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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 June 30, 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 July 31, 2017, 105,812,647 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: FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

VIVUS, INC.

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

	June 30, 2017	December 31, 2016
	Unaudited	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 76,406	$ 84,783
Available-for-sale securities	175,115	184,736
Accounts receivable, net	8,441	9,478
Inventories	15,628	16,186
Prepaid expenses and other current assets	5,333	8,251
Total current assets	280,923	303,434
Property and equipment, net	670	788
Non-current assets	1,198	1,554
Total assets	$ 282,791	$ 305,776
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,384	$ 4,707
Accrued and other liabilities	20,357	15,686
Deferred revenue	1,694	19,174
Current portion of long-term debt	24,601	8,708
Total current liabilities	51,036	48,275
Long-term debt, net of current portion	220,183	232,610
Deferred revenue, net of current portion	5,732	6,449
Non-current accrued and other liabilities	369	257
Total liabilities	277,320	287,591
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; $1.00 par value; 5,000 shares authorized; no shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Common stock; $.001 par value; 200,000 shares authorized; 105,759 and 104,874 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	105	105
Additional paid-in capital	833,244	831,750
Accumulated other comprehensive loss	(382)	(616)
Accumulated deficit	(827,496)	(813,054)
Total stockholders' equity	5,471	18,185
Total liabilities and stockholders' equity	$ 282,791	$ 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue:				
Net product revenue	$ 8,518	$ 12,749	$ 26,138	$ 25,161
License and milestone revenue	—	—	5,000	—
Supply revenue	2,119	—	5,931	1,526
Royalty revenue	590	1,027	1,170	2,413
Total revenue	11,227	13,776	38,239	29,100
Operating expenses:				
Cost of goods sold	3,570	2,647	9,737	6,351
Selling, general and administrative	11,630	13,692	23,061	28,814
Research and development	1,014	1,096	3,194	2,125
Total operating expenses	16,214	17,435	35,992	37,290
(Loss) income from operations	(4,987)	(3,659)	2,247	(8,190)
Interest expense and other expense, net	8,398	7,735	16,700	15,896
Loss before income taxes	(13,385)	(11,394)	(14,453)	(24,086)
Provision for (benefit from) income taxes	1	7	(11)	23
Net loss	$ (13,386)	$ (11,401)	$ (14,442)	$ (24,109)
Basic and diluted net loss per share	$ (0.13)	$ (0.11)	$ (0.14)	$ (0.23)
Shares used in per share computation:				
Basic and diluted	105,712	104,126	105,596	104,099

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	$ (13,386)	$ (11,401)	$ (14,442)	$ (24,109)
Unrealized gain on securities, net of taxes	109	190	234	627
Comprehensive loss	$ (13,277)	$ (11,211)	$ (14,208)	$ (23,482)

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

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

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	$ (14,442)	$ (24,109)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	501	564
Amortization of debt issuance costs and discounts	9,973	9,143
Amortization of discount or premium on available-for-sale securities	442	503
Share-based compensation expense	1,468	1,099
Changes in assets and liabilities:		
Accounts receivable	1,037	(2,045)
Inventories	558	2,793
Prepaid expenses and other assets	2,912	2,523
Accounts payable	(323)	1,140
Accrued and other liabilities	4,783	(7,052)
Deferred revenue	(18,197)	(1,894)
Net cash used for operating activities	(11,288)	(17,335)
Cash flows from investing activities:		
Property and equipment purchases	(21)	—
Purchases of available-for-sale securities	(20,915)	(32,523)
Proceeds from maturity of available-for-sale securities	23,120	37,450
Proceeds from sales of available-for-sale securities	7,208	3,703
Net cash provided by investing activities	9,392	8,630
Cash flows from financing activities:		
Repayments of notes payable	(6,507)	(4,169)
Sale of common stock through employee stock purchase plan	26	24
Net cash used for financing activities	(6,481)	(4,145)
Net decrease in cash and cash equivalents	(8,377)	(12,850)
Cash and cash equivalents:		
Beginning of year	84,783	95,395
End of period	$ 76,406	$ 82,545

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 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 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. 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 and six months ended June 30, 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 June 30, 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 for the six months ended June 30, 2017.

Recent Accounting Pronouncements Adopted

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 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.

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." The Company plans to adopt this standard in the first quarter of 2018 using the modified retrospective basis. The Company has analyzed the effect of this standard on its consolidated financial statements and 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. The Company does expect that the new standard may have an impact on the timing of recognition and the allocation of revenue related to any future license and supply agreements entered into by the Company.

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 overall recognition of expense will be similar to current guidance, though possibly in different classifications, 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 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Cost of goods sold	$ 14	$ 43	$ 27	$ 75
Selling, general and administrative	640	633	1,269	886
Research and development	87	171	172	138
Total share-based compensation expense	$ 741	$ 847	$ 1,468	$ 1,099

Share-based compensation costs capitalized as part of the cost of inventory were $1,000 and $3,000 for the three months ended June 30, 2017 and 2016, respectively, and $5,000 and $6,000 for the six months ended June 30, 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 are presented in the tables that follow (in thousands).

	As of June 30, 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	$ 76,406	$ —	$ —	$ 76,406
U.S. Treasury securities	17,646	1	(93)	17,554
Corporate debt securities	157,851	60	(350)	157,561
Total	251,903	61	(443)	251,521
Less amounts classified as cash and cash equivalents	(76,406)	—	—	(76,406)
Total available-for-sale securities	$ 175,497	$ 61	$ (443)	$ 175,115

	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 June 30, 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 (in thousands):

	As of June 30, 2017			
	Level 1	Level 2	Level 3	Total
Cash and money market funds	$ 76,406	$ —	$ —	$ 76,406
U.S. Treasury securities	17,554	—	—	17,554
Corporate debt securities	—	157,561	—	157,561
Total	$ 93,960	$ 157,561	$ —	$ 251,521

	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	
	June 30, 2017	December 31, 2016
Qsymia	$ 6,968	$ 8,982
STENDRA/SPEDRA	1,610	709
	8,578	9,691
Qsymia allowance for cash discounts	(137)	(213)
Net	$ 8,441	$ 9,478

5. INVENTORIES

Inventories consist of the following (in thousands):

	Balance as of	
	June 30, 2017	December 31, 2016
Raw materials	$ 11,524	$ 9,412
Work-in-process	1,509	2,984
Finished goods	2,595	3,110
Deferred costs	—	680
Inventories	$ 15,628	$ 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	
	June 30, 2017	December 31, 2016
Prepaid sales and marketing expenses	$ 1,868	$ 1,767
Prepaid insurance	489	1,182
Other prepaid expenses and assets	2,976	5,302
Total	$ 5,333	$ 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	
	June 30, 2017	December 31, 2016
Accrued employee compensation and benefits	$ 1,842	$ 3,014
Reserve for product returns	6,585	—
Product-related accruals	5,790	671
Accrued interest on debt (see Note 13)	2,153	1,509
Accrued manufacturing costs	1,016	6,835
Accrued non-recurring charges (see Note 10)	—	5
Other accrued liabilities	2,971	3,652
Total	$ 20,357	$ 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 June 30, 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 June 30, 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	
	June 30, 2017	December 31, 2016
Qsymia deferred revenue - current	$ —	$ 17,558
STENDRA deferred revenue - current	1,694	1,616
Deferred revenue - current	$ 1,694	$ 19,174
STENDRA deferred revenue - non-current	$ 5,732	$ 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 and recorded license revenue of $69.4 million. 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 semi-annually.

For the three and six months ended June 30, 2017, total interest expense related to the Convertible Notes was $8.1 million and $16.0 million, respectively, including amortization of $4.7 million and $9.4 million, respectively, of the debt discount and amortization of $252,000 and $499,000, respectively, of deferred financing costs. For the three and six months ended June 30, 2016, total interest expense related to the Convertible Notes was $7.3 million and $14.6 million, respectively, including amortization of $4.3 million and $8.5 million, respectively, of the debt discount and amortization of $229,000 and $454,000, respectively, of deferred financing costs.

Senior Secured Notes Due 2018

In March 2013, the Company entered into the Purchase and Sale Agreement between the Company and BioPharma Secured Investments III Holdings Cayman LP, or Biopharma, a Cayman Islands exempted limited partnership, providing for the purchase of a debt like instrument, or the Senior Secured Notes. Under the agreement, the Company received $50 million, less $500,000 in funding and facility payments, at the initial closing in April 2013. The scheduled quarterly payments on the Senior Secured Notes are subject to the net sales of (i) Qsymia and (ii) any other obesity agent developed or marketed by us or our affiliates or licensees. The scheduled quarterly

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

For the three and six months ended June 30, 2017, the interest expense related to the Senior Secured Notes was $1.0 million and $2.0 million, respectively, including amortization of deferred financing costs of $41,000 and $79,000, respectively. For the three and six months ended June 30, 2016, the interest expense related to the Senior Secured Notes was $1.1 million and $2.3 million, respectively, including amortization of deferred financing costs of $67,000 and $142,000, respectively.

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

	June 30, 2017
Convertible Senior Notes due 2020	$ 250,000
Senior Secured Notes due 2018	25,756
	275,756
Less: Debt issuance costs	(1,638)
Less: Discount on convertible senior notes	(29,334)
	244,784
Less: Current portion	(24,601)
Long-term debt, net of current portion	$ 220,183
Future estimated payments on the Senior Secured Notes as of June 30, 2017 are as follows:	
2017 (remaining 6 months)	$ 15,625
2018	32,580
Total	48,205
Less: Interest portion	(22,449)
Senior Secured Notes	$ 25,756

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 significantly reduce or remove the requirements of the CVOT. To date, the Company has not incurred expenses related to the CVOT.

14. NET INCOME (LOSS) PER SHARE

The Company computes basic net income (loss) per share applicable to common stockholders based on the weighted average number of common shares outstanding during the applicable period. Diluted net income per share is based on the weighted average number of common and common equivalent shares, which represent shares that may be issued in the future upon the exercise of outstanding stock options or upon a net share settlement of the Company's Convertible Notes. Common share equivalents are excluded from the computation in periods in which they have an anti-dilutive effect. Stock options for which the price exceeds the average market price over the period have an anti-dilutive effect on net income per share and, accordingly, are excluded from the calculation. The triggering conversion conditions that allow holders of the Convertible Notes to convert have not been met. If such conditions are met and the note holders opt to convert, the Company may choose to pay in cash, common stock, or a combination thereof; however, if this occurs, the Company has the intent and ability to net share settle this debt security; thus the Company uses the treasury stock method for earnings per share purposes. Due to the effect of the capped call instrument purchased in relation to the Convertible Notes, there would be no net shares issued until the market value of the Company's stock exceeds $20 per share, and thus no impact on diluted net income per share.

