
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

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

For The Quarterly Period Ended September 30, 2013

OR

o 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
(State or other jurisdiction of
incorporation or organization)

94-3136179
(IRS employer
identification number)

**351 East Evelyn Avenue
Mountain View, California**
(Address of principal executive office)

94041
(Zip Code)

(650) 934-5200
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒

Accelerated filer ☐

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

Smaller reporting company ☐

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

At October 28, 2013, 101,704,865 shares of common stock, par value \$.001 per share, were outstanding.

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PART I: FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

VIVUS, INC.

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

	September 30, 2013 (Unaudited)	December 31, 2012 Note 1
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 143,121	\$ 58,605
Available-for-sale securities	203,328	155,981
Accounts receivable, net	6,589	2,778
Inventories	37,918	25,353
Prepaid expenses and other assets	20,680	19,159
Total current assets	411,636	261,876
Property and equipment, net	2,968	1,951
Non-current assets	7,874	287
Total assets	\$ 422,478	\$ 264,114
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 17,730	\$ 25,375
Accrued and other liabilities	21,112	14,680
Deferred revenue	20,147	1,150
Total current liabilities	58,989	41,205
Long term debt	209,642	—
Total liabilities	268,631	41,205
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; \$1.00 par value; 5,000 shares authorized; no shares issued and outstanding	—	—
Common stock; \$.001 par value; 200,000 shares authorized; 101,082 and 100,659 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	101	101
Additional paid-in capital	797,092	708,921
Accumulated other comprehensive income	92	33
Accumulated deficit	(643,438)	(486,146)
Total stockholders' equity	153,847	222,909
Total liabilities and stockholders' equity	\$ 422,478	\$ 264,114

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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenue:				
Net product revenue	\$ 6,379	\$ 41	\$ 16,025	\$ 41
License revenue	21,000	—	21,000	—
Total revenue	27,379	41	37,025	41
Operating expenses:				
Cost of goods sold	741	4	1,703	4
Inventory impairment and commitment fee	—	—	10,225	—
Research and development	8,405	9,300	24,683	24,307
Selling, general and administrative	38,167	31,269	121,666	59,351
Non-recurring charges	20,743	—	24,667	—
Total operating expenses	68,056	40,573	182,944	83,662
Loss from operations	(40,677)	(40,532)	(145,919)	(83,621)
Interest and other expense (income):				
Interest expense	7,674	—	11,786	3
Interest and other (income) expense, net	(5)	(59)	31	(133)
Total interest and other expense (income)	7,669	(59)	11,817	(130)
Loss from continuing operations before income taxes	(48,346)	(40,473)	(157,736)	(83,491)
Provision for income taxes	33	3	46	13
Loss from continuing operations	(48,379)	(40,476)	(157,782)	(83,504)
Income from discontinued operations, net of tax	175	80	490	282
Net loss	\$ (48,204)	\$ (40,396)	\$ (157,292)	\$ (83,222)
Basic and diluted net loss per share:				
Continuing operations	\$ (0.48)	\$ (0.40)	\$ (1.56)	\$ (0.85)
Discontinued operations	0.00	0.00	0.00	0.00
Net loss per share	\$ (0.48)	\$ (0.40)	\$ (1.56)	\$ (0.85)
Shares used in per share computation:				
Basic and diluted	100,904	100,438	100,769	97,505

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net loss	\$ (48,204)	\$ (40,396)	\$ (157,292)	\$ (83,222)
Other comprehensive income:				
Unrealized gain on securities, net of taxes	118	50	59	12
Comprehensive loss	\$ (48,086)	\$ (40,346)	\$ (157,233)	\$ (83,210)

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

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

	Nine Months Ended September 30,	
	2013	2012

Cash flows from operating activities:		
Net loss from continuing operations	\$ (157,782)	\$ (83,504)
Adjustments to reconcile net loss to net cash used for operating activities from continuing operations:		
Provision for cash discounts	—	10
Depreciation	673	124
Amortization of debt issuance costs and discounts	5,377	—
Amortization of discount or premium on available-for-sale securities	1,816	3,104
Share-based compensation expense	27,755	10,922
Loss on disposal of property and equipment	105	—
Inventory impairment	7,525	—
Changes in assets and liabilities:		
Accounts receivable	(3,811)	(73)
Inventories	(19,623)	(3,011)
Prepaid expenses and other assets	(1,521)	(13,319)
Accounts payable	(7,850)	9,627
Accrued and other liabilities	7,335	3,376
Deferred revenue	18,997	453
Net cash used for operating activities from continuing operations	(121,004)	(72,291)
Net cash used for operating activities from discontinued operations	(208)	(839)
Net cash used for operating activities	(121,212)	(73,130)
Cash flows from investing activities:		
Property and equipment purchases	(1,795)	(1,030)
Purchases of available-for-sale securities	(230,854)	(218,652)
Proceeds from sales and maturities of available-for-sale securities	181,750	110,638
Non-current assets	(1,419)	(282)
Net cash used for investing activities	(52,318)	(109,326)
Cash flows from financing activities:		
Net proceeds from debt issuances	290,247	—
Payments for capped call transactions	(34,709)	—
Net proceeds from exercise of common stock options	2,000	13,054
Proceeds from sale of common stock through employee stock purchase plan	508	122
Net proceeds from issuance of common stock	—	192,000
Net cash provided by financing activities	258,046	205,176
Net increase in cash and cash equivalents	84,516	22,720
Cash and cash equivalents:		
Beginning of period	58,605	39,554
End of period	<u>\$ 143,121</u>	<u>\$ 62,274</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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VIVUS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2013

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013. Management has evaluated all events and transactions that occurred after September 30, 2013 through the date these unaudited condensed consolidated financial statements were filed. There were no events or transactions during this period which require recognition or disclosure in these unaudited condensed consolidated financial statements, except as disclosed in Note 14. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. The unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2012, as filed on February 26, 2013 and as amended by the Form 10-K/A filed on April 30, 2013 and by the Form 10-K/A filed on June 12, 2013, with the Securities and Exchange Commission, or SEC. The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

When we refer to "we," "our," "us," the "Company" or "VIVUS" in this document, we mean the current Delaware corporation, or VIVUS, Inc., and its California predecessor, as well as all of our consolidated subsidiaries.

Reclassifications

Certain prior year amounts in the unaudited condensed consolidated financial statements have been reclassified to conform to the current year presentation.

Use of Estimates

The preparation of these unaudited condensed consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. On an ongoing basis, the Company evaluates its estimates, including critical accounting policies or estimates related to available-for-sale securities, debt instruments, research and development expenses, income taxes, inventories, revenues, contingencies and litigation and share-based compensation. The Company bases its estimates on historical experience, information received from third-parties and on various market specific and other relevant assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ significantly from those estimates under different assumptions or conditions.

Revenue from Multiple Element Arrangements

The Company accounts for multiple element arrangements, such as license and commercialization agreements in which a customer may purchase several deliverables, in accordance with ASC Topic 605-25, *Revenue Recognition — Multiple-Element Arrangements*, or ASC 605-25. The Company evaluates how the deliverables in an arrangement should be separated and how the consideration should be allocated. The Company allocates non-contingent consideration to each stand-alone deliverable based upon the relative selling price of each element. When applying the relative selling price method, the Company determines the selling price for each deliverable using vendor-specific objective evidence, or VSOE, of selling price, if it exists, or third-party evidence, or TPE, of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, the Company uses best estimated selling price, or BEBP, for that deliverable. Revenue allocated to each element is then recognized based on when the following four basic revenue recognition criteria are met for each element: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the price is fixed or determinable; and (iv) collectability is reasonably assured.

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

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

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

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

Fair Value of Financial Instruments

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

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

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

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

Recent Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements during the three and nine months ended September 30, 2013, as compared to the recent accounting pronouncements described in the Company's Form 10-K for the year ended December 31, 2012,

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2. SHARE-BASED COMPENSATION

The Company accounts for share-based compensation arrangements in accordance with the Financial Accounting Standards Board, or FASB's, Accounting Standards Codification, or ASC, topic 718, *Compensation—Stock Compensation*, or ASC 718.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Research and development	\$ 363	\$ 1,194	\$ 2,217	\$ 2,659
Selling, general and administrative	2,740	3,486	12,822	8,263
Non-recurring charges	12,716	—	12,716	—
Share-based compensation expense	<u>\$ 15,819</u>	<u>\$ 4,680</u>	<u>\$ 27,755</u>	<u>\$ 10,922</u>

On July 18, 2013, the Company entered into a settlement agreement with First Manhattan Company, or First Manhattan, in connection with a proxy contest related to our 2013 Annual Meeting of Stockholders. According to the terms of the settlement agreement, more than a majority of the members of the Company's Board of Directors resigned and new members were appointed. The change in the majority of the members of the Company's Board of Directors, effective July 19, 2013, triggered certain "change of control" benefits in accordance with the Amended and Restated Change of Control and Severance Agreements, or the Amended Agreements, with certain of the Company's employees; specifically, all unvested stock options held by these employees automatically vested in full and became immediately exercisable. In accordance with ASC 718, all unamortized expense for options that were expected to vest on the date of grant and the modified fair value of the options that were not expected to vest on the date of grant (due to expected forfeitures) were immediately expensed. As a result, in the three months ended September 30, 2013, the Company recognized approximately \$12.7 million in additional share-based compensation expense related to this event.

Total share-based compensation cost capitalized as part of the cost of inventory is \$75,000 and \$467,000 for the three and nine months ended September 30, 2013, respectively.

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

The fair value and the amortized cost of cash, cash equivalents, and available-for-sale securities by major security type at September 30, 2013 and December 31, 2012 are presented in the tables that follow.

As of September 30, 2013 (in thousands):

Cash and cash equivalents and available-for-sale securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and money market funds	\$ 143,121	\$ —	\$ —	\$ 143,121
U.S. Treasury securities	203,236	92	—	203,328
Total	346,357	92	—	346,449
Less amounts classified as cash equivalents	(143,121)	—	—	(143,121)
Total available-for-sale securities	<u>\$ 203,236</u>	<u>\$ 92</u>	<u>\$ —</u>	<u>\$ 203,328</u>

As of December 31, 2012 (in thousands):

Cash and cash equivalents and available-for-sale securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and money market funds	\$ 58,605	\$ —	\$ —	\$ 58,605
U.S. Treasury securities	155,948	33	—	155,981
Total	214,553	33	—	214,586
Less amounts classified as cash equivalents	(58,605)	—	—	(58,605)
Total available-for-sale securities	<u>\$ 155,948</u>	<u>\$ 33</u>	<u>\$ —</u>	<u>\$ 155,981</u>

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As of September 30, 2013, the Company's available-for-sale securities have original contractual maturities up to 23 months. However, the Company may or may not hold securities with stated maturities greater than 12 months until maturity. In response to changes in the availability of and the yield on alternative investments as well as liquidity requirements, the Company may sell these securities prior to their stated maturities. As these securities are viewed by the Company as available to support current operations, securities with maturities beyond 12 months are classified as current assets. Due to their short-term maturities, the Company believes that the fair value of its bank deposits, accounts payable and accrued expenses approximate their carrying value.

Fair Value Measurements

As of September 30, 2013 and December 31, 2012, all of the Company's cash and cash equivalents and available-for-sale securities were measured at fair value on a recurring basis, and classified as Level 1 in the fair value hierarchy. There were no assets or liabilities measured on a recurring basis where Level 2 or Level 3 valuation techniques were used.

4. INVENTORIES

Inventories consist of (in thousands):

	Balance as of	
	September 30, 2013	December 31, 2012
Raw materials	\$ 23,746	\$ 5,139
Work in process	609	2,635
Finished goods	12,981	17,506
Deferred costs	582	73
Total	<u>\$ 37,918</u>	<u>\$ 25,353</u>

As of September 30, 2013 and December 31, 2012, the raw materials inventories consist primarily of the active pharmaceutical ingredients, or API, for the commercialization of Qsymia® (phentermine and topiramate extended-release) capsules CIV, the finished goods inventory consists of both Qsymia and STENDRA™ (avanafil) primarily for commercialization, while the work in process and deferred costs inventories relate exclusively to Qsymia. The deferred costs represent the costs of Qsymia product shipped to customers, including wholesalers, certified retail pharmacies and certified mail order pharmacies, but not yet shipped to patients through prescriptions, and for which recognition of revenue has been deferred.

Inventories are stated at the lower of cost or market. Cost is determined using the weighted average method. The Company periodically evaluates the carrying value of inventory on hand for potential excess amount over demand using the same lower of cost or market approach as that used to value the inventory. As a result of this evaluation, for the nine months ended September 30, 2013, the Company recognized a total charge of \$10.2 million for inventories on hand in excess of demand, plus a purchase commitment fee. No additional charge was required in the three months ended September 30, 2013.

5. PREPAID EXPENSES AND OTHER ASSETS

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

	Balance as of	
	September 30, 2013	December 31, 2012
Prepaid insurance	\$ 3,382	\$ 6,979
Prepaid sales and marketing expenses	4,791	5,735
Prepaid medical affairs expenses	3,136	1,782
Manufacturing capacity commitment fees	823	2,300
Withholding tax receivable	5,322	—
Other prepaid expenses and assets	3,226	2,363
Total	<u>\$ 20,680</u>	<u>\$ 19,159</u>

The amounts included in prepaid expenses and other assets consist primarily of prepaid insurance, deposits and prepayments for future services, primarily related to prepaid product commercialization costs for services relating to future periods in support of the sales and marketing of Qsymia in the U.S., prepayments related to medical affairs activities for Qsymia and STENDRA, interest income receivable, withholding tax receivable and manufacturing capacity commitment fees. The withholding tax receivable represents refundable foreign tax withheld on payments Menarini Group, through its

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subsidiary Berlin-Chemie AG, or Menarini, made to the Company. These amounts represent probable future economic benefits obtained or controlled by the Company as a result of past transactions or events, which meet the definition of an asset under FASB Concept Statement 6. As such, these costs have been deferred as prepaid expenses and other assets on the condensed consolidated balance sheet and will be either (i) charged to expense accordingly when the related prepaid services are rendered to the Company, or (ii) converted to cash when the receivables are collected by the Company.

6. NON-CURRENT ASSETS

Non-current assets consist of (in thousands):

	Balance as of	
	September 30, 2013	December 31, 2012
Debt issuance costs	\$ 6,169	\$ —
Other non-current assets	1,705	287
Total	<u>\$ 7,874</u>	<u>\$ 287</u>

The amounts included in non-current assets consist of debt issuance costs relating to the Convertible Notes and the Senior Secured Notes Due 2018 (see Note 11), which primarily consist of investment banker, legal and other professional fees, and other assets which are not expected to be realized in the next 12 months.

7. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities consist of (in thousands):

	Balance as of	
	September 30, 2013	December 31, 2012
Accrued employee compensation and benefits	\$ 5,999	\$ 3,859

Accrued manufacturing costs	407	4,135
Accrued sales and marketing expenses	624	2,908
Accrued interest on debt (see Note 11)	6,385	—
Accrued research and clinical expenses	3,405	1,372
Other accrued liabilities	4,292	1,503
Liabilities of discontinued operations	—	903
Total	<u>\$ 21,112</u>	<u>\$ 14,680</u>

The amounts included in accrued and other liabilities consist of obligations for past services, primarily related to accrued employee compensation and benefits, accrued manufacturing and product commercialization costs for services relating to past periods in support of the commercial launch of Qsymia in the U.S., accrued interest on debt, and accrued research and clinical expenses.

8. NON-RECURRING CHARGES

Total non-recurring charges, primarily related to the proxy contest with First Manhattan, consist of (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Share-based compensation (see Note 2)	\$ 12,716	\$ —	\$ 12,716	\$ —
Proxy contest expenses	5,155	—	8,863	—
Employee termination and related costs	2,872	—	2,872	—
Operating lease exit costs	—	—	216	—
Non-recurring charges	<u>\$ 20,743</u>	<u>\$ —</u>	<u>\$ 24,667</u>	<u>\$ —</u>

On July 18, 2013, the Company entered into a settlement agreement with First Manhattan in connection with a proxy contest related to the Company's 2013 Annual Meeting of Stockholders. According to the terms of the settlement agreement, more than a majority of the members of the Company's Board of Directors resigned and new members were appointed. The change in the majority of the members of the Company's Board of Directors, effective July 19, 2013, triggered certain "change of control" benefits in accordance with the Amended Agreements with certain of the Company's employees. Under the Amended Agreements, all unvested stock options held by these employees automatically vested in full.

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and became immediately exercisable. In addition, the resignations of both the Company's Chief Executive Officer and President resulted in severance charges under the Amended Agreements. As part of the settlement agreement with First Manhattan, the Company agreed to pay the reasonable and documented expenses incurred by First Manhattan in connection with its proxy contest, which are estimated at approximately \$3.0 million.

9. DEFERRED REVENUE

Qsymia Deferred Revenue

At September 30, 2013, the Company had \$9.5 million in deferred revenue, which represents Qsymia product shipped to the Company's certified home delivery pharmacy services networks, wholesalers and certified retail pharmacies, but not yet shipped to patients through prescriptions, net of prompt payment discounts.

SPEDRA™ Deferred Revenue

As further discussed in Note 10 below, in September 2013, the Company received €6.7 million, (€8 million, net of approximately 16% reimbursable withholding tax) from Menarini as a prepayment for future royalties on sales of SPEDRA. The gross prepayment amount of €8 million, or \$10.6 million, is recorded as deferred revenue as of September 30, 2013 and will be recognized through future earnings and deducted by Menarini against future royalties owed to the Company until such amount, plus interest cost, is depleted in full.

10. LICENSE AND COMMERCIALIZATION AGREEMENT AND COMMERCIAL SUPPLY AGREEMENT WITH MENARINI

On July 5, 2013, the Company entered into a License and Commercialization Agreement, or the License Agreement, with Menarini to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, plus Australia and New Zealand. VIVUS and Menarini also entered into a Commercial Supply Agreement whereby VIVUS will supply Menarini with SPEDRA drug product.

Under the terms of the License Agreement, VIVUS has received certain upfront payments and is eligible to receive various approval and sales milestones potentially totaling €79 million, plus royalties on SPEDRA sales. Upon the signing of the License Agreement, we received a payment of €6.7 million, (€8 million, net of approximately 16% reimbursable withholding tax), for the non-refundable, non-creditable license fee, as well as a payment of €6.7 million, (€8 million, net of approximately 16% reimbursable withholding tax), for a regulatory milestone payment, related to the approval of the SPEDRA marketing authorization by the European Commission. Although this payment was described in the License Agreement as a regulatory milestone payment for the marketing authorization approval in Europe, it is essentially an additional license fee because the approval by the European Commission was obtained prior to the final execution of the License Agreement. In addition, in September 2013, VIVUS received another payment of €6.7 million, (€8 million, net of approximately 16% reimbursable withholding tax), as a prepayment for future royalties on sales of SPEDRA. This amount has been recorded as deferred revenue as of September 30, 2013 and will be recognized as royalty income when earned. For the three months and nine months ended September 30, 2013, VIVUS has recognized €16.0 million, or \$21.0 million, as license revenue, as the Company has determined that revenue was earned upon the delivery of the license rights and related know-how. Under the Commercial Supply Agreement, VIVUS will supply the SPEDRA drug product to Menarini on a cost-plus basis.

In accordance with ASC 605-25, VIVUS identified the license and related know-how and supply services as separate deliverables under the agreements. The Company determined that the license and related know-how and supply services individually represent separate units of accounting because each deliverable has stand-alone value. The Company determined that the license and related know-how have stand-alone value based on various facts and circumstances in the arrangement, including Menarini's option to sublicense. Although Menarini is precluded from reselling the license, Menarini's ability to use the delivered license and related know-how for its intended purpose without the receipt of the remaining deliverable indicated that the license and related know-how have stand-alone value.

VIVUS determined that the supply services have stand-alone value because: (i) the manufacturing process is not proprietary to the Company; (ii) a third party manufacturer produces the product, and (iii) Menarini may at any time with notice to the Company elect to accept assignment of VIVUS's agreements with the third party manufacturer, or manufacture the licensed product itself or contract with a third party manufacturer to produce it.

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The Company allocated the non-contingent consideration relating to the stand-alone deliverables on the basis of relative selling price, which is BESP because VSOE or TPE are unavailable for these deliverables. The objective of BESP is to determine the price at which the Company would transact a sale if the product or service were sold on a stand-alone basis. BESP for the license is based on discounted future projected cash flows relating to the licensed territories. Revenue related to the license was recognized in the third quarter of 2013 when the license and all related knowledge and data had been transferred. BESP for the supply services is based on third party costs to manufacture the licensed product, plus a mark-up consistent with similar agreements. Revenues allocated to the supply services will be recognized when the product has met all required specifications and the related title and risk of loss and damages have been transferred to Menarini. The Company has determined that achievement of any and all of the milestones is dependent solely upon the results of Menarini and therefore none of the milestones are deemed to be substantive. Royalties to be received from Menarini will be recognized by the Company based upon the net sales of the product by Menarini. As of September 30, 2013, no supply services have been provided and the SPEDRA drug product has not yet launched, thus no revenues for supply services and royalties have been recognized.

11. LONG TERM DEBT

Convertible Senior Notes Due 2020

On May 21, 2013, the Company closed an offering of \$220.0 million in 4.5% Convertible Senior Notes due May 1, 2020, or the Convertible Notes. The Convertible Notes are governed by an indenture, dated as of May 21, 2013 between the Company and Deutsche Bank National Trust Company, as trustee. On May 29, 2013, the Company closed on an additional \$30.0 million of Convertible Notes upon exercise of an option by the initial purchasers of the Convertible Notes. Total net proceeds from the Convertible Notes were approximately \$241.8 million.

The Convertible Notes are senior unsecured obligations of the Company and bear interest at a fixed rate of 4.50% per annum, payable semiannually in arrears on May 1 and November 1 of each year, beginning on November 1, 2013, unless earlier purchased or converted.

The Convertible Notes are convertible into approximately 16,826,000 shares of the Company's common stock under certain circumstances prior to maturity at a conversion rate of 67.3038 shares per \$1,000 principal amount of Convertible Notes, which represents a conversion price of approximately \$14.858 per share, subject to adjustment under certain conditions. The Convertible Notes are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding November 1, 2019 only under certain conditions. On or after November 1, 2019, holders may convert all or any portion of their Convertible Notes at their option at the conversion rate then in effect at any time, regardless of these conditions. Subject to certain limitations, the Company will settle conversions of the Convertible Notes by paying or delivering, as the case may be, cash, shares of its common stock or a combination of cash and shares of its common stock, at its election. The conversion rate of the Convertible Notes, and the corresponding conversion price, will be subject to adjustment for certain events, but will not be adjusted for accrued interest. In addition, following certain corporate transactions that occur on or prior to the maturity date for the Convertible Notes, the Company will increase the conversion rate for a holder that elects to convert its Convertible Notes in connection with such a corporate transaction. The Convertible Notes were issued to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended, or the Securities Act. Neither the Convertible Notes nor any shares of VIVUS's common stock issuable upon conversion of the Convertible Notes have been or are expected to be registered under the Securities Act or under any state securities laws.

The Convertible Notes are accounted for in accordance with ASC 470-20, *Debt with Conversion and Other Options*. Under ASC 470-20, issuers of convertible debt instruments that may be settled in cash upon conversion, including partial cash settlement, are required to separately account for the liability (debt) and equity (conversion option) components. The Company analyzed the conversion feature to determine if it was required to be bifurcated and treated as a derivative liability and determined that it did not. Rather, the Company is required to separately account for the liability and equity components of the convertible debt instrument. The Company determined the fair value of the liability component by estimating a risk adjusted interest rate, or market yield, at the time of issuance for similar notes that do not include the equity component. To arrive at the appropriate risk adjusted rate, or market yield, for the Convertible Notes, the Company performed (i) a synthetic credit rating analysis estimating the issuer level credit rating of the Company using a regression model; (ii) research on appropriate market yields using option adjusted spread indications for similar credit ratings, and (iii) considered the market yield implied for the Convertible Notes from a binomial lattice model, or Level 3 inputs. The risk adjusted interest rate was used to compute the initial fair value of the liability component of \$154.7 million. The excess of the proceeds received from the Convertible Notes over the amount allocated to the liability component, of \$95.3 million, is allocated to the equity component and recorded to additional paid-in capital. This excess is reported as a debt discount and is amortized as non-cash interest expense, using the interest method, over the expected life of the Convertible Notes. The conversion option will not be subsequently remeasured as long as it continues to meet conditions for equity classification.

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In connection with the issuance of the Convertible Notes, the Company incurred \$8.2 million of issuance costs, which primarily consisted of investment banker, legal and other professional fees. The portion of the costs related to the equity component of \$3.1 million was charged to additional paid-in capital. The remaining portion related to the debt component of \$5.1 million was recorded as a deferred charge and included in non-current assets, and is being amortized and recorded as additional interest expense over the expected life of the Convertible Notes.

The combined effective interest rate on the liability component was 15.2%. Total interest expense of \$5.7 million and \$8.1 million was recognized during the three and nine month periods ended September 30, 2013, respectively, which includes \$3.4 million and \$4.9 million of amortization of the debt discount during the three and nine month periods ended September 30, 2013, respectively. The remaining expected life of the Convertible Notes at September 30, 2013 is 5.2 years. As of September 30, 2013, the Convertible Notes were not convertible and the if-converted value did not exceed their principal amount.

In connection with the issuance of the Convertible Notes, the Company entered into capped call transactions with certain counterparties affiliated to the underwriters. The capped call transactions are expected to reduce potential dilution of earnings per share upon conversion of the Convertible Notes. Under the capped call transactions, the Company purchased capped call options that in the aggregate relate to the total number of shares of the Company's common stock underlying the Convertible Notes, with a strike price equal to the conversion price of the notes and with a cap price equal to \$20 per share. The fair value of the purchased capped calls of \$34.7 million was recorded to stockholders' equity.

Senior Secured Notes Due 2018

On March 25, 2013, the Company entered into the Purchase and Sale Agreement, or the Agreement, between the Company and BioPharma Secured Investments III Holdings Cayman LP, a Cayman Islands exempted limited partnership, or BioPharma, providing for the purchase of a debt-like instrument, or the Senior Secured Notes. Under the Agreement, the Company received \$50 million, less \$500,000 in funding and facility payments, at the initial closing on April 9, 2013. The Company may also elect prior to December 31, 2013, subject to certain terms and conditions, to receive an additional \$60 million, less \$600,000 in a funding payment, at the secondary closing no earlier than April 30, 2013 and no later than January 15, 2014. The Company was responsible for all reasonable and documented out-of-pocket legal costs and fees incurred by BioPharma related to the Agreement, subject to a cap of \$300,000.

Net proceeds from the initial financing were approximately \$48.4 million. The Company is obligated to make scheduled quarterly payments. The first payment is scheduled to be made in the second quarter of 2014 and the final payment is scheduled to be made in the second quarter of 2018. The scheduled quarterly payments are subject to the net sales of (i) Qsymia® (and any derivative or improvement thereof, including Qsiva™ as it relates to the European Union), or the Product, and (ii) any other obesity agent developed or marketed by the Company or its 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. Regardless, the Company may pay scheduled quarterly payments out of any available funds notwithstanding Product net sales. The Company also has the option to prepay all scheduled quarterly payments as specified in the Agreement. Assuming all scheduled quarterly payments are made timely and in full, the annual implied effective interest rate is 13.38% per annum. The imputed interest for the Senior Secured Notes was \$1.7 million and \$3.2 million during the three and nine month periods ended September 30, 2013, respectively.

To secure its obligations in connection with the Agreement, the Company granted BioPharma a security interest to (i) the purchased receivables which are defined in the Agreement as the scheduled quarterly payments, any underpayments of such payments based on an audit of the Company's records and any interest due on the foregoing amounts, and (ii) the Company's patents, trademarks, copyrights and regulatory filings related to the Product, or the Additional Collateral.

In connection with the issuance of the Senior Secured Notes, the Company incurred \$1.6 million of issuance costs, which primarily consisted of funding and facility fees, legal and other professional fees. These costs are being amortized and recorded as additional interest expense using the interest method through 2018.

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

	September 30, 2013
Convertible Senior Notes due 2020:	
Fair value of the liability component	\$ 154,738
Accumulated accretion of discount	4,904
Net carrying value	<u>\$ 159,642</u>
Senior Secured Notes due 2018:	
Carrying value	<u>\$ 50,000</u>
Total Notes:	
Fair value of the liability component	\$ 204,738
Accumulated accretion of discount	4,904
Net carrying amount	<u><u>\$ 209,642</u></u>

12. NET INCOME (LOSS) PER SHARE

The Company computes basic net income (loss) per share applicable to common stockholders based on the weighted average number of common shares outstanding during the period. Diluted net income per share is based on the weighted average number of common and common equivalent shares, which represent shares that may be issued in the future upon the exercise of outstanding stock options or upon a net share settlement of the Company's Convertible Notes. Common share equivalents are excluded from the computation in periods in which they have an anti-dilutive effect. Stock options for which the price exceeds the average market price over the period have an anti-dilutive effect on net income per share and, accordingly, are excluded from the calculation. As discussed in Note 11, the triggering conversion conditions that allow holders of the Convertible Notes to convert have not been met. If such conditions are met and the note holders opt to convert, the Company may choose to pay in cash, common stock, or a combination thereof; however, if this occurs, the Company has the intent and ability to net share settle this debt security; thus the Company uses the treasury stock method for earnings per share purposes. Due to the effect of the capped call instrument purchased in relation to the Convertible Notes, there would be no net shares issued until the market value of the Company's stock exceeds \$20 per share, and thus no impact on diluted net income per share. Further, when there is a net loss, potentially dilutive common equivalent shares are not included in the calculation of net loss per share since their inclusion would be anti-dilutive.

