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VIVUS INC

FORM 10-Q
(Quarterly Report)

Filed 05/03/17 for the Period Ending 03/31/17

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Fiscal Year	12/31

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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 March 31, 2017

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)
900 E. Hamilton Avenue, Suite 550 Campbell, California	**95008**
(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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

At April 28, 2017, 105,682,863 shares of common stock, par value $.001 per share, were outstanding.

VIVUS, INC.

Quarterly Report on Form 10-Q

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PART I: FINANCIA L INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

VIVUS, INC.

CONDENSED CONSOLIDATED BALANCE SHEET S
(In thousands, except par value)

	March 31, 2017	December 31, 2016
ASSETS	Unaudited	
Current assets:		
Cash and cash equivalents	$ 67,753	$ 84,783
Available-for-sale securities	192,477	184,736
Accounts receivable, net	11,443	9,478
Inventories	17,190	16,186
Prepaid expenses and other current assets	4,505	8,251
Total current assets	293,368	303,434
Property and equipment, net	738	788
Non-current assets	1,379	1,554
Total assets	$ 295,485	$ 305,776
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,907	$ 4,707
Accrued and other liabilities	20,313	15,686
Deferred revenue	1,505	19,174
Current portion of long-term debt	9,311	8,708
Total current liabilities	36,036	48,275
Long-term debt, net of current portion	234,866	232,610
Deferred revenue, net of current portion	6,232	6,449
Non-current accrued and other liabilities	370	257
Total liabilities	277,504	287,591
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; $1.00 par value; 5,000 shares authorized; no shares issued and outstanding at March 31, 2017 and December 31, 2016	—	—
Common stock; $.001 par value; 200,000 shares authorized; 105,629 and 104,874 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	105	105
Additional paid-in capital	832,477	831,750
Accumulated other comprehensive loss	(491)	(616)
Accumulated deficit	(814,110)	(813,054)
Total stockholders' equity	17,981	18,185
Total liabilities and stockholders' equity	$ 295,485	$ 305,776

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

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

	Three Months Ended March 31,	
	2017	2016
Revenue:		
Net product revenue	$ 17,620	$ 12,412
License and milestone revenue	5,000	—
Supply revenue	3,812	1,526
Royalty revenue	580	1,386
Total revenue	27,012	15,324
Operating expenses:		
Cost of goods sold	6,167	3,704
Selling, general and administrative	11,431	15,122
Research and development	2,180	1,029
Total operating expenses	19,778	19,855
Income (loss) from operations	7,234	(4,531)
Interest expense and other expense, net	8,302	8,161
Loss before income taxes	(1,068)	(12,692)
(Benefit from) provision for income taxes	(12)	16
Net loss	$ (1,056)	$ (12,708)
Basic and diluted net loss per share	$ (0.01)	$ (0.12)
Shares used in per share computation:		
Basic and diluted	105,479	104,071

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2017	2016
Net loss	$ (1,056)	$ (12,708)
Unrealized gain on securities, net of taxes	125	437
Comprehensive loss	$ (931)	$ (12,271)

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

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

	Three Months Ended March 31,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$ (1,056)	$ (12,708)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	252	291
Amortization of debt issuance costs and discounts	4,935	4,535
Amortization of discount or premium on available-for-sale securities	245	253
Share-based compensation expense	727	252
Changes in assets and liabilities:		
Accounts receivable	(1,965)	(2,858)
Inventories	(1,004)	2,178
Prepaid expenses and other assets	3,740	4,104
Accounts payable	200	604
Accrued and other liabilities	4,740	(5,644)
Deferred revenue	(17,886)	(2,745)
Net cash used for operating activities	(7,072)	(11,738)
Cash flows from investing activities:		
Property and equipment purchases	(21)	—
Purchases of available-for-sale securities	(20,915)	(30,423)
Proceeds from maturity of available-for-sale securities	12,234	29,000
Proceeds from sales of available-for-sale securities	820	3,666
Net cash (used for) provided by investing activities	(7,882)	2,243
Cash flows from financing activities:		
Repayments of notes payable	(2,076)	(2,199)
Net cash used for financing activities	(2,076)	(2,199)
Net decrease in cash and cash equivalents	(17,030)	(11,694)
Cash and cash equivalents:		
Beginning of year	84,783	95,395
End of period	$ 67,753	$ 83,701

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2017

1. BASIS OF PRESENTATION

VIVUS is a biopharmaceutical company committed to the development and commercialization of innovative therapies that focus on advancing treatments for patients with serious unmet medical needs, with two approved therapies and one product candidate in active clinical development. Qsymia® (phentermine and topiramate extended release) is approved by FDA for chronic weight management and STENDRA® (avanafil) is approved by FDA for erectile dysfunction, or ED, and by the European Commission, or EC, under the trade name, SPEDRA, for the treatment of ED in the EU. Tacrolimus is in clinical development for the treatment of Pulmonary Arterial Hypertension, or PAH.

Qsymia incorporates a proprietary formulation combining low doses of active ingredients from two previously approved drugs, phentermine and topiramate, and is being commercialized by the Company in the U.S. primarily through a sales force who promote Qsymia to physicians. Avanafil is an oral phosphodiesterase type 5 inhibitor that is being commercialized in the U.S., EU and other countries through commercialization collaborators.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017. Management has evaluated all events and transactions that occurred after March 31, 2017 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 December 31, 2016 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, 2016 as filed on March 8, 2017 with the Securities and Exchange Commission, or SEC, and as amended by the Form 10-K/A filed on April 26, 2017 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.

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

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, 2016 with the exception of the following:

Revenue Recognition

Product Revenue:

The Company recognizes product revenue when:

(i) persuasive evidence that an arrangement exists,
(ii) delivery has occurred and title has passed,
(iii) the price is fixed or determinable, and
(iv) collectability is reasonably assured.

Revenue from sales transactions where the customer has the right to return the product is recognized at the time of sale only if: (i) the Company's price to the customer is substantially fixed or determinable at the date of sale, (ii) the customer has paid the Company, or the customer is obligated to pay the Company and the obligation is not contingent on resale of the product, (iii) the customer's obligation to the Company would not be changed in the event of theft or physical destruction or damage of the product, (iv) the customer acquiring the product for resale has economic substance apart from that provided by the Company, (v) the Company does not have significant obligations for future performance to directly bring about resale of the product by the customer, and (vi) the amount of future returns can be reasonably estimated.

Product revenue is recognized net of consideration paid to the Company's customers, wholesalers and certified pharmacies. Such consideration is for services rendered by the wholesalers and pharmacies in accordance with the wholesalers and certified pharmacy services network agreements, and includes a fixed rate per prescription shipped and monthly program management and data fees. These services are not deemed sufficiently separable from the customers' purchase of the product; therefore, they are recorded as a reduction of revenue at the time of revenue recognition.

Other product revenue allowances include certain prompt pay discounts and allowances offered to the Company's customers, program rebates and chargebacks. These product revenue allowances are recognized as a reduction of revenue at the later of the date at which the related revenue is recognized or the date at which the allowance is offered. The Company also offers discount programs to patients. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates or chargebacks. The Company reviews the adequacy of product revenue allowances on a quarterly basis. Amounts accrued for product revenue allowances are adjusted when trends or significant events indicate that adjustment is appropriate and to reflect actual experience.

The Company ships units of Qsymia through a distribution network that includes certified retail pharmacies. The Company began shipping Qsymia in September 2012 and grants rights to its customers to return unsold product from six months prior to and up to 12 months subsequent to product expiration. This has resulted in a potential return period of from 24 to 36 months depending on the ship date of the product. As the Company had no previous experience in selling Qsymia and given its lengthy return period, the Company was not initially able to reliably estimate expected returns of Qsymia at the time of shipment, and therefore recognized revenue when units were dispensed to patients through prescriptions, at which point, the product is not subject to return, or when the expiration period had ended.

Beginning in the first quarter of 2017, with 48 months of returns experience, the Company now believes that it has sufficient data and experience from selling Qsymia to reliably estimate expected returns. Therefore, beginning in the first quarter of 2017, the Company began recognizing revenue from the sales of Qsymia upon shipment and recording a reserve for expected returns at the time of shipment.

In accordance with this change in accounting estimate, the Company recognized a one-time adjustment of $7.3 million of revenues, net of expected returns reserve and gross-to-net charges, in the first quarter of 2017 relating to products that had been previously shipped. This increase in net product revenue resulted in a decrease in net loss of $6.0 million or $0.06 per share.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* . This standard is a comprehensive new revenue recognition model that requires revenue to be recognized in a manner to depict the transfer of goods or services to a customer at an amount that reflects the consideration expected to be received in exchange for those goods or services. This new standard will supersede most current revenue recognition guidance. In July 2015, the FASB voted to delay the effective date of this standard by one year to the first quarter of 2018. Early adoption is permitted, but not before the first quarter of 2017. This new revenue standard may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized in retained earnings as of the date of adoption, or the "modified retrospective basis." Preliminarily, the Company plans to adopt this standard in the first quarter of 2018 using the modified retrospective basis. The Company currently does not expect the adoption of this standard to have a material impact on the Company's net product revenues in the first quarter of adoption or on the timing of future recognition of net product revenues.

In July 2015, the FASB issued Accounting Standards Update 2015-11, *Simplifying the Measurement of Inventory - Inventory (Topic 330),* which changes the measurement principle for inventory from the lower of cost or market to the lower of cost or net realizable value. Net realizable value is defined as the "estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation." This standard eliminates the guidance that entities consider replacement cost or net realizable value less an approximately normal profit margin in the subsequent measurement of inventory when cost is determined on a first-in, first-out or average cost basis. The Company adopted this standard in the first quarter of 2017 and it did not have a material impact on the Company's condensed consolidated financial statements.

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. This 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, this standard is effective for annual and interim periods beginning on or after December 15, 2018. Early adoption is permitted. The Company's only significant lease is its operating lease for its corporate headquarters, and, while the Company cannot yet estimate the amounts by which its financial statements will be affected by the adoption of this guidance, it expects that the recognition of expense will be similar to current guidance but that there will be a significant change in the balance sheet due to the recognition of right of use assets and the corresponding lease liabilities. The Company plans to adopt the new leases guidance effective January 1, 2019 using a modified retrospective transition method.