Further, when there is a net loss, potentially dilutive common equivalent shares are not included in the calculation of net loss per share since their inclusion would be anti-dilutive.

As the Company recognized a net loss for each of the three and six month periods ended June 30, 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 13,992,000 and 13,301,000, respectively for the three and six months ended June 30, 2017 and were 11,448,000 and 10,939,000, respectively, for the three and six months ended June 30, 2016.

15. INCOME TAXES

For the three and six months ended June 30, 2017, the Company recorded a provision of $1,000 and a benefit of $11,000, respectively. For the three and six months ended June 30, 2016, the Company recorded a provision for taxes of $7,000 and $23,000, respectively. 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 June 30, 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 June 30, 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 $78,000. The Company does not expect to have any other significant changes to unrecognized tax benefits through the end of the fiscal year. Because of the Company's 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 indicated that it has set the matter for consideration in October 2017. 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 June 29, 2017, the Company entered into a settlement agreement with Actavis resolving the suit against Actavis. On July 5, 2017, the U.S. District Court for the District of New Jersey entered an order dismissing the suit. In accordance with legal requirements, we have submitted the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

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, now owned by Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc., collectively referred to as DRL, 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, DRL was 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 settlement agreement with Actavis did not resolve the litigation against DRL. Expert discovery is ongoing in that suit and a final pretrial conference is scheduled for August 8, 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 June 30,					
	2017			2016		
	U.S.	ROW	Total	U.S.	ROW	Total
Qsymia—Net product revenue	$ 8,518	$ —	$ 8,518	$ 12,749	$ —	$ 12,749
Qsymia—License revenue	—	—	—	—	—	—
STENDRA/SPEDRA—Supply revenue	—	2,119	2,119	—	—	—
STENDRA/SPEDRA —Royalty revenue	—	590	590	398	629	1,027
Total revenue	$ 8,518	$ 2,709 (1)	$ 11,227	$ 13,147	$ 629 (2)	$ 13,776

	Six Months Ended June 30,					
	2017			2016		
	U.S.	ROW	Total	U.S.	ROW	Total
Qsymia—Net product revenue	$ 26,138	$ —	$ 26,138	$ 25,161	$ —	$ 25,161
Qsymia—License and milestone revenue	5,000	—	5,000	—	—	—
STENDRA/SPEDRA—Supply revenue	3,775	2,156	5,931	—	1,526	1,526
STENDRA/SPEDRA —Royalty revenue	—	1,170	1,170	1,224	1,189	2,413
Total revenue	$ 34,913	$ 3,326 (3)	$ 38,239	$ 26,385	$ 2,715 (4)	$ 29,100

(1) $2.7 million of which was attributable to Germany.

(2) $0.6 million of which was attributable to Germany.

(3) $3.3 million of which was attributable to Germany.

(4) $2.7 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® (phentermine and topiramate extended release) capsules 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 continue to 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 FDA to significantly reduce or remove the requirements of the clinical post-approval cardiovascular outcomes trial, or CVOT;
- our 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, or our potential partners', 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® (avanafil) 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 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 successfully develop or acquire a proprietary formulation of tacrolimus as a precursor to the clinical development process;
- 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 develop a proprietary formulation and to demonstrate through clinical testing the quality, safety, and efficacy of our current or future investigational drug candidates;
- the timing of initiation and completion of clinical trials and submissions to U.S. and 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 and six months ended June 30, 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 for erectile dysfunction, or ED, by FDA and by the EC under the trade name SPEDRA in the EU. Tacrolimus is in active clinical development for the treatment of pulmonary arterial hypertension, or PAH.

Commercial Products

Qsymia

FDA approved Qsymia 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. 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 digital 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 or 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 CV and epidemiology experts in exploring alternate solutions to demonstrate the long-term CV 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. 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 significantly reduce or remove the requirements of the CVOT. 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. 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.

In June 2017, we entered into a settlement agreement with Actavis Laboratories FL, Inc., or Actavis, resolving patent litigation related to Qsymia. The litigation resulted from the submission by Actavis of an Abbreviated New Drug Application to the U.S. Food and Drug Administration seeking approval to market generic versions of Qsymia. The settlement agreement permits Actavis to begin selling a generic version of Qsymia on December 1, 2024, or earlier under certain circumstances. In the event of a launch earlier than December 1, 2024, we will receive a royalty on sales of the generic version of Qsymia.

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. FDA approved STENDRA 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 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 31 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 September 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 Commonwealth of Independent States, or CIS, including Russia, or the Sanofi Territory. Sanofi was responsible for obtaining regulatory approval in its territories. 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. 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 endothelin receptor antagonists, PDE5 inhibitors, prostacyclin analogues, selective prostaglandin I2 receptor agonists, and soluble guanate cyclase 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 bone morphogenetic protein receptor type 2, or 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 occurs two to four 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 are focusing on the development of a proprietary formulation of tacrolimus to be used in a clinical development program and for commercial use.

Business Strategy Review

In 2016, 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, followed by the in-licensing of tacrolimus and ascomycin from Selten, as discussed above. We will continue this process to evaluate strategies for maximizing our current assets as well as to evaluate development and commercial 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 six months ended June 30, 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 June 30, 2017	2016	% Change Increase/ (Decrease) 2017 vs 2016	Six Months Ended June 30, 2017	2016	% Change Increase/ (Decrease) 2017 vs 2016
Revenue:						
Net product revenue	$ 8,518	$ 12,749	(33)%	$ 26,138	$ 25,161	4 %
License and milestone revenue	—	—	N/A	5,000	—	N/A
Supply revenue	2,119	—	N/A	5,931	1,526	289 %
Royalty revenue	590	1,027	(43)%	1,170	2,413	(52)%
Total revenue	$ 11,227	$ 13,776	(19)%	$ 38,239	$ 29,100	31 %

Net product revenue

Net product revenue for 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 six months ended June 30, 2017 includes a one-time adjustment of $7.3 million related to shipments which had previously been deferred. For the three and six months ended June 30, 2017, there were approximately 105,000 and 207,000 Qsymia prescriptions dispensed, respectively and, for the three and six months ended June 30, 2016, there were approximately 116,000 and 232,000 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 three and six months ended June 30, 2017, we shipped approximately 83,000 units and 173,000 units, respectively, 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 decrease from 2016 levels due to market conditions.

License and milestone revenue

License and milestone revenue for the six months ended June 30, 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 June 30, 2017 or for the three and six months ended June 30, 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

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

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 of STENDRA in the U.S.

Cost of goods sold

	Three Months Ended June 30,		% Change Increase/ (Decrease)	Six Months Ended June 30,		% Change Increase/ (Decrease)
	2017	2016	2017 vs 2016	2017	2016	2017 vs 2016
	(In thousands, except percentages)			(In thousands, except percentages)		
Qsymia cost of goods sold	$ 1,581	$ 1,934	(18)%	$ 4,246	$ 4,005	6 %
STENDRA/SPEDRA cost of goods sold	1,989	713	179 %	5,491	2,346	134 %
Total cost of goods sold	$ 3,570	$ 2,647	35 %	$ 9,737	$ 6,351	53 %

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 three and six months ended June 30, 2017 as compared to the same periods in 2016 due primarily to increased STENDRA/SPEDRA supply revenue in 2017.

Selling, general and administrative expense

	Three Months Ended June 30,		% Change Increase/ (Decrease)	Six Months Ended June 30,		% Change Increase/ (Decrease)
	2017	2016	2017 vs 2016	2017	2016	2017 vs 2016
	(In thousands, except percentages)			(In thousands, except percentages)		
Selling and marketing	$ 5,398	$ 5,951	(9)%	$ 10,858	$ 13,599	(20)%
General and administrative	6,232	7,741	(19)%	12,203	15,215	(20)%
Total selling, general and administrative expenses	$ 11,630	$ 13,692	(15)%	$ 23,061	$ 28,814	(20)%

The decrease in selling and marketing expenses for the three and six months ended June 30, 2017, compared to the same periods in 2016, was due primarily to the cost saving efforts to reduce marketing programs and lower promotional activities for Qsymia. Selling and marketing expenses are expected to decrease in the second half of 2017 as compared to the first half of 2017.

The decrease in general and administrative expenses in the three and six months ended June 30, 2017 compared to the same periods in 2016 was primarily due to the results of our continuing efforts to cut costs and lower spending for corporate activities. General and administrative expenses could fluctuate significantly due to the timing of activities within our business strategy review.

Research and development expense

Drug Indication/Description	Three Months Ended June 30, 2017	2016	% Change Increase/(Decrease) 2017 vs 2016	Six Months Ended June 30, 2017	2016	% Change Increase/(Decrease) 2017 vs 2016
	(In thousands, except percentages)			(In thousands, except percentages)		
Qsymia for obesity	$ —	$ —	N/A	$ —	$ 186	(100)%
STENDRA for ED	99	85	16 %	101	63	60 %
PAH	200	—	N/A	1,385	—	N/A
Share-based compensation	87	171	(49)%	172	138	25 %
Overhead costs*	628	840	(25)%	1,536	1,738	(12)%
Total research and development expenses	$ 1,014	$ 1,096	(7)%	$ 3,194	$ 2,125	50 %

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

The decrease in total research and development expenses in the three months ended June 30, 2017 as compared to the same period in 2016 was primarily due to lower overhead costs as a result of our efforts to reduce discretionary spending and share-based compensation expense, partially offset by increases in spending for the development of tacrolimus for the treatment of PAH. The increase in total research and development expenses in the six months ended June 30, 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 increase development activities for 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 and six months ended June 30, 2017 was $8.4 million and $16.7 million, respectively, compared to $7.7 million and $15.9 million, respectively, for the same periods in 2016. 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) for the remainder of 2017 to remain relatively consistent with the levels from the first half of 2017.

(Benefit from) provision for income taxes

For the three and six months ended June 30, 2017, we recorded a provision of $1,000 and a benefit of $11,000, respectively, compared to a provision for income taxes of $7,000 and $23,000, respectively, for the three and six months ended June 30, 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 June 30, 2017.

