013 Increase/ (Decrease)**
	(in thousands, except for percentages)					
Qsymia for obesity	$ 987	$ 2,605	(62)%	$ 3,113	$ 3,210	(3)%
STENDRA for ED	1,242	3,289	(62)%	1,623	6,227	(74)%
Other projects	20	109	(82)%	30	295	(90)%
Share-based compensation	313	944	(67)%	587	1,879	(69)%
Overhead costs*	1,524	2,285	(33)%	3,156	4,667	(32)%
Total research and development expense	$ 4,086	$ 9,232	(56)%	$ 8,509	$ 16,278	(48)%

* 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 decrease in research and development expenses for the three and six months ended June 30, 2014, compared to the same periods in 2013, is primarily due to the completion of the STENDRA 15-minute study, spermatogenesis studies, timing of Qsymia study activities and decreases in employee costs as a result of the 2013 reduction in force, including lower staffing, share-based compensation expense, consultants and other project costs.

We estimate the AQCLAIM study will cost between $180 and $220 million and the study could take as long as five to six years to complete. We submitted a request for Scientific Advice to the EMA regarding use of a pre-specified interim analysis from AQCLAIM to support the resubmission of an application for a marketing authorization for Qsiva for obesity in accordance with the EU centralized marketing authorization procedure. We received feedback earlier this year from European Union regulatory officials regarding the AQCLAIM CVOT protocol, and we have recently received feedback from the FDA regarding the amended protocol. As a part of addressing the FDA comments, we are working to ensure that the planned interim analysis will not jeopardize the overall integrity of the study and will support other objectives in both the EU and U.S.

There will be additional research and development expenses for post-approval studies related to STENDRA and Qsymia. 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.

Selling, general and administrative expense

	Three Months Ended June 30,			Six Months Ended June 30,		
	2014	2013	2014 vs. 2013 Increase/ (Decrease)	2014	2013	2014 vs. 2013 Increase/ (Decrease)
	(in thousands, except for percentages)					
Selling and marketing	$ 17,440	$ 21,232	(18)%	$ 36,108	$ 49,845	(28)%
General and administrative	10,826	18,277	(41)%	20,767	33,654	(38)%
Total selling, general and administrative expense	$ 28,266	$ 39,509	(28)%	$ 56,875	$ 83,499	(32)%

In September 2012, we began distributing Qsymia to the certified home delivery pharmacies in our network, and Qsymia became available in retail pharmacies in July 2013. The decrease in selling and marketing expenses is due primarily to lower Qsymia selling and marketing activities as a result of our more targeted and focused spending on marketing and promotional expenses during the three and six months ended June 30, 2014, compared to the same periods in 2013.

The decrease in general and administrative expenses in the three and six months ended June 30, 2014, compared to the same periods in 2013, is primarily due to lower spending for corporate activities, professional fees, headcount, lower grant costs for continuing medical education programs, and decreased share-based compensation expense as a result of our cost reduction efforts and reduced product liability insurance.

Non-recurring charges

As part of our ongoing efforts to reduce costs by eliminating expenses that are not essential to expanding the use of Qsymia, we implemented a cost reduction plan, announced in November 2013, which reduced our workforce by approximately 20 employees, or 17%, excluding the sales force, in the three months ended December 31, 2013. This cost reduction plan was substantially completed as of December 31, 2013; however, certain employee terminations were finalized in the three months ended March 31, 2014.

There were no non-recurring charges in the three months ended June 30, 2014. For the six months ended June 30, 2014, non-recurring charges were $2.1 million. For the three and six months ended June 30, 2013, non-recurring charges were $3.2 million and $3.9 million, respectively, which related to the proxy contest. For additional information concerning the non-recurring charges, please see Note 10. Non-Recurring Charges to our unaudited condensed consolidated financial statements included elsewhere in this Form 10-Q.

Total interest expense and other expense (income), net

For the three and six months ended June 30, 2014, interest expense was $8.2 million and $16.2 million, respectively, due to interest expense and amortization of issuance costs and discounts from our Convertible Notes and Senior Secured Notes and the amortization of the debt discount on the Convertible Notes. The Convertible Notes were issued in May 2013, and the Senior Secured Notes were issued in April 2013. For the three and six months ended June 30, 2013, interest expense was $4.1 million and $4.1 million, respectively. Other expense and income were not significant.

Provision for (benefit from) income taxes

For the three and six months ended June 30, 2014, the Company recorded a tax benefit of $2,000 and $438,000, respectively. For the three and six months ended June 30, 2013, the Company recorded provisions for income taxes of $7,000 and $13,000, respectively. The tax benefit for the three and six months ended June 30, 2014 relates to tax liabilities in certain states, offset by a tax refund received from the state of New Jersey, as a result of a settlement of an audit and acceptance of a refund claim for the tax year ended December 31, 2007. The tax provision for the three and six months ended June 30, 2013 related to state tax liabilities.

LIQUIDITY AND CAPITAL RESOURCES

Cash, cash equivalents and marketable securities

Cash, cash equivalents and available-for-sale securities totaled $324.2 million at June 30, 2014, as compared to $343.3 million at December 31, 2013. The decrease of $19.1 million is primarily due to cash used for operating activities.

At June 30, 2014, we had $96.3 million in cash and cash equivalents and $227.9 million in available-for-sale securities. We invest our excess cash balances in money market and U.S. government securities, in accordance with our investment policy. At June 30, 2014, all of our cash equivalents and available-for-sale securities were invested in either U.S. government securities or money market funds. 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. 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.

Working capital

Accounts Receivable. We extend credit to our customers for product sales resulting in accounts receivable. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written-off against the allowance for doubtful accounts. Allowances for doubtful accounts are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment.

As of June 30, 2014, accounts receivable, net of allowance for cash discount, was $13.3 million, as compared to $12.2 million at December 31, 2013. The increase in accounts receivable is primarily due to increased shipments of Qsymia to support greater customer demand.

Liabilities. Total liabilities were $281.9 million at June 30, 2014, which is $3.5 million higher than at December 31, 2013.