In March 2016, the FASB issued Accounting Standards Update 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* . This standard is intended to simplify several areas of accounting for share-based compensation arrangements, including the income tax impact, classification on the statement of cash flows and forfeitures. The Company adopted this standard in the first quarter of 2017, and it did not have a material impact on the Company's condensed consolidated financial statements.

In August 2016, the FASB issued Accounting Standards Update 2016-15, *Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments* . The standard clarifies how certain cash receipts and cash payments will be presented and classified in the statement of cash flows. The new standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted. The Company is currently evaluating the impact that the standard will have 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 March 31,	
	2017	2016
Cost of goods sold	$ 14	$ 32
Selling, general and administrative	628	253
Research and development	85	(33)
Total share-based compensation expense	$ 727	$ 252

Share-based compensation costs capitalized as part of the cost of inventory were $4,000 and $3,000 for the three months ended March 31, 2017 and 2016, respectively.

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

The fair value and the amortized cost of cash, cash equivalents, and available-for-sale securities by major security type at March 31, 2017 and December 31, 2016, are presented in the tables that follow (in thousands).

	As of March 31, 2017			
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	$ 67,753	$ —	$ —	$ 67,753
U.S. Treasury securities	24,701	7	(98)	24,610
Corporate debt securities	168,267	68	(468)	167,867
Total	260,721	75	(566)	260,230
Less amounts classified as cash and cash equivalents	(67,753)	—	—	(67,753)
Total available-for-sale securities	$ 192,968	$ 75	$ (566)	$ 192,477

	As of December 31, 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	$ 84,783	$ —	$ —	$ 84,783
U.S. Treasury securities	24,780	7	(110)	24,677
Corporate debt securities	160,571	52	(564)	160,059
Total	270,134	59	(674)	269,519
Less amounts classified as cash and cash equivalents	(84,783)	—	—	(84,783)
Total available-for-sale securities	$ 185,351	$ 59	$ (674)	$ 184,736

As of March 31, 2017, the Company's available-for-sale securities had original contractual maturities up to 67 months. However, the Company may sell these securities prior to their stated maturities in response to changes in the availability of and the yield on alternative investments as well as liquidity requirements. 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.

The following table represents the fair value hierarchy for our cash equivalents and available-for-sale securities by major security type as of March 31, 2017 and December 31, 2016 (in thousands):

	As of March 31, 2017			
	Level 1	Level 2	Level 3	Total
Cash and money market funds	$ 67,753	$ —	$ —	$ 67,753
U.S. Treasury securities	24,610	—	—	24,610
Corporate debt securities	—	167,867	—	167,867
Total	$ 92,363	$ 167,867	$ —	$ 260,230

	As of December 31, 2016			
	Level 1	Level 2	Level 3	Total
Cash and money market funds	$ 84,783	$ —	$ —	$ 84,783
U.S. Treasury securities	24,677	—	—	24,677
Corporate debt securities	—	160,059	—	160,059
Total	$ 109,460	$ 160,059	$ —	$ 269,519

4. ACCOUNTS RECEIVABLE

Accounts receivable consist of the following (in thousands):

	Balance as of	
	March 31, 2017	December 31, 2016
Qsymia	$ 8,909	$ 8,982
STENDRA/SPEDRA	2,719	709
	11,628	9,691
Qsymia allowance for cash discounts	(185)	(213)
Net	$ 11,443	$ 9,478

5. INVENTORIES

Inventories consist of the following (in thousands):

	Balance as of	
	March 31, 2017	December 31, 2016
Raw materials	$ 14,210	$ 9,412
Work-in-process	239	2,984
Finished goods	2,741	3,110
Deferred costs	—	680
Inventories	$ 17,190	$ 16,186

Raw materials inventories consist primarily of the active pharmaceutical ingredients, or API, for Qsymia and STENDRA/SPEDRA. Inventories are stated at the lower of cost or net realizable value. 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 net realizable value approach as that used to value the inventory.

6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	Balance as of	
	March 31, 2017	December 31, 2016
Prepaid sales and marketing expenses	$ 1,821	$ 1,767
Prepaid insurance	836	1,182
Other prepaid expenses and assets	1,848	5,302
Total	$ 4,505	$ 8,251

The amounts included in prepaid expenses and other assets consist primarily of prepayments for future services, non-trade receivables, prepaid interest and interest income receivable. These costs have been deferred as prepaid expenses and other current assets on the condensed consolidated balance sheets and will be either (i) charged to expense accordingly when the related prepaid services are rendered to the Company, or (ii) converted to cash when the 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	
	March 31, 2017	December 31, 2016
Accrued employee compensation and benefits	$ 1,287	$ 3,014
Reserve for product returns	6,201	—
Product-related accruals	5,634	671
Accrued interest on debt (see Note 13)	2,754	1,509
Accrued manufacturing costs	729	6,835
Accrued non-recurring charges (see Note 10)	—	5
Other accrued liabilities	3,708	3,652
Total	$ 20,313	$ 15,686

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

9. NON-CURRENT ACCRUED AND OTHER LIABILITIES

Non-current accrued and other liabilities were $0.4 million and $0.3 million at March 31, 2017 and December 31, 2016, respectively, and were primarily comprised of deferred rent and security deposits.

10. NON-RECURRING CHARGES

The following table sets forth activities for the Company's obligations related to its July 2015 corporate restructuring plan (in thousands):

	Severance obligations
Balance of accrued costs at January 1, 2017	$ 5
Charges	—
Payments	(5)
Balance of accrued costs at March 31, 2017	$ —

Accrued employee severance costs as of December 31, 2016 are included under current liabilities in "Accrued and other liabilities."

11. DEFERRED REVENUE

Deferred revenue consists of the following (in thousands):

	Balance as of	
	March 31, 2017	December 31, 2016
Qsymia deferred revenue - current	$ —	$ 17,558
STENDRA deferred revenue - current	1,505	1,616
Deferred revenue - current	$ 1,505	$ 19,174
STENDRA deferred revenue - non-current	$ 6,232	$ 6,449

The Company ships units of Qsymia through a distribution network that includes certified retail pharmacies. The Company was not initially able to reliably estimate expected returns of Qsymia at the time of shipment, and therefore recognized revenue when units were dispensed to patients through prescriptions, at which point, the product is not subject to return, or when the expiration period had ended. Qsymia deferred revenue at December 31, 2016 consisted 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 prescriptions, net of prompt payment discounts. Beginning in the first quarter of 2017, the Company began recognizing revenue from the sales of Qsymia upon shipment and recording a reserve for expected returns at the time of shipment. Accordingly, all of the Qsymia deferred revenue, net of appropriate reserves, was recognized as revenue as of January 1, 2017 (See Note 1).

SPEDRA deferred revenue relates to a prepayment for future royalties on sales of SPEDRA.

12. LICENSE, COMMERCIALIZATION AND SUPPLY AGREEMENTS

During 2013, the Company entered into separate license and commercialization agreements and separate commercial supply agreements with each of the Menarini Group, through its subsidiary Berlin Chemie AG, or Menarini, Auxilium Pharmaceuticals, Inc, or Auxilium, and Sanofi and its affiliate, or Sanofi, to commercialize and promote avanafil (STENDRA/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 was 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 March 23, 2017, the Company and Sanofi entered into the Termination, Rights Reversion and Transition Services Agreement, or the Transition Agreement, effective February 28, 2017. Under the Transition Agreement, effective upon the thirtieth (30th) day following February 28, 2017, the license and commercialization agreement with Sanofi terminated for all countries in the Sanofi territory. In addition, under the Transition Agreement, Sanofi will provide the Company with certain transition services in support of ongoing regulatory approval efforts while the Company seeks to obtain a new commercial partner or partners for the Sanofi territory. The Company will pay certain transition service fees to Sanofi as part of the Transition Agreement.

On September 30, 2016, the Company entered into a license and commercialization agreement, or the Metuchen License Agreement, and a commercial supply agreement, or the Metuchen Supply Agreement, with Metuchen Pharmaceuticals LLC, or Metuchen. Under the terms of the Metuchen License Agreement, Metuchen received an exclusive license to develop, commercialize and promote STENDRA in the United States, Canada, South America and India, or the Metuchen 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 Metuchen Territory for a limited time period, subject to certain exceptions. The Metuchen License Agreement will terminate upon the expiration of the last-to-expire payment obligations under the Metuchen License Agreement; upon expiration of the term of the Metuchen License Agreement, the exclusive license granted under the Metuchen License Agreement shall become fully paid-up, royalty-free, perpetual and irrevocable as to the Company but not certain trademark royalties due to Mitsubishi Tanabe Pharmaceutical Corporation, or MTPC.

Metuchen will obtain STENDRA exclusively from the Company. For each calendar year during the term of the Metuchen 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 Metuchen 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 Metuchen 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 Metuchen License Agreement. The Metuchen License Agreement is royalty-free as to the Company, but Metuchen will reimburse the Company for payments made to cover royalty and milestone obligations to MTPC during the term of the Metuchen 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 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 months ended March 31, 2017, total interest expense related to the Convertible Notes was $7.9 million, including amortization of $4.7 million of the debt discount and amortization of $247,000 of deferred financing costs. For the three months ended March 31, 2016, total interest expense related to the Convertible Notes was $7.2 million, including amortization of $4.2 million of the debt discount and amortization of $225,000 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 months ended March 31, 2017, the interest expense related to the Senior Secured Notes was $1.0 million, including amortization of deferred financing costs of $38,000. For the three months ended March 31, 2016, the interest expense related to the Senior Secured Notes was $1.2 million, including amortization of deferred financing costs of $76,000.

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

	March 31, 2017
Convertible Senior Notes due 2020	$ 250,000
Senior Secured Notes due 2018	30,188
	280,188
Less: Debt issuance costs	(1,932)
Less: Discount on convertible senior notes	(34,079)
	244,177
Less: Current portion	(9,311)
Long-term debt, net of current portion	$ 234,866
Future estimated payments on the Senior Secured Notes as of March 31, 2017 are as follows:	
2017 (remaining 9 months)	$ 20,625
2018	39,027
Total	59,652
Less: Interest portion	(29,464)
Senior Secured Notes	$ 30,188

As a condition of 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 FDA to determine a pathway to provide 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 the three months ended March 31, 2017 and 2016, 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 were 12,731,000 and 10,354,000 for the three months ended March 31, 2017 and 2016, respectively.

