VIVUS INC
Form 10-Q
November 09, 2016
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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 September 30, 2016

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 (Do not check if a smaller reporting company)	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 October 31, 2016, 104,843,301 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)

	September 30, 2016	December 31, 2015
ASSETS	Unaudited	Note 1
Current assets:		
Cash and cash equivalents	$ 154,137	$ 95,395
Available-for-sale securities	129,449	146,168
Accounts receivable, net	10,295	8,997
Inventories	11,259	13,602
Prepaid expenses and other current assets	5,552	9,430
Total current assets	310,692	273,592
Property and equipment, net	715	994
Non-current assets	1,744	2,616
Total assets	$ 313,151	$ 277,202
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 6,440	$ 7,060
Accrued and other liabilities	9,944	15,891
Deferred revenue	89,128	22,142
Current portion of long-term debt	9,015	14,356
Total current liabilities	114,527	59,449
Long-term debt, net of current portion	229,876	217,034
Deferred revenue, net of current portion	6,845	6,508
Non-current accrued and other liabilities	16	1,296
Total liabilities	351,264	284,287
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock; $1.00 par value; 5,000 shares authorized; no shares issued and outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock; $.001 par value; 200,000 shares authorized; 104,819 and 104,055 shares issued and outstanding at September 30, 2016 and December	105	104

31, 2015, respectively		
Additional paid-in capital	831,192	829,428
Accumulated other comprehensive income (loss)	207	(261)
Accumulated deficit	(869,617)	(836,356)
Total stockholders' deficit	(38,113)	(7,085)
Total liabilities and stockholders' deficit	$ 313,151	$ 277,202

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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Net product revenue	$ 12,294	$ 14,011	$ 37,455	$ 40,652
License and milestone revenue	—	—	—	11,574
Supply revenue	—	10,056	1,526	26,651
Royalty revenue	1,059	869	3,472	1,210
Total revenue	13,353	24,936	42,453	80,087
Operating expenses:				
Cost of goods sold	2,065	11,765	8,416	31,531
Selling, general and administrative	10,440	17,129	39,254	65,730
Research and development	1,696	1,532	3,821	6,825
Inventory impairment and other non-recurring charges	—	2,539	—	32,061
Total operating expenses	14,201	32,965	51,491	136,147
Loss from operations	(848)	(8,029)	(9,038)	(56,060)
Interest expense and other expense, net	8,313	8,076	24,209	24,851
Loss before income taxes	(9,161)	(16,105)	(33,247)	(80,911)
(Benefit) Provision for income taxes	(9)	1	14	13
Net loss	$ (9,152)	$ (16,106)	$ (33,261)	$ (80,924)
Basic and diluted net loss per share	$ (0.09)	$ (0.15)	$ (0.32)	$ (0.78)
Shares used in per share computation:				
Basic and diluted	104,484	104,014	104,228	103,950

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$ (9,152)	$ (16,106)	$ (33,261)	$ (80,924)
Unrealized (loss) gain on securities, net of taxes	(158)	51	469	124
Comprehensive loss	$ (9,310)	$ (16,055)	$ (32,792)	$ (80,800)

See accompanying notes to unaudited condensed consolidated financial statements.

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VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$ (33,261)	$ (80,924)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	823	1,079
Amortization of debt issuance costs and discounts	13,860	12,761
Amortization of discount or premium on available-for-sale securities	700	1,940
Share-based compensation expense	1,740	3,032
Inventory impairment charge	—	29,522
Changes in assets and liabilities:		
Accounts receivable	(1,298)	(3,299)
Inventories	2,343	(4,113)
Prepaid expenses and other assets	4,206	3,611
Accounts payable	(620)	(2,908)
Accrued and other liabilities	(7,227)	(2,563)
Deferred revenue	67,323	781
Net cash provided by (used for) operating activities	48,589	(41,081)
Cash flows from investing activities:		
Property and equipment purchases	—	(310)
Purchases of available-for-sale securities	(50,523)	(176,510)
Proceeds from maturity of available-for-sale securities	60,050	219,500
Proceeds from sales of available-for-sale securities	6,960	—
Net cash provided by investing activities	16,487	42,680
Cash flows from financing activities:		
Repayments of notes payable	(6,359)	(5,402)
Sale of common stock through employee stock purchase plan	25	125
Net cash used for financing activities	(6,334)	(5,277)
Net increase (decrease) in cash and cash equivalents	58,742	(3,678)
Cash and cash equivalents:		
Beginning of year	95,395	83,174
End of period	$ 154,137	$ 79,496

See accompanying notes to unaudited condensed consolidated financial statements.

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VIVUS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2016

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 nine months ended September 30, 2016, are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. Management has evaluated all events and transactions that occurred after September 30, 2016, 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, 2015 as filed on March 9, 2016 with the Securities and Exchange Commission, or SEC, and as amended by the Form 10-K/A filed on April 22, 2016 with the 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 reference is made to the “Company” or “VIVUS” in these footnotes, it refers to the Delaware corporation, or VIVUS, Inc., and its California predecessor, as well as all of its consolidated subsidiaries.

Implementation of ASU 2015-03

In April 2015, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2015-03, Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. The standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The Company adopted this standard as required beginning in the first quarter of 2016 and retrospectively applied this standard to the balance sheet as of December 31, 2015. The amounts impacted by the adoption of this standard are as follows:

	As Reported December 31, 2015	Adjustment to reflect ASU 2015-03	As Adjusted December 31, 2015
Prepaid expenses and other assets	$ 10,624	$ (1,194)	$ 9,430
Total current assets	$ 274,786	$ (1,194)	$ 273,592
Non-current assets	$ 4,801	$ (2,185)	$ 2,616
Total assets	$ 280,581	$ (3,379)	$ 277,202
Long-term debt, current portion	$ 15,550	$ (1,194)	$ 14,356
Total current liabilities	$ 60,643	$ (1,194)	$ 59,449
Long-term debt, net of current portion	$ 219,219	$ (2,185)	$ 217,034
Total liabilities	$ 287,666	$ (3,379)	$ 284,287
Total liabilities and stockholders’ equity	$ 280,581	$ (3,379)	$ 277,202

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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.

Significant Accounting Policies

Other than the implementation of ASU 2015-03 discussed above, 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, 2015.

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update 2016-02, Leases (Topic 842), which modifies the accounting by lessees for all leases with a term greater than 12 months. The standard will require lessees to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. For public companies, the standard is effective for annual and interim periods beginning on or after December 15, 2018 and must be applied retrospectively. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In March 2016, the FASB issued Accounting Standards Update 2016-09, Improvements to Employee Share-Based Payment Accounting, which is designed to simplify several aspects of accounting for share-based payment award transactions, including income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and forfeiture rate calculations. For public companies, the standard is effective for annual and interim periods beginning on or after December 15, 2016. Early adoption is permitted. The Company is currently evaluating the impact of this guidance on its 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Cost of goods sold	$ 40	$ 34	$ 115	$ 86
Selling, general and administrative	413	207	1,299	2,550
Research and development	188	(49)	326	332
Non-recurring charges	—	64	—	64
Total share-based compensation expense	$ 641	$ 256	$ 1,740	$ 3,032

Share-based compensation costs capitalized as part of the cost of inventory were $19,000 and $26,000 for the three and nine months ended September 30, 2016, respectively, and $11,000 and $35,000 for the three and nine months ended September 30, 2015, respectively.

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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 September 30, 2016 and December 31, 2015, are presented in the tables that follow (in thousands).

	As of September 30, 2016			
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	$ 154,137	$ —	$ —	$ 154,137
U.S. Treasury securities	28,223	13	(1)	28,235
Corporate debt securities	101,018	236	(40)	101,214
Total	283,378	249	(41)	283,586
Less amounts classified as cash and cash equivalents	(154,137)	—	—	(154,137)
Total available-for-sale securities	$ 129,241	$ 249	$ (41)	$ 129,449

	As of December 31, 2015			
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	$ 95,395	$ —	$ —	$ 95,395
U.S. Treasury securities	84,734	—	(107)	84,627
Corporate debt securities	61,696	20	(175)	61,541
Total	241,825	20	(282)	241,563
Less amounts classified as cash and cash equivalents	(95,395)	—	—	(95,395)
Total available-for-sale securities	$ 146,430	$ 20	$ (282)	$ 146,168

As of September 30, 2016, the Company’s available-for-sale securities had original contractual maturities up to 57 months. However, 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 readily marketable and 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

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Three levels of inputs, of which the first two are considered observable and the last unobservable, may be used to measure fair value. The three levels are:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.

- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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The following table represents the fair value hierarchy for our cash equivalents and available-for-sale securities by major security type as of September 30, 2016 and December 31, 2015 (in thousands):

	As of September 30, 2016			
	Level 1	Level 2	Level 3	Total
Cash and money market funds	$ 154,137	$ —	$ —	$ 154,137
U.S. Treasury securities	28,235	—	—	28,235
Corporate debt securities	—	101,214	—	101,214
Total	$ 182,372	$ 101,214	$ —	$ 283,586

	As of December 31, 2015			
	Level 1	Level 2	Level 3	Total
Cash and money market funds	$ 95,395	$ —	$ —	$ 95,395
U.S. Treasury securities	84,627	—	—	84,627
Corporate debt securities	—	61,541	—	61,541
Total	$ 180,022	$ 61,541	$ —	$ 241,563

4. ACCOUNTS RECEIVABLE

Accounts receivable consist of the following (in thousands):

	Balance as of	
	September 30, 2016	December 31, 2015
Qsymia	$ 9,216	$ 8,508
STENDRA/SPEDRA	1,245	652
	10,461	9,160
Qsymia allowance for cash discounts	(166)	(163)

Net	$ 10,295	$ 8,997

5. INVENTORIES

Inventories consist of the following (in thousands):

	Balance as of September 30, 2016	December 31, 2015
Raw materials	$ 7,587	$ 8,645
Work-in-process	1,112	247
Finished goods	2,013	4,282
Deferred costs	547	428
Inventories	$ 11,259	$ 13,602

Raw materials inventories consist primarily of the active pharmaceutical ingredients, or API, for Qsymia and STENDRA/SPEDRA. Deferred costs inventories consist primarily of Qsymia and represent 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.