As the Company recognized a net loss for the three and nine months ended September 30, 2013 and September 30, 2012, all potential common equivalent shares were excluded for these periods as they were anti-dilutive. For the three months ended September 30, 2013 and September 30, 2012, 5,626,000 and 4,242,000 options outstanding, respectively, were not included in the computation of diluted net loss per share because the effect would be anti-dilutive. For the nine months ended September 30, 2013 and September 30, 2012, 6,026,000 and 4,053,000 options outstanding, respectively, were not included in the computation of diluted net loss per share because the effect would be anti-dilutive.

13. LEGAL MATTERS

Securities Related Class Action Lawsuits

The Company and two of its officers were defendants in a putative class action lawsuit captioned *Kovtun v. Vivus, Inc., et al.*, Case No. 4:10-CV-04957-PJH, in the U.S. District Court, Northern District of California. The action, filed in November 2010, alleged violations of Section 10(b) and 20(a) of the federal Securities Exchange Act of 1934 based on allegedly false or misleading statements made by the defendants in connection with the Company's clinical trials and NDA for Qsymia as a treatment for obesity. The Court granted defendants' motions to dismiss both plaintiff's Amended Class Action Complaint and Second Amended Class Action Complaint; by order dated September 27, 2012, the latter dismissal was with prejudice and final judgment was entered for defendants the same day. On October 26, 2012, plaintiff filed a Notice of Appeal to the U.S. Court of Appeals for the Ninth Circuit. Briefing of the appeal is complete, and the parties are awaiting word on whether the Court of Appeals wishes to entertain oral argument.

Additionally, certain of the Company's officers and directors are defendants in a shareholder derivative lawsuit captioned *Turberg v. Logan, et al.*, Case No. CV-10-05271-PJH, pending in the same federal court. In the plaintiff's Verified Amended Shareholder Derivative Complaint filed June 3, 2011, the plaintiff largely restated the allegations of the *Kovtun* action and alleged that the directors breached fiduciary duties to the Company by purportedly permitting the Company to violate the federal securities laws as alleged in the *Kovtun* action. The same individuals are also named defendants in consolidated shareholder derivative suits pending in the California Superior Court, Santa Clara County under the caption *In*

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re VIVUS, Inc. Derivative Litigation, Master File No. 11 0 CV188439. The allegations in the state court derivative suits are substantially similar to the other lawsuits. The Company is named as a nominal defendant in these actions, neither of which seeks any recovery from the Company. The parties have agreed to stay the derivative lawsuits pending the outcome of the appeal of the securities class action.

The Company and its directors cannot predict the outcome of the various shareholder lawsuits, but they believe the various shareholder lawsuits are without merit and intend to continue vigorously defending them.

On July 12, 2013, various current and former officers and directors of the Company were named as defendants in a separate shareholder derivative lawsuit filed in the California Superior Court, Santa Clara County and captioned *Ira J. Gaines IRA, et al. v. Leland F. Wilson, et al.*, Case No.1-13-CV-249436. The lawsuit generally alleges breaches of the fiduciary duty of care in connection with the launch of Qsymia, breaches of the duty of loyalty and insider trading by some defendants for selling Company stock while purportedly being aware that the Qsymia launch would be less successful than predicted and corporate waste. Again, the Company is named as a nominal defendant, and no recovery from the Company is sought. As with the other shareholder litigation, the Company does have certain indemnification obligations to the named defendants, including to advance defense costs to the individuals. The Company also maintains directors' and officers' liability insurance that it believes affords coverage for much of the anticipated cost of the proceedings, subject to the policies' terms and conditions. The individual defendants deny the material allegations and have indicated an intention to defend them vigorously. On October 21, 2013, the Company filed a demurrer seeking to have the lawsuit dismissed in its entirety for failure to make a pre-suit demand upon the Company's Board of Directors or plead sufficient facts to show that such demand would have been futile.

Proxy Related Lawsuit

On July 16, 2013, First Manhattan, the owner of approximately 9.9% of the outstanding shares of common stock of the Company, commenced an action in the Court of Chancery of the State of Delaware, naming the then-serving members of the board of directors of the Company as defendants and the Company as a nominal defendant. The action was captioned *First Manhattan Co. v. Leland F. Wilson, et al.*, C.A. No. 8731-VCL. In its verified complaint, First Manhattan alleged that the Company's directors breached their fiduciary duties in connection with the Board's decision to adjourn the annual stockholders meeting from July 15, 2013 until July 18, 2013. The verified complaint sought declaratory and injunctive relief, including enjoining the defendants from soliciting proxies, directing the inspector of elections to certify the election of directors based on votes that were present and prepared to be voted on July 15, 2013 before the annual stockholders meeting was adjourned, and prohibiting defendants from taking any actions as directors of the Company. The verified complaint did not seek damages from the Company or the defendant board members. The parties entered into a settlement agreement on July 18, 2013, and the action was dismissed with prejudice on July 19, 2013. As part of the settlement agreement with First Manhattan, the Company agreed to pay the reasonable and documented expenses incurred by First Manhattan in connection with its proxy contest, which are estimated at approximately \$3.0 million.

14. SUBSEQUENT EVENTS

License and Commercialization Agreement and Commercial Supply Agreement for STENDRA

On October 10, 2013, the Company, entered into a License and Commercialization Agreement, or the License Agreement, and a Commercial Supply Agreement, or the Supply Agreement, with Auxilium Pharmaceuticals, Inc., or Auxilium.

Under the terms of the License Agreement, Auxilium received an exclusive license to commercialize and promote VIVUS's drug STENDRA™ (avanafil) for the treatment of erectile dysfunction in the United States and Canada and their respective territories, or the Territory. Additionally, following the completion of certain events, VIVUS has agreed to transfer to Auxilium ownership of the product marketing authorization for STENDRA for the treatment of erectile dysfunction, which was granted by the FDA in April 2012. Each party agreed not to develop, commercialize, or in-license any other product that operates as a PDE5 inhibitor for the treatment of erectile dysfunction in the Territory for a limited time period, subject to certain exceptions. A PDE5 inhibitor means any product that operates as a phosphodiesterase type 5 inhibitor.

VIVUS received an upfront license fee of \$30 million in October 2013, and is expected to receive various milestone payments, plus royalty payments on STENDRA sales. VIVUS is eligible to receive a regulatory milestone payment of \$15 million upon approval by the FDA of a specific time of onset claim for STENDRA in the Territory. In addition, VIVUS is eligible to receive up to an aggregate of \$255 million in potential milestone payments based on certain net sales targets by

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Auxilium. Further, VIVUS is eligible to receive royalty payments based on tiered percentages of the aggregate annual net sales of STENDRA in the Territory on a quarterly basis. The percentage of Auxilium's aggregate annual net sales to be paid to VIVUS increases in accordance with the achievement of specific thresholds of aggregate annual net sales of STENDRA in the Territory. If Auxilium's net sales of STENDRA in a country are reduced by certain amounts following the entry of a generic product to the market, royalty payments will be reduced by certain percentages based on such reductions. Auxilium will also reimburse VIVUS for payments made to cover various obligations to Mitsubishi Tanabe Pharmaceutical Corporation during the term of the License Agreement.

Auxilium will receive an exclusive license, with a right to sublicense, subject to certain limitations, under certain of VIVUS's trademarks, including STENDRA, to market, sell and distribute STENDRA for the treatment of erectile dysfunction in the Territory. In addition, Auxilium will receive an exclusive license, with a right to sublicense, subject to certain limitations, under certain of VIVUS's patents and know-how (i) to use, distribute, import, promote, market, sell, offer for sale and otherwise commercialize STENDRA for the treatment of erectile dysfunction in the Territory, (ii) to make and have made STENDRA anywhere in the world, with certain exceptions, where STENDRA is solely for use or sale for the treatment of erectile dysfunction in the Territory, and (iii) to conduct certain development activities on STENDRA for the treatment of erectile dysfunction in support of obtaining regulatory approval in the Territory.

Auxilium will obtain STENDRA exclusively from VIVUS for a mutually agreed term pursuant to the Supply Agreement, as further described below. Auxilium may elect to transfer the control of the supply chain for STENDRA for the Territory to itself or its designee by assigning to Auxilium VIVUS's agreements with the contract manufacturer, which is referred to below as the Supply Chain Transfer.

At VIVUS's sole cost and expense, VIVUS shall be responsible for preparing and filing with the FDA the appropriate documents to obtain a label expansion for STENDRA referencing a specific time of onset claim. VIVUS shall use commercially reasonable efforts to obtain approval of such label expansion filing. Further, VIVUS shall be responsible for conducting any post-regulatory studies of STENDRA that are required by the FDA in the Territory. Such costs will be split equally between the parties up to a specified amount and then once the specified amount is reached VIVUS shall be solely responsible for the remainder of the costs.

The License Agreement will terminate on a country-by-country basis upon the later to occur of the following: (a) ten (10) years after the STENDRA product launch in such country; or (b) the expiration of the last to expire patents within the VIVUS patents covering STENDRA in such country. In addition, Auxilium may terminate the License Agreement (i) for any reason following the one (1) year anniversary of the STENDRA launch in the U.S upon one hundred eighty (180) days written notice, and (ii) upon the entry of a generic avanafil product into the market upon thirty (30) days written notice. VIVUS may terminate the License Agreement (i) immediately upon written notice to Auxilium if Auxilium is excluded from participation in the U.S. federal healthcare programs and fails to cure such exclusion within one hundred twenty (120) days, and (ii) if Auxilium challenges the VIVUS patents covering STENDRA upon written notice to Auxilium. Either party may terminate the License Agreement for the other party's uncured material breach or bankruptcy.

Under the terms of the Supply Agreement, VIVUS will supply Auxilium with STENDRA drug product until December 31, 2018 at the latest. For 2015 and each subsequent year during the term of the Supply Agreement, if Auxilium fails to purchase an agreed minimum purchase amount of STENDRA from VIVUS, it will reimburse VIVUS for the shortfall as it relates to VIVUS's out of pocket costs to acquire certain raw materials needed to manufacture STENDRA. Either party may terminate the Supply Agreement for the other party's uncured material breach or bankruptcy, or upon the termination of the License Agreement. The Supply Agreement will automatically terminate upon completion of the Supply Chain Transfer, as described above.

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Cost Reduction Plan

As part of the Company's ongoing efforts to reduce costs by eliminating expenses that are not essential to expanding the use of Qsymia, the Company has implemented a cost reduction plan which will reduce the Company's workforce by approximately 20 employees, or 17% of our workforce, excluding the sales force of 150, in the fourth quarter of 2013. The Company expects to complete the cost reduction plan by the end of 2013, and anticipates incurring pre-tax non-recurring charges in the range of \$6 million to \$8 million in the fourth quarter of 2013, including approximately \$4 million to \$5 million in employee termination costs, \$1 million to \$1.5 million in non-cash share-based compensation expense related to the automatic acceleration of vesting of unvested stock options held by the terminated employees, and \$1 million to \$1.5 million in operating lease exit costs. The Company expects to realize approximately \$6 million to \$8 million in annual net cost savings beginning in fiscal year 2014. The estimates of the charges and costs that the Company expects to incur and the annual net costs savings that the Company expects to realize in connection with the cost reduction plan, and the timing thereof, are subject to a number of assumptions and actual results may materially differ.

New Principal Financial Officer

On November 4, 2013, the Company and Timothy E. Morris entered into a letter agreement, or the Letter Agreement, in connection with the Amended and Restated Change of Control and Severance Agreement by and between the Company and Mr. Morris, effective as of July 1, 2013, or the Severance Agreement. In connection with the change in the majority of the Board of Directors of the Company and the material reduction or change in job duties and responsibilities as a result of no longer having the duties and responsibilities of the Chief Financial Officer or those associated as the head of investor relations, human resources and corporate development, the Company acknowledges and agrees that Mr. Morris is entitled to terminate his employment for Good Reason (as defined in the Severance Agreement). Under the terms of the Letter Agreement, Mr. Morris will continue his employment with the Company until December 31, 2013 to assist with the transition of his duties. On December 31, 2013, Mr. Morris's employment will terminate automatically for Good Reason, and Mr. Morris will be entitled to severance payments and benefits pursuant to the terms of the Severance Agreement.

On November 5, 2013, the Board of Directors of the Company appointed Svai Sanford, the Company's Corporate Controller, as interim Chief Financial Officer effective November 5, 2013, or the Effective Date. As of the Effective Date, Mr. Sanford has assumed the duties of the Company's principal financial officer on an interim basis.

No new compensatory or severance arrangements were entered into in connection with Mr. Sanford's appointment as interim Chief Financial Officer.