Cash Flows

	Six Months Ended June 30,	
	2014	2013
	(in thousands)	
Cash provided by (used for):		
Operating activities from continuing operations	$ (17,855)	$ (109,920)
Investing activities	9,776	(80,691)
Financing activities	1,079	257,129

Operating Activities. Our operating activities used $17.9 million and $109.9 million in cash during the six months ended June 30, 2014 and 2013, respectively. For the six months ended June 30, 2014, the use of cash resulted from our net operating loss from continuing operations of $41.4 million, which was partially offset by $7.8 million in debt costs amortizations, $5.7 million in non-cash share-based compensation expense and $1.9 million in amortization of securities costs. Additional cash used in operating activities resulted from changes in assets and liabilities during the quarter, including a $1.1 million increase in accounts receivable primarily as a result of increased shipments of Qsymia to pharmacies in support of growing demand for Qsymia, and a $5.5 million decrease in accounts payable, accruals and other liabilities due to the timing of activities and vendor payments. Partially offsetting these uses of funds in operating activities were sources of funds from a $8.0 million net decrease in prepaid expenses and other assets, which is primarily comprised of medical affairs, sales and marketing activities for Qsymia, and a $4.7 million decrease in inventories, primarily for STENDRA.

During the six months ended June 30, 2013, our net operating loss from continuing operations of $109.4 million was partially offset by $12.0 million in non-cash share-based compensation expense due to increased headcount and $7.5 million due to an inventory impairment charge for Qsymia. Additional cash used in operating activities resulted from changes in assets and liabilities during the period, including a net $16.0 million increase in inventories, primarily for Qsymia, and a decrease in accounts payable of $8.8 million during the first half of 2013 due to the timing of vendor payments.

Investing Activities. Our investing activities provided $9.8 million and used $80.7 million in cash during the six months ended June 30, 2014 and 2013, 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 provided cash of $1.1 million and $257.1 million during the six months ended June 30, 2014 and 2013, respectively. In the first six months of 2014, cash provided by financing activities included $0.8 million in proceeds from the exercise of stock options and $0.3 million from the sale of common stock through our employee stock purchase plan. Financing activities during the six months ended June 30, 2013 included $290.2 million in net proceeds from debt issuances, partially offset by $34.7 million in payments for capped call transactions, plus $1.1 million in proceeds from the exercise of stock options and $0.5 million from the sale of common stock through our employee stock purchase plan.

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 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 for the next twelve months. However, we anticipate that we may require additional funding to expand the use of Qsymia through targeted patient and physician education, find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience, create a pathway for centralized approval of the marketing authorization application for Qsiva in the EU, continue the expansion of our distribution of Qsymia through certified retail pharmacy locations, conduct post-approval clinical studies for both Qsymia and STENDRA, conduct non-clinical and clinical research and development work to support regulatory submissions and applications for our future investigational drug candidates, finance the costs involved in filing and prosecuting patent applications and enforcing or defending our patent claims, if any, to fund operating expenses, establish additional or new manufacturing and marketing capabilities, and manufacture quantities of our drugs and investigational drug candidates and to make payments under our existing license and supply agreements for STENDRA.

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.

Commitments and Contingencies

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, shareholder suits and tax matters, as such, we are unable to estimate the potential exposure related to these indemnification agreements. We have not recognized any liabilities relating to these agreements as of June 30, 2014.

Contractual Obligations

During the six months ended June 30, 2014, there were no material changes to our contractual obligations, other than the fulfillment of existing obligations in the ordinary course of business, described under 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, 2013.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market and Interest Rate Risk

Our cash, cash equivalents and available-for-sale securities as of June 30, 2014 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 June 30, 2014 by approximately $1.1 million. 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

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 interim 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 interim Chief Financial Officer, of the effectiveness of the design and operation of VIVUS's 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 interim Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

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 and Shareholder Derivative Lawsuits

The Company, a current officer and a former officer were defendants in a putative class action 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. The Court granted defendants' motions to dismiss both plaintiff's Amended Class Action Complaint and Second Amended Class Action Complaint; by order dated September 27, 2012, the latter dismissal was with prejudice and final judgment was entered 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. Briefing of the appeal is complete, and the parties are awaiting word on whether the Court of Appeals wishes to entertain oral argument.

Additionally, certain of the Company's former officers and directors and a current director 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 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 Company is named as a nominal defendant in these actions, neither of which seeks any recovery from the Company. The parties have agreed to stay the derivative lawsuits pending the outcome of the appeal of the securities class action.

On July 12, 2013, various current and former officers and directors of the Company were named as defendants in a separate shareholder derivative lawsuit filed in the California Superior Court, Santa Clara County, and captioned *Ira J. Gaines IRA, et al. v. Leland F. Wilson, et al.,* Case No.1-13-CV-249436. The lawsuit generally alleged breaches of the fiduciary duty of care in connection with the launch of Qsymia, breaches of the duty of loyalty and insider trading by some defendants for selling Company stock while purportedly being aware that the Qsymia launch would be less successful than predicted and corporate waste. On March 14, 2014, the Court sustained a demurrer and dismissed the complaint with leave to amend. An order memorializing the Court's ruling was entered March 21, 2014. On April 21, 2014, derivative plaintiffs filed an Amended Shareholder Derivative Complaint alleging substantially similar breaches of duty. On May 21, 2014, the Company filed a demurrer to the Amended Complaint. With that demurrer pending, derivative plaintiffs asked the Court in July 2014 to dismiss the action with prejudice as to the named plaintiffs and otherwise without prejudice. The Court did so by order entered July 17, 2014, and the matter is now concluded.

On March 27, 2014, Mary Jane and Thomas Jasin, who purport to be purchasers of VIVUS common stock, filed an Amended Complaint alleging securities fraud against the Company and three of its former officers and directors. Plaintiffs served the defendants a few days after filing the Amended Complaint. The Amended Complaint in the action, styled *Jasin v. VIVUS, Inc.,* Case No. 114-cv-261427 pending in the California Superior Court, Santa Clara County, asserts claims for violation of California Corporations Code Sections 25400 and 25401 and Business and Professions Code Section 17200. Plaintiffs allege generally that defendants misrepresented the prospects for the Company's success, including with the launch of Qsymia, while purportedly selling VIVUS stock for personal profit. The factual allegations include substantial overlap with the allegations in the *Gaines* action. Plaintiffs allege losses of "at least" $2.8 million, and their prayer seeks damages plus attorney's and expert witness fees, among other relief. On June 5, 2014, the Company and the other defendants filed a demurrer to the Amended Complaint seeking its dismissal. That motion is scheduled for a hearing in September 2014. VIVUS cannot predict the outcome of the motion or of the case generally. With the demurrer pending, however, on July 18, 2014, the same plaintiffs filed a complaint in the United States District Court for the Northern District of California, styled *Jasin v. VIVUS, Inc.,* Case No. 5:14-cv-03263. The Jasins' federal complaint alleges violations of Sections 10(b) and 20A of the Securities Exchange Act of 1934, based on substantially similar underlying facts as are alleged in

their state court action. As the federal action has not been served, no schedule exists for defendants' response to the complaint or for other proceedings, and we cannot predict the course or outcome of any federal court proceedings. The Company maintains directors' and officers' liability insurance that it believes affords coverage for much of the anticipated cost of both *Jasin* actions, subject to payment of our self-insured retention and the policies' terms and conditions.