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 amounts over demand using the same lower of cost or market approach as that used to value the inventory. In the second quarter of 2015, the Company recorded inventory impairment charges of $29.5 million primarily for Qsymia API inventory in excess of expected demand.

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6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	Balance as of September 30, 2016	December 31, 2015
Prepaid sales and marketing expenses	$ 2,576	$ 3,434
Prepaid insurance	179	1,124
Other prepaid expenses and assets	2,797	4,872
Total	$ 5,552	$ 9,430

The amounts included in prepaid expenses and other current assets consist primarily of prepayments for future services, a receivable from a supplier and interest income receivable. These costs have been deferred as prepaid expenses and other current assets on the 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 receivable is collected by the Company.

7. NON-CURRENT ASSETS

Non-current assets consist primarily of patent acquisition and assignment costs.

8. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities consist of the following (in thousands):

	Balance as of September 30, 2016	December 31, 2015
Accrued employee compensation and benefits	$ 2,576	$ 3,621
Accrued non-recurring charges (see Note 10)	12	503
Accrued interest on debt (see Note 13)	1,917	1,293

Accrued manufacturing costs	686	5,408
Other accrued liabilities	4,753	5,066
Total	$ 9,944	$ 15,891

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

9. NON-CURRENT ACCRUED AND OTHER LIABILITIES

Non-current accrued and other liabilities at December 31, 2015 primarily consisted of costs associated with the exit of certain operating leases and security deposits relating to the sublease agreements.

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10. INVENTORY IMPAIRMENT AND OTHER NON-RECURRING CHARGES

For the nine months ended September 30, 2015, the Company recognized impairment charges of $29.5 million, primarily for Qsymia API inventory in excess of demand and, to a lesser extent, certain STENDRA raw materials. Additionally, non-recurring charges for the three and nine months ended September 30, 2015 included employee severance and related costs of $2.5 million and share-based compensation of $36,000 related to the July 2015 corporate restructuring plan, which reduced the Company's workforce by approximately 60 job positions. There were no non-recurring charges in the three and nine months ended September 30, 2016. Accruals for severance at September 30, 2016 and December 31, 2015 relate to the Company's 2015 corporate restructuring plan and its 2013 cost reduction plan.

The following table sets forth activities for the Company's cost reduction plan obligations (in thousands):

	Severance obligations	Facilities-related obligations	Total
Balance of accrued costs at December 31, 2015	$ 410	$ 471	$ 881
Charges	—	—	—
Payments	(116)	(26)	(142)
Balance of accrued costs at March 31, 2016	294	445	739
Charges	—	—	—
Payments	(7)	(26)	(33)
Balance of accrued costs at June 30, 2016	287	419	706
Charges	—	—	—
Reclassifications	(268)	(402)	(670)
Payments	(7)	(17)	(24)
Balance of accrued costs at September 30, 2016	$ 12	$ —	$ 12

Total accrued employee severance in the Company's unaudited condensed consolidated balance sheet at September 30, 2016 is included under current liabilities in "Accrued and other liabilities."

The balance of the accrued employee severance and facilities-related costs at September 30, 2016 is anticipated to be paid out as follows (in thousands):

2016 (remaining three months)	$ 7
2017	5
	$ 12

11. DEFERRED REVENUE

Deferred revenue consists of the following (in thousands):

	Balance as of	
	September 30, 2016	December 31, 2015
Qsymia deferred revenue - current	$ 17,566	$ 19,275
STENDRA deferred revenue - current	71,562	2,867
Deferred revenue - current	$ 89,128	$ 22,142
STENDRA deferred revenue - non-current	$ 6,845	$ 6,508

Qsymia deferred revenue consists of product shipped to the Company's wholesalers, certified retail pharmacies and certified home delivery pharmacy services networks, but not yet dispensed to patients through

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prescriptions, net of prompt payment discounts. SPEDRA deferred revenue primarily relates to a prepayment of $70 million in licensing fees from Metuchen Pharmaceuticals LLC, or Metuchen, (see Note 12) and 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 Pharmaceuticals, Inc, or Auxilium, and Sanofi and its affiliate, or Sanofi, to commercialize and promote avanafil (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. Sanofi's territory is comprised of Africa, the Middle East, Turkey and Eurasia. Auxilium's territory was comprised of the United States and Canada and their respective territories. In January 2015, Auxilium was acquired by Endo. Auxilium terminated the supply agreement effective June 30, 2016, and the license agreement effective September 30, 2016.

On September 30, 2016, the Company entered into a license and commercialization agreement, or the license agreement, and a commercial supply agreement, or the supply agreement, with Metuchen. Under the terms of the license agreement, Metuchen received an exclusive license to develop, commercialize and promote STENDRA in the United States, Canada, South America and India, or the Territory, effective October 1, 2016. The Company and Metuchen have agreed not to develop, commercialize, or in-license any other product that operates as a PDE-5 inhibitor in the Territory for a limited time period, subject to certain exceptions. The license agreement will terminate upon the expiration of the last-to-expire payment obligations under the license agreement; upon expiration of the term of the license agreement, the exclusive license granted under the license agreement shall become fully paid-up, royalty-free, perpetual and irrevocable as to the Company but not certain trademark royalties due to MTPC.

Metuchen will obtain STENDRA exclusively from us for a mutually agreed term pursuant to the supply agreement. Metuchen may elect to transfer the control of the supply chain for STENDRA for the Territory to itself or its designee by assigning to Metuchen the Company's agreements with the contract manufacturer For 2016 and each subsequent calendar year during the term of the supply agreement, if Metuchen fails to purchase an agreed minimum purchase amount of STENDRA from the Company, it will reimburse the Company for the shortfall as it relates to the Company's out of pocket costs to acquire certain raw materials needed to manufacture STENDRA. Upon the termination of the supply agreement (other than by Metuchen for the Company's uncured material breach or upon completion of the transfer of the control of the supply chain), Metuchen's agreed minimum purchase amount of STENDRA from the Company shall accelerate for the entire then current initial term or renewal term, as applicable. The initial term under the Supply Agreement will be for a period of five years, with automatic renewal for successive two year periods unless either party provides a termination notice to the other party at least two years in advance of the expiration of the then current term. On September 30, 2016, the Company received $70 million from Metuchen under the license agreement. This amount was recorded as deferred revenue on the consolidated balance sheet at September 30, 2016 and will be recognized as license revenue as we complete our obligations under the license agreement. Metuchen will also reimburse the Company for payments made to cover royalty and milestone obligations to Mitsubishi Tanabe Pharmaceutical Corporation, or MTPC, during the term of the license agreement.

13. LONG-TERM DEBT AND COMMITMENTS

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 May 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 at a conversion rate of approximately $14.86 per share. 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

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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 our common stock, at the Company's election. Interest payments are made quarterly.

For the three and nine months ended September 30, 2016, total interest expense related to the Convertible Notes was $7.5 million and $22.1 million, respectively, including amortization of $4.4 million and $13.0 million, respectively, of the debt discount and amortization of $235,000 and $689,000, respectively, of deferred financing costs. For the three and nine months ended September 30, 2015, total interest expense related to the Convertible Notes was $6.9 million and $20.2 million, respectively, including amortization of $4.0 million and $11.9. million, respectively, of the debt discount and amortization of $215,000 and $630,000, respectively, of deferred financing costs.

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, or Biopharma, 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 scheduled quarterly payments on the Senior Secured Notes are subject to the net sales of (i) Qsymia and (ii) any other obesity agent developed or marketed by us or our affiliates or licensees. The scheduled quarterly payments, other than the payment(s) scheduled to be made in the second quarter of 2018, are capped at the lower of the scheduled payment amounts or 25% of the net sales of (i) and (ii) above. Accordingly, if 25% of the net sales is less than the scheduled quarterly payment, then 25% of the net sales is due for that quarter, with the exception of the payment(s) scheduled to be made in the second quarter of 2018, when any unpaid scheduled quarterly payments plus any accrued and unpaid make whole premiums must be paid. Any quarterly payment less than the scheduled quarterly payment amount will be subject to a make whole premium equal to the applicable scheduled quarterly payment of the preceding quarter less the actual payment made to BioPharma for the preceding quarter multiplied by 1.03. The Company may elect to pay full scheduled quarterly payments if it chooses.

For the three and nine months ended September 30, 2016, the interest expense related to the Senior Secured Notes was $1.3 million and $3.6 million, respectively, including amortization of deferred financing costs of $46,000 and $189,000, respectively. For the three and nine months ended September 30, 2015, the interest expense related to the Senior Secured Notes was $1.5 million and $4.9 million, respectively, including amortization of deferred financing costs of $94,000 and $306,000, respectively.