15. INCOME TAXES

For the three months ended March 31, 2017, the Company recorded a benefit of $12,000. For the three months ended March 31, 2016, the Company recorded a provision for taxes of $16,000. The benefit and provision for income taxes for each of the periods 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 March 31, 2017. 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 March 31, 2017, the Company's unrecognized tax benefit is related to the federal and California research and development credits which result in an unrecognized tax benefit balance of $72,000. 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 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 voluntarily dismissed their state court action with prejudice. Defendants moved to dismiss the federal action and moved to dismiss again after plaintiffs amended their complaint to include additional factual allegations and to add seven new claims under California law. The court granted the latter 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 as well. On April 19, 2016, the court granted defendants' motion to dismiss with prejudice and entered judgment in favor of defendants. Plaintiffs filed a notice of appeal to the Ninth Circuit Court of Appeals on May 18, 2016. Briefing on the appeal has now been completed. The Ninth Circuit has not yet scheduled the matter for oral argument or consideration. 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.

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 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.

On March 5, 2015, the Company received a Paragraph IV certification notice from Teva Pharmaceuticals USA, Inc. indicating that it filed an ANDA with 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.

The schedule for both suits has now been consolidated for expert discovery and trial. Expert discovery is ongoing and a final pretrial conference is scheduled for June 28, 2017. No trial date has been scheduled.

The Company intends to vigorously enforce its intellectual property rights relating to Qsymia, but the Company cannot predict the outcome of these matters.

STENDRA ANDA Litigation

On June 20, 2016, the Company received a Paragraph IV certification notice from Hetero USA, Inc. and Hetero Labs Limited, collectively referred to as Hetero, indicating that it filed an ANDA with 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 (Case No. 16-4560 (KSH)(CLW)). On January 3, 2017, we entered into a settlement agreement with Hetero. Under the settlement agreement, Hetero was granted a license to manufacture and commercialize the generic version of STENDRA described in its ANDA filing in the United States as of the date that is the later of (a) October 29, 2024, which is 180 days prior to the expiration of the last to expire of the patents-in-suit, or (b) the date that Hetero obtains final approval from FDA of the Hetero ANDA. The settlement agreement provides for a full settlement of all claims that were asserted in the suit.

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 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 March 31,					
	2017			2016		
	U.S.	ROW	Total	U.S.	ROW	Total
Qsymia—Net product revenue	$ 17,620	$ —	$ 17,620	$ 12,412	$ —	$ 12,412
Qsymia—License revenue	5,000	—	5,000	—	—	—
STENDRA/SPEDRA—Supply revenue	3,775	37	3,812	—	1,526	1,526
STENDRA/SPEDRA —Royalty revenue	—	580	580	826	560	1,386
Total revenue	$ 26,395	$ 617 (1)	$ 27,012	$ 13,238	$ 2,086 (2)	$ 15,324

(1) $0.6 million of which was attributable to Germany.

(2) $2.1 million of which was attributable to Germany.

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 negative use of these words or other similar words. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to:

- 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 FDA to the data that we will submit relating to post-approval clinical studies required for Qsymia;
- 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-approval cardiovascular outcomes trial, or CVOT, with the goal of reducing trial costs and obtaining FDA agreement that a revised study 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 for Qsymia, 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 that are not related to product development;
- our ability to ensure that the entire supply chain for Qsymia efficiently and consistently delivers Qsymia to our customers and to manage the supply chain for STENDRA/SPEDRA for our collaborators;
- 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;

- 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;
- 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;
- 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;
- our ability to address or potentially reduce our outstanding debt balances:
- 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 months ended March 31, 2017 are not necessarily indicative of the results that may be expected for the full fiscal year or any future period.

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our audited consolidated financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the SEC on March 8, 2017 and as amended by the Form 10-K/A filed with the SEC on April 26, 2017, 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 developing and commercializing innovative, next-generation therapies to address unmet medical needs in human health, with two approved therapies and one product candidate in active clinical development. Qsymia® (phentermine and topiramate extended release) is approved by FDA for chronic weight management and STENDRA® (avanafil) is approved by FDA for ED and by the EC under the trade name, SPEDRA, for the treatment of ED in the EU. Tacrolimus is in active clinical development for the treatment of Pulmonary Arterial Hypertension, or PAH.

Commercial Products

Qsymia

Qsymia was approved by FDA in July 2012, as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult obese 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 who promote Qsymia to physicians. We are focused on maintaining a commercial presence with important Qsymia prescribers, and we have the capacity to cover prescriptions from physicians that begin prescribing branded anti-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.

Our marketing efforts have focused on rolling out unique 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 June 2016, we announced an upgraded simplified patient savings plan to further drive Qsymia brand preference at the point of prescription and to encourage long-term use of the brand.

Upon receiving approval to market Qsymia, FDA required that we perform additional studies of Qsymia including a cardiovascular outcome trial, or CVOT. To date, there have been no indications throughout the Qsymia clinical development program nor post-marketing experience of any increase in adverse cardiovascular events. Given this historical information, along with the established safety profiles of phentermine and topiramate, we continue to believe that Qsymia poses no true cardiovascular safety risk. We met with FDA in May 2015 to discuss alternative strategies for obtaining cardiovascular, or CV, outcomes data that would be substantially more feasible and that ensure timely collection of data to better inform on the CV safety of Qsymia. We worked 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 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 worked with the expert group to develop a protocol and conduct a retrospective observational study. We are in the process of analyzing the collected information for discussion with FDA. Although we and consulted experts believe there is no overt signal for CV risk to justify the CVOT, we are committed to working with FDA to reach a resolution. There is no assurance, however, that FDA will accept any measures short of those specified in the CVOT to satisfy this requirement.

In May 2013, the EC issued a decision refusing the grant of marketing authorization in the EU for Qsiva™, the approved trade name for Qsymia in the EU. In September 2013, we submitted a request to the EMA for

Scientific Advice, a procedure similar to the U.S. Special Protocol Assessment process, regarding use of a pre-specified interim analysis from the CVOT to assess the long-term treatment effect of Qsymia on the incidence of major adverse CV events in overweight and obese subjects with confirmed CV disease. Our request was to allow this interim analysis to support the resubmission of an application for a marketing authorization for Qsiva for the 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 CVOT protocol. As for the EU, even if 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.

STENDRA/SPEDRA

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 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 a license and commercialization agreement, or the Menarini License 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, 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 30 countries within the territory granted to Menarini pursuant to its license and commercialization agreement, in addition to certain territories in Asia licensed directly from MTPC. Under the Menarini License Agreement, we have received payments of $63.0 million relating to license and milestone payments and royalty prepayments. Additionally, we are entitled to receive potential milestone payments based on certain net sales targets, plus royalties on SPEDRA sales. Menarini will also reimburse us for payments made to cover various obligations to MTPC during the term of the Menarini License Agreement.

In October 2013, we entered into a license and commercialization agreement, or the Auxilium License Agreement, and a commercial supply agreement, or the Auxilium Supply Agreement, with Auxilium under which Auxilium received an exclusive license to commercialize and promote STENDRA in the United States and Canada and we would supply Auxilium with STENDRA for commercialization. We received upfront and milestone payments of $45 million in addition to royalty payments based on tiered percentages of the aggregate annual net sales of STENDRA in the Auxilium Territory on a quarterly basis. Auxilium terminated the Auxilium Supply Agreement effective June 30, 2016 and the Auxilium License Agreement effective September 30, 2016.

On September 30, 2016, we entered into a license and commercialization agreement, or the Metuchen License Agreement, and a commercial supply agreement, or the Metuchen Supply Agreement, with Metuchen Pharmaceuticals LLC, or Metuchen. Under the terms of the Metuchen License Agreement, Metuchen received an exclusive license to develop, commercialize and promote STENDRA in the United States, Canada, South America and India, or the Metuchen Territory, effective October 1, 2016. We received an upfront license fee of $70 million under the Metuchen License Agreement. Metuchen will also reimburse us for payments made to cover royalty and milestone obligations to MTPC during the term of the Metuchen License Agreement, but will otherwise owe us no future royalties. Metuchen will obtain STENDRA exclusively from us.

In December 2013, we entered into a license and commercialization agreement with Sanofi, or the Sanofi License Agreement, 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 CIS, including Russia, or the Sanofi Territory. Sanofi was responsible for obtaining regulatory approval in its territories. 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, which terminated according to its terms on June 30, 2015. We received an upfront license fee and milestone payments totaling $10.0 million. In March 2017, we and Sanofi entered into the Termination, Rights Reversion and Transition Services Agreement, or the Transition Agreement, effective February 28, 2017. Under the Transition Agreement, effective upon the thirtieth (30th) day following February 28, 2017, the

Sanofi License Agreement terminated for all countries in the Sanofi Territory as a termination by Sanofi for convenience notwithstanding any notice requirements contained in the Sanofi License Agreement. In addition, under the Transition Agreement, Sanofi will provide us with certain transition services in support of ongoing regulatory approval efforts while we seek to obtain a new commercial partner or partners for the Sanofi Territory. We will pay certain transition service fees to Sanofi as part of the Transition Agreement.

We are currently in discussions with potential collaboration partners to develop, market and sell STENDRA for territories in which we do not currently have a commercial collaboration, including Africa, the Middle East, Turkey, the CIS, including Russia, Mexico and Central America.

Development Program

Pulmonary Arterial Hypertension - Tacrolimus

PAH is a chronic, life-threatening disease characterized by elevated blood pressure in the pulmonary arteries, which are the arteries between the heart and lungs, due to severe constriction of these blood vessels. Pulmonary blood pressure is normally between 8 and 20 mmHg at rest as measured by right heart catheterization; however, in patients with PAH, the pressure in the pulmonary artery is greater than 25 mmHg at rest or 30 mmHg during physical activity. These high pressures make it difficult for the heart to pump blood through the lungs to be oxygenated.