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.

Qsymia ANDA Litigation

On May 7, 2014, the Company received a Paragraph IV certification notice from Actavis Laboratories FL indicating that it filed an abbreviated new drug application, or ANDA, with the U.S. Food and Drug Administration, or FDA, requesting approval to market a generic version of Qsymia and contending that all 6 patents listed for Qsymia in the FDA Orange Book (U.S. Patents 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, and 8,580,299 (collectively "patents-in-suit")) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Qsymia as described in their ANDA. On June 12, 2014, the Company filed a lawsuit in the U.S District Court for the District of New Jersey against Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as Actavis. The lawsuit (Case No. 14-3786 (FSH)(MAH)) was filed on the basis that Actavis' submission of their ANDA to obtain approval to manufacture, use, sell, or offer for sale generic versions of Qsymia prior to the expiration of the patents-in-suit constitutes infringement of one or more claims of those patents.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Actavis, FDA approval of Actavis' ANDA will be stayed until the earlier of (i) November 7, 2016 which is 30 months from the Company's May 7, 2014 receipt of Actavis' Paragraph IV certification notice or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. The Company intends to vigorously enforce its intellectual property rights relating to Qsymia, but the Company cannot predict the outcome of this matter.

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

Changes to our management and strategic business plan may cause uncertainty regarding the future of our business, and may adversely impact employee hiring and retention, our stock price, and our revenue, operating results, and financial condition.

In July 2013, we announced changes to our Board and management. In September and November 2013, and January 2014, we announced further changes to our management team. In November 2013, we announced a reduction in force of approximately 17%, the decision of our Chief Financial Officer to exercise his right to terminate his employment for Good Reason (as defined in his Amended and Restated Change of Control and Severance Agreement with the Company, effective as of July 1, 2013), and the appointment of our Corporate Controller as the Company's interim Chief Financial Officer. In January 2014, we announced that our Chief Executive Officer was assuming the duties and responsibilities of the Company's Chief Commercial Officer. The implementation of these changes, including the recent appointment of a new Chief Executive Officer and interim Chief Financial Officer, the expansion of our Board to include predominantly new members, the resignation of our President, the decision of our Chief Financial Officer to exercise his right to terminate his employment for Good Reason, the assumption of the Chief Commercial Officer's duties and responsibilities by our Chief Executive Officer, and the potential for additional changes to our management, organizational structure and strategic business plan, may cause speculation and uncertainty regarding our future business strategy and direction. These changes may cause or result in:

- disruption of our business or distraction of our employees and management;
- difficulty in recruiting, hiring, motivating and retaining talented and skilled personnel;
- stock price volatility; and
- difficulty in negotiating, maintaining or consummating business or strategic relationships or transactions.

If we are unable to mitigate these or other potential risks, our revenue, operating results and financial condition may be adversely impacted.

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, which will include our ability to:

- expand the use of Qsymia through targeted patient and physician education;
- find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience;
- obtain marketing authorization by the European Commission, or EC for Qsiva™ in the EU through the centralized procedure;
- manage our alliances with Auxilium, Menarini, MTPC and Sanofi, to help ensure the commercial success of avanafil;
- manage costs;
- continue to certify and add to the Qsymia retail pharmacy network nationwide and sell Qsymia through this network;
- improve third-party payor coverage, lower out-of-pocket costs to patients with discount programs, and obtain coverage for obesity under Medicare Part D;
- create market demand for Qsymia through patient and physician education, marketing and sales activities;
- achieve market acceptance and generate product sales;
- comply with the post-marketing requirements established by the FDA, including Qsymia's Risk Evaluation and Mitigation Strategy, or REMS, any future changes to the 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 active pharmaceutical ingredients, or APIs, for Qsymia and avanafil and the finished products 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 and avanafil, from APIs to finished products, efficiently and consistently delivers Qsymia and avanafil to customers.

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 are in the initial stage of commercialization of 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. In addition, we rely on a third-party contract sales organization, PDI, to assist with the hiring of sales representatives and the promotion of Qsymia to physicians. 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 delay in allocating resources to the promotion of Qsymia, could adversely affect the commercialization of Qsymia and materially harm our business, financial condition and results of operations.

We may not fully realize the anticipated benefits from a cost reduction plan we announced in November 2013.

In November 2013, we announced a cost reduction plan to eliminate expenses that are not essential to expanding the use of Qsymia. The plan reduced our workforce by approximately 20 employees, not including our sales force. We substantially completed this cost reduction plan by December 31, 2013, and incurred pre-tax non-recurring charges of $8.0 million in the fourth quarter of 2013, including approximately $5.7 million in employee termination costs, $1.3 million in non-cash share-based compensation expense related to the automatic acceleration of vesting of unvested stock options held by the terminated employees, and $1.0 million in facilities and other lease exit costs. In the first half of 2014, we incurred an additional $2.1 million in non-recurring charges relating to our cost reduction plan. We may not fully realize the anticipated benefits from the cost reduction plan.

We depend on our collaboration partner Auxilium to market and sell STENDRA™ (avanafil) in the United States and Canada, our collaboration partner Sanofi to gain approval, market, and sell avanafil in Africa, the Middle East, Turkey, and the Commonwealth of Independent States, and our collaboration partner Menarini to market and sell SPEDRA™ (avanafil) in over 40 European countries, including the EU, plus Australia and New Zealand.

In December 2013, we entered into a License and Commercialization Agreement with Sanofi under which Sanofi received an exclusive license to commercialize and promote avanafil for therapeutic use in humans in Africa, the Middle East, Turkey, and the Commonwealth of Independent States, or CIS, including Russia. Sanofi will be responsible for obtaining regulatory approval in its territories. Sanofi intends to market avanafil under the trade name SPEDRA or STENDRA. In October 2013, we entered into a License and Commercialization Agreement with Auxilium under which Auxilium received an exclusive license to commercialize and promote STENDRA for the treatment of erectile dysfunction, or ED, in the United States and Canada. In July 2013, we entered into a License and Commercialization Agreement with Menarini under which Menarini received an exclusive license to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, including the EU, plus Australia and New Zealand.

