VIVUS INC

Form 10-Q August 03, 2015 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, 2015
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

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(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
(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 27, 2015, 104,021,069 shares of common stock, par value \$.001 per share, were outstanding.

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VIVUS, INC.

Quarterly Report on Form 10-Q

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PART I: FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

VIVUS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

	June 30, 2015	December 3 2014	1,
ASSETS	Unaudited	Note 1	
Current assets:			
Cash and cash equivalents	\$ 86,366	\$ 83,174	
Available-for-sale securities	187,802	216,397	
Accounts receivable, net	10,254	11,595	
Inventories	9,606	34,447	
Prepaid expenses and other assets	10,371	12,824	
Total current assets	304,399	358,437	
Property and equipment, net	1,153	1,346	
Non-current assets	5,769	7,155	
Total assets	\$ 311,321	\$ 366,938	
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$ 14,993	\$ 10,430	
Accrued and other liabilities	14,450	17,037	
Deferred revenue	20,626	19,445	
Current portion of long-term debt	14,497	10,459	
Total current liabilities	64,566	57,371	
Long-term debt, net of current portion	217,650	217,324	
Deferred revenue, net of current portion	7,732	8,876	
Non-current accrued and other liabilities	700	849	
Total liabilities	290,648	284,420	
Commitments and contingencies			
Stockholders' equity:			
Preferred stock; \$1.00 par value; 5,000 shares authorized; no shares issued and outstanding at June 30, 2015 and December 31, 2014	_		
Common stock; \$.001 par value; 200,000 shares authorized; 103,874 and 103,729 shares issued and outstanding at June 30, 2015 and December 31,	104	104	

2014, respectively

,r		
Additional paid-in capital	828,591	825,691
Accumulated other comprehensive income (loss)	45	(28)
Accumulated deficit	(808,067)	(743,249)
Total stockholders' equity	20,673	82,518
Total liabilities and stockholders' equity	\$ 311,321	\$ 366,938

See accompanying notes to unaudited condensed consolidated financial statements.

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VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months I June 30,	Ended
	2015	2014	2015	2014
Revenue:				
Net product revenue	\$ 14,013	\$ 10,983	\$ 26,641	\$ 20,121
License and milestone revenue		4,181	11,574	23,544
Supply revenue	8,117	5,666	16,595	13,036
Royalty revenue	855	1,051	341	1,871
Total revenue	22,985	21,881	55,151	58,572
Operating expenses:				
Cost of goods sold	9,870	7,015	19,766	16,548
Selling, general and administrative	22,201	28,266	48,601	56,875
Research and development	2,599	4,086	5,293	8,509
Inventory impairment and other non-recurring charges	29,522		29,522	2,054
Total operating expenses	64,192	39,367	103,182	83,986
Loss from operations	(41,207)	(17,486)	(48,031)	(25,414)
Interest expense and other expense, net	8,139	8,341	16,775	16,399
Loss before income taxes	(49,346)	(25,827)	(64,806)	(41,813)
Provision for (benefit from) income taxes	6	(2)	12	(438)
Net loss	\$ (49,352)	\$ (25,825)	\$ (64,818)	\$ (41,375)
Basic and diluted net loss per share Shares used in per share computation:	\$ (0.48)	\$ (0.25)	\$ (0.62)	\$ (0.40)
Basic and diluted	103,845	103,350	103,821	103,320

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended June 30,		Six Months June 30,	Ended
	2015	2014	2015	2014
Net loss	\$ (49,352)	\$ (25,825)	\$ (64,818)	\$ (41,375)
Unrealized gain (loss) on securities, net of taxes	7	(11)	73	32
Comprehensive loss	\$ (49,345)	\$ (25,836)	\$ (64,745)	\$ (41,343)

See accompanying notes to unaudited condensed consolidated financial statements.

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VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$ (64,818)	\$ (41,375)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	731	424
Amortization of debt issuance costs and discounts	8,421	7,806
Amortization of discount or premium on available-for-sale securities	1,489	1,917
Share-based compensation expense	2,775	5,692
Unrealized foreign currency remeasurement gain	_	(235)
Inventory impairment charge	29,522	
Changes in assets and liabilities:		
Accounts receivable	1,341	(1,070)
Inventories	(4,491)	4,681
Prepaid expenses and other assets	2,872	8,042
Accounts payable	4,563	(1,044)
Accrued and other liabilities	(2,926)	(4,479)
Deferred revenue	37	1,786
Net cash used for operating activities	(20,484)	(17,855)
Cash flows from investing activities:		
Property and equipment purchases	(176)	(195)
Purchases of available-for-sale securities	(124,571)	(118,783)
Proceeds from maturity of available-for-sale securities	151,750	129,000
Non-current assets	_	(246)
Net cash provided by investing activities	27,003	9,776
Cash flows from financing activities:		
Payments of notes payable	(3,452)	
Net proceeds from exercise of common stock options and sale of common stock		
through employee stock purchase plan	125	1,079
Net cash (used for) provided by financing activities	(3,327)	1,079
Net increase (decrease) in cash and cash equivalents	3,192	(7,000)
Cash and cash equivalents:		
Beginning of year	83,174	103,262
End of period	\$ 86,366	\$ 96,262
See accompanying notes to unaudited condensed consolidated financial statements.		

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Change in Accounting Estimate

VIVUS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2015
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, 2015, are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. Management has evaluated all events and transactions that occurred after June 30, 2015, 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, 2014 as filed on February 25, 2015 and as amended by the Form 10-K/A filed on April 30, 2015 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, of VIVUS, Inc., and its California predecessor, as well as all of our consolidated subsidiaries.