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Debt is as follows (in thousands):

	September 30, 2016
Principal amount of Convertible Senior Notes due 2020	$ 250,000
Principal amount of Senior Secured Notes due 2018	34,643
	284,643
Less: Debt issuance costs	(2,501)
Less: Discount on convertible senior notes	(43,251)
	238,891
Less: Current portion	(9,015)
Long-term debt, net of current portion	$ 229,876

Future estimated payments on the Senior Secured Notes as of September 30, 2016 are as follows:	
2016 (remaining three months)	$ 8,875
2017	23,750
2018	38,376
Total	71,001
Less: Interest portion	(36,358)
Senior Secured Notes	$ 34,643

As a condition of the FDA granting approval to commercialize Qsymia in the U.S., the Company agreed to complete certain post-marketing requirements. One requirement was to perform a cardiovascular outcomes trial, or CVOT, on Qsymia. The cost of a CVOT is estimated to be between $180 million and $220 million incurred over a period of approximately five years. The Company is working with the FDA to determine a pathway to provide the FDA with information to support the safety of Qsymia in a more cost effective manner. To date, the Company has not incurred expenses related to the CVOT.

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 nine month periods ended September 30, 2016 and 2015, all potential common equivalent shares were excluded for these periods as they were anti-dilutive. Awards and options which were not included in the computation of diluted net loss per share because the effect would be anti-dilutive for the three and nine months ended September 30, 2016 were 10,261,000 and 10,520,000, respectively, and for the three and nine months ended September 30, 2015 were 6,958,000 and 7,582,000, respectively.

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15. INCOME TAXES

For the three and nine months ended September 30, 2016, the Company recorded a benefit of $9,000 and a provision for taxes of $14,000, respectively. For the three and nine months ended September 30, 2015, the Company recorded a provision for taxes of $1,000 and $13,000, respectively. The benefit and provision for income taxes for each of the periods ended September 30, 2016 and 2015 was primarily comprised of state taxes during the period.

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 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 September 30, 2016. 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 September 30, 2016, the Company’s only unrecognized tax benefit is related to California research and development activities in the amount of $66,000. We do not expect to have any other 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

Shareholder Lawsuit

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, 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 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. The court ruled on that motion on June 18, 2015, dismissing the seven California claims with prejudice and dismissing the two federal claims with leave to amend. Plaintiffs filed a Second Amended Complaint on August 17, 2015. Defendants moved to dismiss that complaint on October 2, 2015. On September 10, 2015, plaintiffs moved for entry of judgment on their state claims. Briefing on both defendants' motion to dismiss and plaintiffs' motion for entry of judgment was completed on December 15, 2015. On April 19, 2016, the court issued a ruling granting defendants' motion to dismiss without leave to amend and denying as moot plaintiffs' motion for entry of judgment. On May 18, 2016, the plaintiffs filed a notice of appeal, and on September 23, 2016, plaintiffs filed their opening appellate brief. Defendants' response is due on November 23, 2016. 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 the use of the Company's financial resources to pay for its self-insured retention and the policies' terms and conditions.

The Company and the defendant former officers and directors cannot predict the outcome of the lawsuit, but they believe the lawsuit is without merit and intend to continue vigorously defending against the claims.

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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 the 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 (SRC)(CLW)) 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.

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. On August 17, 2015, the Company filed a third lawsuit in the U.S. District Court for the District of New Jersey against Actavis (Case No. 15-6256 (SRC)(CLW)) in response to the third 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 three lawsuits against Actavis have been consolidated into a single suit (Case No. 14-3786 (SRC)(CLW)). On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit. The Court adopted the Company's proposed constructions for all but one of the disputed claim terms and adopted a compromise construction that was acceptable to the Company for the final claim term. Expert discovery is ongoing and no trial date has been scheduled.

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, 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 Teva's 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.

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On August 5, 2015, the Company received a second Paragraph IV certification notice from Teva 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. On September 18, 2015, the Company filed a second lawsuit in the U.S. District Court for the District of New Jersey against Teva (Case No. 15-6957(SRC)(CLW)) in response to the second Paragraph IV certification notice on the basis that Teva's submission of their ANDA constitutes infringement of one or more claims of the patents-in-suit. The two lawsuits against Teva have been consolidated into a single suit (Case No. 15-2693 (SRC)(CLW)).

On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit. The Court adopted the Company's proposed constructions for all but one of the disputed claim terms and adopted a compromise construction that was acceptable to the Company for the final claim term. On September 27, 2016, Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc., collectively referred to as DRL, were substituted for Teva as defendants in the lawsuit as a result of Teva's transfer to DRL of ownership and all rights in the ANDA that is the subject of the lawsuit. Fact discovery is ongoing and no trial date has been scheduled.

STENDRA ANDA Litigation

On June 20, 2016, the Company received a Paragraph IV certification notice from Hetero USA, Inc. indicating that it filed an ANDA with the FDA, requesting approval to market a generic version of STENDRA and contending that patents listed for STENDRA in the Orange Book at the time of the notice (U.S. Patents 6,656,935, and 7,501,409) (collectively "patents-in-suit") are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of a generic form of STENDRA as described in their ANDA. On July 27, 2016, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Hetero USA, Inc. and Hetero Labs Limited, collectively referred to as Hetero. The lawsuit (Case No. 16-4560 (KSH)(CLW)) was filed on the basis that Hetero's submission of their ANDA to obtain approval to manufacture, use, sell, or offer for sale generic versions of STENDRA 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 Hetero, FDA approval of Hetero's ANDA will be stayed until the earlier of (i) up to 30 months from the expiration of STENDRA's New Chemical Entity, or NCE, exclusivity period (i.e. October 27, 2019) 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 and STENDRA, 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 avanafil (STENDRA/SPEDRA) through a commercialization licensee principally in the EU. The geographic classification of product sales was based on the

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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 September 30,							
	2016				2015			
	U.S.	ROW		Total	U.S.	ROW		Total
Qsymia—Net product revenue	$ 12,294	$ —		$ 12,294	$ 14,011	$ —		$ 14,011
STENDRA/SPEDRA—License and milestone revenue	—	—		—	—	—		—
STENDRA/SPEDRA—Supply revenue	—	—		—	5,020	5,036		10,056
STENDRA/SPEDRA —Royalty revenue	425	634		1,059	307	562		869
Total revenue	$ 12,719	$ 634	(1)	$ 13,353	$ 19,338	$ 5,598	(2)	$ 24,936

	Nine Months Ended September 30,							
	2016				2015			
	U.S.	ROW		Total	U.S.	ROW		Total
Qsymia—Net product revenue	$ 37,455	$ —		$ 37,455	$ 40,652	$ —		$ 40,652
STENDRA/SPEDRA—License and milestone revenue	—	—		—	—	11,574		11,574
STENDRA/SPEDRA—Supply revenue	—	1,526		1,526	16,602	10,049		26,651
STENDRA/SPEDRA —Royalty revenue	1,649	1,823		3,472	(348)	1,558		1,210
Total revenue	$ 39,104	$ 3,349	(3)	$ 42,453	$ 56,906	$ 23,181	(4)	$ 80,087

(1) $0.6 million of which was attributable to Germany.
(2) $5.6 million of which was attributable to Germany.
(3) $3.3 million of which was attributable to Germany.
(4) $23.1 million of which was attributable to Germany.

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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:

- 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;
- our ability to minimize expenses that are not essential to expanding the use of STENDRA and Qsymia or are related to product development;

- 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 SPEDRA™ (avanafil) by our sublicensees in the

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U.S., Canada, South America, India, 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 territories under our license with Mitsubishi Tanabe Pharma Corporation in which we do not have a commercial collaboration, including Mexico and Central America;
- 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 commercialize Qsymia efficiently;
- 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 our ability 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 ability to continue to identify, acquire and 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 or management team; and
- 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 nine months ended September 30, 2016 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

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part of our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC on March 9, 2016 and as amended by the Form 10-K/A filed with the SEC on April 22, 2016, 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 with two therapies approved by the FDA: Qsymia® (phentermine and topiramate extended release) for chronic weight management and STENDRA® (avanafil) 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

Qsymia 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, or BMI, of 30 or greater, or obese patients, or 27 or greater, or overweight patients, in the presence of at least one weight related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol, or 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.

We commercialize Qsymia in the U.S. primarily through a sales force of approximately 50 sales territories, supported by an internal commercial team, who promote Qsymia to physicians. 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 continue to invest 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 deliver clear and compelling communications to potential patients. In 2016, we are optimizing the use of our field sales force and our digital campaign, continuing to work with third-party institutions and advancing our efforts to fulfill, in a cost-effective manner, the remaining Qsymia regulatory post-marketing requirements. In June 2016, we announced an upgraded patient savings plan to further drive Qsymia brand preference at the point of prescription and encourage long-term use of the brand.

We 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 are adequately covered by the VIVUS sales force. We are focused on maintaining a commercial presence with 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. The current alignment addresses this new prescriber group, and we believe we have been successful in initiating and maintaining dialog with these HCPs.

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, potential for interfering with the development of a fetus 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.

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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 AQCLAIM, 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. Our request was to allow this interim analysis to support the resubmission of an application for a marketing authorization for Qsiva 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 AQCLAIM CVOT protocol, and we received feedback from the FDA in late 2014 regarding the amended protocol. As a part of addressing the FDA comments from a May 2015 meeting to discuss alternatives to completion of a CVOT, we are now working with cardiovascular and epidemiology experts in exploring alternate solutions to demonstrate the long-term cardiovascular safety of Qsymia. After reviewing a summary of Phase 3 data relevant to cardiovascular, or CV, risk and post-marketing safety data, the cardiology experts noted that they believe there was an absence of an overt CV risk signal and indicated that they did not believe a randomized placebo controlled CVOT would provide additional information regarding the CV risk of Qsymia. The epidemiology experts maintained that a well-conducted retrospective observational study could provide data to further inform on potential CV risk. We are working with the expert group to develop a protocol for the retrospective observational study. Although we and the consulted experts believe there is no overt signal for CV risk to justify the AQCLAIM CVOT, VIVUS is committed to working with the FDA to reach a resolution. As for the EU, even if the FDA were to accept a retrospective observational study in lieu of a CVOT, there would be no assurance that the EMA would accept the same.