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

This Management's Discussion and Analysis of Financial Conditions and Results of Operations and other parts of this Form 10-Q contain "forward looking" statements that involve risks and uncertainties. These statements typically may be identified by the use of forward looking words or phrases such as "may," "believe," "expect," "forecast," "intend," "anticipate," "predict," "should," "planned," "likely," "opportunity," "estimated," and "potential," the negative use of these words or other similar words. All forward looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward looking statements. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to: (1) our limited commercial experience with Qsymia® in the United States, or U.S.; (2) the timing of initiation and completion of the clinical studies required as part of the approval of Qsymia by the U.S. Food and Drug Administration, or FDA; (3) the response from the FDA to the data that VIVUS will submit relating to post-approval clinical studies; (4) the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy, or REMS, requirements; (5) our ability to continue to certify and add to the Qsymia retail pharmacy network and sell Qsymia through this network; (6) whether the Qsymia retail pharmacy network will simplify and reduce the prescribing burden for physicians, improve access and reduce waiting times for patients seeking to initiate therapy with Qsymia; (7) that we may be required to provide

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further analysis of previously submitted clinical trial data; (8) the negative opinion of the European Medicines Agency's, or EMA, Committee for Medicinal Products for Human Use, or CHMP, regarding the Marketing Authorization Application, or MAA, for Qsiva™ for the treatment of obesity in Europe and the impact of that opinion on the outcome of the planned resubmission of the Qsiva MAA under the centralized procedure; (9) our ability to successfully seek approval for Qsymia in other territories outside the U.S. and European Union, or EU, (10) whether healthcare providers, payors and public policy makers will recognize the significance of the American Medical Association, or AMA, officially recognizing obesity as a disease, or the new American Association of Clinical Endocrinologists, or AACE, guidelines; (11) our ability to successfully commercialize Qsymia including risks and uncertainties related to expansion to retail distribution, the broadening of payor reimbursement, the expansion of Qsymia's primary care presence, and the outcomes of our discussions with pharmaceutical companies and our strategic and franchise-specific pathways for Qsymia; (12) our ability to focus our promotional efforts on health care providers and on patient education that, along with increased access to Qsymia and ongoing improvements in reimbursement, will result in the accelerated adoption of Qsymia; (13) our ability to eliminate expenses that are not essential to expanding the use of Qsymia and fully realize the anticipated benefits from the cost reduction plan, including the timing thereof; (14) the impact of greater cost reduction plan expenses than currently anticipated and lower annual net cost savings than currently expected; (15) the impact of the cost reduction plan on the Company's business and unanticipated charges not currently contemplated that may occur as a result of the cost reduction plan; (16) our ability to ensure that the entire supply chain for Qsymia efficiently and consistently delivers Qsymia to our customers; (17) risks and uncertainties related to the timing, strategy, tactics and success of the launch and commercialization of STENDRA™ (avanafil) in the United States and Canada by Auxilium Pharmaceuticals, Inc., or Auxilium; (18) risks and uncertainties related to the launch and commercialization of SPEDRA™ (avanafil) in the EU, plus Australia and New Zealand, by Menarini Group through its subsidiary Berlin-Chemie AG, or Menarini; (19) risks and uncertainties related to the milestones, payments and royalties under the STENDRA and SPEDRA agreements; (20) our ability to successfully complete on acceptable terms and on a timely basis avanafil partnering discussions for territories in which we do not have a commercialization alliance; (21) the timing of the qualification and subsequent approval by regulatory authorities of Sanofi Chimie as a qualified supplier of STENDRA/SPEDRA, Sanofi Chimie's ability to undertake worldwide manufacturing of the avanafil active pharmaceutical ingredient, or API; (22) whether the FDA and/or EMA will approve the amendments we intend to submit to include the recently announced study results showing avanafil is effective for sexual activity within 15 minutes in men with ED; (23) the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand; (24) our ability to accurately forecast Qsymia demand; (25) our ability to increase Qsymia sales in 2014 through growth in certified retail pharmacies, expansion of reimbursement coverage and the use of a more focused selling message; (26) the number of Qsymia prescriptions dispensed through the mail order system and through certified retail pharmacies, as well as the impact of seasonality on the number of prescriptions and the current weekly prescription trends through the end of 2013; (27) the impact of promotional programs for Qsymia on the Company's net product revenue and net income (loss) in future periods; (28) our history of losses and variable quarterly results; (29) substantial competition; (30) risks related to the failure to protect our intellectual property and litigation in which we may become involved; (31) uncertainties of government or third-party payor reimbursement; (32) our reliance on sole source suppliers; (33) our reliance on third parties and our collaborative partners; (34) our failure to continue to develop innovative investigational drug candidates and drugs; (35) risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; (36) our ability to demonstrate through clinical testing the safety and effectiveness of our investigational drug candidates; (37) the timing of initiation and completion of clinical trials and submissions to foreign authorities; (38) the results of post-marketing studies are not favorable; (39) compliance with post-marketing regulatory standards is not maintained; (40) the volatility and liquidity of the financial markets; (41) our liquidity and capital resources; (42) our expected future revenues, operations and expenditures; (43) potential change in our business strategy to enhance long term stockholder value; (44) the impact, if any, of the expansion of our Board of Directors to include predominantly new members, the recent appointment of a new Chief Executive Officer and an interim Chief Financial Officer, the resignation of our President, and the decision of our Chief Financial Officer to exercise his right to terminate his employment for Good Reason (as defined in his Amended and Restated Change of Control and Severance Agreement with the Company, effective as of July 1, 2013); and (45) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, or the SEC, or the Commission, including those set forth in this filing as "Item 1A. Risk Factors."

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the quarter and nine months ended September 30, 2013, are not necessarily indicative of the results that may be expected for the full fiscal year or any future period.

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.

OVERVIEW

VIVUS is a biopharmaceutical company with two FDA approved therapies, Qsymia and STENDRA. Our drug, Qsymia (phentermine and topiramate extended-release) was approved by the FDA on July 17, 2012, as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 or greater (obese), or 27 or greater (overweight) in the presence of at least one weight-related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol (dyslipidemia). Qsymia incorporates a

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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. On September 17, 2012, we announced the U.S. market availability of Qsymia through a certified home delivery network, which includes CVS Pharmacy, Express Scripts, Walgreens, Wal-Mart Pharmacy, and, for its members only, Kaiser Permanente. On July 1, 2013, we announced initial availability of Qsymia through approximately 8,000 Walgreens, Costco and Duane Reade retail pharmacies nationwide. As of the date of this report, Qsymia is available in over 31,000 certified retail pharmacies nationwide. We intend to continue to certify and add new pharmacies to the Qsymia retail pharmacy network, including national and regional chains as well as independent pharmacies, in the fourth quarter of 2013 and beyond. In addition, Qsymia continues to be available through a certified home delivery pharmacy network for patients who prefer to receive Qsymia by mail.

As part of the approval of Qsymia, we are committed to conducting post-marketing studies. We intend to conduct a study to assess the long-term treatment effect of Qsymia on the incidence of major adverse cardiovascular events in overweight and obese subjects with confirmed cardiovascular disease, 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, as well as animal and in vitro studies. We anticipate beginning certain of these studies in the first quarter of 2014.

In October 2012, we received the formal opinion from the CHMP recommending against approval of the MAA for Qsiva (the approved trade name for Qsymia in the EU) in the EU due to concerns over the potential cardiovascular and central nervous system effects associated with long-term use, teratogenic potential and use by patients for whom Qsiva would not have been indicated. We appealed this opinion and requested a re-examination of the decision by the CHMP. After re-examination, on February 21, 2013, the CHMP affirmed their earlier opinion. On September 20, 2013, we submitted to the EMA a request for scientific advice regarding use of a pre-specified interim analysis from the AQCLAIM cardiovascular outcomes trial to support the resubmission of the MAA for approval in Europe of Qsiva for obesity under the centralized procedure. We also intend to seek approval for Qsymia in other territories outside the United States and EU. We intend to commercialize Qsymia in territories where we obtain approval through collaboration agreements with third-parties.

Our drug, STENDRA, or avanafil, is an oral phosphodiesterase type 5, or PDE5, inhibitor that we have licensed from Mitsubishi Tanabe Pharmaceutical Corporation, or MTPC. STENDRA was approved by the FDA on April 27, 2012, for the treatment of erectile dysfunction, or ED, in the United States. On October 10, 2013, we entered into an agreement providing Auxilium Pharmaceuticals, Inc., or Auxilium, the exclusive rights to market STENDRA in the United States and Canada. As part of the approval of STENDRA, we are committed to conducting post-marketing studies. On June 26, 2013, the European Commission, or EC, adopted the implementing decision granting marketing authorization for SPEDRA (the approved trade name for avanafil in the EU) for the treatment of ED in the EU. On July 5, 2013, we entered into an agreement with Menarini to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, plus Australia and New Zealand. We are currently in discussions with potential collaboration partners to market and sell STENDRA for the remaining territories in which we do not have a commercial alliance.

Foreign regulatory approvals, including approval to market Qsiva in the EU, may not be obtained on a timely basis, or at all, and the failure to receive regulatory approvals in a foreign country would prevent us from marketing our products in that market, which could have a material adverse effect on our business, financial condition and results of operations.

Recent Developments

Management Changes

On August 31, 2013, Anthony P. Zook resigned from the position of Chief Executive Officer of the Company, and from the Board effective as of September 3, 2013, due to recurring issues associated with a previously-diagnosed medical condition. After consultations with his physician, Mr. Zook determined that he must focus attention on a resolution of this condition.

Also on August 31, 2013, the Board appointed Seth H. Z. Fischer to serve as the Chief Executive Officer of the Company and as a member of the Board effective as of September 3, 2013. Mr. Fischer has three decades of healthcare experience in the pharmaceutical and medical device industries, including 29 years with Johnson & Johnson, most recently as Company Group Chairman, Johnson & Johnson and Worldwide Franchise Chairman, Cordis Corporation from 2008 to 2012.

On September 27, 2013, we announced that Peter Y. Tam resigned as President of the Company, effective October 12, 2013.

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On November 4, 2013, we entered into a letter agreement, or the Letter Agreement, in connection with the Amended and Restated Change of Control and Severance Agreement with Timothy E. Morris, effective as of July 1, 2013, or the Severance Agreement. In connection with the change in the majority of the Board of Directors of the Company and the material reduction or change in job duties and responsibilities as a result of no longer having the duties and responsibilities of the Chief Financial Officer or those associated as the head of investor relations, human resources and corporate development, the Company acknowledges and agrees that Mr. Morris is entitled to terminate his employment for Good Reason (as defined in the Severance Agreement). Under the terms of the Letter Agreement, Mr. Morris will continue his employment with the Company until December 31, 2013 to assist with the transition of his duties. On December 31, 2013, Mr. Morris's employment will terminate automatically for Good Reason (as defined in the Severance Agreement), and Mr. Morris will be entitled to severance payments and benefits pursuant to the terms of the Severance Agreement.

On November 5, 2013, the Board of Directors of the Company appointed Svai Sanford, the Company's Corporate Controller, as interim Chief Financial Officer. As of November 5, 2013, Mr. Sanford has assumed the duties of the Company's principal financial officer on an interim basis.

Update to European Filing Strategy for Qsiva

On September 20, 2013, we submitted to the European Medicines Agency, or EMA, a request for scientific advice regarding use of a pre-specified interim analysis from the AQCLAIM cardiovascular outcomes trial to support the resubmission of the marketing authorization application, or MAA, for approval of Qsiva for obesity in Europe under the centralized procedure. In order to accommodate advice from the European authorities, we anticipate that patient enrollment for the AQCLAIM study will commence in the first quarter of 2014.

License and Commercialization Agreement for the Marketing Rights to STENDRA in the United States and Canada

On October 10, 2013, we entered into a License and Commercialization Agreement providing Auxilium the exclusive rights to market STENDRA in the United States and Canada. We also simultaneously signed a Commercial Supply Agreement with Auxilium pursuant to which we will be responsible for the manufacture and supply of STENDRA to Auxilium for a mutually agreed term. Under the License and Commercialization Agreement, we are eligible to receive up to \$300 million based on certain regulatory and sales milestones, including an upfront licensing fee of \$30 million, which we received in October 2013, and a \$15 million payment contingent upon a potential label amendment regarding onset-of-action, in addition to royalties on product sales. The License and Commercialization Agreement will terminate on a country-by-country basis upon the later to occur of the following: (a) ten (10) years after the STENDRA product launch in such country; or (b) the expiration of the last to expire patents within the VIVUS patents covering STENDRA in such country. In addition, Auxilium may terminate the License and Commercialization Agreement (i) for any reason following the one (1) year anniversary of the STENDRA launch in the U.S upon one hundred eighty (180) days written notice, and (ii) upon the entry of a generic avanafil product into the market upon thirty (30) days written notice. VIVUS may terminate the License and Commercialization Agreement (i) immediately upon written notice to Auxilium if Auxilium is excluded from participation in the U.S. federal healthcare programs and fails to cure such exclusion within one hundred twenty (120) days, and (ii) if Auxilium challenges the VIVUS patents covering STENDRA upon written notice to Auxilium. Either party may terminate the License and Commercialization Agreement for the other party's uncured material breach or bankruptcy.

Cost Reduction Plan

As part of our ongoing efforts to reduce costs by eliminating expenses that are not essential to expanding the use of Qsymia, we have implemented a cost reduction plan which will reduce our workforce by approximately 20 employees, or 17% of our workforce, excluding the sales force of 150, in the fourth quarter of 2013. We expect to complete the cost reduction plan by the end of 2013, and anticipate incurring pre-tax non-recurring charges in the range of \$6 million to \$8 million in the fourth quarter of 2013, including approximately \$4 million to \$5 million in employee termination costs, \$1 million to \$1.5 million in non-cash share-based compensation expense related to the automatic acceleration of vesting of

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unvested stock options held by the terminated employees, and \$1 million to \$1.5 million in operating lease exit costs. We expect to realize approximately \$6 million to \$8 million in annual net cost savings beginning in fiscal year 2014. The estimates of the charges and costs that we expect to incur and the annual net costs savings that we expect to realize in connection with the cost reduction plan, and the timing thereof, are subject to a number of assumptions and actual results may differ materially.

Strategy

Our goal is to build a successful pharmaceutical company through the commercialization and development of innovative proprietary drugs. We intend to achieve this by:

- expanding the use of Qsymia through targeted patient and physician education;
- finding the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience;
- creating a pathway for centralized approval of Qsiva in Europe;
- eliminating expenses that are not essential to expanding the use of Qsymia;
- successfully expanding the certified retail pharmacy distribution channel for Qsymia in the United States;
- continuing to lower out-of-pocket costs for patients with discount programs, increased third-party payor coverage and changes in public policy; and
- establishing medical obesity treatment as a widely accepted, chronic category supported by treatment guidelines.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. On an ongoing basis, we evaluate our estimates, including those related to available-for-sale securities, research and development expenses, income taxes, inventories, revenues, including revenues from multiple element arrangements, contingencies and litigation and share-based compensation. We base our estimates on historical experience, information received from third-parties and on various market specific and other relevant assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates under different assumptions or conditions.

We account for multiple element arrangements, such as license and commercialization agreements in which a customer may purchase several deliverables, in accordance with ASC Topic 605-25, *Revenue Recognition — Multiple-Element Arrangements*, or ASC 605-25. We evaluate how the deliverables in an arrangement should be separated and how the consideration should be allocated. We allocate non-contingent consideration to each deliverable based upon the relative selling price of each element. When applying the relative selling price method, we determine the selling price for each deliverable using vendor-specific objective evidence, or VSOE, of selling price, if it exists, or third-party evidence, or TPE, of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, we use best estimated selling price, or BEBP, for that deliverable. Revenue allocated to each element is then recognized based on when the following four basic revenue recognition criteria are met for each element: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the price is fixed or determinable; and (iv) collectability is reasonably assured.

Determining whether and when some of these criteria have been satisfied often involves assumptions and judgments that can have a significant impact on the timing and amount of revenue we report. Changes in assumptions or judgments, or

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changes to the elements in an arrangement, could cause a material increase or decrease in the amount of revenue that we report in a particular period.