Beginning in 2014, the Company began earning royalty revenue from the sales of STENDRA by its commercialization partners. Product delivered by the Company to these partners can be returned generally within a month after receipt and only if such product does not meet contractual specifications, and not for any other reason. The Company records royalty revenue related to STENDRA based on reports provided by its partners. One of the Company's partners, Auxilium Pharmaceuticals, Inc., or Auxilium, was acquired by Endo International, plc, or Endo, in January 2015. In April 2015, the Company was informed by Endo that Endo had revised its accounting estimate for returns reserve for STENDRA sold in 2014. Under the terms of the license and commercialization agreement, adjustments to the returns reserve can be deducted from the reported net revenue. As a result, in the six months ended June 30, 2015, the Company recorded an adjustment of \$1.2 million to reduce its royalty revenue. The reduction in royalty revenue resulted in an increase to net loss of \$1.2 million or \$0.01 per share for the six months ended June 30, 2015.

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

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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.

Significant Accounting Policies

There have been no changes to the Company's significant accounting policies since the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers, which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most current revenue recognition guidance. As originally issued, the standard would be effective for the Company's fiscal year beginning January 1, 2017, with early adoption not permitted. In July 2015, the FASB voted to delay the effective date of the standard by one year to the first quarter of 2018 to provide companies sufficient time to implement the standard. Early adoption will be permitted, but not before the first quarter of 2017. Adoption can occur using one of two prescribed transition methods. The Company is currently evaluating the method by which it will implement this standard and the impact of the adoption of this standard on the Company's consolidated financial statements.

2. SHARE-BASED COMPENSATION

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

	Three Months Ended		Six Months Ende	
	June 30,		June 30,	
	2015	2014	2015	2014
Cost of goods sold	\$ 22	\$ 29	\$ 52	\$ 63
Research and development	106	313	381	587
Selling, general and administrative	1,097	2,502	2,342	4,699
Non-recurring charges		_		343

Total share-based compensation expense \$ 1,225 \$ 2,844 \$ 2,775 \$ 5,692

There was \$13,000 and \$24,000 of share-based compensation cost capitalized as part of the cost of inventory for the three and six months ended June 30, 2015, respectively. 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.

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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, 2015 and December 31, 2014, are presented in the tables that follow.

	As of June 30, 2015 (in thousands):			
		Gross	Gross	
Cash and cash equivalents and available-for-sale	Amortized	Unrealized	Unrealized	Estimated
securities	Cost	Gains	Losses	Fair Value
Cash and money market funds	\$ 86,366	\$ —	\$ —	\$ 86,366
U.S. Treasury securities	187,757	51	(6)	187,802
Total	274,123	51	(6)	274,168
Less amounts classified as cash and cash equivalents	(86,366)		_	(86,366)
Total available-for-sale securities	\$ 187,757	\$ 51	\$ (6)	\$ 187,802

As of December 31, 2014 (in thousands):

		Gross	Gross	
Cash and cash equivalents and available-for-sale	Amortized	Unrealized	Unrealized	Estimated
securities	Cost	Gains	Losses	Fair Value
Cash and money market funds	\$ 83,174	\$ —	\$ —	\$ 83,174
U.S. Treasury securities	216,425	35	(63)	216,397
Total	299,599	35	(63)	299,571
Less amounts classified as cash and cash equivalents	(83,174)			(83,174)
Total available-for-sale securities	\$ 216,425	\$ 35	\$ (63)	\$ 216,397

As of June 30, 2015, the Company's available-for-sale securities had 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, accounts payable and accrued expenses approximate their carrying value.

Fair Value Measurements

As of June 30, 2015 and December 31, 2014, 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,	December 31,		
	2015	2014		
Qsymia	\$ 10,068	\$ 6,874		
STENDRA/SPEDRA	387	4,871		
	10,455	11,745		
Qsymia allowance for cash discounts	(201)	(150)		
Net	\$ 10,254	11,595		

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5. INVENTORIES

Inventories consist of (in thousands):

	Balance a	s of
	June 30,	December 31,
	2015	
Raw materials	\$ 4,534	\$ 29,765
Work-in-process	324	889
Finished goods	3,918	1,544
Deferred costs	830	2,249
Inventories	\$ 9,606	\$ 34,447

Raw materials inventories as of June 30, 2015 consist primarily of the active pharmaceutical ingredients, or API, for Qsymia and STENDRA. Raw materials inventories as of December 31, 2014 consist primarily of API for Qsymia. Deferred costs inventories consist of both Qsymia and STENDRA. The Qsymia deferred costs represents Qsymia product shipped to the Company's wholesalers and certified retail pharmacies, 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 product with the right of return or credit, which have not met 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.

VIVUS initially introduced Qsymia in September 2012, and for nearly three years post launch sales have not met earlier pre-launch expectations. During the same period, three other competitive products also have been introduced in the anti-obesity market with marginal success. Collectively, the U.S. market for branded anti-obesity pharmacotherapeutics has developed at a substantially lower rate than expected. The relatively shallow obesity market trajectory, combined with lower-than-anticipated Qsymia uptake and the Company's ongoing regulatory obligations in support of the brand, have led to a thorough re-evaluation of the Company's operations and a re-sizing of the Company's commercial and corporate headcount. In April 2015, the Company reduced its sales territories from 150 to 90, and in July 2015, as part of a corporate restructuring plan, the Company announced a plan to further cut the territories to 50. As a result of these actions, the Company's future sales forecast of Qsymia has been reduced and has resulted in excess inventory of Qsymia. For the three and six months ended June 30, 2015, the Company recognized an inventory impairment charge of \$29.5 million, primarily for Qsymia API inventory in excess of demand in addition to certain STENDRA raw materials.

6. PREPAID EXPENSES AND OTHER ASSETS

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

	Balance as of			
	June 30,	December 31,		
	2015	2014		
Prepaid sales and marketing expenses	\$ 2,536	\$ 4,123		
Debt issuance costs	1,223	1,246		
Prepaid insurance	543	1,612		
Other prepaid expenses and assets	6,069	5,843		
Total	\$ 10,371	\$ 12,824		

The amounts included in other prepaid expenses and assets consist primarily of prepayments for future services, a receivable from a supplier, and interest income receivable. These amounts represent probable future economic benefits obtained or controlled by the Company as a result of past transactions or events, which meet the

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definition of an asset under FASB Concept Statement 6. As such, these costs have been deferred as prepaid expenses and other assets on the condensed consolidated balance sheets and will be either (i) charged to expense accordingly when the related prepaid services are rendered to the Company, or (ii) converted to cash when the receivables are collected by the Company.