The current medical therapies for PAH involve ERA, PDE5 inhibitors, prostacyclin analogues, selective IP receptor agonists, and sGC stimulators, which aim to reduce symptoms and improve quality of life. All currently approved products treat the symptoms of PAH, but do not address the underlying disease. We believe that tacrolimus can be used to enhance reduced BMPR2 signaling that is prevalent in PAH patients and may therefore address a fundamental cause of PAH.

The prevalence of PAH varies among specific populations, but it is estimated at between 15 and 50 cases per million adults. PAH usually develops between the ages of 20 and 60 but can occur at any age, with a mean age of diagnosis around 45 years. Idiopathic PAH is the most common type, constituting approximately 40% of the total diagnosed PAH cases, and it occurs 2 to 4 times more frequently in females.

On January 6, 2017, we entered into a Patent Assignment Agreement with Selten Pharma, Inc., or Selten, whereby we received exclusive, worldwide rights for the development and commercialization of BMPR2 activators for the treatment of PAH and related vascular diseases. As part of the agreement, Selten assigned to us its license to a group of patents owned by the Board of Trustees of the Leland Stanford Junior University, or Stanford, which cover uses of tacrolimus and ascomycin to treat PAH. Under this agreement, Selten received an upfront payment of $1.0 million and is entitled to milestone payments based on global development status and future sales milestones, as well as tiered royalty payments on future sales of these compounds. The total potential milestone payments are $39.0 million to Selten. We have assumed full responsibility for the development and commercialization of the licensed compounds for the treatment of PAH and related vascular diseases.

On March 16, 2015, tacrolimus for the treatment of PAH received an Orphan Drug Designation. In 2017, we intend to focus on developing a proprietary formulation of tacrolimus to be used in a clinical development program and for commercial use.

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 to evaluate development opportunities to utilize our cash resources, which could come in the form of a license, a co-development agreement, a merger or acquisition or other form. We will also look for opportunities to restructure our existing debt, including repayment or restructuring the outstanding balances.

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 8, 2017. There has been one significant change in our critical accounting policies during the three months ended March 31, 2017, as outlined below:

Revenue Recognition

Product Revenue

We recognize product revenue when:

(i) persuasive evidence that an arrangement exists,
(ii) delivery has occurred and title has passed,
(iii) the price is fixed or determinable, and
(iv) collectability is reasonably assured.

Revenue from sales transactions where the customer has the right to return the product is recognized at the time of sale only if: (i) our price to the customer is substantially fixed or determinable at the date of sale, (ii) the customer has paid us, or the customer is obligated to pay us and the obligation is not contingent on resale of the product, (iii) the customer's obligation to us would not be changed in the event of theft or physical destruction or damage of the product, (iv) the customer acquiring the product for resale has economic substance apart from that provided by us, (v) we do not have significant obligations for future performance to directly bring about resale of the product by the customer, and (vi) the amount of future returns can be reasonably estimated.

Product Revenue Allowances

Product revenue is recognized net of consideration paid to our customers, wholesalers and certified pharmacies for services rendered by the wholesalers and pharmacies in accordance with the wholesalers and certified pharmacy services network agreements, and includes a fixed rate per prescription shipped and monthly program management and data fees. These services are not deemed sufficiently separable from the customers' purchase of the product; therefore, they are recorded as a reduction of revenue at the time of revenue recognition.

Other product revenue allowances include certain prompt pay discounts and allowances offered to our customers, program rebates and chargebacks. These product revenue allowances are recognized as a reduction of revenue at the later of the date at which the related revenue is recognized or the date at which the allowance is offered. We also offer discount programs to patients. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates or chargebacks. We review the adequacy of product revenue allowances on a quarterly basis. Amounts accrued for product revenue allowances are adjusted when trends or significant events indicate that adjustment is appropriate and to reflect actual experience.

We ship units of Qsymia through a distribution network that includes certified retail pharmacies. Qsymia has a 36–month shelf life and we grant rights to our customers to return unsold product six months prior to and up to 12 months after product expiration and issue credits that may be applied against existing or future invoices. Given our limited history of selling Qsymia and the duration of the return period, in the past, we have not had sufficient information to reliably estimate expected returns of Qsymia at the time of shipment, and therefore revenue was recognized when units were dispensed to patients through prescriptions, at which point, the product is not subject to return.

Beginning in the first quarter of 2017, with 48 months of returns experience, we believe that we have sufficient data and experience from selling Qsymia to reliably estimate expected returns. Therefore, beginning in the first quarter of 2017, we began recognizing revenue from the sales of Qsymia upon shipment and recording a reserve for expected returns at the time of shipment.

In accordance with this change in accounting estimate, we recognized a one-time adjustment of $7.3 million of revenues, net of expected returns reserve and gross-to-net charges, in the first quarter of 2017 relating to products that had been previously shipped.

RESULTS OF OPERATIONS

Revenues

(in thousands, except for percentages)	Three Months Ended March 31, 2017	2016	% Change Increase/ (Decrease) 2017 vs 2016
Revenue:			
Net product revenue	$ 17,620	$ 12,412	42 %
License and milestone revenue	5,000	—	—
Supply revenue	3,812	1,526	150 %
Royalty revenue	580	1,386	(58)%
Total revenue	$ 27,012	$ 15,324	76 %

Net product revenue

Net product revenue for the first quarter of 2016 was recognized when units were dispensed to patients through prescriptions. Beginning in the first quarter of 2017, we began recognizing revenue from the sales of Qsymia upon shipment and recording a reserve for expected returns at the time of shipment. Net product revenue for the three months ended March 31, 2017 includes a one-time adjustment of $7.3 million related to shipments which had previously been deferred. For the three months ended March 31, 2017 and 2016, there were approximately 102,000 and 116,000 Qsymia prescriptions dispensed, respectively. Due to the change in the timing when we recognize revenue on Qsymia shipments, net product revenue on a go-forward basis will be based on units shipped to the wholesaler rather than prescriptions dispensed in a given period. In the first quarter of 2017, we shipped approximately 89,000 units of Qsymia to the wholesalers. The change in the timing of when we recognize revenue could result in higher volatility of Qsymia sales compared to those historically reported. We expect Qsymia net product revenue in 2017 to remain flat or decrease from 2016 levels due to market conditions.

License and milestone revenue

License and milestone revenue for the three months ended March 31, 2017 consisted of a one-time $5.0 million payment received for a license to certain clinical data related to phentermine. There was no license and milestone revenue for the three months ended March 31, 2016. License and milestone revenues are dependent on the timing of entering into new collaborations and the timing of our collaborators meeting certain milestone events. As a result, our license and milestone revenue will fluctuate materially between periods.

Supply revenue

For the three months ended March 31, 2017 and 2016, we recognized $3.8 million and $1.5 million, respectively, in supply revenue. The increase in supply revenue in 2017 as compared to 2016 is due to the timing of orders from our commercialization partners. We supply STENDRA/SPEDRA to our collaborations partners on a cost-plus basis. 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. The timing of purchases by our commercialization partners will be affected by, among other items, their minimum purchase commitments, end user demand, and distributor inventory levels. As a result, supply revenue has and will continue to fluctuate materially between reporting periods.

Royalty revenue

For the three months ended March 31, 2017 and 2016, we recognized $0.6 million and $1.4 million, respectively, in net royalty revenue on net sales reported by our commercialization partners. We record royalty

revenue related to STENDRA based on reports provided by our partners. One of our partners, Auxilium, returned the U.S. and Canadian commercial rights for STENDRA to us on September 30. 2016. Also, on September 30, 2016, we entered into the Metuchen License Agreement and the Metuchen Supply Agreement, providing Metuchen with, among other rights, commercial rights to sell STENDRA/SPEDRA in the U.S., Canada, South America, and India. The Metuchen License Agreement does not include future royalties to us on the sales of STENDRA/SPENDRA in the Metuchen Territory. We expect royalty revenue to decrease in 2017 from 2016 levels, as beginning in the fourth quarter of 2016 we no longer receive royalty revenue from net sales in the U.S.

Cost of goods sold

	Three Months Ended March 31,		% Change Increase/ (Decrease)
	2017	2016	2017 vs 2016
	(In thousands, except percentages)		
Qsymia cost of goods sold	$ 2,665	$ 2,071	29 %
STENDRA/SPEDRA cost of goods sold	3,502	1,633	114 %
Total cost of goods sold	$ 6,167	$ 3,704	66 %

Cost of goods sold for Qsymia dispensed to patients includes the inventory costs of API, third party contract manufacturing and packaging and distribution costs, royalties, cargo insurance, freight, shipping, handling and storage costs, and overhead costs of the employees involved with production. Cost of goods sold for STENDRA/SPEDRA shipped to our commercialization partners includes the inventory costs of API, tableting, bottling, freight, shipping and handling costs. Cost of goods sold increased overall in the first quarter of 2017 as compared to 2016 due primarily to increased product and supply revenue in the first quarter of 2017.

Selling, general and administrative expense

	Three Months Ended March 31,		% Change Increase/ (Decrease)
	2017	2016	2017 vs 2016
	(In thousands, except percentages)		
Selling and marketing	$ 5,459	$ 7,648	(29)%
General and administrative	5,972	7,474	(20)%
Total selling, general and administrative expenses	$ 11,431	$ 15,122	(24)%

The decrease in selling and marketing expenses for the three months ended March 31, 2017, compared to the same period in 2016, was due primarily to the cost saving efforts to reduce marketing programs and lower promotional activities for Qsymia.

The decrease in general and administrative expenses in the three months ended March 31, 2017 compared to the same period in 2016, was primarily due to our continuing efforts to cut costs and lower spending for corporate activities.

Research and development expense

Drug Indication/Description	Three Months Ended March 31,		% Change Increase/(Decrease)
	2017	2016	2017 vs 2016
	(In thousands, except percentages)		
Qsymia for obesity	$ 108	$ 198	(45)%
STENDRA for ED	2	(22)	(109)%
PAH	1,186	—	N/A
Share-based compensation	85	(33)	(358)%
Overhead costs*	799	886	(10)%
Total research and development expenses	$ 2,180	$ 1,029	112 %

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

The increase in total research and development expenses in the three months ended March 31, 2017 as compared to the same period in 2016 was due primarily to the license fees paid to Selten for the development of tacrolimus and ascomycin for the treatment of PAH. We expect that our research and development expenses will

increase in 2017 as we continue to complete our post-marketing requirements for Qsymia, specifically an adolescent safety and efficacy trial, and begin development of tacrolimus for the treatment of PAH. In addition, our research and development expenses could increase materially if we begin development of any additional product candidates.