We are relying on our collaboration partners, Auxilium, Menarini, and Sanofi, to successfully commercialize STENDRA or SPEDRA in their respective territories, inclusive of obtaining any necessary approvals. There can be no assurances that these collaboration partners will be successful in doing so. In general, we cannot control the amount and timing of resources that our collaboration partners devote to the commercialization of our drugs. If any of our collaboration partners fails to successfully commercialize our drug products, our business may be negatively affected. For example, if Sanofi, Auxilium or Menarini do not successfully commercialize STENDRA or SPEDRA, we may receive limited or no revenues under our agreements with them. Additionally, because we lack the resources and experience to commercialize STENDRA or SPEDRA ourselves in these territories, we would need to seek replacement licensees to undertake these commercialization efforts. We may be unable to find other licensees in a timely manner, which could delay or impair our ability to commercialize STENDRA or SPEDRA in these territories.

Under our license agreement with MTPC, we are obligated to ensure that Sanofi, Auxilium and Menarini, as sublicensees, comply with its terms and conditions. MTPC has the right to terminate our license rights to avanafil in the event of any uncured material breach of the license agreement. Consequently, failure by Sanofi, Auxilium or Menarini to comply with these terms and conditions could result in termination of our license rights to avanafil on a worldwide basis, which could delay, impair, or preclude our ability to commercialize avanafil.

If we are unable to enter into agreements with collaborators for the territories that are not covered by our existing commercialization agreements, our ability to commercialize STENDRA in these territories may be impaired.

We intend to enter into collaborative arrangements or a strategic alliance with one or more pharmaceutical partners or others to commercialize STENDRA in our other territories that are not covered by our current commercial collaboration agreements. We may be unable to enter into agreements with third parties for STENDRA for these territories on favorable terms or at all, which could delay, impair, or preclude our ability to commercialize STENDRA in these territories.

We depend on collaborative arrangements or strategic alliances for the commercialization of STENDRA or SPEDRA.

Our dependence on collaborative arrangements or strategic alliances for the commercialization of STENDRA or SPEDRA, including our license agreements with Sanofi, Auxilium and Menarini, 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.

In order to market products in many foreign jurisdictions, we must obtain separate regulatory approvals. Approval by the FDA in the U.S. 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, while our drug STENDRA was approved in both the U.S. and the European Union, or EU, our drug Qsymia was approved in the U.S. but Qsiva (the approved trade name for Qsymia in the EU) was not approved 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 intend to seek approval, either directly or through our collaboration partners, for Qsymia and STENDRA in other territories outside the United States and EU. However, we have had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional testing. Foreign regulatory approvals may not be obtained, by us or our collaboration partners responsible for obtaining approval, on a timely basis, or at all, for any of our products. The failure to receive regulatory approvals in a foreign country would prevent us from marketing and commercializing our products in that country, which could have a material adverse effect on our business, financial condition and results of operations.

We, together with Sanofi, Auxilium and Menarini in certain territories, intend to market STENDRA or SPEDRA outside the U.S., which will subject us to risks related to conducting business internationally.

We, through Sanofi, Auxilium and Menarini in certain territories, intend to manufacture, market, and distribute STENDRA or SPEDRA 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 incidental 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 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.

We have significant inventories on hand and, in the year ended December 31, 2013, we recorded inventory impairment and commitment fees totaling $10.2 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. During the year ended December 31, 2013, we recognized total charges of $10.2 million for Qsymia inventories on hand in excess of demand, plus a purchase commitment fee. The inventory impairment 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 36 months. STENDRA is approved in the U.S. and SPEDRA in the EU for 48 months commercial product shelf life.

Our write-down for excess and obsolete inventory is subjective and requires accurate forecasting of the future market demand for our products. Forecasting demand for Qsymia, a drug in the obesity market in which there had been no new FDA-approved medications in over a decade prior to 2012, and for which reimbursement from third-party payors had previously been non-existent, has been difficult. Forecasting demand for STENDRA or SPEDRA, a drug that is new to a crowded and competitive market and has no sales history, is difficult. 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 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 or compliance with certain requirements of the Qsymia REMS program could compromise the commercialization of this product.

We rely on Cardinal Health 105, Inc., or Cardinal Health, a third-party distribution and supply-chain management company, to warehouse Qsymia and distribute it to the certified home delivery pharmacies and wholesalers that then distribute Qsymia directly to patients and certified retail pharmacies. Cardinal Health provides billing, collection and returns services. 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 wholesalers and through a broader network of certified retail pharmacies. We have contracted through a third-party vendor to certify the retail pharmacies and collect required data to support the Qsymia REMS program. In addition to providing services to support the distribution and use of Qsymia, each of the certified pharmacies has agreed to comply with the

REMS program requirements and, through our third-party data collection vendor, will provide us with the necessary patient and prescribing healthcare provider, or HCP, data. In addition, we have contracted with third-party data warehouses to store this patient and HCP data 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.

We rely on the certified pharmacies to implement a number of safety procedures and report certain information to our third-party REMS data collection vendor. Failure to maintain our contracts with Cardinal Health, our third-party REMS data collection vendor, or with the third-party data warehouses, or the inability or failure of any of them to adequately perform under our contracts with them, 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 finished 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 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 MTPC. MTPC has arrangements for the three main starting materials necessary for the manufacturing of avanafil API. 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 U.S. commercial launch, and future sales of STENDRA in the U.S. and abroad will be adversely affected, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration agreement for the commercialization of STENDRA in our other territories not covered by our agreements with Sanofi, Auxilium and Menarini.

In August 2012, we entered into an amendment to our license 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 as a supplier on or before June 30, 2015. We currently do not have any manufacturing facilities and intend to continue to rely on third parties for the supply of such API and tablets, as well as for the supply of starting materials. However, we cannot be certain that we will be able to obtain the necessary regulatory approvals for these suppliers in a timely manner or at all.

In July 2013, we entered into a Commercial Supply Agreement with Sanofi Chimie to manufacture and supply the API for avanafil on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. In November 2013, we entered into a Manufacturing and Supply Agreement with Sanofi Winthrop Industrie to manufacture and supply the avanafil tablets on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. We intend to submit an amendment to the New Drug Application, or NDA, for avanafil to the FDA, and the Marketing Authorization, or MA, for avanafil to the European Medicines Agency, or EMA, to include Sanofi Chimie as a qualified supplier of the avanafil API and Sanofi Winthrop Industrie as a qualified supplier of the avanafil tablets. We cannot be certain we will receive approval by regulatory authorities, or that we will be able to obtain such approval in a timely manner. The failure to receive such approval in a timely manner or at all could prevent, delay or preclude our ability to establish a reliable supply chain, which could compromise our ability to commercialize avanafil through our relationships with Sanofi, Auxilium and Menarini, or otherwise. In addition, we have entered into supply agreements with Menarini and Auxilium under which we are obligated to supply them with avanafil tablets. If we are unable to establish a reliable supply of avanafil API or tablets from Sanofi Chimie and/or Sanofi Winthrop Industrie, we may be unable to satisfy our obligations under these supply agreements in a timely manner or at all, and we may, as a result, be in breach of one or both of these agreements.