LIQUIDITY AND CAPITAL RESOURCES

Cash. Cash, cash equivalents and available-for-sale securities totaled $251.5 million at June 30, 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. From time to time, the Company may also invest its cash to retire or purchase its outstanding debt in open market purchases, privately negotiated transactions or otherwise. 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 June 30, 2017, was $8.4 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

	Six Months Ended June 30,	
	2017	2016
	(in thousands)	
Cash provided by (used for):		
Operating activities	$ (11,288)	$ (17,335)
Investing activities	9,392	8,630
Financing activities	(6,481)	(4,145)

Operating Activities. For the six months ended June 30, 2017, cash used for operating activities resulted from our net loss as adjusted for non-cash items, including the decrease in deferred revenue. This was partially offset by decreases in accounts receivable and prepaid expenses and increases in accrued liabilities. For the six months ended June 30, 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 six months ended June 30, 2017 and 2016 primarily related to our repayments of $6.5 million and $4.2 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 June 30, 2017.

Contractual Obligations

During the six months ended June 30, 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, and as amended by the Form 10-K/A filed on April 26, 2017 with the SEC, 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 June 30, 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 June 30, 2017, by approximately $1.9 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 INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Shareholder Lawsuit

On March 27, 2014, Mary Jane and Thomas Jasin, who purport to be purchasers of VIVUS common stock, filed an Amended Complaint in Santa Clara County Superior Court alleging securities fraud against the Company and three of its former officers and directors. In that complaint, captioned *Jasin v. VIVUS, Inc.*, Case No. 114-cv-261427, plaintiffs asserted claims under California's securities and consumer protection securities statutes. Plaintiffs alleged generally that defendants misrepresented the prospects for the Company's success, including with respect to the launch of Qsymia, while purportedly selling VIVUS stock for personal profit. Plaintiffs alleged losses of "at least" $2.8 million, and sought damages and other relief. On 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 indicated that it has set the matter for consideration in October 2017. 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 June 29, 2017, the Company entered into a settlement agreement with Actavis resolving the suit against Actavis. On July 5, 2017, the U.S. District Court for the District of New Jersey entered an order dismissing the suit. In accordance with legal requirements, we have submitted the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

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, now owned by Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc., collectively referred to as DRL, 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, DRL was 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 settlement agreement with Actavis did not resolve the litigation against DRL. Expert discovery is ongoing in that suit and a final pretrial conference is scheduled for August 8, 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:

- successfully develop or acquire a proprietary formulation of tacrolimus as a precursor to the clinical development process;
- 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 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. In 2016, we initiated a business strategy review with an outside advisor. 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.

We rely on our collaboration partners, including MTPC, Menarini and Metuchen, to successfully commercialize STENDRA/SPEDRA in their respective territories, including obtaining any necessary approvals and we cannot assure you that they will be successful. Our dependence on our collaborative arrangements for the commercialization of STENDRA/SPEDRA, including our license agreements with MTPC, Menarini and Metuchen, 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 the 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 territories 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, in September 2016, Auxilium terminated its agreement with us to commercialize STENDRA in the U.S. and Canada and, in March 2017, Sanofi terminated its agreement with us to commercialize STENDRA/SPEDRA in Africa, the Middle East, Turkey, and the CIS, including Russia.

In addition, under our license agreement with MTPC, we are obligated to ensure that Menarini, Metuchen, and any future sublicensees comply with the terms and conditions of our license agreement with MTPC, and MTPC

has the right to terminate our license rights to avanafil upon any uncured material breach. Consequently, failure by Menarini, Metuchen, or any future sublicensees to comply with these terms and conditions could result in the termination of our license rights to avanafil on a worldwide basis, which would delay, impair, or preclude our ability to commercialize avanafil.

If any of our collaboration partners fails to successfully commercialize STENDRA/SPEDRA, our business may be negatively affected and we may receive limited or no revenues under our agreements with them.

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, Metuchen 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, Metuchen 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 the then-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 single-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 that will significantly reduce or eliminate the CVOT requirement. 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.

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

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.

On June 29, 2017, the Company entered into a settlement agreement with Actavis resolving the suit against Actavis. On July 5, 2017, the U.S. District Court for the District of New Jersey entered an order dismissing the suit. In accordance with legal requirements, we have submitted the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

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, now owned by DRL, 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 settlement agreement with Actavis did not resolve the litigation against DRL. Expert discovery is ongoing in that suit and a final pretrial conference is scheduled for August 8, 2017. No trial date has been scheduled.

The actual timing of any commercial launch of a generic version of Qsymia is uncertain. The settlement agreement with Actavis will permit Actavis to begin selling a generic version of Qsymia on December 1, 2024, or earlier under certain circumstances, but we cannot predict the timing or outcome of the ANDA litigation proceedings against the remaining non-settling ANDA filer. It is possible that one or more companies that receives FDA approval of an ANDA for a generic version of Qsymia could introduce a generic version of Qsymia before the entry dates specified in our settlement agreement with Actavis or before our patents expire, including if it is determined that the generic product does not infringe our patents, or that our patents are invalid or unenforceable. 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. If a generic version of Qsymia is introduced, 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 June 30, 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 June 30, 2017, we had $251.5 million in cash, cash equivalents and available-for-sale securities. While at June 30, 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 June 30, 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 indicated that it has set the matter for consideration in October 2017.

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 $827.5 million as of June 30, 2017, and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of $827.5 million for the period from our inception through June 30, 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
April 2017	1,021	$ 1.03	1,021	
May 2017	21,495	$ 1.03	21,495	
June 2017	1,019	$ 1.17	1,019	
Total	23,535	$ 1.04	23,535	44,884

(a) In the second 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: August 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††	Settlement Agreement dated June 29, 2017, by and between Actavis Laboratories FL, Inc. and the Registrant.
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 June 30, 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 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.

***** 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.**

SETTLEMENT AGREEMENT

This Settlement Agreement (including Exhibits A through C, the "Agreement") is made and entered into effective this 29th day of June, 2017 (the "Effective Date"), by and between, on the one hand, Vivus, Inc. ("Vivus"), and on the other hand, Actavis Laboratories FL, Inc. ("Actavis") (together with Vivus, the "Parties," or each separately, a "Party").

RECITALS

A. WHEREAS Vivus owns U.S. Patent Nos. 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, 8,580,299, 8,895,057, 8,895,058, 9,011,905, and 9,011,906 (collectively, including any divisionals, continuations, continuations-in-part, reexaminations, or reissues thereof, "the Licensed Patents"), which patents cover Qsymia® brand phentermine and topiramate extended-release product, which product Vivus sells in the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico (the "Territory"), under NDA No. 022580 (the "Vivus NDA");

B. WHEREAS Actavis has sought approval from the U.S. Food and Drug Administration ("FDA") to market a generic phentermine and topiramate extended-release product as defined by ANDA No. 204982 (including all amendments, supplements or Replacements thereto as may be required by the FDA in order to obtain FDA approval thereof, the "Actavis ANDA") as of the Effective Date (hereinafter, the "Actavis Generic Product").

C. WHEREAS an action for patent infringement is pending in the United States District Court for the District of New Jersey (the "Court") regarding the Actavis ANDA and the proposed generic product defined therein, captioned *Vivus, Inc. v. Actavis Laboratories FL, Inc.*, Civil Action No. 14-3786 (SRC)(CLW) (consolidated) (the "Action");

D. WHEREAS, subject to the terms and conditions herein, Vivus has agreed to grant Actavis a non-exclusive license to manufacture and distribute the Actavis Generic Product in the Territory as of the date, and upon the terms, set forth in the License Agreement, as defined and referred to in Section 2 of this Agreement; and

E. WHEREAS the Parties are willing to settle the Action on the terms set forth herein.

NOW THEREFORE, in consideration of the promises and mutual covenants set forth herein, the sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. Stipulation and Order of Dismissal.

In consideration of the mutual benefits of entering into this Agreement, the Parties shall enter into and cause to be filed with the Court, within *** of the Effective Date, a stipulation and order of dismissal substantially in the form annexed hereto as Exhibit A (the "Stipulation and

Order of Dismissal"). If the Court does not grant the Stipulation and Order of Dismissal substantially in the form annexed hereto as Exhibit A, the Parties agree to confer in good faith and revise that document consistent with the terms of this Agreement and the License Agreement and the requirements of the Court.

2. License Agreement.

Contemporaneously with the execution of this Agreement, Vivus and Actavis shall enter into a non-exclusive license agreement in the form annexed hereto as Exhibit B (the "License Agreement"). The definitions set forth in the License Agreement shall apply to this Settlement Agreement and the definitions set forth in this Settlement Agreement shall apply to the License Agreement.

3. Legal Fees.

Consistent with the Stipulation and Order of Dismissal, each Party shall pay its own costs and expenses, including attorney fees, incurred in connection with the Action and in connection with the preparation, execution and performance of this Agreement.

4. Legal Compliance.

The Parties shall submit this Agreement, the License Agreement, and the Stipulation and Order of Dismissal (the "Settlement Documents") to the appropriate personnel at the U.S. Federal Trade Commission ("FTC") and the Antitrust Division of the U.S. Department of Justice (the "DOJ") as soon as practicable after the Effective Date and in no event later than *** after the Effective Date.

5. Released Claims.

In addition to the dismissal of the Action, as set forth in the Stipulation and Order of Dismissal, Actavis and Vivus make the following releases, which shall be effective upon the entry of the Stipulation and Order of Dismissal by the Court in the Action.

(a) Actavis for itself and its Affiliates hereby releases and discharges Vivus and its Affiliates, successors, assigns, directors, officers, employees, agents and customers from all causes of action, demands, claims, damages and liabilities of any nature, whether known or unknown, arising from or in connection with the Action or the Actavis ANDA, occurring prior to the Effective Date of this Agreement, including, without limitation, all claims that Actavis has asserted or could have asserted in the Action or in any judicial, U.S. Patent and Trademark Office ("USPTO"), or other legal or administrative proceeding that any or all of the Licensed Patents are invalid or not infringed by the filing of the Actavis ANDA and/or Actavis'

manufacture, sale, offer for sale or importation of the Actavis Generic Product in the Territory (all of the above collectively, "Actavis' Released Claims"). Actavis' Released Claims do not preclude Actavis from: (i) maintaining and/or (*e.g* in the case of a Replacement ANDA or a recertification pursuant to 21 C.F.R.§ 314.96(d)) filing Paragraph IV certifications with respect the Actavis ANDA against the Licensed Patents, (ii) amending the Paragraph IV Certification in the Actavis ANDA to include any patents that may be listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) for Qsymia after the Effective Date of this Settlement Agreement, (iii) challenging the validity, enforceability and/or infringement of the Licensed Patents in connection with another ANDA or ANDA product referencing an NDA other than the Vivus NDA and owned or sold by Actavis (iv) in the event Vivus or its Affiliates initiate suit against Actavis or its Affiliates alleging that an ANDA or product referencing an NDA other than the Vivus NDA infringes the Licensed Patents, then Actavis or its Affiliates may seek reexamination, inter partes review, or any other post-grant review of the Licensed Patents.