Interest expense and other expense, net

Interest expense and other expense, net for the three months ended March 31, 2017 and 2016 was $8.3 million and $8.2 million, respectively. 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. Other expense and income were not significant. We expect interest and other expense (income) in 2017 to remain relatively consistent with 2016 levels.

(Benefit from) provision for income taxes

For the three months ended March 31, 2017, we recorded a benefit of $12,000, compared to a provision for income taxes of $16,000 for the three months ended March 31, 2016. The benefit and provision for income taxes for both of the periods 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 March 31, 2017.

LIQUIDITY AND CAPITAL RESOURCES

Cash. Cash, cash equivalents and available-for-sale securities totaled $260.2 million at March 31, 2017, as compared to $269.5 million at December 31, 2016. The decrease was primarily due to 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 corporate debt securities in accordance with our investment policy. Our investment policy has the primary investment objectives of preservation of principal; however, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy. If those securities are downgraded or impaired, we would experience realized or unrealized losses in the value of our portfolio, which would have an adverse effect on our results of operations, liquidity and financial condition. Investment securities are exposed to various risks, such as interest rate, market and credit. Due to the level of risk associated with certain investment securities and the level of uncertainty related to changes in the value of investment securities, it is possible that changes in these risk factors in the near term could have an adverse material impact on our results of operations or stockholders' equity.

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. Historically, we have had no significant uncollectable accounts receivable. We offer cash discounts to our customers, generally 2% of the sales price as an incentive for prompt payment.

Accounts receivable (net of allowance for cash discounts) at March 31, 2017, was $11.4 million, as compared to $9.5 million at December 31, 2016. Currently, we do not have any significant concerns related to accounts receivable or collections.

Summary Cash Flows

	Three Months Ended March 31,	
	2017	2016
	(in thousands)	
Cash provided by (used for):		
Operating activities	$ (7,072)	$ (11,738)
Investing activities	(7,882)	2,243
Financing activities	(2,076)	(2,199)

Operating Activities. For the three months ended March 31, 2017, cash used for operating activities resulted from our net loss as adjusted for non-cash items. Additional decreases were due to increases in accounts receivable, partially offset by decreases in prepaid expenses and increases in accrued liabilities. For the three months ended March 31, 2016, the use of cash was primarily due to the net loss as adjusted for non-cash items, in addition to decreases in accrued liabilities and deferred revenue and increases in accounts receivable. These were partially offset by decreases in inventory and prepaid expenses.

Investing Activities. Cash used or provided by investing activities primarily relates to the purchases and maturities of investment securities. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturities of these investment securities.

Financing Activities. Cash used for financing activities for the three months ended March 31, 2017 and 2016 primarily related to our repayments of $2.1 million and $2.2 million, respectively, under the Senior Secured Notes.

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 evaluate development opportunities, which could come in the form of a license, a co-development agreement, a merger or acquisition or other form, create a pathway for centralized approval of the marketing authorization application for Qsiva in the EU, conduct post-approval clinical studies for Qsymia, conduct non-clinical and clinical research and development work to support regulatory submissions and applications for our current and future investigational drug candidates, finance the costs involved in filing and prosecuting patent applications and enforcing or defending our patent claims, if any, to fund operating expenses and manufacture quantities of our investigational drug candidates and to make payments under our existing license agreements and supply agreements.

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 March 31, 2017.

Contractual Obligations

During the three months ended March 31, 2017, 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, 2016, filed with the SEC on March 8, 2017, 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 March 31, 2017, 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, 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 March 31, 2017, by approximately $2.3 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.

PART II: OTHER INFORMATIO N

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 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 voluntarily dismissed their state court action with prejudice. Defendants moved to dismiss the federal action and moved to dismiss again after plaintiffs amended their complaint to include additional factual allegations and to add seven new claims under California law. The court granted the latter 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 as well. On April 19, 2016, the court granted defendants' motion to dismiss with prejudice and entered judgment in favor of defendants. Plaintiffs filed a notice of appeal to the Ninth Circuit Court of Appeals on May 18, 2016. Briefing on the appeal has now been completed. The Ninth Circuit has not yet scheduled the matter for oral argument or consideration. 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 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.

On March 5, 2015, the Company received a Paragraph IV certification notice from Teva Pharmaceuticals USA, Inc. indicating that it filed an ANDA with 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.

The schedule for both suits has now been consolidated for expert discovery and trial. Expert discovery is ongoing and a final pretrial conference is scheduled for June 28, 2017. No trial date has been scheduled.

The Company intends to vigorously enforce its intellectual property rights relating to Qsymia, but the Company cannot predict the outcome of these matters.

STENDRA ANDA Litigation

On June 20, 2016, the Company received a Paragraph IV certification notice from Hetero USA, Inc. and Hetero Labs Limited, collectively referred to as Hetero, indicating that it filed an ANDA with 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 (Case No. 16-4560 (KSH)(CLW)). On January 3, 2017, we entered into a settlement agreement with Hetero. Under the settlement agreement, Hetero was granted a license to manufacture and

commercialize the generic version of STENDRA described in its ANDA filing in the United States as of the date that is the later of (a) October 29, 2024, which is 180 days prior to the expiration of the last to expire of the patents-in-suit, or (b) the date that Hetero obtains final approval from FDA of the Hetero ANDA. The settlement agreement provides for a full settlement of all claims that were asserted in the suit.

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 and that of our collaborators to effectively and profitably commercialize Qsymia® and STENDRA/SPEDRA.

Our success will depend on our ability and that of our collaborators to effectively and profitably commercialize Qsymia and STENDRA/SPEDRA, 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 and Metuchen 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 FDA, including Qsymia's Risk Evaluation and Mitigation Strategy, or REMS, any future changes to the REMS, and any other requirements established by FDA in the future;
- efficiently conduct the post-marketing studies required by 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/SPEDRA and the finished products are manufactured in sufficient quantities and in compliance with requirements of 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/SPEDRA, from APIs to finished products, efficiently and consistently delivers Qsymia and STENDRA/SPEDRA to customers; and

- effectively and efficiently manage our sales force and commercial team for the promotion of Qsymia.

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 be able to successfully develop, launch and commercialize tacrolimus or any other potential future development programs.

We may not be able to effectively develop and profitably launch and commercialize tacrolimus or any other potential future development programs which we may undertake, which will include our ability to:

- effectively conduct phase 2 and phase 3 clinical testing on tacrolimus, which could be delayed by slow patient enrollment, long treatment time required to demonstrate effectiveness, disruption of operations at clinical trial sites, adverse medical events or side effects in treated patients, failure of patients taking the placebo to continue to participate in the clinical trials, and insufficient clinical trial data to support effectiveness of tacrolimus;
- obtain regulatory approval and market authorization for tacrolimus in the U.S., EU and other territories;
- develop, validate and maintain a commercially viable manufacturing process that is compliant with cGMP;
- establish and effectively manage a supply chain for tacrolimus to ensure that the API and the finished products are manufactured in sufficient quantities and in compliance with regulatory requirements and with acceptable quality and pricing in order to meet commercial demand;
- effectively determine and manage the appropriate commercialization strategy;
- manage costs;
- achieve market acceptance by patients, the medical community and third-party payors and generate product sales;
- effectively compete with other therapies;
- maintain a continued acceptable safety profile for tacrolimus following approval;
- comply with healthcare regulatory requirements; and
- maintain and defend our patents, if challenged.

If we are unable to successfully develop, launch and commercialize tacrolimus, 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.

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.

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.

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 the Menarini License Agreement 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 the Auxilium License Agreement and the Auxilium Supply Agreement 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. Auxilium terminated the Auxilium Supply Agreement effective June 30, 2016 and the Auxilium License Agreement effective September 30, 2016. On September 30, 2016, we entered into the Metuchen License Agreement whereby Metuchen received an exclusive license to develop, commercialize and promote STENDRA in the Metuchen Territory, effective October 1, 2016. The Metuchen License Agreement is royalty-free as to us. In December 2013, we entered into the Sanofi License Agreement under which Sanofi received an exclusive license to commercialize and promote avanafil for therapeutic use in humans in the Sanofi Territory. On March 23, 2017, we and Sanofi entered into the Transition Agreement, effective February 28, 2017. Under the Transition Agreement, effective upon the thirtieth (30th) day following February 28, 2017, the Sanofi License Agreement terminated for all countries in the Sanofi Territory as a termination by Sanofi for convenience notwithstanding any notice requirements contained in the Sanofi License Agreement. In addition, under the Transition Agreement, Sanofi will provide us with certain transition services in support of ongoing regulatory approval efforts while we seek to obtain a new commercial partner or partners for the Sanofi Territory. We will pay certain transition service fees to Sanofi as part of the Transition Agreement.

We are relying on our collaboration partners to successfully commercialize STENDRA/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/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 any future 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 any future sublicensees 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/SPEDRA.

Our dependence on collaborative arrangements or strategic alliances for the commercialization of STENDRA/SPEDRA, including our license agreements with MTPC, Menarini and Metuchen, will subject us to a number of risks, including the following:

- We may not be able to control the commercialization of our drug products in the relevant territories, including amount, timing and quality of resources that our collaborators may devote to our drug products;
- our collaborators may experience financial, regulatory or operational difficulties, which may impair their ability to commercialize our drug products;

- our collaborators may be required under the laws of the relevant territory to disclose our confidential information or may fail to protect our confidential information;
- as a requirement of the collaborative arrangement, we may be required to relinquish important rights with respect to our drug products, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to satisfactorily complete its commercialization or other obligations under any collaborative arrangement;
- legal disputes or disagreements may occur with one or more of our collaborators;
- a collaborator could independently move forward with a competing investigational drug candidate developed either independently or in collaboration with others, including with one of our competitors; and
- a collaborator could terminate the collaborative arrangement, which could negatively impact the continued commercialization of our drug products. For example, Auxilium returned the U.S. and Canadian commercial rights for STENDRA to us effective September 30, 2016. Also, effective March 2017, Sanofi terminated the Sanofi License Agreement.