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.

On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the Qsymia ANDA lawsuits. The Court adopted our proposed constructions for all but one of the disputed claim terms and adopted a compromise construction that was acceptable to us for the final claim term. Expert discovery is ongoing and no trial date has been scheduled.

In addition, we have pursued a new indication for Qsymia in obstructive sleep apnea, or OSA. We do not anticipate spending resources on new indications for Qsymia until the CVOT issue is resolved. We also intend to seek regulatory approval for Qsymia in territories outside the U.S. and the EU and, if approved, to commercialize the product through collaboration agreements with third parties. We plan to optimize spending while pursuing these potential objectives.

STENDRA

STENDRA 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. As of the date of this filing, 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 we would supply Auxilium with STENDRA for commercialization. Auxilium began commercializing STENDRA in the U.S. market in December 2013. In January 2015, Auxilium was acquired by Endo International, plc, or Endo. Auxilium terminated the supply agreement effective June 30, 2016 and the license agreement effective September 30, 2016.

On September 30, 2016, we entered into a license and commercialization agreement, or the license agreement, and a commercial supply agreement, or the supply agreement, with Metuchen Pharmaceuticals LLC, or Metuchen. Under the terms of the license agreement, Metuchen received an exclusive license to develop,

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commercialize and promote STENDRA in the United States, Canada, South America and India, or the Territory, effective October 1, 2016. We and Metuchen have agreed not to develop, commercialize, or in-license any other product that operates as a PDE-5 inhibitor in the Territory for a limited time period, subject to certain exceptions. We received an upfront license fee of $70 million. Metuchen will also reimburse VIVUS for payments made to cover royalty and milestone obligations to Mitsubishi Tanabe Pharmaceutical Corporation during the term of the license agreement. Metuchen will obtain STENDRA exclusively from us for a mutually agreed term pursuant to the supply agreement. Metuchen may elect to transfer the control of the supply chain for STENDRA for the Territory to itself or its designee by assigning to Metuchen our agreements with the contract manufacturer.

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.

We are currently in discussions with potential collaboration partners to market and sell STENDRA for our other territories, including Mexico and Central America, in which we do not currently have a commercial collaboration.

On June 20, 2016, we received a Paragraph IV certification notice from Hetero USA, Inc. indicating that it filed an ANDA with the FDA, requesting approval to market a generic version of STENDRA and contending that patents listed for STENDRA in the Orange Book at the time of the notice (U.S. Patents 6,656,935, and 7,501,409), collectively “patents-in-suit”, are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of a generic form of STENDRA as described in their ANDA. On July 27, 2016, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Hetero USA, Inc. and Hetero Labs Limited, collectively referred to as Hetero. The lawsuit was filed on the basis that Hetero’s submission of their ANDA to obtain approval to manufacture, use, sell, or offer for sale generic versions of STENDRA 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 Hetero, FDA approval of Hetero’s ANDA will be stayed until the earlier of (i) up to 30 months from the expiration of STENDRA’s New Chemical Entity, or NCE, exclusivity period (i.e. October 27, 2019) 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 and STENDRA, but the Company cannot predict the outcome of these matters.

Business Strategy Review

Earlier this year, we initiated a business strategy review with an outside advisor. The first announcement was the licensing of STENDRA to Metuchen for the U.S., Canada, South America, and India, as discussed above. We will continue this process to evaluate strategies for maximizing our current assets as well as potentially building our portfolio of development and commercial assets through in-licensing opportunities.

NOL Rights Plan

On November 8, 2016 our board of directors approved an amendment and restatement of our stockholder rights plan originally adopted on March 26, 2007. The amended plan is designed to protect stockholder value by mitigating the likelihood of an “ownership change” that would result in significant limitations to our ability to use our net operating losses or other tax attributes to offset future income. The amended plan is similar to rights plans adopted by other

public companies with significant net operating loss carryforwards.

In connection with the original adoption of the rights plan, one right was distributed for each share of our common stock outstanding as of the close of business on April 13, 2007 and one right was distributed with each share of our common stock that was issued after such date. The amended rights plan provides, subject to certain exceptions, that if any person or group acquires 4.9% or more of our outstanding common stock, there would be a triggering event potentially resulting in significant dilution in the voting power and economic ownership of that person or group. Existing stockholders who hold 4.9% or more of our outstanding common stock as of the date of

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the amended rights plan will trigger a dilutive event only if they acquire an additional 1% of the outstanding shares of our common stock.

As extended and amended, the rights plan will continue in effect until November 9, 2019, unless earlier terminated or the rights are earlier exchanged or redeemed by our Board of Directors. We expect to submit the rights plan to a vote at the 2017 annual meeting of stockholders. If stockholders do not approve the plan at the 2017 annual meeting, it will expire at the close of business of the following day.

Additional information with respect to the amended and restated rights plan will be contained in the Current Report on Form 8-K that we are filing with the Securities and Exchange Commission. A copy of the Form 8-K can be obtained at the SEC's Internet website at www.sec.gov.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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 March 9, 2016. There have been no significant changes in our critical accounting policies during the three and nine months ended September 30, 2016, as compared to those disclosed in our Annual Report.

RESULTS OF OPERATIONS

Revenues

(in thousands, except for percentages)	Three Months Ended September 30, 2016	2015	% Change Increase/ (Decrease) 2016 vs 2015	Nine Months Ended September 30, 2016	2015	% Change Increase/ (Decrease) 2016 vs 2015
Revenue:						
Net product revenue	$ 12,294	$ 14,011	(12) %	$ 37,453	$ 40,652	(8) %
License and milestone revenue	—	—	—	—	11,574	(100) %
Supply revenue	—	10,056	(100) %	1,526	26,651	(94) %
Royalty revenue	1,059	869	22 %	3,472	1,210	187 %
Total revenue	$ 13,353	$ 24,936	(46) %	$ 42,451	$ 80,087	(47) %

Net product revenue

For the three and nine months ended September 30, 2016, there were approximately 109,000 and 342,000 Qsymia prescriptions dispensed, respectively, compared to 146,000 and 434,000, respectively, for the same periods of 2015. Approximately 64% of our total prescriptions for the three and nine months ended September 30, 2016 included either a free good or discount offer, with approximately 11,000 and 42,000, respectively, of those prescriptions dispensed as free goods. In comparison, for the three and nine months ended September 30, 2015,

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approximately 63% of our total prescriptions included either a free good or discount offer, with approximately 26,000 and 80,000, respectively, of those prescriptions dispensed as free goods.

We recognize Qsymia net product revenue when units are dispensed to patients through prescriptions as we have a limited history of selling Qsymia and do not have sufficient information to reliably estimate expected returns of Qsymia at the time of shipment. As of September 30, 2016, we had deferred revenue related to gross sales of Qsymia of $17.6 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 nine months ended September 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. There was no license and milestone revenue for the three and nine months ended September 30, 2016 or for the three months ended September 30, 2015. In September 2016, we received $70 million from Metuchen under the license agreement. This amount was recorded as deferred revenue on the consolidated balance sheet at September 30, 2016 and will be recognized as license revenue as we complete our obligations under the license agreement

Supply revenue

For the three and nine months ended September 30, 2016, we recognized $0.0 and $1.5 million, respectively, in supply revenue, compared to $10.1 million and $26.7 million for the three and nine months ended September 30, 2015. The decrease in supply revenue in 2016 as compared to 2015 is due to the timing of orders from our commercialization partners and the notice by Auxilium that they were returning the rights for STENDRA to us. The variations in supply revenue are a result of the timing of orders placed by our partners and may or may not reflect end user demand for STENDRA/SPEDRA. To date, Sanofi has not launched the commercialization of SPEDRA in its territories.

Royalty revenue

For the three and nine months ended September 30, 2016, we recognized $1.1 million and $3.5 million, respectively, in net royalty revenue on net sales reported by our commercialization partners, compared to $0.9 million and $1.2 million, respectively, in royalty revenue in the three and nine months ended September 30, 2015. 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 its 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. On September 30, 2016, Auxilium returned the U.S. and Canadian commercial rights for STENDRA to us. Also, on September 30, 2016, we entered into a license agreement and a supply agreement with Metuchen Pharmaceuticals LLC, providing them with, among other rights, commercial rights to sell STENDRA/SPEDRA in the U.S., Canada, South America, and India. The license agreement with Metuchen does not include future royalties on the sales of STENDRA/SPENDRA in their territories.

Cost of goods sold

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Qsymia cost of goods sold	$ 1,797	$ 2,323	$ 5,801	$ 6,404
STENDRA/SPEDRA cost of goods sold	268	9,442	2,615	25,127
Cost of goods sold	$ 2,065	$ 11,765	$ 8,416	$ 31,531

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

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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. 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.

Cost of goods sold decreased overall due to the reduction in net product and supply revenue. The change in the cost of goods sold as a percentage of net product and supply revenue was due to the effect of price increases in 2015 and the sales mix between Qsymia and STENDRA/SPEDRA during the periods.