7. NON-CURRENT ASSETS

Non-current assets consist of (in thousands):

	Balance as of				
	June 30, Decembe		ecember 31	,	
	2015	20	2014		
Debt issuance costs	\$ 2,770	\$	3,375		
Other non-current assets	2,999		3,780		
Total	\$ 5,769	\$	7,155		

In September 2014, the Company acquired certain patents from Janssen Pharmaceuticals, Inc. Accordingly, \$3.1 million was recorded as an intangible asset and is being amortized as cost of goods sold through the expiration dates of the patents. For the three and six months ended June 30, 2015, \$0.2 million and \$0.4 million, respectively, was amortized as cost of goods sold. As of June 30, 2015, there was \$2.4 million included in non-current assets on the unaudited condensed consolidated balance sheet, which will be amortized over an estimated remaining life of approximately 4.75 years.

8. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities consist of (in thousands):

	Balance as of		
	June 30, December		
	2015	2014	
Accrued employee compensation and benefits	\$ 2,825	\$ 4,230	
Accrued non-recurring charges (see Note 10)	1,635	3,284	
Accrued interest on debt (see Note 13)	1,553	2,921	
Accrued manufacturing costs	1,333	400	

Other accrued liabilities	7,104	6,202
Total	\$ 14,450	\$ 17,037

The amounts included in other accrued liabilities consist of obligations primarily related to sales, marketing, research, clinical development, corporate activities and royalties, including a payable to Endo related to the royalty revenue adjustment.

9. NON-CURRENT ACCRUED AND OTHER LIABILITIES

Non-current accrued and other liabilities at June 30, 2015 and December 31, 2014 were \$0.7 and \$0.8 million, respectively, and primarily consisted of costs associated with the exit of certain operating leases and security deposits relating to the sublease agreements.

10. INVENTORY IMPAIRMENT AND OTHER NON-RECURRING CHARGES

As discussed in Note 5, for the three and six months ended June 30, 2015, the Company recognized impairment charges of \$29.5 million, primarily for Qsymia API inventory in excess of demand in addition to certain STENDRA raw materials. There were no non-recurring charges in the three months ended June 30, 2014. Non-recurring charges for the six months ended June 30, 2014 consisted of employee severance and related costs of \$1.7 million and share-based compensation of \$0.3 million related to the finalization of the cost reduction plan initiated during 2013, which reduced the Company's workforce by approximately 20 employees, or 17%, excluding the sales force, for the year ended December 31, 2013.

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The following table sets forth activities for the Company's cost reduction plan obligations during the six months ended June 30, 2015 (in thousands):

	Severance obligations			
Balance of accrued costs at December 31, 2014	\$ 3,280	\$ 572	\$ 3,852	
Charges	_		_	
Payments	(923)	(25)	(948)	
Balance of accrued costs at March 31, 2015	\$ 2,357	\$ 547	\$ 2,904	
Charges	_	_		
Payments	(825)	(25)	(850)	
Balance of accrued costs at June 30, 2015	\$ 1,532	\$ 522	\$ 2,054	

Of the total accrued employee severance and facilities-related costs in the Company's unaudited condensed consolidated balance sheet at June 30, 2015, \$1.6 million is included under current liabilities in "Accrued and other liabilities" and \$0.4 million is included in "Non-current accrued and other liabilities."

The balance of the accrued employee severance and facilities-related costs at June 30, 2015 is anticipated to be paid out as follows (in thousands):

2015 (remaining six months)	\$ 1,584
2016	102
2017	341
2018	11
Thereafter	16
	\$ 2.054

11. DEFERRED REVENUE

Qsymia Deferred Revenue

At June 30, 2015, the Company had \$18.4 million in current deferred revenue, which represents Qsymia product shipped to the Company's wholesalers and certified retail pharmacies, but not yet dispensed to patients through prescriptions, net of prompt payment discounts.

STENDRA or SPEDRA Deferred Revenue

At June 30, 2015, the Company had \$2.2 million and \$7.7 million in current and non-current deferred revenue, respectively, related to STENDRA or SPEDRA. The \$2.2 million in current deferred revenue primarily relates to a prepayment for future royalties on sales of SPEDRA. The \$7.7 million in non-current deferred revenue relates to a prepayment for future royalties on sales of SPEDRA.

12. LICENSE, COMMERCIALIZATION AND SUPPLY AGREEMENTS

During 2013, the Company entered into separate license and commercialization agreements and separate commercial supply agreements with each of the Menarini Group, through its subsidiary Berlin Chemie AG, or Menarini, 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 European Union, or EU, plus Australia and New Zealand. Auxilium's territory is comprised of the United States and Canada and their respective territories. In January 2015, Auxilium was acquired by Endo. Sanofi's territory is comprised of Africa, the Middle East, Turkey and Eurasia.

For the six months ended June 30, 2015, the Company recognized \$11.6 million in license and milestone revenue attributable to a milestone payment for the approval of the time-to-onset in Europe which was approved by

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the European Commission, or EC, in January 2015, allowing SPEDRA to be the first and only erectile dysfunction medication approved in the EU that is indicated to be taken as needed approximately 15 to 30 minutes before sexual activity. The Company did not recognize any license and milestone revenue in the three months ended June 30, 2015. 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 attributable to milestone revenue related to product launches in certain EU countries and non-contingent consideration allocated to the licenses based on relative estimated selling prices. For the three and six months ended June 30, 2015, the Company recognized \$8.1 million and \$16.6 million, respectively, in supply revenue relating to STENDRA or SPEDRA delivered under the various commercial supply agreements with Menarini, Endo and Sanofi. For the three and six months ended June 30, 2014, the Company recognized \$5.7 million and \$13.0 million, respectively, in supply revenue relating to STENDRA or SPEDRA. Additionally, in the three and six months ended June 30, 2015, the Company recognized \$0.9 million and \$0.3 million, respectively, in net royalty revenue based on net sales reported by Menarini and Endo. For the three and six months ended June 30, 2014, the Company recognized \$1.1 million and \$1.9 million, respectively, in net royalty revenue.