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/SPEDRA with Menarini 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/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 ceased earning royalty revenue from U.S. sales as a result of the termination of our license and commercialization agreement with Auxilium. Our new license agreement with Metuchen is royalty-free as to us.

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 Africa, the Middle East, Turkey, the CIS, 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 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.

We, together with Menarini and any potential future collaborators in certain territories, intend to market STENDRA/SPEDRA outside the U.S., which will subject us to risks related to conducting business internationally.

We, through Menarini and any potential future collaborators in certain territories, intend to manufacture, market, and distribute STENDRA/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 and 2014, we recorded inventory impairment and commitment fees totaling $29.5 million and $2.2 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 and 2014, we recognized total charges of $29.5 million and $2.2 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/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.

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 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 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/SPEDRA 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 maintain the certified retail pharmacy distribution channel in the United States for Qsymia;
- contraindications for Qsymia and STENDRA/SPEDRA;
- competition and timing of market introduction of competitive drugs;
- quality, safety and efficacy in the approved setting;
- prevalence and severity of any side effects, including those of the 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 our current 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 FDA or other regulatory authorities.

Our drugs may fail to achieve market acceptance or generate significant revenue to achieve sustainable 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 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 FDA in late 2014 regarding the amended protocol. As a part of addressing FDA comments from a May 2015 meeting to discuss alternatives to completion of a CVOT, we worked 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. The epidemiology experts maintained that a well-conducted retrospective observational study could provide data to further inform on potential CV risk. We worked with the expert group to develop a protocol and conduct a retrospective observational study. We are in the process of analyzing the collected information for discussion with FDA. 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 FDA to reach a resolution. As for the EU, even if 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 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, 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 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 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 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/SPEDRA, like all pharmaceutical products, are subject to heightened risk for product liability claims due to inherent potential side effects. For example, because topiramate, a component of Qsymia, may increase the risk of congenital malformation in infants exposed to topiramate during the first trimester of pregnancy and also may increase the risk of suicidal thoughts and behavior, such risks may be associated with Qsymia as well. Other potential risks involving Qsymia may include, but are not limited to, an increase in resting heart rate, acute angle closure glaucoma, cognitive and psychiatric adverse events, metabolic acidosis, an increase in serum creatinine, hypoglycemia in patients with type 2 diabetes, kidney stone formation, decreased sweating and hypokalemia, or lower-than-normal amount of potassium in the blood.

Although we have obtained product liability insurance coverage for Qsymia, we may be unable to maintain this product liability coverage for Qsymia or any other of our approved drugs in amounts or scope sufficient to

provide us with adequate coverage against all potential risks. A product liability claim in excess of, or excluded from, our insurance coverage would have to be paid out of cash reserves and could have a material adverse effect upon our business, financial condition and results of operations. Product liability insurance is expensive even with large self-insured retentions or deductibles, difficult to maintain, and current or increased coverage may not be available on acceptable terms, if at all.

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

If we cannot successfully defend ourselves against a product liability claim, whether involving Qsymia, STENDRA/SPEDRA 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; 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; Jardiance ® (empagliflozin) from Boehringer Ingelheim, an SGLT2 inhibitor; Victoza ® (liraglutide) from Novo Nordisk A/S, a GLP-1 receptor agonist; Invokana ® (canaglifozin) from Johnson & Johnson's Janssen Pharmaceuticals, an SGLT2 inhibitor and Glyxambi ® (empagliflozin/linagliptin) from Boehringer Ingelheim and Eli

Lilly, an SGLT2 inhibitor and DPP-4 inhibitor combination product. Also, EnteroMedics® Inc. markets 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.

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 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 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, 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.

Qsymia 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 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 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 holder 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 FDA grants a waiver allowing the generic competitor to market a generic drug with a separate but comparable REMS.

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. Most recently, on September 30, 2016, we entered into a license and commercialization agreement and a commercial supply agreement with Metuchen. Under the terms of the agreements, 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. Additionally, on January 6, 2017, we entered into a Patent Assignment Agreement with Selten, whereby we received exclusive, worldwide rights for the development and commercialization of tacrolimus for the treatment of PAH and related vascular diseases. Further 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. Most recently, on January 6, 2017, we entered into a Patent Assignment Agreement with Selten, whereby we received exclusive, worldwide rights for the development and commercialization of tacrolimus for the treatment of PAH and related vascular diseases. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical investigational drug candidates and products.

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

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

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition, integration and maintenance costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Further, any investigational drug candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and obtaining approval by 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.

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, is our sole source of clinical and commercial supplies 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.

For avanafil, 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 for STENDRA and SPEDRA 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 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.

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 and Metuchen 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 and Metuchen.

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.

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. The General Data Protection Regulation, or GDPR, an EU-wide regulation that will be fully enforceable by May 25, 2018, will introduce new data protection requirements in the EU and substantial fines for violations of the data protection rules. The GDPR 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; 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 and by the Health Information Technology for Economic and Clinical Health Act, or HITECH, which are collectively referred to as 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 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, or associated adverse publicity, 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.

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

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, 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. 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, 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. 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, FDA has required a REMS that may act to limit access to the drug, reduce our revenues and/or increase our costs. 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 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. FDA could also impose civil penalties. We must also comply with similar regulatory requirements of foreign regulatory agencies.

We obtain the necessary raw materials and components for the manufacture of Qsymia and STENDRA as well as certain services, such as analytical testing packaging and labeling, from third parties. In particular, we rely on Catalent to supply Qsymia capsules and Packaging Coordinators, Inc., or PCI, for Qsymia packaging services. We 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 FDA and by state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Upon inspection of these facilities, 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. Moreover, legislative changes to the Affordable Care Act remain possible and appear likely in the 115th United States Congress and under the Trump Administration. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time consuming, and could have a material adverse effect on our results of operations.

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

The Affordable Care Act expanded the 340B program to include additional entity types: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The Affordable Care Act also obligates the Secretary of the U.S. Department of Health and Human Services, or HHS, 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 initiated the process of updating the agreement with participating manufacturers. The Healthcare Reform Act also obligates the Secretary of HHS to create regulations and processes to improve the integrity of the 340B program. In 2015, HRSA issued proposed omnibus guidance that addresses many aspects of the 340B program, and in August 2016, HRSA issued a proposed regulation regarding an administrative dispute resolution process for the 340B program. It is unclear when or whether the guidance or regulation will be released in final form under the Trump Administration. On January 5, 2017, HRSA issued a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The March 6, 2017 effective date of this regulation is subject to a temporary delay directed by the Trump Administration, and the regulation could be subject to further delay or other modification by the Trump Administration. Implementation of this final rule and the issuance of any other final regulations and guidance 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 an 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 $178,156 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 $12,856 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 $178,156 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-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, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue.

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.
- 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 2017, 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.

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, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The Affordable Care Act also obligates the Secretary of the Department of Health and Human Services 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 initiated the process of updating the agreement with participating manufacturers. The Healthcare Reform 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. In 2015, HRSA issued proposed omnibus guidance that addresses many aspects of the 340B program, and in August 2016, HRSA issued a proposed regulation regarding an administrative dispute resolution process for the 340B program. It is unclear when or whether the guidance or regulation will be released in final form under the Trump Administration. On January 5, 2017, HRSA issued a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The March 6, 2017 effective date of this regulation is subject to a temporary delay directed by the Trump Administration, and the regulation could be subject to further delay or other modification by the Trump Administration. Implementation of this final rule and the issuance of any other final regulations and guidance 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 an 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. Moreover, legislative changes to the Affordable Care Act remain possible and appear likely in the 115th United States Congress and under the Trump Administration. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved.

We expect to experience pricing and reimbursement pressures in connection with the sale of Qsymia, STENDRA and our investigational drug candidates, if approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. In addition, we may confront limitations in insurance coverage for Qsymia, STENDRA and our investigational drug candidates. For

example, the Medicare program generally does not provide coverage for drugs used to treat erectile dysfunction or drugs used to treat obesity. Similarly, other insurers may determine that such products are not covered under their programs. If we fail to successfully secure and maintain reimbursement coverage for our approved drugs and investigational drug candidates or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our approved drugs and investigational drug candidates and our business will be harmed. Congress has enacted healthcare reform and may enact further reform, which could adversely affect the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business.

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

An increasing number of EU Member States and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. In addition, the ongoing budgetary difficulties faced by a number of EU Member States, including Greece and Spain, have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal products, which could negatively impact our revenues and profitability. Moreover, in order to obtain reimbursement of our medicinal products in some countries, including some EU Member States, we may be required to conduct clinical trials that compare the cost effectiveness of our products to other available therapies. There can be no assurance that our medicinal products will obtain favorable reimbursement status in any country.

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

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

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

Despite the implementation of security measures, our internal computer systems and those of our contract sales organization, or CSO, CROs, safety monitoring company and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, accidents, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our investigational drug candidate development programs and drug manufacturing operations. For example, the loss of clinical trial data from completed or ongoing clinical trials for our investigational drug candidates could result in delays in our regulatory approval efforts with 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 FDA accepts for filing a generic application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the reference listed drug, or RLD, NDA holder and patent owner that the application with patent challenge has been submitted, and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner file suit against the generic applicant for patent infringement within 45 days of receiving the Paragraph IV notice, 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. 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 submitted by generic drug companies. These ANDA filings assert that generic forms of Qsymia 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 is approved under the provisions of the Federal Food, Drug and Cosmetic Act, or FDCA, which renders it susceptible to potential competition from generic manufacturers via the Hatch-Waxman Act and ANDA process. The ANDA procedure includes provisions allowing generic manufacturers to challenge the innovator's patent protection by submitting "Paragraph IV" certifications to 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.

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 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.

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.

The schedule for both suits has now been consolidated for expert discovery and trial. Expert discovery is ongoing and a final pretrial conference is scheduled for June 28, 2017. No trial date has been scheduled.