Selling, general and administrative expense

	Three Months Ended September 30,		% Change Increase/ (Decrease)		Nine Months Ended September 30,		% Change Increase/ (Decrease)	
	2016	2015	2016 vs 2015		2016	2015	2016 vs 2015	
	(In thousands, except percentages)				(In thousands, except percentages)			
Selling and marketing	$ 4,37	$ 11,045	(60)	%	$ 17,976	$ 44,34	(59)	%
General and administrative	6,063	6,084	(0)	%	21,278	21,38	(1)	%
Total selling, general and administrative expenses	$ 10,44	$ 17,129	(39)	%	$ 39,254	$ 65,73	(40)	%

The decrease in selling and marketing expenses for the three and nine months ended September 30, 2016, compared to the same periods in 2015, was due primarily to the cost saving efforts to reduce marketing programs and the reduction in the number of territories from 150 to approximately 50 effective in 2015.

The decrease in general and administrative expenses in the three and nine months ended September 30, 2016, compared to the same periods in 2015, was primarily due to the corporate restructuring plan begun in July 2015, as well as our continuing efforts to cut costs and lower spending for corporate activities.

Research and development expense

	Three Months Ended		% Change Increase/(Decrease)	Nine Months Ended		% Change Increase/(Decrease)

Drug Indication/Description	September 30, 2016	2015	2016 vs 2015		September 30, 2016	2015	2016 vs 2015	
	(In thousands, except percentages)				(In thousands, except percentages)			
Qsymia for obesity	$ 488	$ 506	(4)	%	$ 673	$ 1,511	(55)	%
STENDRA for ED	56	84	(33)	%	120	670	(82)	%
Share-based compensation	188	(49)	(484)	%	326	332	(2)	%
Overhead costs*	964	991	(3)	%	2,702	4,312	(37)	%
Total research and development expenses	$ 1,696	$ 1,532	11	%	$ 3,821	$ 6,825	(44)	%

*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 total research and development expenses in the three and nine months ended September 30, 2016 as compared to the same periods in 2015, was due primarily to lower headcount resulting from our corporate restructuring plan begun in July 2015 as well as the timing of studies associated with our post-marketing requirements for STENDRA and Qsymia.

We anticipate additional research and development expenses for post-approval studies related to 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.

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Inventory impairment and other non-recurring charges

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. We introduced Qsymia in September 2012, and to date post-launch sales have not met pre-launch expectations. Collectively, the U.S. market for new branded anti-obesity pharmacotherapeutics has developed at a substantially slower rate than expected. The lower-than-anticipated Qsymia uptake and our ongoing regulatory obligations in support of the brand led to a re-evaluation of our operations and a re-sizing of our commercial and corporate headcount. In April 2015, we reduced our sales territories from 150 to 90. In July 2015, we further reduced our Qsymia sales force to 50 territories and further streamlined our headquarters headcount and cost structure resulting in the elimination of approximately 60 job positions. As a result of these actions, our future sales forecast of Qsymia was reduced, resulting in inventory in excess of Qsymia projected sales. For the nine months ended September 30, 2015, we recognized an inventory impairment charge of $29.5 million, primarily for Qsymia API inventory in excess of demand. In addition, for the three and nine months ended September 30, 2015, we incurred severance costs of $2.5 million in connection with our July 2015 corporate restructuring plan.

Interest expense and other expense, net

Interest expense and other expense, net for the three and nine months ended September 30, 2016 was $8.3 million and $24.2 million, respectively, compared to $8.1 million and $24.9 million, respectively, for the three and nine months ended September 30, 2015. Interest expense and other expense, net consists primarily of interest expense and the amortization of issuance costs from our Convertible Notes and Senior Secured Notes and the amortization of the debt discount on the Convertible Notes. The decrease in interest and other expense (income), net was primarily due to the lowering of the debt balances due to the repayment of debt.

Provision for (benefit from) income taxes

For the three and nine months ended September 30, 2016, we recorded a benefit of $9,000 and a provision for income taxes of $14,000, respectively, compared to a provision of $1,000 and $13,000, respectively, for the three and nine months ended September 30, 2015. The benefit and provision for income taxes for each of the periods ended September 30, 2016 and 2015 is primarily comprised of state taxes during the period.

We periodically evaluate the realizability of our net deferred tax assets based on all available evidence, both positive and negative. The realization of net deferred tax assets is dependent on our ability to generate sufficient future taxable income during periods prior to the expiration of tax attributes to fully utilize these assets. We weighed both positive

and negative evidence and determined that there is a continued need for a full valuation allowance on our deferred tax assets in the U.S. as of September 30, 2016.

LIQUIDITY AND CAPITAL RESOURCES

Cash. Cash, cash equivalents and available-for-sale securities totaled $283.6 million at September 30, 2016, as compared to $241.6 million at December 31, 2015. The increase was primarily due to the cash received from the licensing agreement with Metuchen, partially offset by net cash used for operating activities and debt service obligations during the period.

We invest our excess cash balances in money market, U.S. government securities and highly-rated corporate debt securities, in accordance with our investment policy. At September 30, 2016, all of our cash equivalents and available-for-sale securities were invested in U.S. government securities, highly-rated corporate debt securities or money market funds. Our investment policy has the primary investment objective 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. From time to time, the Company may also invest its cash to retire or purchase its outstanding debt in open market purchases, privately negotiated transactions or otherwise.

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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.

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 September 30, 2016, accounts receivable, net of allowance for cash discount, was $10.3 million, as compared to $9.0 million at December 31, 2015. Currently, we do not have any significant concerns related to the collectability of our accounts receivable.

Summary Cash Flows

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Cash provided by (used for):		
Operating activities	$ 48,589	$ (41,081)
Investing activities	16,487	42,680
Financing activities	(6,334)	(5,277)

Operating Activities. For the nine months ended September 30, 2016, cash provided by operating activities resulted from the receipt of $70 million related to the license agreement with Metuchen, partially offset by the use of cash from our net loss of $33.3 million, adjusted for non-cash charges of $13.9 million in debt issuance cost and discount amortization, and $1.7 million in non-cash share-based compensation expense. Additional cash used in operating activities resulted from changes in assets and liabilities during the quarter, including a decrease of $7.2 million in accrued liabilities, due to the timing of accruals, decreases of $2.7 million in deferred revenue other than the amount received from Metuchen, due to the timing of the recognition of revenue, and an increase of $1.3 million in accounts receivable, due to the timing of the receipt of payments. These were partially offset by decreases in inventory of $2.3 million and prepaid expenses and other assets of $4.2 million, due to the amortization of existing prepaid expenses and the timing of payments.

For the nine months ended September 30, 2015, the use of cash resulted from our net loss of $80.9 million, which was partially offset by non-cash charges of $29.5 million for inventory impairment, $12.8 million in debt issuance cost and

discount amortization, and $3.0 million in non-cash share-based compensation expense. Additional cash used in operating activities resulted from changes in assets and liabilities during the quarter, including an increase of $4.1 million in inventory spending, due to increased inventory production in supporting customer demands for STENDRA, and decreases of $3.6 million in prepaid and other assets, due to the timing and nature of payments, and increases in accounts payable of $2.9 million, due to the timing of activities and vendor payments, and decreases of $2.6 million in accrued and other liabilities, due to timing.

Investing Activities. Cash provided by investing activities for the nine months ended September 30, 2016 and 2015 primarily related to the timing of purchases, sales and maturity of investment securities.

Financing Activities. Cash used for financing activities for the nine months ended September 30, 2016 and 2015 primarily related to our repayments of $6.4 million and $5.4 million, respectively, under the Senior Secured Notes.

The funding necessary to execute our business strategies is subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. Commercialization of Qsymia and STENDRA may be more costly than we planned. In addition, completion of clinical trials and approval by the FDA of investigational drug

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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 conduct post-approval clinical studies for Qsymia, 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, 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 pursuant to indemnification agreements, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, stockholder suits and tax matters and 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 September 30, 2016.

Contractual Obligations

During the nine months ended September 30, 2016, there were no material changes to our contractual obligations 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, 2015, filed with the SEC on March 9, 2016, other than the fulfillment of existing obligations in the ordinary course of business.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market and Interest Rate Risk

In the normal course of business, our financial position is subject to a variety of risks, including market risk associated with interest rate movements and foreign currency exchange risk. Our cash, cash equivalents and available-for-sale securities as of September 30, 2016, consisted primarily of money market funds, U.S. Treasury securities and corporate debt 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,

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and ratings of securities we may consider for investment. Currently, we have focused on investing in U.S. Treasuries until market conditions improve.

Our market risk associated with interest rate movements 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 September 30, 2016, by approximately $1.5 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.

A portion of our operations consist of revenues from outside of the United States, some of which are denominated in Euros, and, as such, we have foreign currency exchange exposure for these revenues and associated accounts receivable. Future fluctuations in the Euro exchange rate may impact our revenues and cash flows.

ITEM 4. CONTROLS AND PROCEDURES

(a.) Evaluation of disclosure controls and procedures. We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the timelines specified in the rules and forms of the SEC and that such information is accumulated and communicated to our management, including our principal executive officer and principal 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), our management carried out an evaluation, under the supervision and with the participation of our principal executive officer and our principal 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 evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective.

(b.) Changes in internal controls. There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act 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.

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PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Shareholder Lawsuit

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, 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 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. The court ruled on that motion on June 18, 2015, dismissing the seven California claims with prejudice and dismissing the two federal claims with leave to amend. Plaintiffs filed a Second Amended Complaint on August 17, 2015. Defendants moved to dismiss that complaint on October 2, 2015. On September 10, 2015, plaintiffs moved for entry of judgment on their state claims. Briefing on both defendants' motion to dismiss and plaintiffs' motion for entry of judgment was completed on December 15, 2015. On April 19, 2016, the court issued a ruling granting defendants' motion to dismiss without leave to amend and denying as moot plaintiffs' motion for entry of judgment. On May 18, 2016, the plaintiffs filed a notice of appeal, and on September 23, 2016, plaintiffs filed their opening appellate brief. Defendants' response is due on November 23, 2016. 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 the use of our financial resources to pay for our self insured retention and the policies' terms and conditions.