13. LONG-TERM DEBT

Convertible Senior Notes Due 2020

In May 2013, the Company closed an offering of \$220.0 million in 4.5% Convertible Senior Notes due May 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. In May 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. The Convertible Notes are convertible at the option of the holders under certain conditions at any time prior to the close of business on the business day immediately preceding November 1, 2019. On or after November 1, 2019, holders may convert all or any portion of their Convertible Notes at any time at their option at the conversion rate then in effect, regardless of these conditions. Subject to certain limitations, the Company will settle conversions of the Convertible Notes by paying or delivering, as the case may be, cash, shares of its common stock or a combination of cash and shares of its common stock, at the Company's election. For the three and six months ended June 30, 2015, total interest expense related to the Convertible Notes was \$6.7 million and \$13.3 million, respectively, including amortization of \$3.9 million and \$7.8 million of the debt discount and \$209,000 and \$415,000 of deferred financing costs, respectively. For the three and six months ended June 30, 2014, total interest expense related to the Convertible Notes was \$6.2 million and \$12.2 million, respectively, including amortization of \$3.6 million and \$7.2 million of the debt discount and \$192,000 and \$381,000 of deferred financing costs, respectively.

Senior Secured Notes Due 2018

In March 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 in April 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, 2015, the interest expense related to the Senior Secured Notes was \$1.7 million and \$3.4 million, respectively, including amortization of deferred financing costs amounting to \$104,000 and \$213,000, respectively. For the three and six months ended June 30, 2014, the interest expense related to the Senior Secured Notes was \$1.9 million and \$3.8 million, respectively, including amortization of deferred financing costs amounting to \$119,000 and \$238,000, respectively.

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

	June 30, 2015
Convertible Senior Notes due 2020:	
Fair value of the liability component	\$ 154,737
Accumulated accretion of discount	30,862
Net carrying value	\$ 185,599
Senior Secured Notes due 2018:	
Carrying value	\$ 46,548
Total Notes:	
Fair value of the liability component	\$ 201,285
Accumulated accretion of discount	30,862
Net carrying amount	232,147
Less: Current portion	(14,497)
Long-term debt, net of current portion	\$ 217,650

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 applicable 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 each of the three and six month periods ended June 30, 2015 and 2014, all potential common equivalent shares were excluded for these periods as they were anti-dilutive. For the three and six months ended June 30, 2015, awards and options outstanding of 7,324,000 and 7,459,000, respectively, were not included in the computation of diluted net loss per share for the Company because the effect would be anti-dilutive. For the three and six months ended June 30, 2014, awards and options outstanding of 8,779,000 and 8,191,000, 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, 2015, the Company recorded a provision for taxes of \$6,000 and \$12,000, respectively. For the three and six months ended June 30, 2014, the Company recorded a tax benefit of \$2,000 and \$438,000, respectively. The provision for income taxes for the three and six months ended June 30, 2015 was primarily comprised of state taxes during the period. The tax benefit for the three and six months ended June 30, 2014 was primarily comprised of 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 Company periodically evaluates the realizability of its net deferred tax assets based on all available evidence, both positive and negative. The realization of net deferred tax assets is dependent on the Company's

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ability to generate sufficient future taxable income during periods prior to the expiration of tax attributes to fully utilize these assets. The Company weighed both positive and negative evidence and determined that there is a continued need for a full valuation allowance on its deferred tax assets in the United States as of June 30, 2015. Should the Company determine that it would be able to realize its remaining deferred tax assets in the foreseeable future, an adjustment to its remaining deferred tax assets would cause a material increase to income in the period such determination is made.

As of December 31, 2014, the Company did not have any uncertain tax positions. There were no material changes to our unrecognized tax benefits in the six months ended June 30, 2015, 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. The Company's policy is to recognize interest and penalties related to uncertain tax positions (if any) as a component of the income tax provision.

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 Securities Exchange Act of 1934 as amended 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. Following briefing of the appeal, the Court of Appeals held oral argument on January 16, 2015. On January 29, 2015, the Court of Appeals issued a Memorandum decision affirming the District Court's ruling. On February 12, 2015, plaintiff asked the Court of Appeals' panel to rehear the case or for the Court to rehear the case en banc. The Ninth Circuit rejected that petition on March 16, 2015, and the time for further appeal has expired. The matter is, accordingly, now concluded.

Additionally, certain of the Company's former officers and directors and a current director were 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 had breached fiduciary duties to the Company by purportedly permitting the Company to violate certain federal securities laws as alleged in the Kovtun action. The same individuals were 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 were substantially similar to the other lawsuits.

The Company was named as a nominal defendant in these actions, neither of which seeks any recovery from the Company. The parties had agreed to stay the derivative lawsuits pending the outcome of the appeal of the securities class action. With the Court of Appeals' action to affirm dismissal of the securities class action, plaintiffs in both the federal and state derivative lawsuits voluntarily dismissed their lawsuits without further proceedings, and these lawsuits are now concluded.