(b) Vivus for itself and its Affiliates hereby releases and discharges Actavis and its Affiliates, successors, assigns, directors, officers, employees, agents, distributors, suppliers, manufacturers, customers, and all other individuals or entities involved or affiliated with the manufacturing, distribution, marketing, and consumption of the Actavis Generic Product from all causes of action, demands, claims, damages, and liabilities of any nature, whether known or unknown, arising from or in connection with the Action or the Actavis ANDA, occurring prior to the Effective Date of this Agreement, including, without limitation, all claims that Vivus has asserted or could have asserted in the Action or in any judicial or administrative proceeding that any or all of the Licensed Patents, or any reissue or reexamination thereof, is or would be infringed by the filing of the Actavis ANDA and/or Actavis' manufacture, sale, offer for sale or importation of the Actavis Generic Product in the Territory (all of the above collectively, "Vivus' Released Claims"). Vivus' Released Claims do not preclude Vivus from asserting any or all of the Licensed Patents against: (i) any ANDA or ANDAs other than the Actavis ANDA and/or against any product or products other than the Actavis Generic Product; or (ii) any Actavis product other than the Actavis Generic Product.

(c) Subject to Actavis' compliance with the terms of this Settlement Agreement and the terms of the License Agreement, Vivus, on behalf of itself and its Affiliates, covenants to Actavis that it will not sue, assert any claim or counterclaim against, otherwise participate in any action or proceeding against Actavis and its Affiliates or any of its licensees, sublicensees, customers, successors, or assigns of the foregoing, or cause, assist, or authorize any person or entity to do any of the foregoing, in each case claiming or otherwise asserting that the Actavis ANDA or the Actavis Generic Product or the manufacture, use, sale, offer for sale, or importation of the Actavis Generic Product, in or for the Territory infringes the Licensed Patents or any other patents or patent applications owned, controlled by or licensed to Vivus that cover

the Actavis Generic Product or Qsymia® ("Vivus Covenant Not to Sue"). Vivus shall impose the Vivus Covenant Not to Sue on any Third Party to which Vivus or any of its Affiliates may after the Effective Date assign, license or otherwise transfer or grant any rights under Licensed Patents.

(d) Subject to Vivus' compliance with the terms of this Settlement Agreement and the terms of the License Agreement, and solely with respect to the Actavis ANDA and the Actavis Generic Product Actavis, on behalf of itself and its Affiliates, covenants to Vivus that it will not sue, assert any claim or counterclaim against, otherwise participate in any action or in any judicial, USPTO, or other legal proceeding against Vivus, its Affiliates or any of its licensees, sublicensees, customers, successors, or assigns of the foregoing, or cause, assist, or authorize any person or entity to do any of the foregoing, in each case claiming or otherwise asserting that any or all of the Licensed Patents or any other U.S. patents or patent applications that cover Qsymia® or could otherwise be asserted against the Actavis Generic Product owned, licensed or controlled by Vivus are invalid or that the Actavis ANDA or the Actavis Generic Product or the manufacture, use, sale, offer for sale, or importation of the Actavis Generic Product, in or for the Territory does or would not infringe valid claims of all of the Licensed Patents or any other U.S. patents or patent applications that cover Qsymia® or could otherwise be asserted against the Actavis Generic Product owned, licensed or controlled by Vivus or its Affiliates either now or in the future ("Actavis Covenant Not to Sue"). Actavis shall impose the Actavis Covenant Not to Sue on any Third Party to which Actavis or any of its Affiliates may after the Effective Date assign, license or otherwise transfer or grant any rights under Actavis ANDA.

(e) Subject to Actavis' compliance with the terms of this Settlement Agreement and the terms of the License Agreement, Vivus, on behalf of itself and its Affiliates, covenants that, on or prior to the *** after the Launch Date, as defined in the License Agreement, neither Vivus nor any of its Affiliates will *** in the Vivus NDA in the Territory other than *** as of the Effective Date.

(f) Subject to Actavis' compliance with the terms of this Settlement Agreement and the terms of the License Agreement, and except as provided below, Vivus, on behalf of itself and its Affiliates, covenants that neither Vivus nor any of its Affiliates shall *** to: (1) ***; or (2) ***. Vivus and its Affiliates further agree ***: (1) ***; (2) ***; (3) *** for the NDA Product prior to the launch of the Actavis Generic Product in the Territory; (4) *** after the launch of the Actavis Generic Product in the Territory; or (5) *** after launch of the Actavis Generic Product in the Territory, unless required by the FDA. In addition, Vivus and its Affiliates hereby waive any and all regulatory exclusivities that may inhibit the Marketing of the Actavis Generic Product in the Territory as of the Launch Date, and will, in response to a request from FDA or a commercially reasonable request from Actavis to enable compliance with applicable Laws, submit appropriate and reasonable documentation to FDA to assist Actavis in effectuating the

license grants, waivers and covenants contained in the Settlement Agreement and the License Agreement. Nothing in this Settlement Agreement shall be construed as preventing Vivus or any of its Affiliates from assisting or cooperating with any Third Party, or from itself initiating or participating in, any activity (including but not limited to the ***.

(g) Subject to Actavis' compliance with the terms of this Settlement Agreement and the terms of the License Agreement, Vivus, on behalf of itself and its Affiliates, agrees that in the *** prior to the *** Launch Date, upon request from Actavis, Vivus will provide written notice to Actavis within *** after each time either: (1) Vivus makes a formal submission to FDA seeking a change in the label for the NDA Product, including any specific labeling amendments or supplements to the Vivus NDA; or (2) FDA either implements such changes or communicates to Vivus a directive to make a change to the label for the NDA Product. In each case such notice shall include the text of the proposed or directed label change.

(h) This Agreement shall constitute a final settlement of the Action between the Parties in the Territory, and, Actavis shall not assist or cooperate with any party in any litigation before a court, or in any Inter Partes review, Covered Business Method review, Post-Grant review, or any other proceeding before the USPTO against Vivus involving any of the Licensed Patents, unless so ordered by the Court or compelled by Law or regulation.

(i) Vivus acknowledges that Actavis is *** with respect to ***.

(j) The Parties, and agents and consultants under their control, shall continue to maintain the confidentiality of any non-public information exchanged between them in the Action to the extent required by the terms of the Discovery Confidentiality Order in the Action or District of New Jersey Local Rule 5.3(b), or any other applicable confidentiality restriction, unless so ordered by the Court or compelled by Law or regulation.

(k) Actavis shall *** in any litigation before a court, or Inter Partes review, Covered Business Method review, Post-Grant review, or any other proceeding before the USPTO against Vivus with respect to a phentermine and topiramate extended-release product or the Licensed Patents.

6. ACKNOWLEDGMENTS.

Actavis and Vivus acknowledge as follows:

(a) ACTAVIS ACKNOWLEDGES THAT IT MAY HEREAFTER DISCOVER CLAIMS OR FACTS IN ADDITION TO OR DIFFERENT FROM THOSE WHICH IT NOW KNOWS OR BELIEVES TO EXIST WITH RESPECT TO ACTAVIS' RELEASED CLAIMS, THE FACTS AND CIRCUMSTANCES ALLEGED IN THE ACTION

AND/OR THE SUBJECT MATTER OF THIS AGREEMENT, WHICH, IF KNOWN OR SUSPECTED AT THE TIME OF EXECUTING THIS AGREEMENT, MAY HAVE MATERIALLY AFFECTED THIS AGREEMENT. NEVERTHELESS, UPON THE EFFECTIVENESS OF THE RELEASE OF ACTAVIS' RELEASED CLAIMS AS SET FORTH IN SECTION 5 ABOVE, ACTAVIS HEREBY ACKNOWLEDGES THAT ACTAVIS' RELEASED CLAIMS INCLUDE WAIVERS OF ANY RIGHTS, CLAIMS OR CAUSES OF ACTION THAT MIGHT ARISE AS A RESULT OF SUCH DIFFERENT OR ADDITIONAL CLAIMS OR FACTS. ACTAVIS ACKNOWLEDGES THAT IT UNDERSTANDS THE SIGNIFICANCE AND POTENTIAL CONSEQUENCES OF SUCH A RELEASE OF UNKNOWN UNITED STATES JURISDICTION CLAIMS AND OF SUCH A SPECIFIC WAIVER OF RIGHTS. ACTAVIS INTENDS THAT THE CLAIMS RELEASED BY IT UNDER THIS RELEASE BE CONSTRUED AS BROADLY AS POSSIBLE TO THE EXTENT THEY RELATE TO UNITED STATES JURISDICTION CLAIMS. ACTAVIS IS AWARE OF CALIFORNIA CIVIL CODE SECTION 1542, WHICH PROVIDES AS FOLLOWS:

> "A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her, must have materially affected his or her settlement with the debtor."

ACTAVIS AGREES TO EXPRESSLY WAIVE ANY RIGHTS IT MAY HAVE UNDER THIS CODE SECTION OR UNDER FEDERAL, STATE OR COMMON LAW STATUTES OR JUDICIAL DECISIONS OF A SIMILAR NATURE, AND KNOWINGLY AND VOLUNTARILY WAIVES SUCH UNKNOWN CLAIMS.