The Company and the defendant former officers and directors cannot predict the outcome of the lawsuit, but they believe the lawsuit is without merit and intend to continue vigorously defending against the claims.

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 the 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)

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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 (SRC)(CLW)) 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.

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. On August 17, 2015, the Company filed a third lawsuit in the U.S. District Court for the District of New Jersey against Actavis (Case No. 15-6256 (SRC)(CLW)) in response to the third 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 three lawsuits against Actavis have been consolidated into a single suit (Case No. 14-3786 (SRC)(CLW)). On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit. The Court adopted the Company's proposed constructions for all but one of the disputed claim terms and adopted a compromise construction that was acceptable to the Company for the final claim term. Expert discovery is ongoing and no trial date has been scheduled.

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, 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 Teva's 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.

On August 5, 2015, the Company received a second Paragraph IV certification notice from Teva 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. On September 18, 2015, the Company filed a second lawsuit in the U.S. District Court for the District of New Jersey against Teva (Case No. 15-6957(SRC)(CLW)) in response to the second Paragraph IV certification notice on the basis that Teva's submission of their ANDA constitutes infringement of one or more claims of the patents-in-suit. The two lawsuits against Teva have been consolidated into a single suit (Case No. 15-2693 (SRC)(CLW)).

On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit. The Court adopted the Company's proposed constructions for all but one of the disputed claim terms and adopted a compromise construction that was acceptable to the Company for the final claim term. On September 27, 2016, Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc., collectively referred to as DRL, were substituted for Teva as defendants in the lawsuit as a result of Teva's transfer to DRL of ownership and all rights in the ANDA that is the subject of the lawsuit. Fact discovery is ongoing and no trial date has been scheduled.

STENDRA ANDA Litigation

On June 20, 2016, the Company received a Paragraph IV certification notice from Hetero USA, Inc. indicating that it filed an ANDA with the FDA, requesting approval to market a generic version of STENDRA and contending that patents listed for STENDRA in the Orange Book at the time of the notice (U.S. Patents 6,656,935,

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and 7,501,409) (collectively "patents-in-suit") are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of a generic form of STENDRA as described in their ANDA. On July 27, 2016, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Hetero USA, Inc. and Hetero Labs Limited, collectively referred to as Hetero. The lawsuit (Case No. 16-4560 (KSH)(CLW)) was filed on the basis that Hetero's submission of their ANDA to obtain approval to manufacture, use, sell, or offer for sale generic versions of STENDRA 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 Hetero, FDA approval of Hetero's ANDA will be stayed until the earlier of (i) up to 30 months from the expiration of STENDRA's New Chemical Entity, or NCE, exclusivity period (i.e. October 27, 2019) 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 and STENDRA, 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.

ITEM 1A. RISK FACTORS

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

Risks Relating to our Business

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

Our success will depend on our ability to effectively and profitably commercialize Qsymia and STENDRA, which will include our ability to:

- expand the use of Qsymia through targeted patient and physician education;
- obtain marketing authorization by the EC for Qsiva™ in the EU through the centralized marketing authorization procedure;
- manage our alliances with MTPC, Menarini, Metuchen 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;

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- efficiently 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 STENDRA 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;
- ensure that the entire supply chain for Qsymia and STENDRA, from APIs to finished products, efficiently and consistently delivers Qsymia and STENDRA to customers; and
- manage our internal sales force and internal commercial team in their commercialization efforts for Qsymia.

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 cannot be certain that we will be successful. If we are unable to successfully commercialize Qsymia, our ability to generate product sales will be severely limited, which will have a material adverse impact on our business, financial condition, and results of operations.

We may not fully realize the anticipated benefits from a corporate restructuring plan we announced in July 2015.

On July 30, 2015, we announced a corporate restructuring plan that reduced our headcount and expenses, with an objective of achieving neutral or positive operating cash flows by the end of 2016. We reduced our Qsymia sales territories to 50 and further streamlined our headquarters headcount resulting in the elimination of approximately 60 job positions. Consequently, our future sales forecast for Qsymia was reduced and has resulted in excess inventory. In addition, we incurred charges for severance of approximately $2.5 million in 2015 related to this corporate restructuring plan. We may not fully realize the anticipated benefits from this corporate restructuring plan.

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.

Since 2013, there have been significant changes in our management. For example, several members of management have departed the Company, including our President in September 2013, our Chief Financial Officer in December 2013, our Vice President, U.S. Operations and General Manager in May 2014, our Chief Financial Officer and Chief Accounting Officer in September 2015 and our Vice President, Clinical Development in December 2015. In addition, we commenced corporate restructuring plans in November 2013 and July 2015 that resulted in significant reductions in our workforce. These changes, 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.

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We depend on our collaboration partners to gain or maintain approval, market, and sell STENDRA/SPEDRA in their respective licensed territories.

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 countries, including the EU, plus Australia and New Zealand. 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 January 2015, Auxilium was acquired by Endo International, plc. Auxilium terminated the supply agreement effective June 30, 2016 and the license agreement effective September 30, 2016. On September 30, 2016, we entered into a license agreement and a supply agreement with Metuchen Pharmaceuticals LLC, or Metuchen, whereby Metuchen received an exclusive license to develop, commercialize and promote STENDRA in the U.S., Canada, South America, and India, effective October 1, 2016. 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 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.

We are relying on our collaboration partners 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 our collaboration partners do not successfully commercialize STENDRA or SPEDRA, we may receive limited or no revenues under our agreements with them.

Under our license agreement with MTPC, we are obligated to ensure that Menarini, Metuchen and Sanofi, 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 Menarini, Metuchen or Sanofi 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.

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 MTPC, Menarini, Metuchen and Sanofi, 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;

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- 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. For example, in December 2015, Auxilium notified us of its intention to return the U.S. and Canadian commercial rights for STENDRA, and such commercial rights returned to us on September 30, 2016.

We currently rely on reports from our commercialization partners in determining our royalty revenues, and these reports may be subject to adjustment or restatement, which may materially affect our financial results.

We have royalty and milestone-bearing license and commercialization agreements for STENDRA or SPEDRA with Menarini and Sanofi and, prior to October 1, 2016, with Auxilium. In determining our royalty revenue from such agreements, we rely on our collaboration partners to provide accounting estimates and reports for various discounts and allowances, including product returns. As a result of fluctuations in inventory, allowances and buying patterns, actual sales and product returns of STENDRA or SPEDRA in particular reporting periods may be affected, resulting in the need for our commercialization partners to adjust or restate their accounting estimates set forth in the reports provided to us. For example, in April 2015, we were informed by Endo, upon their purchase of Auxilium, that Endo had revised its accounting estimate for STENDRA return reserve related to sales made in 2014. Under the terms of our license and commercialization agreement, adjustments to the return reserve can be deducted from reported net revenue. As a result, in the year ended December 31, 2015, we recorded an adjustment of $1.2 million to reduce our royalty revenue on net sales of STENDRA. The reduction in royalty revenue resulted in an increase to net loss of $1.2 million, or $0.01 per share, for the year ended December 31, 2015. Such adjustments or restatements may materially and negatively affect our financial position and results of operations. Beginning October 1, 2016, we will cease earning royalty revenue from U.S. sales as a result of the termination of our license and commercialization agreement with Auxilium.

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 territories that are not covered by our current commercial collaboration agreements, such as Mexico and Central America. 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.

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 has been approved in both the U.S. and the EU, our drug Qsymia has been approved in the U.S. but Qsiva (the intended trade name for Qsymia in the EU) was denied a marketing authorization by the EC 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 U.S. and the 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.

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We, together with Menarini, Sanofi and potential future collaborators 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, Menarini and potential future collaborators 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 have significant inventories on hand and, for the years ended December 31, 2015, 2014 and 2013, we recorded inventory impairment and commitment fees totaling $29.5 million, $2.2 million and $10.2 million, respectively, 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 years ended December 31, 2015, 2014 and 2013, we recognized total charges of $29.5 million, $2.2 million and $10.2 million, respectively, primarily for Qsymia inventories on hand in excess of projected demand. 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 is approved in the EU for 48 months of commercial product shelf life.

Our write-down for excess and obsolete inventory is subjective and requires 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 limited sales history, is also 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.

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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, imposition of additional burdensome REMS requirements, suspension or revocation of regulatory approval 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 topiramate or phentermine, which are the APIs used in Qsymia. We cannot guarantee that we will be successful in entering into supply agreements on reasonable terms or at all or that we will be able to obtain or maintain the necessary regulatory approvals for potential future suppliers in a timely manner or at all.

We anticipate that we will continue to rely on single-source suppliers for phentermine and topiramate for the foreseeable future. Any production shortfall on the part of our suppliers that impairs the supply of phentermine or 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.

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

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the API and tablets for STENDRA ourselves or through third-parties. In 2015, we transferred the manufacturing of the API and tables for STENDRA to Sanofi.