On March 27, 2014, Mary Jane and Thomas Jasin, who purport to be purchasers of VIVUS common stock, filed an Amended Complaint in Santa Clara County Superior Court alleging securities fraud against the Company and three of its former officers and directors. In that complaint, captioned Jasin v. VIVUS, Inc., Case No. 114 cv 261427, plaintiffs asserted claims under California's securities and consumer protection securities statutes. Plaintiffs alleged generally that defendants misrepresented the prospects for the Company's success, including with respect to the launch of Qsymia, while purportedly selling VIVUS stock for personal profit. Plaintiffs alleged losses of "at least" \$2.8 million, and sought damages and other relief. On June 5, 2014, the Company and the other defendants filed a demurrer to the Amended Complaint seeking its dismissal. With the demurrer pending, on July 18, 2014, the same plaintiffs filed a complaint in the United States District Court for the Northern District of California, in an action captioned Jasin v. VIVUS, Inc., Case No. 5:14 cv 03263. The Jasins' federal complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, based on facts substantially similar to

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those alleged in their state court action. On September 15, 2014, pursuant to an agreement between the parties, plaintiffs moved to voluntarily dismiss, with prejudice, the state court action. In the federal action, defendants filed a motion to dismiss on November 12, 2014. On December 3, 2014, plaintiffs filed a First Amended Complaint in the federal action. On January 21, 2015, defendants filed a motion to dismiss the First Amended Complaint. By Order dated June 18, 2015, the Court granted defendants' motion to dismiss the complaint in its entirety, but granted plaintiffs leave to amend their pleading. If plaintiffs elect to amend their complaint further, the new pleading must be filed by August 14, 2015. The Company and the defendant former officers and directors cannot predict whether the Jasin plaintiffs will amend their complaint, and cannot predict the outcome of the lawsuit if they do; however, the Company and the defendant former officers and directors believe the lawsuit is without merit and intend to continue vigorously to defend against the claims.

The Company maintains directors' and officers' liability insurance that it believes affords coverage for much of the anticipated cost of the remaining Jasin action, subject to payment of our self-insured retention and the policies' terms and conditions.

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 six patents listed for Qsymia in the FDA Orange Book at the time the notice was received (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 (SRC)(CLW)) 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) up to 30 months from the Company's May 7, 2014 receipt of Actavis' Paragraph IV certification notice (i.e. November 7, 2016) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

On January 21, 2015, the Company received a second Paragraph IV certification notice from Actavis contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 8,895,057 and 8,895,058) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, or offer for sale of a generic form of Qsymia. On March 4, 2015, the Company filed a second lawsuit in the U.S. District Court for the District of New Jersey against Actavis (Case No. 15-1636 (FSH)(MAH)) in response to the second Paragraph IV certification notice on the basis that Actavis' submission of their ANDA constitutes infringement of one or more claims of the patents-in-suit. The two lawsuits against Actavis have been consolidated into a single suit (Case No. 14-3786 (SRC)(CLW)).

On July 7, 2015, the Company received a third Paragraph IV certification notice from Actavis contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 9,011,905 and 9,011,906) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, or offer for sale of a generic form of Qsymia. Under the Hatch-Waxman Act, the Company has 45 days from receipt of the notice to determine if it will file a patent infringement suit.

On March 5, 2015, the Company received a Paragraph IV certification notice from Teva Pharmaceuticals USA, Inc. indicating that it filed an ANDA with the FDA, requesting approval to market a generic version of Qsymia and contending that eight patents listed for Qsymia in the Orange Book at the time of the notice (U.S. Patents 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, 8,580,299, 8,895,057 and 8,895,058) (collectively "patents-in-suit") are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of a generic form of Qsymia as described in their ANDA. On April 15, 2015, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Teva Pharmaceutical USA, Inc. and Teva Pharmaceutical Industries,

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Ltd., collectively referred to as Teva. The lawsuit (Case No. 15-2693 (SRC)(CLW)) was filed on the basis that Teva's 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 Teva, FDA approval of Teva's ANDA will be stayed until the earlier of (i) up to 30 months from our March 5, 2015 receipt of Actavis' Paragraph IV certification notice (i.e. September 5, 2017) 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 these matters.

The Company is not aware of any other asserted or unasserted claims against it where it believes that an unfavorable resolution would have an adverse material impact on the operations or financial position of the Company.

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 individual customer and 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.

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Net product revenue by geographic region for the three and six months ended June 30, 2015 and 2014 was as follows (in thousands):

	Three Mon 2015	ths Ended June 3	0,	2014		
	U.S.	ROW	Total	U.S.	ROW	Total
Qsymia—Net product revenue	\$ 14,013	\$ —	\$ 14,013	\$ 10,983	\$ —	\$ 10,983
STENDRA/SPEDRA—License	ψ 14,013	Ψ	ψ 14,015	ψ 10,703	Ψ	ψ 10,703
and milestone revenue					4,181	4,181
STENDRA/SPEDRA—Supply					4,101	4,101
revenue	6,569	1,548	8,117	857	4,809	5,666
STENDRA/SPEDRA —Royalty	0,209	1,0 10	0,117	007	1,000	2,000
revenue	303	552	855	430	621	1,051
Total revenue	\$ 20,885	\$ 2,100 (1)	\$ 22,985	\$ 12,270	\$ 9,611 (2)	\$ 21,881
	, _0,000	+ =, (-)	+,,	+,	+ 2,0 (-)	+,
	Six Months	Ended June 30,				
	Six Months 2015	Ended June 30,		2014		
		Ended June 30,	Total	2014 U.S.	ROW	Total
Qsymia—Net product revenue	2015		Total \$ 26,641		ROW \$ —	Total \$ 20,121
Qsymia—Net product revenue STENDRA/SPEDRA—License	2015 U.S.	ROW		U.S.		
	2015 U.S.	ROW		U.S.		
STENDRA/SPEDRA—License	2015 U.S.	ROW \$ —	\$ 26,641	U.S. \$ 20,121	\$ —	\$ 20,121
STENDRA/SPEDRA—License and milestone revenue	2015 U.S.	ROW \$ —	\$ 26,641	U.S. \$ 20,121	\$ —	\$ 20,121
STENDRA/SPEDRA—License and milestone revenue STENDRA/SPEDRA—Supply	2015 U.S. \$ 26,641	ROW \$ — 11,574	\$ 26,641 11,574	U.S. \$ 20,121 406	\$ — 23,138	\$ 20,121 23,544
STENDRA/SPEDRA—License and milestone revenue STENDRA/SPEDRA—Supply revenue	2015 U.S. \$ 26,641	ROW \$ — 11,574	\$ 26,641 11,574	U.S. \$ 20,121 406	\$ — 23,138	\$ 20,121 23,544
STENDRA/SPEDRA—License and milestone revenue STENDRA/SPEDRA—Supply revenue STENDRA/SPEDRA—Royalty	2015 U.S. \$ 26,641 — 11,581	ROW \$ — 11,574 5,014	\$ 26,641 11,574 16,595	U.S. \$ 20,121 406 5,406	\$ — 23,138 7,630	\$ 20,121 23,544 13,036

^{(1)\$2.1} million of which was attributable to Germany.