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. We license the rights to Qsymia from Dr. Najarian. We believe we are in compliance with the material terms of our license agreements with MTPC 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 the use of Qsymia through targeted patient and physician education;
- our ability to find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience;
- our ability to obtain marketing authorization by the EC for Qsiva in the EU through the centralized procedure;
- our ability to successfully expand the certified retail pharmacy distribution channel in the United States;
- contraindications for Qsymia and STENDRA;
- competition and timing of market introduction of competitive drugs;
- quality, safety and efficacy 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;
- 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, product insert, or new REMS 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 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, or AQCLAIM, 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. We estimate the AQCLAIM study will cost between $180 million and $220 million and the study could take as long as five to six years to complete. On September 20, 2013, we submitted to the EMA a request for Scientific Advice regarding use of a pre-specified interim analysis from the AQCLAIM cardiovascular outcomes trial to support the resubmission of the Marketing Authorization Application, or MAA, for approval of Qsiva for the treatment of obesity in accordance with the centralized marketing authorization procedure. Based on feedback from the EMA health authority, as well as various country health authorities associated with review of the AQCLAIM trial application, the protocol has been revised and resubmitted to the FDA. There can be no assurance that the FDA or EMA will not request or require us to provide additional information or undertake additional preclinical studies and clinical studies or retrospective observational studies.

At the FDA's request, we initiated a retrospective observational study, known as FORTRESS, 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. We announced preliminary results from FORTRESS in December 2011. We submitted the final report for the FORTRESS study to the FDA in the second quarter of 2013. If the FDA determines that 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 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.

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 would differ. As a result, Qsymia may be subject to substitution by prescribing physicians, or by pharmacists, 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, both of the approved APIs (phentermine and topiramate extended-release) that are combined to produce Qsymia are 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, or pharmacists from dispensing, 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. In the third quarter of 2013, Supernus Pharmaceuticals, Inc. launched Trokendi XR™ and in the second quarter of 2014, Upsher-Smith Laboratories, Inc. launched Qudexy™. Both products provide an extended-release formulation of the generic drug topiramate that is indicated for certain types of seizures. 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, which could limit our pricing of Qsymia and negatively impact our revenues.

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 even with large self-insured retentions or deductibles, 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.

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 and erectile dysfunction. 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 that 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 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™, an orally disintegrating tablet (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. Newer agents recently approved for type 2 diabetes include Invokana® (canaglifozin) from Johnson & Johnson's Janssen Pharmaceuticals, an SGLT2 inhibitor that has demonstrated modest, single-digit weight loss in clinical studies. In addition, there are several other investigational drug candidates in Phase 2 clinical trials for the treatment of obesity. 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 condition 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.

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, which was acquired by Actavis, Inc. and is now known as Actavis plc, has licensed the U.S. rights to udenafil, a PDE5 inhibitor, from Dong-A Pharmaceutical. 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 future 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.

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.

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, contract with, 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 approved drugs or investigational drug candidates 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 avanafil, we currently rely on MTPC to supply the API (avanafil) and the avanafil tablets for STENDRA and SPEDRA. 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 avanafil API or tablets in sufficient quantities to meet projected demand, future sales could be adversely affected, which in turn could have a detrimental impact on our financial results, our license, commercialization, and supply agreements with our collaboration partners, and our ability to enter into a collaboration agreement for the commercialization in other territories.

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 parties. According to the amendment, the transition of manufacturing from MTPC must occur on or before June 30, 2015. 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. 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, are unable to effectively transfer the technology or supply on commercially reasonable terms, partnerability and commercial success of STENDRA could be adversely impacted. Additionally, we cannot be certain that we will be successful in entering into appropriate 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.

In July 2013, we entered into a Commercial Supply Agreement with Sanofi Chimie to manufacture and supply the API for avanafil on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU,

Latin America and other territories. On November 18, 2013, we entered into a Manufacturing and Supply Agreement with Sanofi Winthrop Industrie to manufacture and supply the avanafil tablets on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. We intend to submit an amendment to the NDA for avanafil to the FDA, and the MA for avanafil to the EMA, to include Sanofi Chimie as a qualified supplier of the avanafil API and Sanofi Winthrop Industrie as a qualified supplier of the avanafil tablets. We cannot be certain we will receive approval by regulatory authorities, and the failure to receive such approval could prevent, delay, or preclude our ability to establish a reliable supply chain, which could compromise our ability to commercialize avanafil through our relationships with Sanofi, Auxilium, Menarini, or otherwise.

Any future manufacturing sites, including those of Sanofi Chimie and Sanofi Winthrop Industrie, 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 have a detrimental impact on our ability to commercialize STENDRA under our agreements with Sanofi, Auxilium and Menarini and our ability to enter into a collaboration agreement for the commercialization of STENDRA in our other territories not covered by our agreements with Sanofi, Auxilium and Menarini.

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.

The collection and use of personal health data in the EU is governed by the provisions of the Data Protection Directive. This Directive imposes a number of requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict rules on the transfer of personal data out of the EU to the United States. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the EU Member States may result in fines and other administrative penalties. The draft EU Data Protection Regulation currently going through the adoption process is expected to introduce new data protection requirements in the EU and substantial fines for breaches of the data protection rules. If the draft Data Protection Regulation is adopted in its current form, it may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules. This may be onerous and increase our cost of doing business.

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.

Our arrangements with third-party payors and customers expose us to broadly applicable federal and state healthcare laws and regulations pertaining to fraud and abuse. The restrictions under applicable federal and state healthcare laws and 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, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare items or service for which payment may be made, in whole or in part, by federal healthcare programs such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Further, the Affordable Care Act, among other things, clarified that a person or entity needs not to have actual knowledge of the federal Anti-Kickback statute or specific intent to violate it. In addition, the Affordable Care Act amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Law constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Law protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exemption or safe harbor may be subject to scrutiny. 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 civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing, or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the civil 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 civil 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, among others, 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 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;

- analogous state laws and regulations, such as state anti-kickback and false claims laws, 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. In addition, California, Connecticut, 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;

- the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain pharmaceutical manufacturers to engage in extensive tracking of payments or transfers of value to physicians and teaching hospitals, maintenance of a payments database, and public reporting of the payment data. Pharmaceutical manufacturers with products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program are required to track and report such payments. 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 applicable manufacturers must begin tracking on August 1, 2013, and must report payment data to CMS by March 31, 2014, and annually thereafter; and

- the federal Foreign Corrupt Practices Act of 1997 and other similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the U.S. Securities and Exchange Commission. A determination that our operations or activities are not, or were not, in compliance with United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

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 significant civil, criminal and administrative penalties, damages, fines, exclusion from government-funded 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 or regulations, 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.