(b) VIVUS ACKNOWLEDGES THAT IT MAY HEREAFTER DISCOVER CLAIMS OR FACTS IN ADDITION TO OR DIFFERENT FROM THOSE WHICH IT NOW KNOWS OR BELIEVES TO EXIST WITH RESPECT TO VIVUS' RELEASED CLAIMS, THE FACTS AND CIRCUMSTANCES ALLEGED IN THE ACTION AND/OR THE SUBJECT MATTER OF THIS AGREEMENT, WHICH, IF KNOWN OR SUSPECTED AT THE TIME OF EXECUTING THIS AGREEMENT, MAY HAVE MATERIALLY AFFECTED THIS AGREEMENT. NEVERTHELESS, UPON THE EFFECTIVENESS OF THE RELEASE OF VIVUS' RELEASED CLAIMS AS SET FORTH IN SECTION 5 ABOVE, VIVUS HEREBY ACKNOWLEDGES THAT VIVUS' RELEASED CLAIMS INCLUDE WAIVERS OF ANY RIGHTS, CLAIMS OR CAUSES OF ACTION THAT MIGHT ARISE AS A RESULT OF SUCH DIFFERENT OR ADDITIONAL CLAIMS OR FACTS. VIVUS ACKNOWLEDGES THAT IT UNDERSTANDS THE SIGNIFICANCE AND POTENTIAL CONSEQUENCES OF SUCH A RELEASE OF UNKNOWN UNITED STATES JURISDICTION CLAIMS AND OF SUCH A SPECIFIC WAIVER OF RIGHTS. VIVUS

INTENDS THAT THE CLAIMS RELEASED BY IT UNDER THIS RELEASE BE CONSTRUED AS BROADLY AS POSSIBLE TO THE EXTENT THEY RELATE TO UNITED STATES JURISDICTION CLAIMS. VIVUS IS AWARE OF CALIFORNIA CIVIL CODE SECTION 1542, WHICH PROVIDES AS FOLLOWS:

> "A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her, must have materially affected his or her settlement with the debtor."

VIVUS AGREES TO EXPRESSLY WAIVE ANY RIGHTS IT MAY HAVE UNDER THIS CODE SECTION OR UNDER FEDERAL, STATE OR COMMON LAW STATUTES OR JUDICIAL DECISIONS OF A SIMILAR NATURE, AND KNOWINGLY AND VOLUNTARILY WAIVES SUCH UNKNOWN CLAIMS.

7. Confidentiality.

The terms of this Agreement shall be maintained in strict confidence by the Parties except: (a) as provided by Section 4 of this Agreement; (b) that Vivus may disclose such terms as may be necessary in connection with any litigation or other legal proceeding relating to any of the Licensed Patents, provided that such disclosure is made subject to a protective order and/or confidentiality agreement; (c) that either Party may disclose such terms, including but not limited to the Launch Date as defined in the License Agreement, if and as required by Law or regulation, including, without limitation, SEC reporting requirements, or by the rules or regulations of any stock exchange to which such party is subject; (d) that either Party may disclose such terms to the extent necessary to allow attorneys, auditors and advisors, who agree to keep such terms confidential, to render professional services to the Parties; (e) that the Parties may each issue a press release disclosing that the Parties have settled the Action, and that Actavis has received a license to the Licensed Patents, that will permit Actavis to commercially launch its Generic Product on the Launch Date, or earlier in certain circumstances, so long as such press release is approved by the other Party, which approval shall not be unreasonably withheld, conditioned, or delayed; and (f) that either Party may disclose such terms as needed to perform under this Agreement and the License Agreement. The Parties acknowledge and agree that, upon its filing with the Court, the Stipulation and Order of Dismissal will be a matter of public record and shall not be subject to any confidentiality restrictions. The Parties further agree that, upon the filing of the Stipulation and Order of Dismissal with the Court, the fact that the Parties have settled the Action will be a matter of public record and shall not be subject to any confidentiality restrictions, but the terms of such settlement shall be maintained in confidence as provided by this Section 7.

8. Term and Termination.

This Agreement shall continue from the Effective Date until the earlier of: (a) the expiration of the last to expire of the Licensed Patents, including any extensions and/or pediatric exclusivities; or (b) the date of a final judgment, from which no appeal has been or can be taken other than a petition to the Supreme Court for a writ of certiorari, that all of the asserted claims of all of the asserted Licensed Patents are invalid and/or unenforceable. The releases and discharges set forth in Section 5 shall survive the termination of this Agreement and the confidentiality obligations set forth in Section 7 shall survive for a period of *** from the Effective Date, notwithstanding any earlier expiration or termination of this Agreement. The License Agreement shall remain in full force and effect pursuant to its own terms notwithstanding the expiration or termination of this Agreement.

9. No Assignment.

This Agreement may not be assigned or transferred to a third party without the express prior written consent of all the other Parties hereto, which consent shall not be unreasonably withheld, conditioned, or delayed, except to a successor to all or substantially all of the business of the assigning or transferring Party to which this Agreement pertains (whether by license or sale of assets, stock, merger, consolidation or otherwise), in which case the Party shall assign this Agreement to such successor, provided that a Party may in the ordinary course of its business assign its rights under this Agreement to an Affiliate or may transfer the rights under this Agreement from one Affiliate to another without the prior consent of the other. The covenants, rights and obligations of a Party under this Agreement shall remain binding upon the transferring Party and shall inure to the benefit of and be binding upon any successor or permitted assignee of the Party, any assignee of the Actavis ANDA, and any assignee of any of the Licensed Patents.

10. Notice.

Any notice required or permitted to be given or sent under this Agreement shall be hand delivered or sent by express delivery service or certified or registered mail, postage prepaid, to the Parties at the addresses indicated below.

If to Vivus, to:

Vivus, Inc.
900 E. Hamilton Ave.
Suite 550
Campbell, CA 95008
Attn: General Counsel

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with a copy to:

Nick Cerrito
Quinn Emanuel Urquhart & Sullivan, LLP
51 Madison Avenue
22nd Floor
New York, NY 10010

If to Actavis, to:

Staci L. Julie
SVP and Chief IP Counsel
Teva Pharmaceuticals USA, Inc.
425 Privet Rd.
Hosham, PA 19044

with a copy to:

Jay P. Lefkowitz
Kirkland & Ellis LLP
601 Lexington Avenue
New York, NY 10022
Fax: (212) 446-4900

Any such notice shall be deemed to have been received on the date actually received. Either Party may change its address by giving the other Party written notice, delivered in accordance with this Section.

11. Entire Agreement.

This Agreement, as defined herein to include Exhibits A through C, constitutes the complete, final and exclusive agreement between the Parties with respect to the subject matter hereof and supersedes and terminates any prior or contemporaneous agreements and/or understandings between the Parties, whether oral or in writing, relating to such subject matter. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement. No subsequent alteration, amendment, change, waiver or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of

each Party. Each Party in deciding to execute this Agreement has retained counsel and has not relied on any understanding, agreement, representation or promise by the other Party that is not explicitly set forth herein.

12. Governing Law.

This Agreement shall be governed, interpreted and construed in accordance with the laws of the State of New Jersey, without giving effect to choice of law principles. The Parties irrevocably agree that the United States District Court for the District of New Jersey shall have exclusive jurisdiction to deal with any disputes arising out of or in connection with this Agreement and that, accordingly, any such proceedings arising out of or in connection with this Agreement shall be brought in the United States District Court for the District of New Jersey. Notwithstanding the foregoing, if there is any dispute for which the United States District Court for the District of New Jersey does not have subject matter jurisdiction, the state courts in New Jersey shall have jurisdiction. In connection with any dispute arising out of or in connection with this Agreement, each Party hereby expressly consents and submits to the personal jurisdiction of the federal and state courts in the State of New Jersey.

13. Severability.

If any provision of this Agreement is declared illegal, invalid or unenforceable by a court having competent jurisdiction, it is mutually agreed that this Agreement shall endure except for the part declared invalid or unenforceable by order of such court; provided, however, that in the event that the terms and conditions of this Agreement are materially altered, the Parties will, in good faith, renegotiate the terms and conditions of this Agreement (including Section 5 hereof) to reasonably replace such invalid or unenforceable provisions in light of the intent of this Agreement.

14. Waiver.

Any delay or failure in enforcing a Party's rights under this Agreement, or any acquiescence as to a particular default or other matter, shall not constitute a waiver of such Party's rights to the enforcement of such rights, nor operate to bar the exercise or enforcement thereof at any time or times thereafter, except as to an express written and signed waiver as to a particular matter for a particular period of time.

15. Counterparts.

This Agreement shall become binding when any one or more counterparts hereof, individually or taken together, bears the signatures of each of the Parties hereto. This Agreement may be executed in any number of counterparts (including facsimile or electronic counterparts),

each of which shall be an original as against a Party whose signature appears thereon, but all of which taken together shall constitute one and the same instrument.

16. Representations and Warranties.

The Parties hereby represent and warrant that: (a) they have approved the execution of this Agreement and have authorized and directed the signatory officers below to execute and deliver this Agreement; (b) they each have the full right and power to enter into this Agreement, and there are no other persons or entities whose consent or joinder in this Agreement is necessary to make fully effective those provisions of this Agreement that obligate, burden or bind either of them; (c) when so executed by each Party, this Agreement shall constitute a valid and binding obligation of such Party, enforceable in accordance with its terms; and (d) they have not transferred or assigned or pledged to any third party, whether or not Affiliated, the right to bring, pursue or settle any of the claims, counterclaims or demands made in the Action.

17. Construction.

This Agreement has been jointly negotiated and drafted by the Parties through their respective counsel and no provision shall be construed or interpreted for or against any of the Parties on the basis that such provision, or any other provision, or the Agreement as a whole, was purportedly drafted by the particular Party. All references to an Affiliate or Affiliates in this Agreement shall have the same meaning as set forth in the License Agreement attached as Exhibit B hereto.

18. Headings.

The article and section headings contained in this Settlement Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Settlement Agreement.

* * * * *

IN WITNESS WHEREOF, this Agreement has been executed by the duly authorized representatives of the Parties.

VIVUS, INC.

By: /s/ Mark Oki
Name: Mark Oki
Title: Chief Financial Officer

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IN WITNESS WHEREOF, this Agreement has been executed by the duly authorized representatives of the Parties.

ACTAVIS LABORATORIES FL, INC.

By: /s/ Daniel N. Motto
Name: Daniel N. Motto
Title: SVP, Global Business Development

ACTAVIS LABORATORIES FL, INC.

By: /s/ Colman B. Ragan
Name: Colman B. Ragan
Title: Associate General Counsel, U.S. IP Litigation

EXHIBIT A

Stipulation and Order of Dismissal

***** 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.**

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

VIVUS, INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 14-3786-SRC-CLW
ACTAVIS LABORATORIES FL, INC.,	)	(consolidated)
Defendant.	)	

STIPULATION AND ORDER OF DISMISSAL

Pursuant to Federal Rules of Civil Procedure 41(a)(1)(A)(ii) and 41(c), and by agreement between Plaintiff Vivus, Inc. ("Vivus") and Defendant Actavis Laboratories FL, Inc. ("Actavis," and together with Vivus, the "Parties"), the Parties hereby stipulate and agree that all claims, counterclaims and affirmative defenses asserted by the Parties against each other in the above-captioned action (the "Action") are hereby dismissed without prejudice and without costs, disbursements, or attorneys' fees to any party. It is further stipulated that the U.S. District Court for the District of New Jersey retains jurisdiction to enforce and resolve any disputes related to the Parties' resolution of the Action.