18. SUBSEQUENT EVENT

On July 30, 2015, the Company announced a corporate restructuring plan that will reduce its headcount and expenses, with an objective of achieving neutral or positive operating cash flows by year-end 2016. The Company will be reducing its Qsymia sales force to fifty territories and streamlining further its headquarters headcount resulting in the

^{(2)\$9.6} million of which was attributable to Germany.

^{(3)\$17.5} million of which was attributable to Germany.

^{(4)\$26.3} million of which was attributable to Germany.

elimination of approximately 60 job positions and consequently, the Company's future sales forecast for Qsymia will be reduced and has resulted in excess inventory as disclosed in Note 5. In addition, the Company will incur additional charges for severance and facility closure of approximately \$3.6 million in the third quarter of 2015. The Company expects annual savings of approximately \$14.4 million in operating expenses beginning in fiscal year 2016.

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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 Quarterly Report on 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 neg 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:

- · our limited commercial experience with Osymia® in the United States, or U.S.;
- the timing of initiation and completion of the post-approval clinical studies required as part of the approval of Qsymia by the U.S. Food and Drug Administration, or FDA;
- · the response from the FDA to the data that we will submit relating to post-approval clinical studies;
- the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy requirements;
- · our ability to continue to certify and add to the Qsymia retail pharmacy network and sell Qsymia through this network;
- · 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;
 - that we may be required to provide further analysis of previously submitted clinical trial data;
- our ability to work with leading cardiovascular outcome trial experts in planning substantial revisions to the original design and execution of the clinical post-marketing cardiovascular outcomes trial, or CVOT, with the goal of reducing trial costs and obtaining FDA agreement that the revised CVOT would fulfill the requirement of demonstrating the long-term cardiovascular safety of Qsymia;
 - our ongoing dialog with the European Medicines Agency, or EMA, relating to our CVOT, and the resubmission of an application for the grant of a marketing authorization to the 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;
- · our ability to successfully seek approval for Qsymia in other territories outside the U.S. and EU;
- · 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;
- · 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;
- · 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;

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our ability to eliminate expenses that are not essential to expanding the use of Qsymia and fully realize the anticipated benefits from our cost reduction and corporate restructuring plans, including the timing thereof; the impact of lower annual net cost savings than currently expected;

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- the impact of our cost reduction and corporate restructuring plans on our business and unanticipated charges not currently contemplated that may occur as a result of such cost reduction and corporate restructuring plans;
- · our ability to ensure that the entire supply chain for Qsymia efficiently and consistently delivers Qsymia to our customers;
- · risks and uncertainties related to the timing, strategy, tactics and success of the launches and commercialization of STENDRA® (avanafil) or SPEDRATM (avanafil) by our sublicensees in the U.S., Canada, the EU, Australia, New Zealand, Africa, the Middle East, Turkey, and the Commonwealth of Independent States, including Russia;
- 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 in which we do not have a commercial collaboration;
- the timing of the qualification and subsequent approval by regulatory authorities of Sanofi Chimie and Sanofi Winthrop Industrie as qualified suppliers of STENDRA/SPEDRA, Sanofi Chimie's ability to undertake manufacturing of the avanafil active pharmaceutical ingredient and Sanofi Winthrop Industrie's ability to undertake manufacturing of the tablets for avanafil;
- the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand;
- · our ability to accurately forecast Qsymia demand;
- · our ability to increase Qsymia sales in 2015 through growth in certified retail pharmacies, expansion of reimbursement coverage and the use of a more focused selling message;
- the number of Qsymia prescriptions dispensed through the mail order system and through certified retail pharmacies;
- · the impact of promotional programs for Qsymia on our net product revenue and net income (loss) in future periods;
- · our history of losses and variable quarterly results;
- · substantial competition;
- · risks related to the failure to protect our intellectual property and litigation in which we are involved or may become involved;
- · uncertainties of government or third-party payor reimbursement;
- · our reliance on sole-source suppliers, third parties and our collaborative partners;
- · our failure to continue to develop innovative investigational drug candidates and drugs;
- · risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations;
- · our ability to demonstrate through clinical testing the quality, safety, and efficacy of our investigational drug candidates:
- · the timing of initiation and completion of clinical trials and submissions to foreign authorities;
- · the results of post-marketing studies are not favorable;
- · compliance with post-marketing regulatory standards, post-marketing obligations or pharmacovigilance rules is not maintained;
- · the volatility and liquidity of the financial markets;
- · our liquidity and capital resources;
- · our expected future revenues, operations and expenditures;
- · potential change in our business strategy to enhance long-term stockholder value;
- the impact, if any, of changes to our Board of Directors and management team, including the resignation of our Vice President, U.S. Operations and General Manager; and

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• other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, or the SEC, 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 three and six months ended June 30, 2015 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, 2014, as filed with the SEC on February 25, 2015 and as amended by the Form 10-K/A filed with the SEC on April 30, 2015, and other disclosures (including the disclosures under "Part II. Item 1A. Risk Factors") included in this Quarterly Report on Form 10-Q. Our unaudited 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 commercializing and developing innovative, next-generation therapies to address unmet needs in obesity, sleep apnea, diabetes and sexual health, and we have two therapies approved by the FDA: Qsymia for chronic weight management and STENDRA for erectile dysfunction, or ED. STENDRA is also approved by the European Commission, or EC, under the trade name, SPEDRA, for the treatment of ED in the EU.