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

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

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

Fair Value of Financial Instruments

Financial instruments include cash equivalents, available-for-sale securities, accounts payable and accrued liabilities. Available-for-sale securities are carried at estimated fair value. The carrying value of cash equivalents, accounts payable and accrued liabilities approximate their estimated fair value due to the relatively short nature of these instruments. All of our cash equivalents and available-for-sale securities, totaling \$346.4 million at September 30, 2013, have been classified as Level 1 assets.

In May 2013, we closed on an offering totaling \$250.0 million in Convertible Notes. The fair value of the liability component of the Convertible Notes, excluding the conversion feature, was derived using a binomial lattice model, or Level 3 inputs. To arrive at the appropriate risk adjusted rate, or market yield, for the Convertible Notes, we performed (i) a synthetic credit rating analysis estimating the issuer level credit rating of the Company using a regression model; (ii) research on appropriate market yields using option adjusted spread indications for similar credit ratings, and (iii) considered the market yield implied for the Convertible Notes from a binomial lattice model. Using these inputs, the initial fair value of the liability component of the Convertible Notes was estimated at \$154.7 million. The Convertible Notes are described further below and in Note 11 to the unaudited condensed consolidated financial statements contained in this Form 10-Q.

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

Our Convertible Notes contain a conversion option which is classified as equity. The fair value of the liability component of the debt instrument was deducted from the initial proceeds to determine the proceeds to be allocated to the conversion option. The excess of the proceeds received from the Convertible Notes over the initial amount allocated to the liability component, is allocated to the equity component. This excess is reported as a debt discount and subsequently amortized as non-cash interest expense, using the interest method, over the expected life of the Convertible Notes.

Issuance costs related to the equity component of the Convertible Notes were charged to additional paid-in capital. The remaining portion related to the debt component has been capitalized as a deferred charge and included in non-current assets in the unaudited condensed consolidated balance sheets, and is being amortized and recorded as additional interest expense over the expected life of the Convertible Notes. In connection with the issuance of the Convertible Notes, we entered into capped call transactions with certain counterparties affiliated to the underwriters. The fair value of the purchased capped calls was recorded to stockholders' equity.

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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, 2012 provides a more complete discussion of our critical accounting policies and estimates.

Recent Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements during the quarter and nine months ended September 30, 2013, as compared to the recent accounting pronouncements described in our Form 10-K for the year ended December 31, 2012, that are of significance, or potential significance to the Company.

RESULTS OF OPERATIONS

For the third quarter of 2013, net product revenue from sales of Qsymia was \$6.4 million. In addition, we recognized \$21.0 million in license revenue from the SPEDRA commercialization agreement with Menarini. In September 2012, we began distributing Qsymia to the certified home delivery pharmacies in our network, and Qsymia became available in retail pharmacies in July 2013. For the three and nine months ended September 30, 2012, net product revenue from sales of Qsymia was \$41,000.

Net loss for the third quarter of 2013 was \$48.2 million, or \$0.48 net loss per share, as compared to a net loss of \$40.4 million, or \$0.40 net loss per share, during the third quarter of 2012. The increased net loss for the third quarter of 2013, as compared to the third quarter of 2012, is primarily attributable to higher selling, general and administrative expenses of \$6.9 million, increased interest expense of \$7.7 million related to the debt financings as described below under Contractual Obligations, and \$20.7 million of non-recurring charges related to the proxy contest in connection with our 2013 Annual Meeting of Stockholders, which was resolved in July 2013 and resulted in a change in the majority of the members of our Board of Directors. Included in the non-recurring charges for the third quarter of 2013 were \$2.9 million of severance charges in connection with the resignations of both our former Chief Executive Officer and President, \$5.1 million of fees and related expenses (including approximately \$3.0 million of out-of-pocket expenses to be reimbursed to First Manhattan Company), and \$12.7 million of non-cash share-based compensation expense related to the automatic acceleration of vesting of unvested stock options held by certain employees, which resulted from the change in the majority of the members of our Board. These increases were partially offset by license revenue of \$21.0 million.

Net product revenue from sales of Qsymia for the first nine months of 2013 was \$16.0 million, and the license revenue was \$21.0 million. For the nine months ended September 30, 2013, we reported a net loss of \$157.3 million or \$1.56 net loss per share, as compared to a net loss of \$83.2 million, or \$0.85 net loss per share, during the first nine months of 2012. The increased net loss for the first nine months of 2013 is primarily attributable to increased selling and marketing expenses related to commercialization activities for Qsymia and higher interest expense related to the long-term debt incurred in April and May of 2013. Included in the net loss for the nine months ended September 30, 2013 were \$24.7 million in non-recurring charges in connection with our 2013 Annual Meeting of Stockholders and related severance charges, including \$12.7 million of non-cash share-based compensation expense, and a total charge of \$10.2 million for Qsymia inventories on hand in excess of demand, plus a purchase commitment fee for Qsymia. These increases were partially offset by license revenue of \$21.0 million.

We may have continued losses in future periods, depending on our success in commercializing Qsymia and the timing of our research and development expenditures, and our continued investment in the clinical development of our research and future investigational drug candidates, primarily related to the post-marketing study requirements for our approved drugs.

Continuing operations

Net product revenue

Net product revenue was \$6.4 million and \$16.0 million for the three and nine months ended September 30, 2013, respectively. We began distributing Qsymia to the certified home delivery pharmacies in our network in September 2012, and Qsymia became available in certified retail pharmacies in July 2013. As a result, for the three and nine months ended September 30, 2012, net product revenue from sales of Qsymia was minimal. We recognize net product revenue for Qsymia based on prescription sell-through by our certified retail pharmacies and home delivery pharmacy services networks to patients as we did not have sufficient historical information to reliably estimate returns. We expect to continue to recognize revenue for Qsymia using this method for the foreseeable future.

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In the three months ended September 30, 2013, there were approximately 109,000 Qsymia prescriptions dispensed, an increase of 35% over the second quarter of 2013. However, net product revenue growth for the same period was only 15%. Approximately 56% of our total prescriptions for the third quarter of 2013 included either a free good or discount offer, with approximately 28,000 of those prescriptions dispensed as free goods. In comparison, in the second quarter of 2013, approximately 44% of our total prescriptions included either a free good or discount offer, with approximately 24,000 of those prescriptions dispensed as free goods.

We anticipate the current weekly prescription trends to continue through the end of 2013; however, we believe there may be a certain level of seasonality in demand as we approach the holidays in November and December. We believe that recent growth in certified retail pharmacies, expanded reimbursement coverage and a more focused selling message will allow us to increase sales in 2014.

At September 30, 2013, we had Qsymia deferred revenue of \$9.5 million, which represents Qsymia product shipped to our certified home delivery pharmacy services networks, wholesalers and certified retail pharmacies, but not yet shipped to patients through prescriptions, net of prompt payment discounts.

License revenue

Under the terms of the License and Commercialization Agreement, or License Agreement, with Menarini, we have received certain upfront payments and are eligible to receive various approval and sales milestones potentially totaling €79 million, plus royalties on SPEDRA sales. Upon the signing of the License Agreement, we received a payment of €6.7 million, (€8 million, net of approximately 16% reimbursable withholding tax), for the non-refundable, non-creditable license fee, as well as a payment of €6.7 million, (€8 million, net of approximately 16% reimbursable withholding tax), for a regulatory milestone payment, related to the approval of the SPEDRA marketing authorization by the European Commission. Although this payment was described in the License Agreement as a regulatory milestone payment for the marketing authorization approval in Europe, it is essentially an additional

license fee because the approval by the European Commission was obtained prior to the final execution of the License Agreement. In addition, in September 2013, we received another payment of €6.7 million, (€8 million, net of approximately 16% reimbursable withholding tax), as a prepayment for future royalties on sales of SPEDRA. This amount has been recorded as deferred revenue as of September 30, 2013 and will be recognized as royalty income when earned. For the three and nine months ended September 30, 2013, we have recognized €16.0 million, or \$21.0 million, as license revenue, as we have determined that revenue was earned upon the delivery of the license rights and related know-how. For further discussion on the license revenue, refer to Note 10 in the Unaudited Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q.

Cost of goods sold

Cost of goods sold was \$741,000 and \$1.7 million for the three and nine months ended September 30, 2013, respectively. Cost of goods sold relates to our product shipments of Qsymia to patients and includes the inventory costs of APIs, third-party contract manufacturing and packaging and distribution costs, royalties, cargo insurance, freight, shipping, handling and storage costs, and overhead costs of the employees involved with production. The cost of goods sold associated with deferred revenue on Qsymia product shipments is recorded as deferred costs, which are included in inventories in the unaudited condensed consolidated balance sheets, until such time as the deferred revenue is recognized.

Inventory impairment and commitment fee

Inventories are stated at the lower of cost or market. Cost is determined using the weighted average method. We periodically evaluate the carrying value of inventory on hand for potential excess amount over demand using the same lower of cost or market approach as that used to value the inventory. As a result of this evaluation, for the nine months ended September 30, 2013, we recognized a total charge of \$10.2 million for inventories on hand in excess of demand, plus a purchase commitment fee. No charge was required and none was taken in the three months ended September 30, 2013. We will continue to evaluate our inventories on a periodic basis and we may incur additional inventory write-downs in future periods if actual events differ materially from our current assumptions.

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Research and development expenses

Drug Indication/Description	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	2013 vs. 2012 Increase/ (Decrease) (In thousands, except percentages)	2013	2012	2013 vs. 2012 Increase/ (Decrease)
Qsymia for obesity	\$ 4,225	\$ 3,652	16%	\$ 7,435	\$ 9,058	(18)%
STENDRA for ED	1,932	1,465	32%	8,159	5,296	54%
Other projects	18	511	(96)%	313	1,345	(77)%
Share-based compensation	363	1,194	(70)%	2,217	2,659	(17)%
Overhead costs*	1,867	2,478	(25)%	6,559	5,949	10%
Total research and development expenses	<u>\$ 8,405</u>	<u>\$ 9,300</u>	<u>(10)%</u>	<u>\$ 24,683</u>	<u>\$ 24,307</u>	<u>2%</u>

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

The decrease in research and development expenses for the three months ended September 30, 2013, as compared to the same period in 2012, is primarily due to decreases in share-based compensation and overhead costs, partially offset by the ramp up for the post-approval cardiovascular outcomes study for Qsymia, known as AQCLAIM. In the nine months ended September 30, 2013, as compared to the same period in 2012, research and development expenses increased primarily due to start-up and enrollment costs associated with the post-approval studies for STENDRA and start-up costs associated with the AQCLAIM study, including a corresponding increase in headcount to support these projects.

We estimate the AQCLAIM study will cost between \$180 and \$250 million and the study could take as long as five to six years to complete. We have submitted to the EMA a request for scientific advice regarding use of a pre-specified interim analysis from AQCLAIM to support the resubmission of the MAA for approval in Europe of Qsiva for obesity under the centralized procedure. In order to accommodate advice from the European authorities, we anticipate that patient enrollment for the AQCLAIM study will commence in the first quarter of 2014. There will be additional research and development expenses for post-approval studies related to STENDRA and Qsymia. Our research and development expenses may fluctuate from period to period due to the timing and scope of our development activities and the results of clinical and pre-clinical studies.

Selling, general and administrative expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	2013 vs. 2012 Increase (In thousands, except percentages)	2013	2012	2013 vs. 2012 Increase
Selling and marketing	\$ 22,593	\$ 19,094	18%	\$ 72,438	\$ 30,809	135%
General and administrative	15,574	12,175	28%	49,228	28,542	72%
Total selling, general and administrative expenses	<u>\$ 38,167</u>	<u>\$ 31,269</u>	<u>22%</u>	<u>\$ 121,666</u>	<u>\$ 59,351</u>	<u>105%</u>

The increase in selling, general and administrative expenses, excluding the non-recurring charges as described below, for the three months ended September 30, 2013 is primarily due to increased selling and marketing spending for Qsymia commercialization activities of \$3.5 million, including expenses related to the contract sales organization and marketing programs, as compared to the quarter ended September 30, 2012, which was the period Qsymia was

initially launched. General and administrative spending increased by \$3.4 million for the three months ended September 30, 2013, as compared to the quarter ended September 30, 2012, primarily due to incremental increases in corporate expenses. In September 2012, we began distributing Qsymia to the certified home delivery pharmacies in our network, and Qsymia became available in retail pharmacies in July 2013. As a result, the selling, marketing and administrative activities for the third quarter of 2013 have increased significantly in comparison to the same period in 2012.

The increase in selling, general and administrative expenses for the nine months ended September 30, 2013 is primarily due to increased selling and marketing spending for Qsymia commercialization activities of \$41.6 million, including expenses related to the contract sales organization, marketing programs and additional headcount, as compared to the nine months ended September 30, 2012. General and administrative spending increased by \$20.7 million for the nine months ended September 30, 2013 due to increased medical affairs-related expenses of \$5.8 million, primarily related to Continuing Medical Education, or CME, grants, REMS program and additional headcount; incremental increases in other corporate expenses totaling \$10.3 million, including product liability insurance, and professional fees; and increased share-

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based compensation expense (a non-cash expense) of \$4.6 million, as compared to the nine months ended September 30, 2012.

Non-Recurring Charges

Non-recurring charges were \$20.7 million and \$24.7 million for the three and nine months ended September 30, 2013. On July 18, 2013, we entered into a settlement agreement with First Manhattan Company in connection with a proxy contest related to our 2013 Annual Meeting of Stockholders. According to the terms of the settlement agreement, more than a majority of the members of our Board of Directors resigned and new members of our Board of Directors were appointed. The change in the majority of the members of our Board of Directors, effective July 19, 2013, triggered certain “change of control” benefits in accordance with the Amended and Restated Change of Control and Severance Agreements, or the Amended Agreements, with certain of our employees. In the nine months ended September 30, 2013, non-recurring charges included \$12.7 million in share-based compensation related to the automatic acceleration of vesting of unvested stock options held by certain employees per the terms of the Amended Agreements, \$2.9 million in severance charges related to the resignations of both our Chief Executive Officer and President, and \$8.9 million in proxy contest expenses, including approximately \$3.0 million of out-of-pocket expenses to be reimbursed to First Manhattan Company.

Interest expense

Interest expense was \$7.7 million and \$11.8 million in the three and nine months ended September 30, 2013, respectively, primarily due to interest expense and amortization of issuance costs and discounts from our Convertible Notes and Senior Secured Notes (as defined below under Contractual Obligations) and the amortization of the debt discount on the Convertible Notes. The Convertible Notes were issued in May 2013 and the Senior Secured Notes were issued in April 2013, as such there were no interest expense in the corresponding periods in 2012.