In the EU, the advertising and promotion of our products will also be subject to EU Member States' laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices, as well as other EU Member State legislation governing statutory health insurance, bribery and anti-corruption. Failure to comply with these rules can result in enforcement action by the EU Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

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

The FDA, and third country authorities, including the competent authorities of the EU Member States, have 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. 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 pharmaceutical 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 that may result in significant expense and limit our ability to commercialize Qsymia. The FDA has also required the distribution of a Medication Guide to Qsymia 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 maintain FDA approval, or receive a marketing authorization from the EC, 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 or EU marketing authorization may be varied, suspended or 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.

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 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.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the Medicaid Drug Rebate program, established by the Omnibus Budget Reconciliation Act of 1990 and amended by the Veterans Health Care Act of 1992 as well as subsequent legislation. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug.

The Affordable Care Act made significant changes to the Medicaid Drug Rebate program. Effective in March 2010, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. With regard to the amount of the rebates owed, the Affordable Care Act increased the minimum Medicaid rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products and from 11% to 13% for non-innovator products; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, the Affordable Care Act and subsequent legislation changed the definition of average manufacturer price. Finally, the Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2014 (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.

In 2012, CMS issued proposed regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act but has not yet issued final regulations. CMS is currently expected to release the final regulations in 2014. Moreover, in the future, Congress could enact legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time consuming, and could have a material adverse effect on our results of operations.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing discount program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Affordable Care Act and CMS's issuance of final regulations implementing those changes also could affect our 340B ceiling price calculations and negatively impact our results of operations.

The Affordable Care Act expanded the 340B program to include additional entity types: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act. The Affordable Care Act also obligates the Secretary of the U.S. Department of Health and Human Services, or HHS, to create regulations and processes to improve the integrity of the 340B program and to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The Health Resources and Services Administration, or HRSA, is expected to issue a comprehensive proposed regulation in 2014 that will address many aspects of the 340B program. When that regulation is finalized, it could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current average manufacturer prices and best prices for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed 12 quarters from the quarter in which the data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B drug discount program.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false average manufacturer price or best price information to the government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. Our failure to submit monthly/quarterly average manufacturer price and best price data on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs.

In September 2010, CMS and the Office of the Inspector General indicated that they intend to pursue more aggressively companies that fail to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

Federal law requires that, for a company to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies and certain federal grantees, it also must participate in the Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. To participate, we are required to enter into an FSS contract with the VA, under which we must make our innovator "covered drugs" available to the "Big Four" federal agencies—the VA, the Department of Defense, or DoD, the Public Health Service, and the Coast Guard—at pricing that is capped pursuant to a statutory federal ceiling price, or FCP, formula set forth in Section 603 of the Veterans Health Care Act of 1992, or VHCA. The FCP is based on a weighted average wholesaler price known as the "non-federal average manufacturer price," or Non-FAMP, which manufacturers are required to report on a quarterly and annual basis to the VA. If a company misstates Non-FAMPs or FCPs it must restate these figures. Pursuant to the VHCA, knowingly providing false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of $100,000 for each item of false information.

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing is reduced to an agreed "tracking customer." Further, in addition to the "Big Four" agencies, all other federal agencies and some non-federal entities are authorized to access FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the "Big Four" agencies "negotiated pricing" for covered drugs that is not capped by the FCP; instead, such pricing is negotiated based on a mandatory disclosure of the contractor's commercial "most favored customer" pricing. We offer one single FCP-based FSS contract price to all FSS purchasers for all products.

In addition, pursuant to regulations issued by the DoD TRICARE Management Activity, or TMA, now Defense Health Agency, or DHA, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, each of our covered drugs is listed on a Section 703 Agreement with TMA under which we have agreed to pay rebates on covered drug prescriptions dispensed to TRICARE beneficiaries. Companies are required to list their innovator products on Section 703 Agreements in order for

those products to be eligible for DoD formulary inclusion. The formula for determining the rebate is established in the regulations and our Section 703 Agreement and is based on the difference between the Annual Non-FAMP and the FCP (as described above, these price points are required to be calculated by us under the VHCA).

If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Changes in reimbursement procedures by government and other third-party payors, including changes in healthcare law and implementing regulations, may limit our ability to market and sell our approved drugs, or any future drugs, if approved, may limit our product revenues and delay profitability, and may impact our business in ways that we cannot currently predict. These changes could have a material adverse effect on our business and financial condition.

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.

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.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and Actual Acquisition Cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS, the federal agency that administers the Medicare and Medicaid Drug Rebate program, has made draft National Average Drug Acquisition Cost, or NADAC, and draft National Average Retail Price, or NARP, data publicly available on at least a monthly basis. In July 2013, CMS suspended the publication of draft NARP data, pending funding decisions. In November 2013, CMS moved to publishing final rather than draft NADAC data and has since made updated NADAC data publicly available on a weekly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products.

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.

In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together the Affordable Care Act. 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 in March 2010, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. This expanded eligibility affects rebate liability for that utilization.

- With regard to the amount of the rebates owed, the Affordable Care Act increased the minimum Medicaid rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products and from 11% to 13% for non-innovator products; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price.

- Effective in January 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 coverage 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 in January 2011, the Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2014, (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.

- Some states have elected to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level. For each state that does not choose to expand its Medicaid program, there may 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.

Many of the Affordable Care Act's most significant reforms do not take effect until 2014. In 2012, CMS issued proposed regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act but has not yet issued final regulations. CMS is currently expected to release the final regulations in 2014. 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.

The Affordable Care Act also expanded the Public Health Service's 340B drug pricing discount program. The 340B pricing program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The Affordable Care Act expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act. The Affordable Care Act also obligates the Secretary of the Department of Health and Human Services to create regulations and processes to improve the integrity of the 340B program and to ensure the agreement that manufacturers must sign to participate in the 340B program obligates a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The HRSA is expected to issue a comprehensive proposed regulation in 2014 that will address many aspects of the 340B program. When that regulation is finalized, it could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

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.

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 approved drugs and investigational drug candidates or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our approved drugs and 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, if approved, for any other indication, 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.

An increasing number of EU Member States and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. In addition, the ongoing

budgetary difficulties faced by a number of EU Member States, including Greece and Spain, have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal products, which could negatively impact our revenues and profitability. Moreover, in order to obtain reimbursement of our medicinal products in some countries, including some EU Member States, we may be required to conduct clinical trials that compare the cost effectiveness of our products to other available therapies. There can be no assurance that our medicinal products will obtain favorable reimbursement status in any country.