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, Qsymia became available in the U.S. market through a limited number of certified home delivery networks. In July 2013, Qsymia became available in retail pharmacies through approximately 8,000 Walgreens, Costco and Duane Reade pharmacies nationwide. As of the date of this report, Qsymia is available in over 42,000 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. In the third quarter of 2015, we intend to directly hire many of the current contract sale representatives to continue promoting Qsymia to physicians and to hire additional sales representatives as necessary to fill open territories. 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. Most recently, we have rolled out unique marketing programs to encourage targeted prescribers to gain more experience with Qsymia with their obese patient population. We are increasing our investment in digital media in order to amplify our messaging to information-seeking consumers. The digital messaging encourages those consumers most likely to take action to speak with their physicians about obesity treatment options. We believe our enhanced web-based strategies will deliver clear and compelling communications to potential patients. We have also employed a physician referral service to help patients identify prescribers in their area.

Challenges continue within the obesity pharmacotherapy market, in particular with respect to the tendency on the part of healthcare providers to treat the co-morbid conditions of obesity rather than the obesity disease itself. In addition, there is a narrow focus on certain patient types for treatment, a historically low third-party insurance coverage, and the continued exclusion of anti-obesity medications from Medicare Part D.

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We continue to develop efficient ways to address the obesity market. We completed a realignment of our field sales territories during April 2015, reducing the number of territories from 150 to approximately 90. A further reduction in force was implemented in July 2015, bringing the number of territories to 50. Each of these adjustments was accompanied by a parallel streamlining of corporate headquarters headcount as we have sought to right-size the organization to match the market opportunity as it currently exists.

We have defined and identified the healthcare provider, or HCP, audience of anti-obesity prescribers as numbering approximately 8,000 to 10,000. Of these, we believe the most highly productive writers will be more than adequately covered by the newly-configured VIVUS sales force. We are focused on maintaining a commercial presence with the important Qsymia prescribers, and we have capacity to cover new potential prescribers, who are those physicians that begin prescribing branded obesity products. We are constantly monitoring prescribing activity in the market, and we have seen new prescriptions being written by HCPs on whom we have not previously dedicated field sales resources. We believe that part of the current realignment addresses this new prescriber group, and we look forward to initiating and maintaining dialog with these HCPs.

Qsymia is approved for the treatment of obesity in the U.S. In the EU, in October 2012, we received a negative opinion from the European Medicines Agency, or EMA, Committee for Medicinal Products for Human Use, or CHMP, recommending refusal of the marketing authorization for the medicinal product QsivaTM (the intended 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 of the CHMP opinion, in February 2013, the CHMP adopted a final opinion that reaffirmed the Committee's earlier negative opinion to refuse the marketing authorization for Qsiva in the EU. In May 2013, the EC issued a decision refusing the grant of marketing authorization for Qsiva in the EU.

In September 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 CVOT known as AOCLAIM to assess the long-term treatment effect of Osymia on the incidence of major adverse cardiovascular events in overweight and obese subjects with confirmed cardiovascular disease. Our request was to allow this interim analysis to support the resubmission of an application for a marketing authorization for Osiva for treatment of obesity in accordance with the EU centralized marketing authorization procedure. We received feedback in 2014 from the EMA and the various competent authorities of the EU Member States associated with review of the AOCLAIM CVOT protocol, and we received feedback from the FDA in late 2014 regarding the amended protocol. As a part of addressing the FDA comments, we are now working with leading cardiovascular outcome trial experts in planning substantial revisions to the original design and execution of the CVOT, with the goal of reducing costs while also fulfilling the requirement of further demonstrating the long-term cardiovascular safety of Osymia. We met recently with the FDA to provide a program update and to share our plans to modify the CVOT design. This dialog is ongoing, and we are committed to involving the FDA in reviewing alternative proposals that will satisfy the existing requirements. As one component of this clinical project, we plan to conduct and complete by 2017 a Osymia heart rate variability study that will guide and inform the redesigned CVOT. The total cost of this study is expected to be approximately \$5.0 million.

In addition, we are in the process of pursuing a new indication for Qsymia in obstructive sleep apnea, or OSA. We also intend to seek regulatory approval for Qsymia in other territories outside the United States and EU and, if approved, to commercialize the product through collaboration agreements with third parties. We plan to optimize spending while pursuing these potential objectives.

Our drug STENDRA, or avanafil, is an oral phosphodiesterase type 5, or PDE5, inhibitor that we have licensed from Mitsubishi Tanabe Pharma Corporation, or 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 a 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, as well as Australia and New Zealand. Menarini commenced its commercialization launch of the product in the EU in early 2014, and as of the date of this filing,

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SPEDRA is commercially available in 25 countries within the territory granted to Menarini pursuant to the license and commercialization agreement.

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 January 2015, Auxilium was acquired by Endo.

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, Endo and Sanofi, avanafil is expected to be commercialized in over 100 countries worldwide. For all three license agreements collectively, we have the potential to earn up to \$461.0 million in license and milestone payments, in addition to royalty revenue. Through June 30, 2015, we have received approximately \$117.5 million in license and milestone payments, plus royalties. In addition, we are currently in discussions with potential collaboration partners to market and sell STENDRA for our other territories, including Latin America, in which we do not currently have a commercial collaboration.

On September 18, 2014, the FDA approved a supplemental new drug application (sNDA) for STENDRA. STENDRA is now the only FDA-approved ED medication indicated to be taken as early as approximately 15 minutes before sexual activity. Additionally, on January 23, 2015, the EC adopted a commission implementing decision amending the marketing authorization for SPEDRA (avanafil). SPEDRA is now the first and only ED medication approved in the EU that is indicated to be taken as needed approximately 15 to 30 minutes before sexual activity.

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 that have failed to receive such approval in that market, which could have a material adverse effect on our business, financial condition and results of operations.