Income from discontinued operations

Income from discontinued operations of \$175,000 and \$490,000 in the three and nine months ended September 30, 2013, respectively, relates primarily to adjustments to our sales reserves for accrued product returns related to the MUSE product, which was disposed of in November 2010. The net income from discontinued operations in the three and nine months ended September 30, 2012 was \$80,000 and \$282,000, respectively.

LIQUIDITY AND CAPITAL RESOURCES

Continuing Operations

Cash. Cash, cash equivalents and available-for-sale securities totaled \$346.4 million at September 30, 2013, as compared to \$214.6 million at December 31, 2012. The increase of \$131.8 million is primarily due to cash provided by financing activities. In April 2013, we received a net amount of \$48.4 million through the sale of a debt-like instrument to BioPharma, or the Senior Secured Notes. On May 21, 2013, we closed an offering of \$220.0 million in 4.5% Convertible Senior Notes due May 1, 2020. On May 29, 2013, we closed on an additional \$30.0 million of Convertible Notes upon the exercise of an option by the initial purchasers of the Convertible Notes. Total net proceeds from the Convertible Notes were approximately \$241.8 million. In addition, in the third quarter of 2013, we received upfront payments totaling \$26.6 million, net of withholding taxes, under the License Agreement with Menarini.

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Since inception, we have financed operations primarily from the issuance of equity, debt and debt-like securities. Through September 30, 2013, we have raised approximately \$720.9 million from financing activities, received \$150 million from the sale of Evamist, and had an accumulated deficit of \$643.4 million at September 30, 2013.

At September 30, 2013, we had \$143.1 million in cash and cash equivalents and \$203.3 million in available-for-sale securities. We invest our excess cash balances in money market and marketable securities and U.S. government securities, in accordance with our investment policy. At September 30, 2013, all of our cash equivalents and available-for-sale securities were invested in either U.S. government securities or money market funds. The investment policy has the primary investment objectives of preservation of principal; however, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy. If those securities are downgraded or impaired, we would experience realized or unrealized losses in the value of our portfolio, which would have an adverse effect on our results of operations, liquidity and financial condition.

Investment securities are exposed to various risks, such as interest rate, market and credit. Due to the level of risk associated with certain investment securities and the level of uncertainty related to changes in the value of investment securities, it is possible that changes in these risk factors in the near term could have an adverse material impact on our results of operations or stockholders' equity.

Liabilities. Total liabilities were \$268.6 million at September 30, 2013, which is \$227.4 million higher than at December 31, 2012, the increase of which was primarily due to the issuances of our Convertible Notes and Senior Secured Notes as well as the deferred revenue related to Qsymia and the License Agreement with Menarini.

Operating Activities. Our operating activities used \$121.2 million and \$73.1 million in cash during the nine months ended September 30, 2013 and 2012, respectively. During the nine months ended September 30, 2013, our net operating loss from continuing operations of \$157.8 million was offset by \$27.8 million in non-cash share-based compensation expense due to increased headcount and the automatic acceleration of vesting of unvested stock options held by certain employees per the terms of the Amended Agreements, and \$7.5 million due to the inventory impairment charge for Qsymia. Additional cash used in operating activities resulted from changes in assets and liabilities during the period, including a net \$19.6 million increase in inventories, primarily for Qsymia, an increase of \$19.0 million in deferred revenue related to Qsymia and the SPEDRA agreement with Menarini, and a decrease in accounts payable of \$7.9 million during the first nine months of 2013, due to the timing of vendor payments.

During the nine months ended September 30, 2012, our net operating loss from continuing operations of \$83.5 million was offset by \$10.9 million in non-cash share-based compensation expense and a \$9.6 million net increase in accounts payable, primarily due to startup costs for the post-approval STENDRA and Qsymia clinical trials and an increase in marketing and sales activities. These positive cash flows to our net operating loss were in turn offset by a \$13.3 million net increase in prepaid expenses and other assets, which primarily was comprised of prepayments related to Qsymia product liability insurance, medical affairs activities for Qsymia, and prepaid product commercialization costs for establishing sales and marketing infrastructure in support of the commercial launch of Qsymia in the United States. In addition, there was a net \$3.0 million increase in inventories, primarily for Qsymia.

Investing Activities. Our investing activities used \$52.3 million and \$109.3 million in net cash during the nine months ended September 30, 2013 and 2012, respectively. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturity of investment securities.

Financing Activities. Financing activities provided net cash of \$258.0 million and \$205.2 million during the nine months ended September 30, 2013 and 2012, respectively. In the first nine months of 2013, net cash provided by financing activities included \$290.2 million in net proceeds from debt issuances, partially offset by \$34.7 million in payments for capped call transactions. In the first nine months of 2012, cash provided by financing activities included \$192.0 million in net proceeds from an underwritten public offering of our common stock.

The funding necessary to execute our business strategies is subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. Commercialization of Qsymia may be more costly than we planned. In addition, completion of clinical trials and approval by the FDA of investigational drug candidates may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of an investigational drug candidate. It is also important to note that if an investigational drug candidate is identified, the further development of that candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, lack of efficacy or safety or change in market demand.

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We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs at least through 2014. However, we anticipate that we may require additional funding to expand the use of Qsymia through targeted patient and physician education, find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience, create a pathway for centralized approval of Qsiva in Europe, continue the expansion of our distribution of Qsymia through certified retail pharmacy locations, conduct post-approval clinical studies for both Qsymia and STENDRA, conduct non-clinical and clinical research and development work to support regulatory submissions and applications for our future investigational drug candidates, finance the costs involved in filing and prosecuting patent applications and enforcing or defending our patent claims, if any, to fund operating expenses, establish additional or new manufacturing and marketing capabilities, and manufacture quantities of our drugs and investigational drug candidates and to make payments under our existing license agreements for Qsymia and STENDRA.

If we require additional capital, we may seek any required additional funding through collaborations, public and private equity or debt financings, capital lease transactions or other available financing sources. Additional financing may not be available on acceptable terms, or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing stockholders may result. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our commercialization or development programs or obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop on our own.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet financing arrangements and have not established any special purpose entities. We have not guaranteed any debt or commitments of other entities or entered into any options on non-financial assets.

Commitments and Contingencies

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, shareholder suits and tax matters, as such, we are unable to estimate the potential exposure related to these indemnification agreements. We have not recognized any liabilities relating to these agreements as of September 30, 2013.

Contractual Obligations

The following contractual obligations are recent transactions and are in addition to our other contractual obligations as previously disclosed in our Annual Report on Form 10-K.

Convertible Senior Notes Due 2020

On May 21, 2013 the Company closed an offering of \$220.0 million in 4.5% Convertible Senior Notes due May 1, 2020. The Convertible Notes are governed by an indenture, dated as of May 21, 2013 between the Company and Deutsche Bank National Trust Company, as trustee. On May 29, 2013, we

closed on an additional \$30.0 million of Convertible Notes upon the exercise of an option by the initial purchasers of the Convertible Notes. Total net proceeds from the Convertible Notes were approximately \$241.8 million.

The Convertible Notes are senior unsecured obligations of the Company and bear interest at a fixed rate of 4.50% per annum, payable semiannually in arrears on May 1 and November 1 of each year, beginning on November 1, 2013, unless earlier purchased or converted.

The Convertible Notes are convertible into approximately 16,826,000 unregistered 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 the Convertible Notes, which represents a conversion price of approximately \$14.858 per share, subject to adjustment under certain conditions. The Convertible Notes are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding November 1, 2019, only under certain conditions. On or after November 1, 2019, holders may convert all or any portion of their Convertible Notes at their option at the conversion rate then in effect at any time, regardless of these conditions. Subject to certain limitations, we will settle conversions of the Convertible Notes by paying or delivering, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The conversion rate of the Convertible Notes, and the corresponding conversion price, will be subject to adjustment for certain events, but will not be adjusted for accrued interest. In addition, following certain corporate

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transactions that occur on or prior to the maturity date for the Convertible Notes, we will increase the conversion rate for a holder that elects to convert its Convertible Notes in connection with such a corporate transaction.

Senior Secured Notes Due 2018

On March 25, 2013, we entered into the Purchase and Sale Agreement with BioPharma providing for the purchase of a debt-like instrument, or the Senior Secured Notes. Under the BioPharma agreement, we received \$50 million, less \$500,000 in funding and facility payments, at the initial closing on April 9, 2013. We may also elect prior to December 31, 2013, subject to certain terms and conditions, to receive an additional \$60 million, less \$600,000 in a funding payment, at the secondary closing no earlier than April 30, 2013 and no later than January 15, 2014. We were responsible for all reasonable and documented out-of-pocket legal costs and fees incurred by BioPharma related to the BioPharma agreement, subject to a cap of \$300,000. Net proceeds from the initial financing were approximately \$48.4 million.

We are obligated to make scheduled quarterly payments under the BioPharma agreement. The first payment is scheduled to be made in the second quarter of 2014 and the final payment is scheduled to be made in the second quarter of 2018. The scheduled quarterly payments are subject to the net sales of (i) Qsymia (and any derivative or improvement thereof, including Qsiva as it relates to the EU), or the Product, 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. Regardless, we may pay scheduled quarterly payments out of any available funds notwithstanding Product net sales. We also have the option to prepay all scheduled quarterly payments as specified in the BioPharma agreement.

To secure our obligations in connection with the BioPharma agreement, we granted BioPharma a security interest to (i) the purchased receivables which are defined in the BioPharma agreement as the scheduled quarterly payments, any underpayments of such payments based on an audit of our records and any interest due on the foregoing amounts, and (ii) our patents, trademarks, copyrights and regulatory filings related to the Product, or the Additional Collateral.

Future minimum contractual payments of the long-term notes payable, subject to the payment terms of the BioPharma agreement as described above, as of September 30, 2013 are as follows (in thousands):

	Convertible Notes	Senior Secured Notes	Total
2013	\$ 5,000	\$ —	\$ 5,000
2014	11,250	9,000	20,250
2015	11,250	18,000	29,250
2016	11,250	20,000	31,250
2017	11,250	20,000	31,250
Thereafter	278,125	6,700	284,825
Total	<u>\$ 328,125</u>	<u>\$ 73,700</u>	<u>\$ 401,825</u>

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The SEC's rule related to market risk disclosure requires that we describe and quantify our potential losses from market risk sensitive instruments attributable to reasonably possible market changes. Market risk sensitive instruments include all financial or commodity instruments and other financial instruments that are sensitive to future changes in interest rates, currency exchange rates, commodity prices or other market factors.

Market and Interest Rate Risk

Our cash, cash equivalents and available-for-sale securities as of September 30, 2013 consisted primarily of money market funds and U.S. Treasury securities. Our cash is invested in accordance with an investment policy approved by our Board of Directors that specifies the categories (money market funds, U.S. Treasury securities and debt securities of U.S. government agencies, corporate bonds, asset-backed securities, and other securities), allocations, and ratings of securities we may consider for investment. Currently, we have focused on investing in U.S. Treasuries until market conditions improve.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable debt securities. The primary objective of our investment activities is to preserve principal. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment may decline. A hypothetical 100 basis point increase in interest rates would reduce the fair value of our available-for-sale securities at September 30, 2013 by approximately \$893,000. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

ITEM 4. CONTROLS AND PROCEDURES

(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 Exchange Act reports 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 Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of VIVUS's disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

(b.) Changes in internal controls. There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Securities Related Class Action Lawsuits

The Company and two of its officers were defendants in a putative class action lawsuit captioned *Kovtun v. Vivus, Inc., et al.*, Case No. 4:10-CV-04957-PJH, in the U.S. District Court, Northern District of California. The action, filed in November 2010, alleged violations of Section 10(b) and 20(a) of the federal Securities Exchange Act of 1934 based on allegedly false or misleading statements made by the defendants in connection with the Company's clinical trials and New Drug Application, or NDA, for Qsymia as a treatment for obesity. The Court granted defendants' motions to dismiss both plaintiff's Amended Class Action Complaint and Second Amended Class Action Complaint; by order dated September 27, 2012, the latter dismissal was with prejudice, and final judgment was entered for defendants the same day. On October 26, 2012, plaintiff filed a Notice of Appeal to the U.S. Court of Appeals for the Ninth Circuit. Briefing of the appeal is complete, and the parties are awaiting word on whether the Court of Appeals wishes to entertain oral argument.

Additionally, certain of the Company's officers and directors are defendants in a shareholder derivative lawsuit captioned *Turberg v. Logan, et al.*, Case No. CV-10-05271-PJH, pending in the same federal court. In the plaintiff's Verified Amended Shareholder Derivative Complaint filed June 3, 2011, the plaintiff largely restated the allegations of the *Kovtun* action and alleged that the directors breached fiduciary duties to the Company by purportedly permitting the Company to violate the federal securities laws as alleged in the *Kovtun* action. The same individuals are also named defendants in consolidated shareholder derivative suits pending in the California Superior Court, Santa Clara County under the caption *In re VIVUS, Inc. Derivative Litigation*, Master File No. 11 0 CV188439. The allegations in the state court derivative suits are substantially similar to the other lawsuits. The Company is named as a nominal defendant in these actions, neither of which seeks any recovery from the Company. The parties have agreed to stay the derivative lawsuits pending the outcome of the appeal of the securities class action.

The Company and its directors cannot predict the outcome of the various shareholder lawsuits, but they believe the various shareholder lawsuits are without merit and intend to continue vigorously defending them.

On July 12, 2013, various current and former officers and directors of the Company were named as defendants in a separate shareholder derivative lawsuit filed in the California Superior Court, Santa Clara County and captioned *Ira J. Gaines IRA, et al. v. Leland F. Wilson, et al.*, Case No.1-13-CV-249436. The lawsuit generally alleges breaches of the fiduciary duty of care in connection with the launch of Qsymia, breaches of the duty of loyalty and insider trading by some defendants for selling Company stock while purportedly being aware that the Qsymia launch would be less successful than predicted and corporate waste. Again, the Company is named as a nominal defendant, and no recovery from the Company is sought. As with the other shareholder litigation, the Company does have certain indemnification obligations to the named defendants, including to advance defense costs to the individuals. The Company also maintains directors' and officers' liability insurance that it believes affords coverage for much of the anticipated cost of the proceedings, subject to the policies' terms and conditions. The individual defendants deny the material allegations and have indicated an intention to defend them vigorously. On October 21, 2013, the Company filed a demurrer seeking to have the lawsuit dismissed in its entirety for failure to make a pre-suit demand upon our Board of Directors or plead sufficient facts to show that such demand would have been futile.