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 with the FDA, the EC, or the competent authorities of the EU Member States, 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.

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, hindered our Qsymia sales efforts. 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 current 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 condition.

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, we cannot make assurances as to how much protection, if any, will be provided by our issued 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 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 (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 have received notice of an ANDA filing for Qsymia submitted by a generic drug company. This ANDA filing asserts that a generic form of Qsymia would not infringe on our issued patents. As a result of this filing, we have commenced litigation to defend our patent rights, which is expected to be costly and time-consuming and, depending on the outcome of the litigation, we may face competition from lower cost generic or follow-on products in the near term.

Qsymia is approved under the provisions of the Federal Food, Drug and Cosmetic Act, or FDCA, which renders it susceptible to potential competition from generic manufacturers via the Hatch-Waxman Act and ANDA process. Generic manufacturers pursuing ANDA approval are not required to conduct costly and time-consuming clinical trials to establish the safety and efficacy of their products; rather, they are permitted to rely on the innovator's data regarding safety and efficacy. Additionally, generic drug companies generally do not expend significant sums on sales and marketing activities, instead relying on physicians or payors to substitute the generic form of a drug for the branded form. Thus, generic manufacturers can sell their products at prices much lower than those charged by the innovative pharmaceutical or biotechnology companies who have incurred substantial expenses associated with the research and development of the drug product and who must spend significant sums marketing a new drug.

The ANDA procedure includes provisions allowing generic manufacturers to challenge the innovator's patent protection by submitting "Paragraph IV" certifications to the FDA in which the generic manufacturer claims that the innovator's patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the generic product. A patent owner who receives a Paragraph IV certification may choose to sue the generic applicant for patent infringement.

We have received a Paragraph IV certification notice from Actavis Laboratories FL, Inc., or Actavis, contending that our patents listed in the Orange Book for Qsymia (U.S. Patents 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, and 8,580,299) are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of a generic form of Qsymia. In response to this notice, we have filed suit to defend our patent rights.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Actavis, FDA approval of Actavis' ANDA will be stayed until the earlier of (i) November 7, 2016 which is 30 months from our May 7, 2014 receipt of Actavis' Paragraph IV certification notice or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

Although we intend to vigorously enforce our intellectual property rights relating to Qsymia, there can be no assurance that we will prevail in our defense of our patent rights. Our existing patents could be invalidated, found unenforceable or found not to cover a generic form of Qsymia. If an ANDA filer were to receive approval to sell a generic version of Qsymia and/or prevail in any patent litigation, Qsymia would become subject to increased competition and our revenue would be adversely affected.

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 infringe 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 countries.

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.

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 make 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.

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 or development 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 next twelve months. 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:

- our ability to expand the use of Qsymia through targeted patient and physician education;
- our ability to find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience on a timely basis;
- our ability to obtain marketing authorization by the EC for Qsiva in the EU through the centralized procedure;
- our ability to manage costs;
- the substantial cost to expand into certified retail pharmacy locations and the cost required to maintain the REMS program for Qsymia;
- 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;

- our ability, along with our collaboration partners, to successfully commercialize STENDRA in the U.S., Canada, the EU, Australia, New Zealand, Africa, the Middle East, Turkey, and the CIS, including Russia;
- our ability to successfully commercialize STENDRA in our other territories in which we do not currently have a commercial collaboration;
- 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 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; and
- the activities of competitors.

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.

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 equity and debt securities. 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.

In May 2013, we closed an offering of $220.0 million in 4.5% Convertible Senior Notes due May 1, 2020, which we refer to as the Convertible Notes. In May 2013, we closed on an additional $30.0 million of Convertible Notes upon exercise of an option by the initial purchasers of the Convertible Notes. Total net proceeds from the Convertible Notes were approximately $241.8 million. The Convertible Notes are convertible into approximately 16,826,000 shares of our common stock under certain circumstances prior to maturity at a conversion rate of 67.3038 shares per $1,000 principal amount of Convertible Notes, which represents a conversion price of approximately $14.858 per share, subject to adjustment under certain conditions. The Convertible Notes are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding November 1, 2019, only under certain conditions. Investors in our common stock will be diluted to the extent the Convertible Notes are converted into shares of our common stock, rather than being settled in cash.

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 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 that may cause losses and affect the liquidity of these investments.

At June 30, 2014, we had $96.3 million in cash and cash equivalents and $227.9 million in available-for-sale securities. While at June 30, 2014, 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 June 30, 2014. 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.

Our involvement in securities-related class action and shareholder 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, despite the granting of the prior two motions to dismiss by the U.S. District Court for the Northern District of California in a putative class action lawsuit captioned *Kovtun v. Vivus, Inc., et al.*, Case No. 4:10-CV-04957-PJH, on October 26, 2012, plaintiff filed a Notice of Appeal to the U.S. Court of Appeals for the Ninth Circuit. Briefing of the appeal is complete, and the parties are awaiting word on whether the Court of Appeals wishes to entertain oral argument.

Additionally, certain of our former officers and directors and a current director 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. 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. We are named as a nominal defendant in these actions, neither of which seeks any recovery from the Company. The parties have agreed to stay the derivative lawsuits pending the outcome of the appeal of the securities class action.

Furthermore, on March 27, 2014, Mary Jane and Thomas Jasin, who purport to be purchasers of VIVUS common stock, filed an Amended Complaint alleging securities fraud against the Company and three of its former officers and directors. Plaintiffs served the defendants a few days after filing the Amended Complaint. The Amended Complaint in the action, styled *Jasin v. VIVUS, Inc.,* Case No. 114-cv-261427 pending in the California Superior Court, Santa Clara County, asserts claims for violation of California Corporations Code Sections 25400 and 25401 and Business and Professions Code Section 17200. Plaintiffs allege generally that defendants misrepresented the prospects for the Company's success, including with the launch of Qsymia, while purportedly selling VIVUS stock for personal profit. Plaintiffs allege losses of "at least" $2.8 million, and their prayer seeks damages plus attorney's and expert witness fees, among other relief. On June 5, 2014, the Company and the other defendants filed a demurrer to the Amended Complaint seeking its dismissal. That motion is scheduled for a hearing in September 2014. VIVUS cannot predict the outcome of the motion or of the case generally. With the demurrer pending, however, on July 18, 2014, the same plaintiffs filed a complaint in the United States District Court for the Northern District of California, styled *Jasin v. VIVUS, Inc.,* Case No. 5:14-cv-03263. The Jasins' federal complaint alleges violations of Sections 10(b) and 20A of the Securities Exchange Act of 1934, based on substantially similar underlying facts as are alleged in their state court action. As the federal action has not been served, no schedule exists for defendants' response to the complaint or for other proceedings, and we cannot predict the course or outcome of any federal court proceedings. The Company maintains directors' and officers' liability insurance that it believes affords coverage for much of the anticipated cost of both *Jasin* actions, subject to payment of our self-insured retention and the policies' terms and conditions.