The discussion and analysis of our financial condition and results of operations are based upon our unaudited consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. 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.

Our significant accounting policies are more fully described in Note 1 to our audited consolidated financial statements and in "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates" contained in our Annual Report on Form 10-K, or our Annual Report, as filed with the SEC on February 25, 2015. There have been no significant changes in our critical accounting policies during the six months ended June 30, 2015, as compared to those disclosed in our Annual Report.

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RESULTS OF OPERATIONS

For the three and six months ended June 30, 2015, net loss was \$49.3 million and \$64.8 million or \$0.48 and \$0.62 net loss per share, respectively, as compared to a net loss of \$25.8 million and \$41.4 million or \$0.25 and \$0.40 net loss per share, respectively, during the same periods in 2014. The increase in the net loss in the three and six months ended June 30, 2015 as compared to the same periods in 2014 is primarily attributable to the inventory impairment charge of \$29.5 million taken by the Company in the second quarter of 2015.

We may continue to generate losses in future periods, depending on our ability to successfully commercialize Qsymia, our commercialization partners' success in promoting STENDRA or SPEDRA, the timing of our research and development expenditures, and our continued investment in the clinical development of our research and future investigational drug candidates, primarily related to the post marketing study requirements for our approved drugs.

	Three Months Ended June 30,		2015 vs 2014 Increase/		Six Month	Six Months Ended June 30,		4
					June 30,			
(in thousands, except for percentages)	2015	2014	(Decrease))	2015	2014	(Decrease)	
Revenue:								
Net product revenue	\$ 14,013	\$ 10,983	28	%	\$ 26,641	\$ 20,121	32	%
License and milestone revenue	_	4,181	(100)	%	11,574	23,544	(51)	%
Supply revenue	8,117	5,666	43	%	16,595	13,036	27	%
Royalty revenue	855	1,051	(19)	%	341	1,871	(82)	%
Total revenue	\$ 22,985	\$ 21,881	5	%	\$ 55,151	\$ 58,572	(6)	%

Net product revenue

For the three months ended June 30, 2015, there were approximately 152,000 Qsymia prescriptions dispensed, compared to 138,000 for the same period of 2014. For the six months ended June 30, 2015, there were approximately 288,000 Qsymia prescriptions dispensed, compared to 259,000 for the same period of 2014. Approximately 64% of our total prescriptions for the second quarter of 2015 included either a free good or discount offer, with approximately 29,000 of those prescriptions dispensed as free goods. In comparison, for the three months ended June 30, 2014, approximately 61% of our total prescriptions included either a free good or discount offer, with approximately 31,000 of those prescriptions dispensed as free goods.

Approximately 63% of our total prescriptions for the first six months of 2015 included either a free good or discount offer, with approximately 54,000 of those prescriptions dispensed as free goods. In comparison, for the six months ended June 30, 2014, approximately 58% of our total prescriptions included either a free good or discount offer, with approximately 55,000 of those prescriptions dispensed as free goods.

As of June 30, 2015, we had deferred revenue related to sales of Qsymia of \$18.4 million, which represents Qsymia product shipped to wholesalers and certified retail pharmacies, but not yet dispensed to patients through prescriptions, net of prompt-payment discounts.

License and milestone revenue

For the six months ended June 30, 2015, under the terms of the license and commercialization agreement with Menarini, we recognized \$11.6 million in license and milestone revenue related to the time-to-onset claim, which was approved by the EC in January 2015, allowing SPEDRA to be the first and only erectile dysfunction medication approved in the EU that is indicated to be taken as needed approximately 15 to 30 minutes before sexual activity. 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, 2015, we recognized \$8.1 million and \$16.6 million in supply revenue, compared to \$5.7 million and \$13.0 million for the three and six months ended June 30, 2014, respectively.

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The increase in supply revenue for the 2015 periods as compared to the 2014 periods is due to the rollout of SPEDRA in Europe. As of June 30, 2015, SPEDRA was available at retail pharmacies in 25 countries within the Menarini territory, compared to 20 countries at June 30, 2014. To date, Sanofi has not launched the commercialization of SPEDRA in its territories.

Royalty revenue

For the three and six months ended June 30, 2015, we recognized \$0.9 million and \$0.3 million, respectively, in net royalty revenue on net sales reported by our commercialization partners, compared to \$1.1 million and \$1.9 million in royalty revenue in the three and six months ended June 30, 2014, respectively. Beginning in 2014, we began earning royalty revenue from sales of STENDRA by these partners. The product that we deliver to these partners can be returned generally within a month after receipt and only if such product does not meet contractual specifications, and not for any other reason. We record royalty revenue related to STENDRA based on reports provided by our partners. One of our partners, Auxilium, was acquired by Endo in January 2015. In April 2015, we were informed by Endo that Endo had revised its accounting estimate for return reserve for STENDRA sold in 2014. Under the terms of the license and commercialization agreement, adjustments to the return reserve can be deducted from the reported net revenue. As a result, in the first quarter of 2015, we recorded an adjustment of \$1.2 million to reduce our royalty revenue.

Cost of goods sold

Cost of goods sold for the three and six months ended June 30, 2015 was \$9.9 million and \$19.8 million, respectively, as compared to \$7.0 million and \$16.5 million for the three and six months ended June 30, 2014, respectively. For the three and six months ended June 30, 2015, cost of goods sold related to Qsymia was \$2.2 million and \$4.1 million, respectively, and cost of goods sold related to STENDRA or SPEDRA was \$7.7 million and \$15.7 million, respectively. For the three and six months ended June 30, 2014, cost of goods sold related to Qsymia was \$1.4 million and \$3.2 million, respectively, and cost of goods sold related to STENDRA or SPEDRA was \$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 our commercialization partners includes the inventory costs of purchased tablets, freight, shipping and handling costs, and overhead costs of the employees involved with managing production. 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 condensed consolidated balance sheets, until such time as the deferred revenue is recognized.

Selling, general and administrative expense