Proxy Related Lawsuit

On July 16, 2013, First Manhattan, the owner of approximately 9.9% of the outstanding shares of common stock of the Company, commenced an action in the Court of Chancery of the State of Delaware, naming the then-serving members of the Board as defendants and the Company as a nominal defendant. The action was captioned *First Manhattan Co. v. Leland F. Wilson, et al.*, C.A. No. 8731-VCL. In its verified complaint, First Manhattan alleged

that the Company's directors breached their fiduciary duties in connection with the Board's decision to adjourn the annual stockholders meeting from July 15, 2013 until July 18, 2013. The verified complaint sought declaratory and injunctive relief, including enjoining the defendants from soliciting proxies, directing the inspector of elections to certify the election of directors based on votes that were present and prepared to be voted on July 15, 2013 before the annual stockholders meeting was adjourned, and prohibiting defendants from taking any actions as directors of the Company. The verified complaint did not seek damages from the Company or the defendant board members. The parties entered into a settlement agreement on July 18, 2013, and the action was dismissed with prejudice on July 19, 2013. As part of the settlement agreement with First Manhattan, the Company agreed to pay the reasonable and documented expenses incurred by First Manhattan in connection with its proxy contest, which are estimated at approximately \$3.0 million.

ITEM 1A. RISK FACTORS

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

Risks Relating to our Business

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

In July 2013, we announced changes to our Board and management. In September and November 2013, we announced further changes to our management team. In November 2013, we announced a reduction in force of approximately 17%, the decision of our Chief Financial Officer to exercise his right to terminate his employment for Good Reason (as defined in his Amended and Restated Change of Control and Severance Agreement with the Company, effective as of July 1, 2013), and the appointment of our Corporate Controller as the Company's interim Chief Financial Officer. The implementation of these changes, including the recent appointment of a new Chief Executive Officer and interim Chief Financial Officer, the expansion of our Board to include predominantly new members, the resignation of our President, the decision of our Chief Financial Officer to exercise his right to terminate his employment for Good Reason, 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;

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- stock price volatility; and
- difficulty in negotiating, maintaining or consummating business or strategic relationships or transactions.

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

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

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

- expand the use of Qsymia through targeted patient and physician education;
- find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience;
- create a pathway for centralized approval of Qsiva™ in Europe;
- eliminate expenses that are not essential to expanding the use of Qsymia;
- continue to certify and add to the Qsymia retail pharmacy network nationwide and sell Qsymia through this network;
- lower out-of-pocket costs to patients with discount programs, improve third-party payor coverage and change public policy;
- create market demand for Qsymia through patient and physician education, marketing and sales activities;
- achieve market acceptance and generate product sales;
- comply with the post-marketing requirements established by the U.S. Food and Drug Administration, or FDA, including the Risk Evaluation and Mitigation Strategy, or REMS, and any other requirements established by the FDA in the future;
- conduct the post-marketing studies required by the FDA;
- comply with other healthcare regulatory requirements;
- maintain and defend our patents, if challenged;
- ensure that the active pharmaceutical ingredients, or APIs, for Qsymia and the finished product are manufactured in sufficient quantities and in compliance with requirements of the FDA and similar foreign regulatory agencies and with an acceptable quality and pricing level in order to meet commercial demand; and

- ensure that the entire supply chain for Qsymia, from APIs to finished product, efficiently and consistently delivers Qsymia to our customers.

Prior to the commercialization of Qsymia, we have not had any commercial products since the divestiture of MUSE in November 2010. While our management and key personnel have significant experience developing, launching and commercializing drugs at VIVUS and at other companies, we have only recently begun to work together to commercialize Qsymia and we cannot be certain that we will be successful. If we are unable to successfully commercialize Qsymia, our ability to generate product sales will be severely limited, which will have a material adverse impact on our business, financial condition, and results of operations.

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

On November 5, 2013, we announced a cost reduction plan to eliminate expenses that are not essential to expanding the use of Qsymia. The plan will reduce our workforce by approximately 20 employees. We expect to complete the cost reduction plan by the end of 2013, and anticipate incurring pre-tax non-recurring charges in the range of \$6 million to \$8 million in the fourth quarter of 2013, including approximately \$4 million to \$5 million in employee termination costs, \$1 million to \$1.5 million in non-cash share-based compensation expense related to the automatic acceleration of vesting of unvested stock options held by the terminated employees, and \$1 million to \$1.5 million in operating lease exit costs. We expect to realize approximately \$6 million to \$8 million in annual net cost savings beginning in fiscal year 2014.

Our ability to achieve the anticipated cost savings and other benefits from this cost reduction plan within the expected timeframe are subject to many estimates and assumptions, and the actual savings and timing for those savings may vary materially based on factors such as negotiations with third parties and operational requirements. These estimates and assumptions are subject to significant economic, competitive and other uncertainties, some of which are beyond our control. There can be no assurance that we will fully realize the anticipated benefits from this cost reduction plan. To the extent that we are unable to successfully implement our business plan, further cost reduction measures may be required in the future.

We depend on our collaboration partners, Auxilium and Menarini, to market and sell STENDRATM (avanafil) in the United States and Canada, and SPEDRATM (avanafil) in over 40 European countries, plus Australia and New Zealand, respectively.

On October 10, 2013, we entered into a License and Commercialization Agreement and a Commercial Supply Agreement with Auxilium to commercialize and promote STENDRA for the treatment of erectile dysfunction, or ED, in the United States and Canada. On July 5, 2013, we entered into a License and Commercialization Agreement and a Commercial Supply Agreement with Menarini to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, plus Australia and New Zealand.

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

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

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

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

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

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

- we may not be able to control the commercialization of our drug products in the relevant territories, including amount, timing and quality of resources that our collaborators may devote to our drug products;

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- our collaborators may experience financial, regulatory or operational difficulties, which may impair their ability to commercialize our drug products;
- our collaborators may be required under the laws of the relevant territory to disclose our confidential information or may fail to protect our confidential information;

- as a requirement of the collaborative arrangement, we may be required to relinquish important rights with respect to our drug products, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to satisfactorily complete its commercialization or other obligations under any collaborative arrangement;
- legal disputes or disagreements may occur with one or more of our collaborators;
- a collaborator could independently move forward with a competing investigational drug candidate developed either independently or in collaboration with others, including with one of our competitors; and
- a collaborator could terminate the collaborative arrangement, which could negatively impact the continued commercialization of our drug products.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.

In order to market products in many foreign jurisdictions, we must obtain separate regulatory approvals. Approval by the FDA in the U.S. does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. For example, while our drug SPEDRA was approved in both the U.S. and the EU, our drug Qsymia was approved in the U.S. but Qsiva (the approved trade name for Qsymia in the EU) was not approved in the EU due to concerns over the potential cardiovascular and central nervous system effects associated with long-term use, teratogenic potential and use by patients for whom Qsiva would not have been indicated. We intend to seek approval for Qsymia and STENDRA in other territories outside the United States and EU. However, we have had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional testing. Foreign regulatory approvals may not be obtained on a timely basis, or at all, for any of our products and the failure to receive regulatory approvals in a foreign country would prevent us from marketing 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 in certain territories, intend to market SPEDRA outside the U.S. which will subject us to risks related to conducting business internationally.

We, through Menarini in certain territories, intend to manufacture, market, and distribute 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;

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- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- production shortages resulting from events affecting raw material supply or manufacturing capabilities abroad;
- potential liability resulting from development work conducted by these distributors; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

We rely in part on a third-party contract sales organization for certain sales and marketing support services for Qsymia.

We rely on PDI, Inc., or PDI, a third-party contract sales organization, to assist with the hiring of sales representatives and the promotion of Qsymia to physicians. Our internal sales and marketing personnel manage and supervise the activities of this sales force. Nevertheless, we face risks in our partial reliance on the third-party contract sales organization including the following:

- PDI may not apply the expected financial resources or required expertise to successfully promote Qsymia;
- PDI may not invest in the continued development of a sales force and the related infrastructure at levels that ensure that sales of Qsymia reach their full potential;

- PDI, or its sales representatives, may not comply with applicable legal or regulatory requirements, including the requirement to promote drugs only for uses for which they have been approved;
- disputes may arise between us and PDI, including between the contract sales representatives, who are PDI employees, and sales management, who are VIVUS employees, that may adversely affect Qsymia sales or profitability; and
- PDI may enter into agreements with other parties that have products that could compete with Qsymia.

We depend on the success of PDI in performing its services, and we cannot be certain PDI will cooperate with us to perform its obligations under the agreement. Although they are contractually obligated, we cannot control the amount of resources that will be devoted by PDI to the promotion of Qsymia. Any failure of PDI to perform its obligations or to continue to allocate resources to the promotion of Qsymia could adversely affect the commercialization of Qsymia and materially harm our business, financial condition and results of operations.

We have significant inventories on hand and, in the first nine months of 2013, we recorded inventory impairment and commitment fees totaling \$10.2 million, primarily to write off excess inventory related to Qsymia.

We maintain significant inventories and evaluate these inventories on a periodic basis for potential excess and obsolescence. For the nine months ended September 30, 2013, we recognized total charges of \$10.2 million for inventories on hand in excess of demand, plus a purchase commitment fee. No additional charge was required in the three months ended September 30, 2013. The inventory impairment charges were based on our analysis of current Qsymia inventory on hand and remaining shelf life, in relation to our projected demand for the product. The current FDA-approved commercial product shelf life for Qsymia and STENDRA is 36 months. We have submitted a request to the FDA to extend the shelf life of STENDRA to 48 months.

Our allowance for excess and obsolete inventory is subjective and requires accurate forecasting of the future market demand for our products. Forecasting demand for Qsymia, a drug in the obesity market in which there have been no new FDA-approved medications in over a decade and for which reimbursement from third-party payors had previously been non-existent, has been difficult. We have experienced significant differences between our forecasts and actual demand for our products. Differences between forecasts and actual demand may occur in the future. 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, if the FDA does not approve the extension of the shelf life for STENDRA, or if any significant unanticipated changes in future product demand or market conditions occur. Any of these events, or a combination thereof, could result in additional inventory write-downs in future periods, which could be material.

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Our failure to manage and maintain our distribution network for Qsymia or compliance with certain requirements of the Qsymia REMS program could compromise the commercialization of this product.

We rely on Cardinal Health 105, Inc., or Cardinal Health, a third-party distribution and supply-chain management company, to warehouse Qsymia and distribute it to the certified home delivery pharmacies and wholesalers that then distribute Qsymia directly to patients and certified retail pharmacies. Cardinal Health provides billing, collection and returns services. Cardinal Health is our exclusive supplier of distribution logistics services, and accordingly we depend on Cardinal Health to satisfactorily perform its obligations under our agreement with them.

Pursuant to the REMS program applicable to Qsymia, our distribution network is through a small number of certified home delivery pharmacies, wholesalers and 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 physician data. In addition, we have contracted with a third-party data warehouses to store this patient and prescribing physician 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 warehouse, or the inability or failure of any of them to adequately perform under our contracts with them, could negatively impact the distribution of Qsymia, or adversely affect our ability to comply with the REMS applicable to Qsymia. Failure to comply with a requirement of an approved REMS can result in, among other things, civil penalties, operating restrictions and criminal prosecution. Failure to coordinate financial systems could also negatively impact our ability to accurately report and forecast product revenue. If we are unable to effectively manage the distribution and data collection process, sales of Qsymia could be severely compromised and our business, financial condition and results of operations would be harmed.

If we are unable to enter into agreements with suppliers or our suppliers fail to supply us with the APIs for our products or if we rely on sole source suppliers, we may experience delays in commercializing our products.

We currently do not have supply agreements for extended-release topiramate or phentermine, which are 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 these suppliers in a timely manner or at all.

We anticipate that we will continue to rely on single source suppliers for phentermine and extended-release topiramate for the foreseeable future. Any production shortfall on the part of our suppliers that impairs the supply of phentermine or extended-release topiramate could have a material adverse effect on our business, financial condition and results of operations. If we are unable to obtain a sufficient quantity of these compounds, there could be a substantial delay in successfully developing a second source supplier. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could adversely affect our ability to satisfy demand for Qsymia, which could adversely affect our product sales and operating results materially, which could significantly harm our business.

The API and the tablets for STENDRA are currently manufactured by MTPC. MTPC has arrangements for the three main starting materials necessary for the manufacturing of avanafil API. The MTPC manufacturing sites for the API (avanafil) and STENDRA tablets have been inspected by the U.S. authorities. We do not believe the results of those inspections will have an impact on MTPC's ability to supply STENDRA. However, if MTPC is unable to receive approval from foreign regulators and maintain ongoing FDA or foreign regulatory compliance, or manufacture STENDRA's API or tablets in sufficient quantities to meet projected demand, the U.S. commercial launch, and future sales of STENDRA will be adversely effected, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration agreement for the commercialization of STENDRA in territories not covered by our agreements with Auxilium and Menarini.

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In August 2012, we entered into an amendment to our agreement with MTPC that permits us to manufacture the API and tablets for STENDRA ourselves or through third-party suppliers at any time, and we are required under the amendment to transition away from MTPC supply on or before June 30, 2015. On July 31, 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, Latin America and other territories. We intend to submit an amendment to the New Drug Application, or NDA, for avanafil to the FDA, and the MAA for avanafil to the European Medicines Agency, or EMA, to include Sanofi Chimie as a qualified supplier of the avanafil API. We cannot be certain we will receive approval by regulatory authorities, and the failure to receive such approval could prevent or delay our ability to establish a reliable supply chain, which could compromise our ability to commercialize avanafil through our relationships with Auxilium and Menarini, or otherwise. We currently do not have any manufacturing facilities and intend to continue to rely on third parties for the supply of the starting materials, API and tablets. However, we cannot be certain that we will be successful in entering into such agreements with other suppliers or that we will be able to obtain the necessary regulatory approvals for these suppliers in a timely manner or at all.

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. For example, we are obligated to use our best commercial efforts to market STENDRA in the U.S. by December 31, 2013. On October 10, 2013, we entered into a License and Commercialization Agreement and a Commercial Supply Agreement with Auxilium to commercialize and promote STENDRA for the treatment of erectile dysfunction, or ED, in the United States and Canada. Although Auxilium plans to launch STENDRA in the U.S. prior to December 31, 2013, the failure of Auxilium to launch STENDRA in the U.S. before this date may result in us losing our license to STENDRA in the U.S. and could adversely impact the commercial future of STENDRA outside of the U.S. In addition, we license the rights to Qsymia from Dr. Najarian. We believe we are in compliance with the material terms of our license agreements with MTPC and Dr. Najarian. However, there can be no assurance that this compliance will continue or that the licensors will not have a differing interpretation of the material terms of the agreements. If the license agreements were terminated early or if the terms of the licenses were contested for any reason, it would have a material adverse impact on our ability to commercialize products subject to these agreements, our ability to raise funds to finance our operations, our stock price and our overall financial condition. The monetary and disruption costs of any disputes involving our agreements could be significant despite rulings in our favor.