SO STIPULATED:

Dated: _____, 2017

Saul Ewing LLP

Charles M. Lizza
William C. Baton
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Vivus, Inc.

Walsh Pizzi O'Reilly Falanga LLP

Liza M. Walsh
Christine I. Gannon
One Riverfront Plaza, Suite 600
Newark, New Jersey 07102
(973) 757-1100
lwalsh@thewalshfirm.com

Attorneys for Defendant
Actavis Laboratories FL, Inc.

SO ORDERED:

This _____day of _____, 2017

Hon. Stanley R. Chelser, U.S.D.J.

EXHIBIT B

License Agreement

***** 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.**

LICENSE AGREEMENT

This License Agreement (the "License Agreement") is made and entered into this 29th day of June, 2017 ("the Execution Date") by and between, on the one hand, Vivus, Inc. ("Vivus"), and on the other hand, Actavis Laboratories FL, Inc. ("Actavis") (together with Vivus, the "Parties," or each separately, a "Party").

RECITALS:

A. WHEREAS Vivus owns U.S. Patent Nos. 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, 8,580,299, 8,895,057, 8,895,058, 9,011,905, and 9,011,906 (collectively, including any divisionals, continuations, continuations-in-part, reexaminations, or reissues thereof, "the Licensed Patents"), which patents cover Qsymia® brand phentermine and topiramate extended-release product, which product Vivus sells in the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico (the "Territory"), under NDA No. 022580 (the "Vivus NDA");

B. WHEREAS Actavis has sought approval from the U.S. Food and Drug Administration ("FDA") to market the Actavis Generic Product as defined herein;

C. WHEREAS, pursuant to a settlement agreement to which this License Agreement is Exhibit B (the "Settlement Agreement"), executed contemporaneously with this License Agreement, Vivus and Actavis have agreed to settle their disputes in the Action described therein, which relate to the Licensed Patents and Actavis' filing of the Actavis ANDA as defined herein with the FDA; and

D. WHEREAS, as part of such settlement, Vivus and Actavis agreed to enter into this License Agreement, which, as of the date and upon the terms set forth herein, grants Actavis a non-exclusive license to manufacture and/or sell in the Territory the generic phentermine and topiramate extended-release product currently defined by the Actavis ANDA.

NOW THEREFORE, in consideration of the mutual promises and covenants set forth herein, the sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. Definitions.

1.1 "Actavis ANDA" shall mean ANDA No. 204982, including all amendments, supplements and Replacements thereto as may be required by the FDA in order to obtain FDA approval thereof.

1.2 "Actavis *"** means *** (***) of ***.

1.3 "**Actavis ***"** means, with respect to the Actavis Generic Product, (i) ***, inclusive of ***; (ii) *** and (iii) ***, in each case in accordance with GAAP as reflected

in Actavis's or one of its Affiliate's financial statements and as applied on a consistent basis and measured in United States dollars.

1.4 "Actavis Generic Product" shall mean the generic phentermine and topiramate extended-release product described in the Actavis ANDA as of the Execution Date, subject to any amendments, supplements or Replacements to such ANDA as may be required by the FDA in order to obtain FDA approval of such product.

1.5 "Affiliate" shall mean, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock or other equity interest of such entity, or by contract or otherwise. For clarity, a person or other entity shall be deemed an Affiliate only for so long as this definition is satisfied with respect to such person or entity.

1.6 "ANDA" shall mean an Abbreviated New Drug Application.

1.7 "Authorized Generic" shall mean any product that: (a) contains the Compounds as the only active ingredients; (b) is Marketed in the Territory pursuant to NDA No. 022580; and (c) is Marketed in the Territory without the Trademark.

1.8 "Compounds" shall mean phentermine and topiramate extended-release.

1.9 "*"** means *** (i) ***, and (ii) ***.

1.10 "Effective Date" shall mean the date that the Stipulation And Order Of Dismissal is entered by the Court.

1.11 "Extended Unit Sales" means the number of Qsymia units sold as reported in the IMS Data (whether reported monthly or quarterly).

1.12 "FDA" shall mean the U.S. Food and Drug Administration.

1.13 "Final Court Decision" shall mean the issuance of a final decision from a district court from which no appeal has been or can be taken, or a mandate from a court of appeals from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken.

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1.14 "Generic Equivalent" shall mean a pharmaceutical product that has received FDA approval for Marketing in the Territory pursuant to an ANDA or 505(b)(2) filing as an AB-rated equivalent to the NDA Product.

1.15 "GMPs" shall mean the then current good manufacturing practice regulations promulgated by the FDA.

1.16 "Launch Date" shall mean the earliest of:

i. December 1, 2024;

ii. the date of ***;

iii. ***;

iv. *** prior to the ***;

v. the date the ***;

vi. The date on which ***; or

vii. Beginning on ***, the date that is the *** of (a) the first day following the *** of the *** compared to the *** or, (b) the day following the last day of any *** period during which the *** of the *** has ***, in the aggregate, during such ***, where such ***. Notwithstanding the foregoing, if any of *** identified in Section 1.16(vii)(a)-(b) above *** the calendar quarter immediately preceding the *** and including the calendar quarter ending ***, it will be deemed as if ***. For the avoidance of doubt if any *** identified above in Section 1.16(vii)(a)-(b) occurs ***. Notwithstanding the foregoing, *** identified in Section 1.16(vii)(a)-(b) above occur as the result of a ***. For purposes of this subparagraph, a "Force Majeure Event" shall be defined as any of the following: fire, explosion, earthquake, flood, other natural disasters or other acts of God; new acts, regulations, or Laws of any Governmental Entity; war (whether or not declared), acts of terrorism, failure of public utilities or common carriers; inability to obtain material (including shortage of active ingredients from FDA-qualified suppliers); inability to manufacture the NDA Product; Third-Party supply disruptions; or insolvency of any Third-Party manufacturer of the NDA Product. In the event of a Force Majeure Event, Vivus shall notify Actavis and take reasonable steps to mitigate or otherwise remedy the impact of such event.

7.1 "Laws" shall mean all applicable international, supranational, national, federal, state, provincial, regional and local laws, statutes, ordinances, codes, rules, regulations, orders, decrees or other pronouncements of any governmental, administrative or judicial authority in the Territory.

7.2 "License" shall have the meaning assigned to such term in Section 2.1 of this License Agreement.

7.3 "Licensed Patents" shall mean U.S. Patent Nos. 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, 8,580,299, 8,895,057, 8,895,058, 9,011,905, 9,011,906, including any divisionals, continuations, continuations-in-part, reexaminations, or reissues thereof, and all patent term extensions and any pediatric exclusivities applicable to the corresponding NDA Product, in each case whether granted or allowed prior to or after the Execution Date.

7.4 "Manufacture" shall mean to make or have made in accordance with GMPs and the provisions of an ANDA approved by the FDA.

7.5 "Market" shall mean to distribute, import, use, market, sell, and offer to sell, and "Marketing" shall have a corresponding meaning.

7.6 "Net Sales" shall mean, with respect to the Actavis Generic Product sold in the Territory, the aggregate gross sales amount invoiced by Actavis and its Affiliates on an arms-length basis to Third Parties in the Territory, less the following deductions, all determined in accordance with Actavis' standard practices for other pharmaceutical products, consistently applied:

a. cash discounts given by Actavis (and its Affiliates) with respect to sales of the product in the Territory, ***;

b. reasonable *** affecting the product;

c. reasonable ***;

d. reasonable ***, based on sales by Actavis and its Affiliates to any *** or similar programs;

e. reasonable *** for *** and *** to *** on account of *** or ***;

f. any government mandated ***, including, without limitation, *** (as amended or replaced); and

g. other specifically identifiable amounts that have been *** listed above.

For purposes of clarity, *** for the Actavis Generic Product will not be *** shall include the ***, but shall not include ***.

Actavis will not use the *** that would result in *** in this Section 1.22 to the ***.

7.7 "NDA" shall mean New Drug Application.

7.8 "NDA Product" shall mean the product Marketed under the Trademark that contains the Compounds as the only active ingredients and that is approved for Marketing in the Territory pursuant to NDA No. 022580 as of the Execution Date.

7.9 "Replacement" shall mean a new ANDA filing referencing the Vivus NDA that describes a product that is materially identical to the Actavis Generic Product, but assigned a new ANDA number without any new or different active pharmaceutical ingredient(s), and "replaced" shall have a corresponding meaning in the context of an ANDA owned or controlled by Actavis or its Affiliates.

7.10 "Stipulation and Order of Dismissal" shall have the meaning assigned to such term in Section 1 of the Settlement Agreement.

7.11 "Term" shall mean the period from the Execution Date of this License Agreement until the date on which this License Agreement terminates as provided in Section 13.

7.12 "Territory" shall mean the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico.

7.13 "Third Party" shall mean any person or entity other than a Party or its Affiliates.

7.14 "Trademark" shall mean the trademark Qsymia® and any other trademark, service mark, corporate name or logo owned or controlled by Vivus and used in connection with the sale or distribution of a phentermine and topiramate extended-release product pursuant to NDA No. 022580 in the Territory.

7.15 "Wholesaler or API Affiliate" means a subsidiary or Affiliate of a Party whose primary business is wholesale distribution of pharmaceutical products or the production of active pharmaceutical ingredients for incorporation into Third Parties' finished dosage products.

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For clarity, Actavis' Wholesaler or API Affiliates as of the Effective Date are ***. Notwithstanding the foregoing or anything to the contrary in this License Agreement, a Wholesaler Affiliate or API Affiliate shall not be deemed *** for any purposes under this License Agreement.

2. License

2.1 Effective on and after the Launch Date, Vivus hereby grants to Actavis (and to the extent necessary, its suppliers, distributors and customers, as the case may be) a non-exclusive license to the Licensed Patents to the extent it would otherwise be infringed by the Marketing or Manufacture of the Actavis Generic Product in the Territory. Except to the extent of the assignment permitted pursuant to Section 14.2, Actavis shall not have the right to sublicense or assign any of its rights under this license.

2.2 Notwithstanding anything to the contrary contained in Section 2.1, prior to the Launch Date, Actavis may engage in the following *** activities:

(a) Discussions with potential customers to make them aware of the upcoming availability of the Actavis Generic Product from Actavis, starting not earlier than *** Launch Date;

(b) Sales order booking starting not earlier than *** Launch Date;

(c) Import or Manufacture of the Actavis Generic Product in the Territory starting not earlier than *** Launch Date.