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 have obtained approval from the FDA and the European Medicines Agency, or EMA, of Sanofi Chimie as a qualified supplier of avanafil API and of Sanofi Winthrop Industrie as a qualified supplier of the avanafil tablets. We have entered into supply agreements with Menarini and Metuchen under which we are obligated to supply them with avanafil tablets. If we are unable to maintain 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 for Qsymia;
- contraindications for Qsymia and STENDRA;
- competition and timing of market introduction of competitive drugs;
- quality, safety and efficacy in the approved setting;

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

As part of the approval of Qsymia, we are required to conduct several post-marketing studies and trials, including a clinical trial 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 trial as currently designed will cost between $180 million and $220 million and the trial could take as long as five to six years to complete. 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 AQCLAIM, 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. Our request was to allow this interim analysis to support the resubmission of an application for a marketing authorization for Qsiva 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 AQCLAIM CVOT protocol, and we received feedback from the FDA in late 2014 regarding the amended protocol. As a part of addressing the FDA comments from a May 2015 meeting to discuss alternatives to completion of a CVOT, we are now working with cardiovascular and epidemiology experts in exploring alternate solutions to demonstrate the long-term cardiovascular safety of Qsymia. After reviewing a summary of Phase 3 data relevant to CV risk and post-marketing safety data, the cardiology experts noted that they believe there was an absence of an overt CV risk signal and indicated that they did not see a justification for a

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randomized placebo controlled CVOT trial. The epidemiology experts maintained that a well-conducted retrospective observational study could provide data to further inform on potential CV risk. We are working with the expert group to develop a protocol for the retrospective observational study. Although we and the consulted experts believe there is no overt signal for CV risk to justify the AQCLAIM CVOT, VIVUS is committed to working with the FDA to reach a resolution. As for the EU, even if the FDA were to accept a retrospective observational study in lieu of a CVOT, there would be no assurance that the EMA would accept the same. There can be no assurance that we will be successful in developing a further revised protocol or that any such revised protocol will reduce the costs of the study or obtain FDA or EMA agreement that it will fulfill the requirement of demonstrating the long-term cardiovascular safety of Qsymia. Furthermore, 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 trials or retrospective observational studies.

In addition to these studies, the FDA may also require us to perform other lengthy post-approval studies or trials, 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, including the completion of post-marketing studies and trials, can result in, among other things, civil monetary 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 have not complied with all the regulatory timelines for the required post-marketing trials and studies, and this may be considered a violation of the statute if the FDA does not find good cause.

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 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) 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. 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 and migraines. Topiramate is not approved for obesity treatment, and phentermine is only approved for short-term treatment of obesity. However, because the price

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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.

Once an applicant receives authorization to market a medicinal product in an EU Member State, through any application route, the applicant is required to engage in pricing discussions and negotiations with a separate pricing authority in that country. The legislators, policymakers and healthcare insurance funds in the EU Member States continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to healthcare cost containment and other austerity measures in the EU. Certain of these changes could impose limitations on the prices pharmaceutical companies are able to charge for their products. The amounts of reimbursement available from governmental agencies or third-party payors for these products may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products. Furthermore, 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 the price 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.

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.

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If we cannot successfully defend ourselves against a product liability claim, whether involving Qsymia, STENDRA or a future investigational drug candidate or product, 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; Suprenza™, an orally disintegrating tablet (phentermine hydrochloride), marketed by Akrimax Pharmaceuticals, LCL; Contrave® (naltrexone/bupropion), Orexigen Therapeutics, Inc.'s anti-obesity compound; and Saxenda® (liraglutide), an anti-obesity compound marketed by Novo Nordisk A/S. Agents that have been approved for type 2 diabetes that have demonstrated weight loss in clinical studies may also compete with Qsymia. These include Farxiga™ (dapagliflozin) from AstraZeneca and Bristol-Myers Squibb, an SGLT2 inhibitor, approved January 8, 2014; Jardiance® (empagliflozin) from Boehringer Ingelheim, an SGLT2 inhibitor, approved August 1, 2014; Victoza® (liraglutide) from Novo Nordisk A/S, a GLP-1 receptor agonist approved January 25, 2010; Invokana® (canaglifozin) from Johnson & Johnson's Janssen Pharmaceuticals, an SGLT2 inhibitor, approved March 29, 2013 and Glyxambi® (empagliflozin/linagliptin) from Boehringer Ingelheim and Eli Lilly, an SGLT2 inhibitor and DPP-4 inhibitor combination product, approved January 30, 2015. Also, on January 14, 2015, FDA approved the Maestro Rechargeable System for certain obese adults, the first weight loss treatment device that targets the nerve pathway between the brain and the stomach that controls feelings of hunger and fullness. The Maestro

Rechargeable System is approved to treat patients aged 18 and older who have not been able to lose weight with a weight loss program, and who have a body mass index of 35 to 45 with at least one other obesity-related condition, such as type 2 diabetes.

There are also 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

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phentermine. Phentermine is sold at much lower prices than we charge for Qsymia. 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 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.

We anticipate that generic PDE5 inhibitors will enter the market in the U.S. in late 2017. 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 changed its name to Actavis plc, has licensed the U.S. rights to udenafil, a PDE5 inhibitor, from Dong-A Pharmaceutical, now known as Mezzion Pharma Co. Ltd. Actavis, Inc. acquired Allergan, changed its name to Allergan, plc and has announced that it is being acquired by Pfizer. 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. 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 FDA's finding that the innovator's product is safe and effective. 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 FDCA provides that an ANDA and an innovator drug with a REMS with Elements to Assure Safe use, like Qsymia, must use a single shared REMS system to assure safe use unless FDA waives this requirement and permits the ANDA holder to implement a separate but comparable REMS. We cannot predict the outcome or impact on our business of any future action that we may take with regard to sharing our REMS program or if the FDA grants a waiver allowing the generic competitor to market a generic drug with a separate but compatible REMS.

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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 identify, 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

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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 retain or hire 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.

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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. While Catalent has significant experience in commercial scale manufacturing, there is no assurance that Catalent will be successful in continuing to supply Qsymia at current levels or increasing the scale of the 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 meet current demand or 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 Sanofi to supply the API and tablets for STENDRA and SPEDRA. Sanofi is responsible for all aspects of manufacture, including obtaining the starting materials for the production of API. If Sanofi is unable to manufacture the 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 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. Sanofi received FDA and EMA approval in 2015 and began manufacturing API and tablets for avanafil in 2015.

Any failure of current or future manufacturing sites, including those of Sanofi Chimie and Sanofi Winthrop Industrie, to receive or maintain 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 Menarini, Metuchen and Sanofi and our ability to enter into a collaboration agreement for the commercialization of STENDRA in our other territories not covered by our agreements with Menarini, Metuchen and Sanofi.

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 or breach affecting that information could have a material adverse effect on the outcome of a clinical study, our business, financial condition and results of operations.

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The collection and use of personal health data and other personal data in the EU is governed by the provisions of the Data Protection Directive as implemented into national laws by the EU Member States. This Directive imposes restrictions on the processing (e.g., collection, use, disclosure) of personal data, including a number of requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals prior to processing their personal data, 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 restrictions 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. On December 15, 2015, a proposal for an EU Data Protection Regulation, intended to replace the current EU Data Protection Directive, was agreed to by the European Parliament, the Council of the European Union and the European Commission. The EU Data Protection Regulation, which will be officially adopted in early 2016, will introduce new data protection requirements in the EU and substantial fines for violations of the data protection rules. The EU Data Protection Regulation, which will be applicable two years after the date of its publication in the Official Journal for the European Union, will increase our responsibility and liability in relation to EU 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 and privacy and data security laws and regulations, we could face substantial penalties, liability and adverse publicity 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. In addition, our operations expose us to privacy and data security laws and regulations. The restrictions under applicable federal and state healthcare laws and regulations, and privacy and data security 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 liability may be established under the federal Anti-Kickback Law without proving 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;

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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 U.S. federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and protection of personal information. Other countries also have, or are developing, laws governing the collection, use, disclosure and protection of personal information. In addition, most healthcare providers who prescribe our products 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, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA. We are not a HIPAA-covered entity and we do not operate as a business associate to any covered entities. Therefore, the HIPAA privacy and security requirements do not apply to us (other than potentially with respect to providing certain employee benefits). 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 and/or conspiring to commit a 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 security continues to evolve, and there has been an increasing amount of focus on privacy and data security issues with the potential to affect our business. These privacy and data security laws and regulations could increase our cost of doing business, and failure to comply with these laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and 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 certain health care providers 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. 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 and other transfers of value to physicians and teaching hospitals, and to submit such data to CMS, which will then make all of this data publicly available on the CMS website. Pharmaceutical manufacturers with products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program were required to have started tracking reportable payments on August 1, 2013, and must submit a report to CMS on or before the 90th day of each calendar year disclosing reportable payments made in the previous calendar year. Failure to comply with the reporting obligations may result in civil monetary penalties; and
- the federal Foreign Corrupt Practices Act of 1977 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 SEC. 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

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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 and regulations 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 and regulations, 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 data, security and fraud laws and regulations 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.

Significant disruptions of information technology systems or security breaches could adversely affect our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including but not limited to trade secrets or other intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third party vendors with whom we contract, and the large amounts of confidential information stored on those systems, make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third party vendors, and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication, and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information.

Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including but not limited to trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm

of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business.

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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 REMS or 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.

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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 rely on Sanofi Chimie and Sanofi Winthrop to supply avanafil API and tablets. 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 2015, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law.

In February 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act These regulations become effective on April 1, 2016. We are evaluating the impact of these regulations on our business and operations. 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

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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, the agency that administers the 340B program, recently issued a proposed regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, as well as proposed omnibus guidance that addresses many aspects of the 340B program. HRSA is currently expected to issue additional proposed regulations in 2016. When such regulations and guidance are finalized, they 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.

If we misstate Non-FAMPs or FCPs, we must restate these figures. Additionally, pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject us to penalties of $100,000 for each item of false information. If we overcharge the government in connection with our FSS contract or the Tricare Retail Pharmacy Program, 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-

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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 Medicare and the Medicaid Drug Rebate program, surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost, or NADAC, files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. 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. Further, federal budgetary concerns could result in the implementation of significant federal spending cuts, including cuts in Medicare and other health related spending in the near-term. For example, recent legislative enactments have resulted in Medicare payments being subject to a two percent reduction, referred to as sequestration, until 2025. 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, collectively referred to in this report as 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.