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.

We have an accumulated deficit of $702.0 million as of June 30, 2014, and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of $702.0 million for the period from our inception through June 30, 2014, 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, 2013, we had approximately $545.1 million and $229.1 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 50 percentage points over a rolling three-year period. We have not completed a recent study to assess whether any change of control has occurred or whether there have been multiple changes of control since the Company's formation, due to the significant complexity and cost associated with the study. We have completed studies in prior periods and concluded no adjustments were required. If we have experienced a change of control at any time since our formation, our NOL carryforwards and tax credits may not be available, or their utilization could be subject to an annual limitation under Section 382. A full valuation allowance has been provided against our NOL carryforwards, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Accordingly, there would be no impact on the consolidated balance sheet or statement of operations.

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.

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;
- our ability to find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience;
- our ability to obtain marketing authorization for our products in foreign jurisdictions, including authorization from the EC for Qsiva in the EU through the centralized procedure;
- the costs, timing and outcome of post-approval clinical studies which the FDA has required us to perform as part of the approval for Qsymia and STENDRA;
- the substantial cost to expand into certified retail pharmacy locations and the cost required to maintain the REMS program for Qsymia;
- 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.

These factors and fluctuations, as well as political and other market conditions, may adversely affect 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, although we have entered into license and commercialization agreements with Sanofi, Auxilium and Menarini, to commercialize avanafil for the treatment of ED on an exclusive basis in Africa, the Middle East, Turkey, and the CIS, including Russia, to commercialize and promote STENDRA for the treatment of ED in the U.S. and Canada, and to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, including the EU, plus Australia and New Zealand, respectively, we may not be successful in commercializing avanafil in these territories. 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 Amended and Restated 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 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.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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(2)	Amended and Restated Bylaws of the Registrant.
3.3(3)	Amendment No. 1 to the Amended and Restated Bylaws of the Registrant.
3.4(4)	Amendment No. 2 to the Amended and Restated Bylaws of the Registrant.
3.5(5)	Amendment No. 3 to the Amended and Restated Bylaws of the Registrant.
3.6(6)	Amendment No. 4 to the Amended and Restated Bylaws of the Registrant.
3.7(7)	Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Registrant.
4.1(8)	Specimen Common Stock Certificate of the Registrant.
4.2(9)	Preferred Stock Rights Agreement dated as of March 27, 2007, between the Registrant and Computershare Investor Services, LLC.
4.3(10)	Indenture dated as of May 21, 2013, by and between the Registrant and Deutsche Bank Trust Company Americas, as trustee.
4.4(11)	Form of 4.50% Convertible Senior Note due May 1, 2020.
31.1	Certification of Chief Executive Officer, dated August 7, 2014, 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 August 7, 2014, 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 June 30, 2014, 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 Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) related notes.

(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 3.2 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 20, 2012.
(3) Incorporated by reference to Exhibit 3.3 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013, filed with the Commission on May 8, 2013.
(4) Incorporated by reference to Exhibit 3.4 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013, filed with the Commission on May 8, 2013.
(5) Incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 13, 2013.
(6) Incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on July 24, 2013.
(7) 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.
(8) Incorporated by reference to Exhibit 4.1 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.
(9) 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.
(10) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 21, 2013.
(11) Incorporated by reference to Exhibit 4.2 filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 21, 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: August 7, 2014

VIVUS, Inc.

/s/ SVAI S. SANFORD
Svai S. Sanford
Chief Financial Officer and Chief Accounting Officer

/s/ SETH H. Z. FISCHER
Seth H. Z. Fischer
Chief Executive Officer

VIVUS, INC.

INDEX TO EXHIBITS

EXHIBIT NUMBER	DESCRIPTION
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2(2)	Amended and Restated Bylaws of the Registrant.
3.3(3)	Amendment No. 1 to the Amended and Restated Bylaws of the Registrant.
3.4(4)	Amendment No. 2 to the Amended and Restated Bylaws of the Registrant.
3.5(5)	Amendment No. 3 to the Amended and Restated Bylaws of the Registrant.
3.6(6)	Amendment No. 4 to the Amended and Restated Bylaws of the Registrant.
3.7(7)	Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Registrant.
4.1(8)	Specimen Common Stock Certificate of the Registrant.
4.2(9)	Preferred Stock Rights Agreement dated as of March 27, 2007, between the Registrant and Computershare Investor Services, LLC.
4.3(10)	Indenture dated as of May 21, 2013, by and between the Registrant and Deutsche Bank Trust Company Americas, as trustee.
4.4(11)	Form of 4.50% Convertible Senior Note due May 1, 2020.
31.1	Certification of Chief Executive Officer, dated August 7, 2014, 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 August 7, 2014, 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 June 30, 2014, 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 Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) related notes.

(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 3.2 filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 20, 2012.
(3) Incorporated by reference to Exhibit 3.3 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013, filed with the Commission on May 8, 2013.
(4) Incorporated by reference to Exhibit 3.4 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013, filed with the Commission on May 8, 2013.
(5) Incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 13, 2013.
(6) Incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on July 24, 2013.
(7) 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.
(8) Incorporated by reference to Exhibit 4.1 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.
(9) 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.
(10) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 21, 2013.
(11) Incorporated by reference to Exhibit 4.2 filed with the Registrant's Current Report on Form 8-K filed with the Commission on May 21, 2013.

Exhibit 31.1

CERTIFICATION

I, Seth H. Z. Fischer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VIVUS, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2014

By: /s/ SETH H. Z. FISCHER
Seth H. Z. Fischer
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Svai S. Sanford, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VIVUS, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2014

By: /s/ SVAI S. SANFORD
Svai S. Sanford
Chief Financial Officer and Chief Accounting Officer

Exhibit 32

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Seth H. Z. Fischer, Chief Executive Officer of VIVUS, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended June 30, 2014, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: August 7, 2014

By: /s/ SETH H. Z. FISCHER
Seth H. Z. Fischer

I, Svai S. Sanford, Chief Financial Officer and Chief Accounting Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended June 30, 2014, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: August 7, 2014

By: /s/ SVAI S. SANFORD
Svai S. Sanford