On June 20, 2016, we have received a Paragraph IV certification notice from Hetero USA Inc. and Hetero Labs Limited, collectively referred to as 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. On July 27, 2016, we filed a lawsuit in the U.S. District Court for the District of New Jersey against Hetero. On January 3, 2017, we entered into a settlement agreement with Hetero. Under the settlement agreement, Hetero was granted a license to manufacture and commercialize the generic version of STENDRA described in its ANDA filing in the United States as of the date that is the later of (a) October 29, 2024, which is 180 days prior to the expiration of the last to expire of the Asserted Patents, or (b) the date that Hetero obtains final approval from FDA of the Hetero ANDA. The Settlement Agreement provides for a full settlement of all claims that were asserted in the suit.

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

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

Our commercial success also depends, in part, upon our ability to develop future investigational drug candidates, market and sell approved drugs and conduct our other research, development and commercialization activities without infringing or misappropriating the patents and other proprietary rights of others. There are many patents and patent applications owned by others that could be relevant to our business. For example, there are numerous U.S. and foreign issued patents and pending patent applications owned by others that are related to the therapeutic areas in which we have approved drugs or future investigational drug candidates as well as the therapeutic targets to which these drugs and candidates are directed. There are also numerous issued patents and patent applications covering chemical compounds or synthetic processes that may be necessary or useful to use in our research, development, manufacturing or commercialization activities. Because patent applications can take

many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our approved drugs, future investigational drug candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our approved drugs, investigational drug candidates or technologies may infringe. Further, it is not always clear to industry participants, including us, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. We cannot assure you that others holding any of these patents or patent applications will not assert infringement claims against us for damages or seek to enjoin our activities. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, and we may not be able to do this.

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

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

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

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

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

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

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

Risks Relating to our Financial Position and Need for Financing

We may require additional capital for our future operating plans and debt servicing requirements, 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, the development of our research and development pipeline and the servicing requirements of our debt. 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 FDA has required us to perform as part of the approval for Qsymia;
- our ability, along with our collaboration partners, to successfully commercialize STENDRA/SPEDRA;
- 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 businesses, products and technologies. On January 6, 2017, we entered into a Patent Assignment Agreement with Selten whereby we received exclusive, worldwide rights for the development and commercialization of BMPR2

activators for the treatment of PAH and related vascular diseases. Selten received an upfront payment of $1.0 million and is entitled to milestone payments based on global development status and future sales milestones, as well as tiered royalty payments on future sales of these compounds. The total potential milestone payments are $39.6 million.

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 March 31, 2017, 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.

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 March 31, 2017, we had $260.2 million in cash, cash equivalents and available-for-sale securities. While at March 31, 2017, 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 March 31, 2017. 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 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 us and three of our 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 our 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 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 voluntarily dismissed their state court action with prejudice. Defendants moved to dismiss the federal action and moved to dismiss again after plaintiffs amended their complaint to include additional factual allegations and to add seven new claims under California law. The court granted the latter 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 as well. On April 19, 2016, the court granted defendants' motion to dismiss with prejudice and entered judgment in favor of defendants. Plaintiffs filed a notice of appeal to the Ninth Circuit Court of Appeals on May 18, 2016. Briefing on the appeal has now been completed. The Ninth Circuit has not yet scheduled the matter for oral argument or consideration.

We maintain directors' and officers' liability insurance that we believe 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 $814.1 million as of March 31, 2017, and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of $814.1 million for the period from our inception through March 31, 2017, 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, 2016, we had approximately $635.7 million and $265.0 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 June 30, 2016 and concluded no adjustments were required. If we have experienced a change of control at any time since our formation, our NOL carryforwards and tax credits may not be available, or their utilization could be subject to an annual limitation under Section 382. A full valuation allowance has been provided against our NOL carryforwards, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Accordingly, there would be no impact on the consolidated balance sheet or statement of operations.

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

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

Risks Relating to an Investment in our Common Stock

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

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

- our ability to meet the expectations of investors related to the commercialization of Qsymia and STENDRA;
- our ability to find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience;
- our ability to obtain marketing authorization for our products in foreign jurisdictions, including authorization from the EC for Qsiva in the EU through the centralized marketing authorization procedure;
- the costs, timing and outcome of post-approval clinical studies which 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;
- the status of the CVOT and our related discussions with FDA;
- 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 or efficacy of our drugs or future investigational drug candidates developed by us.

These factors and fluctuations, as well as political and other market conditions, may adversely affect the market price of our common stock. Additionally, volatility or a lack of positive performance in our stock price may adversely affect our ability to retain or recruit key employees, all of whom have been or will be granted 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. Product sales of Qsymia may never increase or become profitable. In addition, although we have entered into license and commercialization agreements with Menarini to commercialize and promote SPEDRA for the treatment of ED in over 40 countries, including the EU, plus Australia and New Zealand and with Metuchen to commercialize STENDRA in the U.S., Canada, South America and India, we and they 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 or 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;
- 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
January 2017	3,508	$ 1.20	3,508	
February 2017	21,495	$ 1.08	21,495	
March 2017	1,019	$ 1.11	1,019	
Total	26,022	$ 1.10	26,022	68,419

(a) In the first quarter of 2017, 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.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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.

SIGNATURES

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

Date: May 3, 2017

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

VIVUS, INC.

INDEX TO EXHIBITS

EXHIBIT NUMBER	DESCRIPTION
3.1 [1]	Amended and Restated Certificate of Incorporation of the Registrant.
3.2 [2]	Amended and Restated Bylaws of the Registrant.
3.3 [3]	Amendment No. 1 to the Amended and Restated Bylaws of the Registrant.
3.4 [4]	Amendment No. 2 to the Amended and Restated Bylaws of the Registrant.
3.5 [5]	Amendment No. 3 to the Amended and Restated Bylaws of the Registrant.
3.6 [6]	Amendment No. 4 to the Amended and Restated Bylaws of the Registrant.
3.7 [7]	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]	Amended and Restated Preferred Stock Rights Agreement dated as of November 9, 2016, between the Registrant and Computershare Trust Company, N.A.
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† [13]	Patent Assignment Agreement dated as of January 6, 2017, by and between the Registrant and Selten Pharma, Inc.
10.2† [14]	License Assignment Agreement dated as of January 6, 2017, by and between the Registrant and Selten Pharma, Inc.
10.3††	Termination, Rights Reversion and Transition Services Agreement dated March 23, 2017, by and between the Registrant and Sanofi.
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.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101 The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, 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 treatment granted.

†† 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 Current Report on Form 8-K filed with the SEC on November 9, 2016.

(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.

(13) Incorporated by reference to Exhibit 10.55 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed with the SEC on March 8, 2017.

(14) Incorporated by reference to Exhibit 10.56 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed with the SEC on March 8, 2017.

***** INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

TERMINATION, RIGHTS REVERSION AND TRANSITION SERVICES AGREEMENT

between

SANOFI

and

VIVUS, INC.

TERMINATION, RIGHTS REVERSION AND TRANSITION SERVICES AGREEMENT

This **TERMINATION, RIGHTS REVERSION AND TRANSITION SERVICES AGREEMENT** (this " **Agreement** ") is made as of February 28, 2017 (the " **Execution Date** "), by and between **Sanofi** , a French corporation having its registered office at 54 rue la Boétie, 75008, Paris, France (" **Sanofi** ") and **VIVUS, Inc.** , a Delaware corporation with its principal office at 900 E. Hamilton Avenue, Suite 550, Campbell, California, 95008, United States of America (" **Vivus** "). Sanofi and Vivus are each referred to individually as a " **Party** " and together as the " **Parties** ."

RECITALS

WHEREAS , Sanofi and Vivus entered into a License and Commercialization Agreement dated December 11, 2013 (the " **License Agreement** "), pursuant to which Vivus granted Sanofi an exclusive license for the development, manufacture and commercialization of the Product and the API in the Field in the Sanofi Territory;

WHEREAS , Sanofi desires to abandon and relinquish all rights to the Product and the API under the License Agreement and to terminate the License Agreement, on the terms and subject to the conditions set forth in this Agreement;

WHEREAS , Vivus desires to accept the rights to the Product and the API being terminated by Sanofi and to the termination of the License Agreement, on the terms and subject to the conditions set forth in this Agreement; and

WHEREAS , Sanofi and Vivus have also agreed, on the terms and subject to the conditions of this Agreement, that Sanofi will provide to Vivus certain transition services related to the termination of the rights to the Product and the API and the termination of the License Agreement.

NOW, THEREFORE , in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

1. **Definitions** . Capitalized terms used in this Agreement shall have the meanings given to those terms in the License Agreement, except for those capitalized terms specifically defined in this Agreement, or as set forth in this Section 1 .

" **Category A Countries** " means the following countries where Sanofi has reasonably determined (in consultation with Vivus) that the transfer of Regulatory Materials for the Product to Vivus does not create an adverse impact on the Regulatory Approval of the Product: *** ; and *** .

" **Category B Countries** " means the following counties where Sanofi has reasonably determined (in consultation with Vivus) that the transfer of Regulatory Materials for the Product to Vivus is reasonably likely to create an adverse impact on the Regulatory Approval of the Product: *** ; *** ; *** ; *** ; *** ; *** ; *** ; *** ; *** ; *** ; *** ; and *** .

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" **Other Countries** " means the following countries where Sanofi (in consultation with Vivus) has not made a determination as to whether the country is a Category A Country or a Category B Country: *** ; *** ; *** ; and *** .

" **Transition Date** " means the earlier of (a) on a Category B Country-by-Category B Country basis, the date on which Vivus and Sanofi agree in writing that the transfer of Regulatory Materials for the Product to Vivus in such country is no longer likely to create an adverse impact on the Regulatory Approval of the Product in such Category B Country, or (b) *** from the Effective Date.

2. **Term; Termination of License Agreement; Effect of Termination** .

a. This Agreement shall be effective from and after the Execution Date and shall terminate upon the satisfaction of all the Parties' obligations under Section 4 (the " **Termination Date** "). On the thirtieth (30 th) day following the Execution Date (the " **Effective Date** "), the License Agreement shall terminate for all of the countries in the Sanofi Territory, as if such termination was made by Sanofi, pursuant to Section 13.5 of the License Agreement (a " **Sanofi Termination for Convenience** "), notwithstanding any notice period set forth therein.

b. In accordance with, and without limiting the provisions of, Section 13.8 of the License Agreement (*Effect of Early Termination of the Agreement*), Section 13.8 of the License Agreement shall apply from and after the Effective Date, solely to the extent applicable as a result of a Sanofi Termination for Convenience and unless otherwise modified by this Agreement.

c. Except as specifically set forth in this Agreement or as the context of this Agreement may require, the License Agreement shall be unaffected by this Agreement. Without limiting the foregoing, Section 13.13 of the License Agreement (*Survival*) shall apply in accordance with its terms on and after the Effective Date.