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- 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 have coverage under Medicare Part D for our drugs, 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 2016, 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.

In February 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate Program under the Affordable Care Act. These regulations become effective on April 1, 2016. We are evaluating the impact of these regulations on our business and operations. 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 Health Resources and Services Administration, or HRSA, the agency that administers the 340B program, recently issued a proposed regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, as well as proposed omnibus guidance that addresses many aspects of the 340B program. HRSA is currently expected to issue additional proposed regulations in 2016. When such regulations and guidance are finalized, they 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

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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

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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. 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

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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.

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, 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 notices of ANDA filings for Qsymia and STENDRA submitted by generic drug companies. These ANDA filings assert that generic forms of Qsymia and STENDRA would not infringe on our issued patents. As a result of these filings, 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 and STENDRA are 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. 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. We have 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, or sale of a generic form of Qsymia. In response to this second notice, we have filed a second

lawsuit against Actavis. We have 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, or sale of a generic form of Qsymia. In response to this third notice, we have filed a third lawsuit against Actavis. The lawsuits have been consolidated into a single suit. On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit. Expert discovery is ongoing and no trial date has been scheduled.

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 our May 7, 2014

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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.

We have received a Paragraph IV certification notice from Teva Pharmaceutical USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, Teva) contending that eight of our patents listed in the Orange Book for Qsymia (U.S. Patents 7,056,890, 7,533,818, 7,659,256, 7,674,776, 8,580,298, 8,580,299, 8,895,057, and 8,895,058) 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 against Teva to defend our patent rights. We have received a second Paragraph IV certification notice from Teva 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, or sale of a generic form of Qsymia. In response to this second notice, we have filed a second lawsuit against Teva. The lawsuits have been consolidated into a single suit. On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit. On September 27, 2016, Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc., collectively referred to as DRL, were substituted for Teva as defendants in the lawsuit. Fact discovery is ongoing and no trial date has been scheduled.

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 Teva's 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.

We have received a Paragraph IV certification notice from Hetero USA Inc., or Hetero, contending that our patents listed in the Orange Book for STENDRA (U.S. Patents 6,656,935 and 7,501,409) are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of a generic form of STENDRA. 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 Hetero, FDA approval of Hetero's ANDA will be stayed until the earlier of (i) up to 30 months from the expiration of STENDRA's New Chemical Entity, or NCE, exclusivity period (i.e. October 27, 2019) 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 and STENDRA, 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 and/or STENDRA. If an ANDA filer were to receive approval to sell a generic version of Qsymia and/or STENDRA and/or prevail in any patent litigation, Qsymia and/or STENDRA 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

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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.

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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 marketing authorization 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 Qsymia;
- our ability, along with our collaboration partners, to successfully commercialize STENDRA in the U.S., Canada, South America, India, the EU, Australia, New Zealand, Africa, the Middle East, Turkey, and the CIS, including Russia;
- our ability to successfully commercialize STENDRA through a third party in 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.

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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.

As of September 30, 2016, we have $250.0 million in 4.5% Convertible Senior Notes due May 1, 2020, which we refer to as the Convertible Notes. 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. On October 8, 2015, IEH Biopharma LLC, a subsidiary of Icahn Enterprises L.P., announced that it had received tenders for $170,165,000 of the aggregate principal amount of our Convertible Notes in its previously announced cash tender offer for any and all of the outstanding Convertible Notes. 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. 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 Secured Investments III Holdings Cayman LP, or 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.

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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 September 30, 2016, we had $283.6 million in cash, cash equivalents and available-for-sale securities. While at September 30, 2016, our excess cash balances were invested in money market, U.S. Treasury securities and corporate debt 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. These factors could impact the liquidity or valuation of our available-for-sale securities, all of which were invested in U.S. Treasury securities or corporate debt securities as of September 30, 2016. 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 were a defendant in federal and consolidated state shareholder derivative lawsuits. These securities-related class action lawsuits generally alleged 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, 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, 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 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. The court ruled on that motion

on June 18, 2015, dismissing the seven California claims with prejudice and dismissing the two federal claims with leave to amend. Plaintiffs filed a Second Amended Complaint on August 17, 2015. Defendants moved to dismiss the complaint on October 2, 2015. On September 10, 2015, plaintiffs moved for entry of judgment on their state claims. Briefing on both defendants' motion to dismiss and plaintiffs' motion for entry of judgment was completed on December 15, 2015. On April 19, 2016, the court issued a ruling granting defendants' motion to dismiss without leave to amend and denying as moot plaintiffs' motion for entry of judgment. On May 18, 2016, the plaintiffs filed a notice of appeal, and on September 23, 2016, plaintiffs filed their opening appellate brief. Defendants' response is due on November 23, 2016. The Company and the defendant former officers and directors

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cannot predict the outcome of the lawsuit, but believe that 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 the use of our financial resources to pay for our self-insured retention and the policies' terms and conditions.

We have an accumulated deficit of $869.6 million as of September 30, 2016, and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of $869.6 million for the period from our inception through September 30, 2016, 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, 2015, we had approximately $675.6 million and $301.5 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. 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 through December 31, 2015 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.

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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 marketing authorization 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.

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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 equity awards 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 Menarini, Metuchen and Sanofi to commercialize and promote SPEDRA for the treatment of ED in over 40 countries, including the EU, plus Australia and New Zealand, to commercialize STENDRA in the U.S., Canada, South America and India, and to commercialize avanafil for the treatment of ED in Africa, the Middle East, Turkey, and the CIS, including Russia, 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. Any of our executive officers or directors may adopt trading plans under SEC Rule 10b5-1 to dispose of a portion of their stock. 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.

On November 8, 2016, our Board of Directors adopted an amendment and restatement of our Preferred Stock Rights Plan, which was originally adopted on March 26, 2007. As amended and restated, the Preferred Stock Rights Plan is designed to protect stockholder value by mitigating the likelihood of an "ownership change" that would result in significant limitations to our ability to use our net operating losses or other tax attributes to offset future income. As amended and restated, the Preferred Stock Rights Plan will continue in effect until November 9, 2019, unless earlier terminated or the rights are earlier exchanged or redeemed by our Board of Directors. We expect to submit the plan to a vote at the 2017 annual meeting of stockholders. If stockholders do not approve the plan at the 2017 annual meeting, it will expire at the close of business of the following day. The Preferred Stock Rights Plan has the effect of causing substantial dilution to a person or group that acquires more than 4.9% of our shares without the approval of our Board

of Directors. The existence of the Preferred Stock 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;

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- 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

Issuer Purchases of Equity Securities

Period	(a) Total number of shares (or units) purchased	(b) Average price paid per share (or unit)	(c) Total number of shares (or units) purchased as part of publicly announced plans or programs	(d) Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs
July 2016 (July 1, 2016 through July 31, 2016)	4,248	$ 1.10	4,248	
August 2016 (August 1, 2016 through August 31, 2016)	4,275	$ 1.07	4,275	
September 2016 (September 1, 2016 through September 30, 2016)	4,248	$ 1.11	4,248	
Total	12,771	$ 1.09	12,771	36,988

(a) In the third quarter of 2016, restricted stock unit awards held by certain non-employee directors of the Company vested. These restricted stock units were settled by issuing to each non-employee director shares in the amount due to the director upon vesting, less the portion required to satisfy the estimated income tax liability based on the published stock price at the close of market on the settlement date or the next trading day, which the Company issued to the non-employee director in cash.

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ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

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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: November 9, 2016 VIVUS, Inc.

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

/s/ MARK K. OKI
Mark K. Oki
Chief Financial Officer and Chief Accounting Officer

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VIVUS, INC.

INDEX TO EXHIBITS

1. 2. 3.

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)	Amendment No. 5 to the Amended and Restated Bylaws of the Registrant.
3.8(8)	Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Registrant.
4.1(9)	Specimen Common Stock Certificate of the Registrant.
4.2(10)	Preferred Stock Rights Agreement dated as of March 27, 2007, between the Registrant and Computershare Investor Services, LLC.
4.3(11)	Indenture dated as of May 21, 2013, by and between the Registrant and Deutsche Bank Trust Company Americas, as trustee.
4.4(12)	Form of 4.50% Convertible Senior Note due May 1, 2020.
10.1	Letter Regarding Termination Notice dated as of August 29, 2016, from Auxilium Pharmaceuticals, LLC and Endo Ventures Limited to the Registrant.
10.2	First Amendment to Lease effective August 30, 2016, between the Registrant and MV Campus Owner, LLC, the successor in interest to SFERS Real Estate Corp. U.
10.3	Office Lease effective September 2, 2016, between the Registrant and AG-SW Hamilton Plaza Owner, L.P.

10.4††	License and Commercialization Agreement dated as of September 30, 2016, by and between the Registrant and Metuchen Pharmaceuticals LLC.
10.5††	Commercial Supply Agreement dated as of September 30, 2016, by and between the Registrant and Metuchen Pharmaceuticals LLC.
31.1	Certification of Chief Executive Officer 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 pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.

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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 September 30, 2016, 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.

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

(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 SEC 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 SEC 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 SEC 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 SEC 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 SEC 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 SEC on July 24, 2013.

(7) Incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on September 18, 2015.

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

(9) 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 SEC on April 16, 1997.

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

(11) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on May 21, 2013.

(12) Incorporated by reference to Exhibit 4.2 filed with the Registrant's Current Report on Form 8-K filed with the SEC on May 21, 2013.