2.3 If necessary for Actavis to Market the Actavis Generic Product, Vivus further agrees to *** associated with the NDA Product, under commercially reasonable terms to be negotiated by the Parties in good faith.

3. Limitations On License

3.1 Except to the extent permitted by the License of Section 2.1 and the permitted *** activities of Section 2.2, neither Actavis nor any of its Affiliates, distributors or agents shall under any circumstances Manufacture or Market any Generic Equivalent of the NDA Product in the Territory prior to the expiration of the last to expire of the patents included in the Licensed Patents.

4. Non-Exclusivity

4.1 Except as provided in Section 1.16, the License and rights granted in Sections 2.1 and 2.2 above shall be non-exclusive.

4.2 Consistent with the provisions of Sections 1.16 and 4.1, Vivus specifically reserves the right to license any other party who files or has filed an ANDA referencing the NDA Product to Market a Generic Equivalent of the NDA Product in the Territory (an "ANDA Filer") in settlement of any pending or threatened litigation or other legal proceeding regarding any of the Licensed Patents or otherwise.

4.3 Consistent with the provisions of Section 4.1, Vivus specifically reserves the right to authorize and license any Third Party to Market an Authorized Generic in the Territory, and further specifically reserves the right to Market an Authorized Generic in the Territory itself or through an Affiliate.

5. Effect of Post-Approval FDA Commitments

5.1 Vivus represents and warrants to Actavis that as part of its ***. Vivus further represents and warrants: (i) ***; (ii) that the ***; and (iii) that the *** as ***. Therefore, *** as follows:

(a) If the ***, or may be *** by ***, then the Launch Date will remain December 1, 2024, *** pursuant to Sections 1.16(ii)-(vii) above;

(b) If the ***, and Vivus ***, then the Launch Date will be *** pursuant to Sections 1.16(ii)-(vii) above;

(c) If the *** that the ***, and Vivus ***, then the Launch Date may be *** pursuant to Sections 1.16(ii)-(vii) above:

(i) If ***, then the Launch Date will ***;

(ii) If the ***, is ***, then the Launch Date will ***;

(iii) If the ***, is ***, then the Launch Date will ***;

(iv) If the ***, is ***, then the Launch Date will ***;

(d) If, by ***, then the Launch Date will be ***, *** pursuant to Sections 1.16(ii)-(vii) above;

(e) Vivus may *** the Launch Date to *** of the Actavis Generic Product ***.

5.2 If Vivus *** as set forth in Section 5.1(c) above, Vivus will ***.

6. Royalty

6.1 If the Launch Date is accelerated pursuant to Sections 1.16(ii)-(vii) or Sections 5.1(b)-(e) above, Actavis will pay a Royalty according to the following schedule:

(a) ***;

(a) ***;

(a) ***;

6.2 Within *** after the end of the applicable calendar quarter following the Launch Date, Actavis shall submit to Vivus the Royalty owed pursuant to Section 6.1, if any, along with a royalty report outlining in reasonable detail the ***.

6.3 ***** True-Up**. During the License Term, ***, following the ***, Teva shall perform a "true up" reconciliation within *** after the end of the applicable calendar year (and shall provide Vivus with a written report of such reconciliation) of the deductions outlined in the definition of "Net Sales" and the costs included in "Actavis ***." The reconciliation shall be based on *** for any remaining liabilities incurred related to the product, but not yet paid at the end of the ***. If the foregoing reconciliation report shows either an underpayment or an overpayment between the Parties, the Party owing payment to the other Party shall pay the amount of the difference to the other Party within *** after the date of delivery of such report.

6.4 ***** True-Up**. Within *** of the end of the last calendar year during the Term in which fees are payable to Vivus pursuant to this Section 6, Actavis shall perform a "true-up" reconciliation (and shall provide Vivus with a written report of such reconciliation) of the items comprising deductions from Net Sales and the costs included in "Actavis ***." If the foregoing reconciliation report shows either an underpayment or an overpayment between the Parties, the Party owing payment to the other Party shall pay the amount of the difference to the other Party within *** after the date of delivery of such report.

6.5 To the extent that Vivus disagrees with the calculation of the Royalty made by Actavis under Section 6, Vivus shall have the right, but not the obligation, no more frequently than *** after delivery of the report setting forth such computation, to engage an independent certified public accounting firm of nationally recognized standing which is mutually agreeable to the Parties, such agreement not to be unreasonably withheld,

conditioned or delayed ("General Auditor"), to conduct an audit, ***, of applicable books and records of Actavis and its

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Affiliates solely for the purposes of determining the accuracy of any such Royalty calculation. The General Auditor shall be given access to and shall be permitted to examine such books and records during normal business hours and at such location where such books and records are regularly maintained, upon *** prior written notice by Vivus to Actavis. Prior to any such examination taking place, Actavis may require the General Auditor to enter into a commercially reasonable and customary confidentiality agreement with respect to the information to which the General Auditor is given access. General Auditor shall not disclose to Vivus or any Third Party any information reasonably labeled by Actavis as being confidential customer information regarding pricing or other competitively sensitive proprietary information. Vivus shall provide, without condition or qualification, Actavis with a copy of the report or other summary of findings prepared by such accountants promptly following its receipt of same. If as a result of any inaccuracies set forth in such report, the amount(s) paid to Vivus under Section 6.1 was either deficient or excessive, then Actavis or Vivus, as the case may be, shall pay to the other an amount equal to the deficiency or excess within *** of the receipt of the auditor's report. In the event the General Auditor determines that the subject Royalty calculation is inaccurate, and such inaccuracy represents more than *** of the calculated amount and is in favor of Vivus, Actavis shall pay to Vivus the reasonable and documented fees and expenses of the General Auditor in performing such audit. In the event of any dispute between Vivus and Actavis regarding the findings of any such inspection or audit, the Parties shall initially attempt in good faith to resolve the dispute amicably between themselves, and if the Parties are unable to resolve such dispute within a commercially reasonable period of time, such dispute shall be resolved by an accountant from an internationally recognized independent accounting firm that is mutually agreeable to both of the Parties, and such accountant's determination shall be binding.

7. At Risk Launch

7.1 In the event that a Third Party commences sale of a Generic Equivalent in the Territory without a license or other written authorization from Vivus (an "At Risk Launch") Actavis shall *** by the *** or (ii) the Launch Date (the "Actavis ***"), but only if either (a) *** after such At Risk Launch; or (b) Vivus ***.

7.2 If Vivus ***, then Actavis, upon receipt of written notice from Vivus of such ***.

8. Quality Assurance

8.1 Actavis represents and

warrants to Vivus that all Generic Product Marketed by Actavis will be Manufactured, stored, shipped, handled and Marketed by it and its designees in accordance with GMPs and all applicable Laws, rules and regulations.

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9. Confidentiality

9.1 The terms of this License Agreement shall be maintained in strict confidence by the Parties except: (a) as provided by Section 4 of the Settlement Agreement; (b) that Vivus may disclose such terms as may be necessary in connection with any litigation or other legal proceeding relating to any of the Licensed Patents, provided that such disclosure is made subject to a protective order and/or confidentiality agreement; (c) that either Party may disclose such terms, including but not limited to the Launch Date, if and as required by Law or regulation, including, without limitation, SEC and FDA reporting requirements, or by the rules or regulations of any stock exchange to which such party is subject; (d) that either Party may disclose such terms to the extent necessary to allow attorneys, auditors and advisors, who agree to keep such terms confidential, to render professional services to the Parties; (e) that the Parties may each issue a press release disclosing that the Parties have settled the Action, and that Actavis has received a license to the Licensed Patents, that will permit Actavis to commercially launch its Generic Product on the Launch Date, or earlier in certain circumstances, so long as such press release is approved by the other Party, which approval shall not be unreasonably withheld, conditioned, or delayed; and (f) that either Party may disclose such terms as needed to perform under the Settlement Agreement and this License Agreement. The Parties acknowledge and agree that, upon its filing with the Court, the Stipulation and Order of Dismissal will be a matter of public record and shall not be subject to any confidentiality restrictions. The Parties further agree that, upon the filing of the Stipulation and Order of Dismissal with the Court, the fact that the Parties have settled the Action will be a matter of public record and shall not be subject to any confidentiality restrictions, but the terms of such settlement shall be maintained in confidence as provided by this Section 9.1.

10. General Representations

10.1 Each Party represents and warrants to the other that the execution and delivery by such Party of this License Agreement and the performance of its obligations hereunder have been duly authorized by all necessary corporate action and do not conflict with the terms of any other contract, agreement, arrangement or understanding to which such Party is a party.

10.2 Vivus represents and warrants that it has the right to license the Licensed Patents to Actavis under the terms and conditions set forth in the Settlement Agreement and this License Agreement.

10.3 Vivus represents that, if at any time before or after the Effective Date, Vivus or

any of its Affiliates enters into, or has entered into, any agreement with a Third Party granting such Third Party a license, covenant or other authorization under any of the Licensed Patents to use, sell, offer to sell, make, have made, and/or import a Generic Equivalent in the

Territory having (i) *** set forth in Section 1.16, (ii) any launch date *** pursuant to Sections 1.16(ii)-(vii) or Sections 5.1(b)-(e), or (iii) *** than the respective periods of time set forth in Sections 2.2(a)-(c), then Vivus shall notify Actavis within *** in this License Agreement ***.

10.4 Each Party represents and warrants to the other Party that the grant of the Actavis License pursuant to this License Agreement constitutes the sole consideration being exchanged by or on behalf of the Parties in connection with the Settlement Agreement and no other form of compensation or other accommodation has been made between the Parties.

11. Indemnities; Product Liability; Insurance

11.1 Indemnity by Actavis. Actavis will indemnify and hold harmless Vivus and its Affiliates and their respective officers, directors, employees and agents from and against any loss, damage, liability or expense in connection with any and all actions, suits, claims, demands or prosecutions that may be brought or instituted against Vivus or such other indemnitees by Third Parties (including, without limitation, governmental authorities) based on or relating to: (i) any breach by Actavis of this License Agreement; and/or (ii) any aspect of the Actavis Generic Product that differs from the NDA Product, including, without limitation, any ***. The Parties agree that the foregoing indemnities shall ***.

11.2 Indemnity by Vivus. Vivus will indemnify and hold harmless Actavis and its Affiliates and their respective officers, directors, employees and agents from and against any loss, damage, liability or expense in connection with any and all actions, suits, claims, demands, or prosecutions that may be brought or instituted against Actavis or such other indemnitees by Third Parties (including, without limitation, governmental authorities) based on or relating to any breach by Vivus of this License Agreement.