3. **Regulatory Milestone Payments** . Notwithstanding any provision of the License Agreement to the contrary, Sanofi shall not owe to Vivus and Vivus hereby waives any right that Vivus may have under Section 7.2 of the License Agreement (*Regulatory Milestone Payments*) to any payments that would otherwise be owed to Vivus thereunder, regardless of whether the milestone event referred to therein occurred on or before the Effective Date.

4. **Transition Services** . The Parties acknowledge that in order to assist in the orderly transfer of the rights and licenses being terminated by Sanofi under the License Agreement and the reversion of those rights and licenses to Vivus (collectively, the " **Transfer** "), Sanofi shall provide to Vivus certain transition services, in particular so that the Transfer does not, to the greatest extent practicable, adversely impact Regulatory Approval of the Product in any country in the Sanofi Territory.

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a. *Transfer of Regulatory Materials and Approvals for Category A Countries* . As soon as practicable after the Effective Date, but in no event before *** (the " **Materials Transfer Commencement Date** "), Sanofi shall transfer to Vivus, at a location specified by Vivus (either a physical or electronic location), all Regulatory Materials and, as applicable, Regulatory Approvals, for the Category A Countries. Sanofi shall use all reasonable efforts to complete the transfer of the Regulatory Materials and Regulatory Approvals (if applicable) for the Category A Countries within *** following the Materials Transfer Commencement Date. In any event, Sanofi shall transfer the Regulatory Materials for the Category A Countries within *** following the Material Transfer Commencement Date or, if sooner, within *** of Regulatory Approval in any Category A Country, with respect to that Category A Country, as applicable.

b. *Transition of Regulatory Responsibilities for Category B Countries* . The Parties acknowledge that as of the Execution Date and through the Effective Date, Sanofi is performing its obligations under the License Agreement to obtain Sanofi Territory Approvals. From and after the Effective Date until the Transition Date, with respect to each Category B Country, Sanofi shall continue to pursue Regulatory Approvals for the Product in the Category B Countries in the same manner and with the same care and diligence that Sanofi is pursuing Regulatory Approval for the Category B Countries as of and prior to the Execution Date and, subject to obtaining such Regulatory Approvals and to the timely provision of all required information from Vivus, maintaining those Regulatory Approvals, in accordance with applicable law. Without limiting the foregoing, the Parties shall, within *** of the Execution Date prepare a mutually acceptable written work plan setting forth the responsibilities of Sanofi with respect to its obligations to continue to pursue Regulatory Approval for the Product in each Category B Country, as well as the eventual transfer of all Regulatory Materials and Regulatory Approvals, in each case, for such Category B Country to Vivus. Upon the Transition Date, Sanofi shall promptly transfer to Vivus, at a location specified by Vivus (either a physical or electronic location), all Regulatory Materials and, as applicable, Regulatory Approvals, for the Category B Countries not previously transferred.

c. *Transition Service Fees* . In full consideration for the services to be provided by Sanofi to Vivus under Sections 4(a) and 4(b) above (the " **Transition Services** "), Vivus shall pay to Sanofi the sum of *** Dollars ($ *** US) for *** period during which these services are being performed (the " **Service Fee** "). The Service Fee shall be paid in arrears, in equal, *** installments of *** ($ *** US) by wire transfer of immediately available funds, *** following the receipt by Vivus of a written invoice for the portion of the Service Fee then due. For clarity, the first written invoice for the first installment of the Service Fee shall be issued *** from the Effective Date. Vivus shall be responsible for all filing fees and similar fees accruing after the Effective Date payable to Third Parties in connection with the performance by Sanofi of the Transition Services (" **Third Party Fees** "). Any Third Party Fees shall be approved in writing by Vivus in advance, prior to being paid. At the election of the Parties, Sanofi may pay any Third

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Party Fees on Vivus's behalf. Sanofi may include on its Service Fee invoice the amount of any unreimbursed Third Party Fees.

d. *Other Countries* . As promptly as possible following the Execution Date, the Parties shall determine whether an Other Country is a Category A Country or a Category B Country. Once such determination is made with respect to an Other Country, then such Other Country shall be deemed to be a Category A Country or Category B Country, as applicable.

e. *Other Regulatory Responsibilities* . Except as set forth in this Agreement, Vivus shall be responsible for obtaining and maintaining all Regulatory Approvals for the Product both within and outside the Sanofi Territory.

5. **Manufacturing and Supply Agreements; Pharmacovigilance Agreement** .

Nothing in this Agreement shall affect either

- the Manufacturing and Supply Agreement dated September 1, 2013 by and between Sanofi Winthrop Industrie (an Affiliate of Sanofi) and Vivus, or the Commercial Supply Agreement dated January 1, 2014 by and between Sanofi Chimie (an Affiliate of Sanofi) and Vivus (collectively, the " **Manufacturing and Supply Agreements** "); or

- the Global Safety Data Exchange Agreement dated August 1, 2016 by and between Sanofi-Aventis Recherche et Developpement (an Affiliate of Sanofi) and Vivus (the " **Pharmacovigilance Agreement** ").

The Manufacturing and Supply Agreements and the Pharmacovigilance Agreement are, and shall continue to be, in full force and effect, in accordance with their terms.

The Pharmacovigilance Agreement shall terminate, unless earlier terminated, on the Termination Date.

6. **Miscellaneous** .

a. *Governing Law* . Resolution of all disputes arising out of or related to this Agreement or the validity, construction, interpretation, enforcement, breach, performance, application or termination of this Agreement and any remedies related thereto, shall be governed by and construed in accordance with the substantive laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive laws of another jurisdiction.

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b. *Assignment* . Neither Party shall assign this Agreement, by operation of law or otherwise, without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed or conditioned. Any such attempted assignment without such consent shall be void. Unless otherwise agreed in writing, no assignment by any Party shall be effective until the assignee shall have unconditionally assumed in writing all of assignor's obligations hereunder and a written notice of such assignment is given to all other Parties. Notwithstanding the foregoing, either Party may assign this Agreement and its rights and obligations hereunder without notice or the prior written consent of the other Party to an Affiliate or to an acquirer of all or substantially all of its assets or business to which this Agreement relates; provided, that such Affiliate or acquirer also unconditionally assumes in writing all of assignor's obligations hereunder. This Agreement shall be binding upon and inure to the benefit of the Parties' respective successors and permitted assigns, and any assigning Party remains jointly and severally liable for the failure of any successor's or permitted assign's failure to perform its obligations hereunder.

c. *Notices* . Notwithstanding anything to the contrary, all notices, requests, demands, communications and deliveries required or made hereunder or thereunder must be made in writing signed by or on behalf of the Party making the same, and shall be (a) personally delivered, or (b) sent by overnight courier service with a contemporaneous notice sent by electronic mail confirming the notice sent by overnight courier service, in each case as follows:

If to Vivus:	VIVUS, Inc. 900 E. Hamilton Ave, Suite 550 Campbell, CA 95008 Attention: John Slebir, General Counsel Email: Slebir@vivus.com
With a copy to:	Hogan Lovells US LLP 3 Embarcadero Center, Suite 1500 Attention: Jon Layman Email: jon.layman@hoganlovells.com
If to Sanofi:	Sanofi 54 rue la Boétie 75008 Paris, France Attention: Vice-President Corporate Licensing Email: BD@sanofi.com
With a copy to:	Sanofi 54 rue la Boétie 75008 Paris, France

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Attention: Counsel, International Operations

or to such other representative or at such other address of a Party as such Party may furnish to the other Parties in writing in accordance with this Section 6(c) . Any such notice, communication or delivery shall be deemed given or made (a) on the date of delivery, if delivered in person, or (b) on the first Business Day following delivery to the overnight courier service.

d. *Waiver; Amendment* . No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party. No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

e. *Severability* . If any provision hereof should be held invalid, illegal or unenforceable in any respect in any jurisdiction, the Parties shall substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions which valid provisions in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalidity, illegality or unenforceability of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid, illegal or unenforceable provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid, illegal or unenforceable provisions.

f. *Entire Agreement* . This Agreement, together with all ancillary agreements referred to herein, including the provisions of the License Agreement that survive termination, constitutes and contains the complete, final and exclusive understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof and thereof.

g. *Counterparts* . This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same instrument. A signed copy of this Agreement delivered by facsimile, email or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

h. *Confidentiality* . Article 12 of the License Agreement (*Confidentiality*), shall be incorporated into this Agreement as if the terms of such Article 12 were fully set forth in this Agreement.

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i. *Dispute Resolution* . Any dispute arising out of or related to this Agreement shall be determined in accordance with Sections 14.1 through 14.4 of the License Agreement (*Dispute Resolution*).

Signature page follows

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IN WITNESS WHEREOF , the Parties have caused this Agreement to be duly executed by their respective authorized officers as of the day and year first above written.

SANOFI

By: /s/ Karen Linehan
Name: Karen Linehan
Title: General Counsel

VIVUS, INC.

By: /s/ John L. Slebir
Name: John L. Slebir
Title: SVP, General Counsel
Dated: 23 March 2017

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Exhibit 31.1

CERTIFICATION

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

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

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

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

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

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

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

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

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

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

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

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

Date: May 3, 2017

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

Exhibit 31.2

CERTIFICATION

I, Mark K. Oki, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 3, 2017

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

Exhibit 32

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

I, Seth H. Z. Fischer, Chief Executive Officer of VIVUS, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended March 31, 2017, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: May 3, 2017

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

I, Mark K. Oki, Chief Financial Officer and Chief Accounting Officer of VIVUS, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended March 31, 2017, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: May 3, 2017

By: /s/ MARK K. OKI
Mark K. Oki