11.3 Control of Litigation. A Party seeking indemnification hereunder shall provide prompt written notice to the other Party (and, in any event, ***) of the assertion of any claim against such Party as to which indemnity is to be requested hereunder; provided, however, that any delay or failure to provide such notice shall not relieve the indemnifying party of its indemnity obligations unless, and solely to the extent that, such delay or failure to notify materially prejudices the indemnifying party's ability to defend such claims. The indemnifying Party shall have sole control over, and shall assume all expenses with respect to, the defense, settlement, adjustment or compromise of any claim as to which this Section 11 requires it to indemnify the other, provided that: (a) the other Party may, if it so desires, employ counsel at its own

expense to assist in the handling of such claim; and (b) the indemnifying Party shall obtain the prior written approval of the other Party, which shall not be unreasonably withheld, conditioned, or delayed, before entering into any settlement, adjustment or compromise of such claim or ceasing to defend against such claim if, pursuant thereto or as a result thereof: (i)

injunctive or other relief would be imposed upon the other Party; or (ii) would result in an admission of wrongdoing by the other Party.

11.4 Limitation on Representations, Warranties and Indemnification. NEITHER PARTY SHALL BE DEEMED TO MAKE ANY REPRESENTATIONS OR WARRANTIES, WHETHER EXPRESS OR IMPLIED, EXCEPT AS SPECIFICALLY SET FORTH HEREIN. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE HEREBY DISCLAIMED BY EACH PARTY. IN NO EVENT SHALL EITHER PARTY HAVE ANY LIABILITY TO THE OTHER FOR INDIRECT OR OTHER REMOTE MEASURES OF DAMAGES, INCLUDING LOST PROFITS, IN CONNECTION WITH GENERIC PRODUCT SOLD OR DISTRIBUTED BY SUCH PARTY OR OTHERWISE ARISING IN RESPECT OF THIS LICENSE AGREEMENT.

11.5 Certain Rights Unaffected. The Parties acknowledge that nothing set forth in this License Agreement, including, without limitation, the provisions of Section 11.5 shall be deemed to limit or otherwise affect the availability of any rights or remedies arising at law or equity to which Vivus may be entitled as a result of the sale or distribution in the Territory by Actavis or any Affiliate of any Actavis Generic Product prior to the Launch Date or the Actavis At Risk Period. The Parties stipulate and agree that any such sale or distribution in the Territory by Actavis or any Affiliate of any Actavis Generic Product prior to the Launch Date or the Actavis At Risk Period would cause immediate irreparable harm to Vivus for which there would be no adequate remedy in damages or otherwise at law. The parties further stipulate that any such sale or distribution of the Actavis Generic Product by Actavis or any Affiliate prior to the Launch Date or the Actavis At Risk Period will constitute a material breach of this agreement entitling Vivus to injunctive relief against Actavis. For the avoidance of doubt, internal transfers of the Actavis Generic Product between and among Actavis and its Affiliates and Wholesaler Affiliates shall not be deemed "sale or distribution" of the Actavis Generic Product.

12. Trademarks and Trade Names

12.1 Actavis shall have no right to use any of Vivus' names or any Trademark and shall have no rights to any other intellectual property or regulatory exclusivities or approvals held by Vivus or its Affiliates other than to the extent of the License provided by Section 2.1 and activities permitted under Section 2.2.

13. Term and Termination

13.1 Unless earlier terminated in accordance with the terms hereof, the term of this License Agreement (the "Term") shall extend from the Execution Date until the earlier of:

(a) the expiration of the last to expire of the patents included in the Licensed Patents, including any reissue or reexamination thereof; or (b) the date of a Final Court Decision that all of the asserted claims of the Licensed Patents are invalid and/or unenforceable. For the avoidance of doubt, as defined in Section 1.19 of this License Agreement, the Licensed Patents includes all patent term extensions and pediatric exclusivities applicable to the NDA Product corresponding to the Licensed Patents, in each case whether granted or allowed prior to or after the Execution Date, and the Term shall run until the last to expire of such extensions and pediatric exclusivities, whenever granted.

13.2 Each Party may terminate this License Agreement and its obligations hereunder in the event of a material breach by the other Party, which breach remains uncured for *** (in the ***) after written notice is provided to the breaching Party specifying the nature of the breach in reasonable detail and demanding its cure.

13.3 Notwithstanding any other provision of this License Agreement, the Parties acknowledge and agree that the sale of any Actavis Generic Product before the Launch Date or the Actavis At Risk Period by Actavis or any of its Affiliates, distributors, or agents shall constitute an immediate, material breach by Actavis of this License Agreement for which Vivus may elect to terminate this License Agreement without prior notice or an opportunity to cure.

13.4 This License Agreement may be terminated by either Party upon at least *** prior written notice thereof if the other Party makes an assignment for the benefit of creditors, is the subject of proceedings in voluntary or involuntary bankruptcy instituted on behalf of or against such Party, or has a receiver or trustee appointed for all or substantially all of its property, provided that in the case of an involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within *** after the filing thereof.

13.5 Expiration or termination of this License Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or early termination of this License Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this License Agreement prior to termination.

14. Miscellaneous

14.1 **Notice.** Any notice required or permitted to be given or sent under this License Agreement shall be hand delivered or sent by express delivery service or certified or registered

mail, postage prepaid, to the Parties at the addresses indicated below.

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If to Vivus, to:	Vivus, Inc. 900 E. Hamilton Ave. Suite 550 Campbell, CA 95008 Attn: General Counsel
with a copy to:	Nick Cerrito Quinn Emanuel Urquhart & Sullivan, LLP 51 Madison Avenue 22nd Floor New York, New York 10010
If to Actavis, to:	Staci L. Julie SVP and Chief IP Counsel Teva Pharmaceuticals USA, Inc. 425 Privet Rd. Hosham, PA 19044
with a copy to:	Jay P. Lefkowitz Kirkland & Ellis LLP 601 Lexington Avenue New York, NY 10022 Fax: (212) 446-4900

Any such notice shall be deemed to have been received on the date actually received. Either Party may change its address by giving the other Party written notice, delivered in accordance with this Section.

14.2 No Assignment. This License Agreement may not be assigned or transferred to a third party without the express prior written consent of all the other Parties hereto, which consent shall not be unreasonably withheld, conditioned, or delayed, except to a successor to all or substantially all of the business of the assigning or transferring Party to which

this License Agreement pertains (whether by license or sale of assets, stock, merger, consolidation or otherwise), in which case the Party shall assign this License Agreement to such successor, provided that a Party may in the ordinary course of its business assign its rights under this License Agreement to an Affiliate or may transfer the rights under this License Agreement from one Affiliate to another without the prior consent of the other. The covenants, rights and obligations of a Party under this License Agreement shall remain binding upon the transferring Party and shall inure to the benefit of and be binding upon any successor or permitted assignee of the Party, any assignee of the Actavis ANDA, and any assignee of any of the Licensed Patents.

14.3 Amendment. This License Agreement may not be changed, waived, discharged or terminated orally, but only by an instrument in writing signed by the Party against which enforcement of such change, waiver, discharge or termination is sought.

14.4 Superiority of Agreements. The Parties agree that the provisions of this License Agreement, together with any written amendments hereto, supersede and shall prevail over any inconsistent statements or provisions contained in any prior discussions, arrangements or comments between the Parties or in any documents passing between the Parties. Notwithstanding the foregoing, the Settlement Agreement shall be deemed of equal dignity to this License Agreement and this License Agreement shall be construed together with the Settlement Agreement in a consistent manner as reflecting a single intent and purpose.

14.5 Governing Law. This License Agreement shall be governed, interpreted and construed in accordance with the laws of the State of New Jersey, without giving effect to choice of law principles. The Parties irrevocably agree that the United States District Court for the District of New Jersey shall have exclusive jurisdiction to adjudicate any disputes arising out of or in connection with this License Agreement and that, accordingly, any such proceeding arising out of or in connection with this License Agreement shall be brought in the United States District Court for the District of New Jersey. Notwithstanding the foregoing, if there is any dispute for which the federal district court in the State of New Jersey does not have subject matter jurisdiction, the state courts in New Jersey shall have jurisdiction. In connection with any dispute arising out of or in connection with this License Agreement each Party hereby expressly consents and submits to the personal jurisdiction of the state and federal courts located in the State of New Jersey.

14.6 Counterparts. This License Agreement may be executed simultaneously in

several counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

14.7 **Headings.** The Headings of this License Agreement are solely for the convenience of reference and shall not affect its interpretation.

***** 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.**

14.8 Negation of Agency. Nothing contained herein shall be deemed to create any relationship, whether in the nature of agency, joint venture, partnership or otherwise, between Actavis and Vivus. Neither Party shall be authorized to bind or obligate the other Party in any manner.

* * * * *

***** 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.**

IN WITNESS WHEREOF, the undersigned have executed this License Agreement as of the date and year first above written.

VIVUS, INC.

By: /s/ Mark Oki
Name: Mark Oki
Title: Chief Financial Officer

***** 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.**

IN WITNESS WHEREOF, the undersigned have executed this License Agreement as of the date and year first above written.

ACTAVIS LABORATORIES FL, INC.

By: /s/ Daniel N. Motto
Name: Daniel N. Motto
Title: SVP, Global Business Development

ACTAVIS LABORATORIES FL, INC.

By: /s/ Colman B. Ragan
Name: Colman B. Ragan
Title: Associate General Counsel, U.S. IP Litigation

***** 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.**

EXHIBIT C

Draft Language for FDA Side Letter

Dear [FDA],

Pursuant to 21 C.F.R. §314.94(a)(12)(v), Vivus, Inc. together with Actavis Laboratories FL, Inc. (collectively the "Parties") write to inform the United States Food and Drug Administration ("FDA") that the Parties have reached a settlement concerning the following litigation pending in the United States District Court for the District of New Jersey: *Vivus, Inc., v. Actavis Laboratories FL, Inc.*, Civil Action No. 14-3786 (SRC)(CLW) concerning ANDA No. 204982.

The terms of the settlement are confidential. However, provided that Actavis and Vivus abide by the settlement terms, no patent disputes between the Parties would prevent FDA from granting final approval to that ANDA.

Exhibit 31.1

CERTIFICATION

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

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

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

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

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

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

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

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

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

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

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

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

Date: August 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: August 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 June 30, 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: August 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 June 30, 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: August 3, 2017

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