Our ability to gain market acceptance and generate revenues will be subject to a variety of risks, many of which are out of our control.

Qsymia and STENDRA may not gain market acceptance among physicians, patients, healthcare payors or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from such drugs will depend on a number of factors, including:

- our ability to expand the use of Qsymia through targeted patient and physician education;
- our ability to find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience;
- our ability to create a pathway for centralized approval of Qsiva in Europe;
- our ability to successfully expand our distribution system for Qsymia from a certified home delivery pharmacy network to certified retail pharmacy locations;

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- contraindications for Qsymia and STENDRA;
- competition and timing of market introduction of competitive drugs;
- efficacy and safety in the approved setting;
- prevalence and severity of any side effects, including those of the generic components of our drugs;
- emergence of previously unknown side effects, including those of the generic components of our drugs;
- results of any post-approval studies;

- potential or perceived advantages or disadvantages over alternative treatments including generics;
- the relative convenience and ease of administration and dosing schedule;
- the convenience and ease of purchasing the drug, as perceived by potential patients;
- strength of sales, marketing and distribution support;
- price, both in absolute terms and relative to alternative treatments;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- the effect of current and future healthcare laws;
- availability of coverage and reimbursement from government and other third-party payors;
- the level of mandatory discounts required under federal and state healthcare programs and the volume of sales subject to those discounts;
- recommendations for prescribing physicians to complete certain educational programs for prescribing drugs;
- the willingness of patients to pay out-of-pocket in the absence of government or third-party coverage; and
- product labeling or product insert requirements of the FDA or other regulatory authorities.

Our drugs may fail to achieve market acceptance or generate significant revenue to achieve or sustain profitability. In addition, our efforts to educate the medical community and third-party payors on the safety and benefits of our drugs may require significant resources and may not be successful.

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

As part of the approval for STENDRA, the FDA is requiring us to perform two post-approval clinical studies. The first is a randomized, double-blind, placebo-controlled, parallel group multicenter clinical trial on the effect of STENDRA on spermatogenesis in healthy adult males and males with mild ED. The other study is a double-blind, randomized, placebo-controlled, single-dose clinical trial to assess the effects of STENDRA on multiple parameters of vision, including, but not limited to, visual acuity, intraocular pressure, pupillometry, and color vision discrimination in healthy male subjects. If we are unable to complete these studies or the results of these studies reveal unacceptable safety risks, we could be required to perform additional tests and regulatory approval could even be withdrawn.

As part of the approval of Qsymia, we are required to conduct several post-marketing studies, including a study to assess the long-term treatment effect of Qsymia on the incidence of major adverse cardiovascular events in overweight and obese subjects with confirmed cardiovascular disease, or AQCLAIM, studies to assess the safety and efficacy of Qsymia for weight management in obese pediatric and adolescent subjects, studies to assess drug utilization and pregnancy exposure and a study to assess renal function. We estimate the AQCLAIM study will cost between \$180 and \$250 million and the study

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could take as long as five to six years to complete. We have submitted to the EMA a request for scientific advice regarding use of a pre-specified interim analysis from AQCLAIM to support the resubmission of the MAA for approval in Europe of Qsiva for obesity under the centralized procedure. In order to accommodate advice from the European authorities, we anticipate that patient enrollment for the AQCLAIM study will commence in the first quarter of 2014. There can be no assurance that the FDA or EMA will not request or require us to provide additional information or undertake additional prospective studies or retrospective observational studies.

At the FDA's request, we initiated a retrospective observational study utilizing existing electronic medical claims healthcare databases to review fetal outcomes, including the incidence of congenital malformations and oral cleft, in the offspring of women who received treatment with topiramate, for any condition or at any dose, or FORTRESS. We announced preliminary results from FORTRESS in December 2011. We submitted the final report for the FORTRESS study to the FDA in the second quarter of 2013. If the FDA determines that the results of this study reveal unacceptable safety risks for topiramate, we could be required to perform additional studies and regulatory approval could even be withdrawn.

In addition to these studies, the FDA may also require us to commit to perform other lengthy post-approval studies, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results, financial condition and stock price. Failure to comply with the applicable regulatory requirements can result in, among other things, civil penalties, suspensions of regulatory approvals, operating restrictions and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition, results of operations and stock price.

We depend upon consultants and outside contractors extensively in important roles within our company.

We outsource many key functions of our business and therefore rely on a substantial number of consultants, and we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials or other development activities may be extended, delayed or terminated, and we may not be able to complete our post-approval clinical trials for Qsymia and STENDRA, obtain regulatory approval for our future investigational drug candidates, successfully commercialize our approved drugs or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on commercially reasonable terms, or at all.

Qsymia is a combination of two active ingredient drug products approved individually by the FDA that are commercially available and marketed by other companies, although the specific dose strengths would differ. As a result, Qsymia may be subject to substitution by prescribing physicians, or by pharmacists, with individual drugs contained in the Qsymia formulation, which would adversely affect our business.

Although Qsymia is a once-a-day, proprietary extended-release formulation, each of the approved APIs (phentermine and topiramate extended-release) that is combined to produce Qsymia is commercially available as drug products at prices that together are lower than the price at which we sell Qsymia. In addition, the distribution and sale of these drug products is not limited under a REMS program, as is the case with Qsymia. Further, the individual drugs contained in the Qsymia formulation are available in retail pharmacies and neither has a Pregnancy Category X, which is used to indicate that the risks involved in the use of the drug in pregnant women clearly outweigh potential benefits, as is the case with Qsymia. We cannot be sure that physicians will view Qsymia as sufficiently superior to a treatment regimen of Qsymia's individual APIs to justify the significantly higher cost for Qsymia, and they may prescribe the individual generic drugs already approved and marketed by other companies instead of our combination drug. Although our U.S. and European patents contain composition, product formulation and method-of-use claims that we believe protect Qsymia, these patents may be ineffective or impractical to prevent physicians from prescribing, or pharmacists from dispensing, the individual generic constituents marketed by other companies instead of our combination drug. Phentermine and topiramate are currently available in generic form, although the doses used in Qsymia are currently not available. In the third quarter of 2013, Supernus Pharmaceuticals, Inc. launched Trokendi XR™, an extended-release pediatric formulation of the generic drug topiramate that is indicated for epilepsy, in the United States. 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.

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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.

If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage.

Qsymia and STENDRA, like all pharmaceutical products, are subject to heightened risk for product liability claims due to inherent potential side effects. For example, because topiramate, a component of Qsymia, may increase the risk of congenital malformation in infants exposed to topiramate during the first trimester of pregnancy and also may increase the risk of suicidal thoughts and behavior, such risks may be associated with Qsymia as well. Other potential risks involving Qsymia may include, but are not limited to, an increase in resting heart rate, acute angle closure glaucoma, cognitive and psychiatric adverse events, metabolic acidosis, an increase in serum creatinine, hypoglycemia in patients with type 2 diabetes, kidney stone formation, decreased sweating and hypokalemia, or lower-than-normal amount of potassium in the blood.

Although we have obtained product liability insurance coverage for Qsymia, we may be unable to maintain this product liability coverage for Qsymia or any other of our approved drugs in amounts or scope sufficient to provide us with adequate coverage against all potential risks. A product liability claim in excess of, or excluded from, our insurance coverage would have to be paid out of cash reserves and could have a material adverse effect upon our business, financial condition and results of operations. Product liability insurance is expensive, difficult to maintain, and current or increased coverage may not be available on acceptable terms, if at all.

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

If we cannot successfully defend ourselves against a product liability claim, whether involving Qsymia, STENDRA or a future investigational drug candidate, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- injury to our reputation;
- withdrawal of clinical trial patients;
- costs of defending the claim and/or related litigation;
- cost of any potential adverse verdict;
- substantial monetary awards to patients or other claimants; and
- the inability to commercialize our drugs.

Damages awarded in a product liability action could be substantial and could have a negative impact on our financial condition. Whether or not we were ultimately successful in product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources, and might result in adverse publicity, all of which would impair our business. In addition, product liability claims could result in an FDA investigation of the safety or efficacy of our product, our third-party manufacturing processes and facilities, or our marketing programs. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension or withdrawal of approval.

The markets in which we operate are highly competitive and we may be unable to compete successfully against new entrants or established companies.

Competition in the pharmaceutical and medical products industries is intense and is characterized by costly and extensive research efforts and rapid technological progress. We are aware of several pharmaceutical companies also actively engaged in the development of therapies for the treatment of obesity and erectile dysfunction. Many of these companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human

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resources than we do. Some of the drugs which may compete with Qsymia may not have a REMS requirement and the accompanying complexities such a requirement presents. Our competitors may develop technologies and products that are more effective than those we are currently marketing or researching and developing. Such developments could render Qsymia and STENDRA less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience.

Qsymia for the treatment of chronic weight management competes with several approved anti-obesity drugs including, Belviq® (lorcaserin), Arena Pharmaceutical's approved anti-obesity compound marketed by Eisai Inc., Eisai Co., Ltd.'s U.S. subsidiary; Xenical (orlistat), marketed by Roche; alli®, the over-the-counter version of orlistat, marketed by GlaxoSmithKline; and Suprenza, an orally disintegrating tablet (phentermine hydrochloride), marketed by Akrimax Pharmaceuticals, LCL. In addition, Orexigen Therapeutics, Inc., or Orexigen, has an investigational drug in late stage testing, Contrave®, which, according to Orexigen, could be approved and on the market in 2014. Contrave would be marketed by Takeda Pharmaceutical Company Limited.

There are also several drugs in development for obesity including an investigational drug candidate, liraglutide, in Phase 3 clinical trials being developed by Novo Nordisk A/S. Victoza® (liraglutide) is approved by the FDA for the treatment of type 2 diabetes and also is being developed for the treatment of obesity. In addition, there are several other investigational drug candidates in Phase 2 clinical trials. There are also a number of generic pharmaceutical drugs that are prescribed for obesity, predominantly phentermine. Phentermine is sold at much lower prices than we charge for Qsymia and is available in retail pharmacies. The availability of branded prescription drugs, generic drugs and over-the-counter drugs could limit the demand for, and the price we are able to charge for, Qsymia.

We also may face competition from the off-label use of the generic components in our drugs. In particular, it is possible that patients will seek to acquire phentermine and topiramate, the generic components of Qsymia. Neither of these generic components has a REMS program and both are available at retail pharmacies. Although the dose strength of these generic components has not been approved by the FDA for use in the treatment of obesity, the off-label use of the generic components in the U.S. or the importation of the generic components from foreign markets could adversely affect the commercial potential for our drugs and adversely affect our overall business, financial conditions and results of operations.

There are also surgical approaches to treat severe obesity that are becoming increasingly accepted. Two of the most well established surgical procedures are gastric bypass surgery and adjustable gastric banding, or lap bands. In February 2011, the FDA approved the use of a lap band in patients with a BMI of 30 (reduced from 35) with comorbidities. The lowering of the BMI requirement will make more obese patients eligible for lap band surgery. In addition, other potential approaches that utilize various implantable devices or surgical tools are in development. Some of these approaches are in late stage development and may be approved for marketing.

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

As patents for the three major PDE5 inhibitors, sildenafil citrate, tadalafil and vardenafil, expire beginning in 2017, we anticipate that generic PDE5 inhibitors will enter the market. Generic PDE5 inhibitors would likely be sold at lower prices and may reduce the demand for STENDRA especially at the prices we would be required to charge for STENDRA to cover our manufacturing and other costs. In addition, PDE5 inhibitors are in various stages of development by other companies. Warner-Chilcott plc has licensed the U.S. rights to udenafil, a PDE5 inhibitor, from Dong-A Pharmaceutical. Warner-Chilcott continues Phase 3 development of this compound. Warner-Chilcott was acquired by Actavis in a transaction that is expected to close by the end of 2013. Other treatments for ED exist, such as needle injection therapies, vacuum constriction devices and penile implants, and the manufacturers of these products will most likely continue to develop or improve these therapies.

Qsymia and STENDRA may also face challenges and competition from newly developed generic products. Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, newly approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act stimulates competition by providing incentives to generic pharmaceutical manufacturers to introduce non-infringing forms of patented pharmaceutical products and to challenge patents on branded pharmaceutical products. If we are unsuccessful at challenging an Abbreviated New Drug Application, or ANDA, filed pursuant to the Hatch-Waxman Act, a generic version of Qsymia or STENDRA may be launched, which would harm our business.

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New developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical and medical technology industries at a rapid pace. These developments may render our drugs and future investigational drug candidates obsolete or noncompetitive. Compared to us, many of our potential competitors have substantially greater:

- research and development resources, including personnel and technology;
- regulatory experience;
- investigational drug candidate development and clinical trial experience;
- experience and expertise in exploitation of intellectual property rights; and

- access to strategic partners and capital resources.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our future investigational drug candidates. Our competitors may also develop drugs or surgical approaches that are more effective, more useful and less costly than ours and may also be more successful in manufacturing and marketing their products. In addition, our competitors may be more effective in commercializing their products. We currently outsource our manufacturing and therefore rely on third parties for that competitive expertise. There can be no assurance that we will be able to develop or contract for these capabilities on acceptable economic terms, or at all.

We may participate in new partnerships and other strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we consider strategic transactions, such as out-licensing or in-licensing of compounds or technologies, acquisitions of companies and asset purchases. Additional potential transactions we may consider include a variety of different business arrangements, including strategic partnerships, joint ventures, spin-offs, restructurings, divestitures, business combinations and investments. In addition, another entity may pursue us as an acquisition target. Any such transactions may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges, require additional expertise or disrupt our management or business, any of which could harm our operations and financial results.

As part of an effort to enter into significant transactions, we conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the expected benefits of the transaction. If we fail to realize the expected benefits from any transaction we may consummate, whether as a result of unidentified risks, integration difficulties, regulatory setbacks or other events, our business, results of operations and financial condition could be adversely affected.

Our failure to successfully acquire, develop and market additional investigational drug candidates or approved drugs would impair our ability to grow.

As part of our growth strategy, we may acquire, in-license, develop and/or market additional products and investigational drug candidates. We have not in-licensed any new product candidates in several years. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical investigational drug candidates and products.

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

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

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

Further, any investigational drug candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and obtaining approval by the FDA and applicable foreign regulatory authorities. All investigational drug candidates are prone to certain failures that are relatively common in the field of drug development, including the possibility that an investigational drug candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot be certain that any drugs that we develop or approved products that we may acquire will be commercialized profitably or achieve market acceptance.

If we fail to retain our key personnel and hire, train and retain qualified employees, we may not be able to compete effectively, which could result in reduced revenues or delays in the development of our investigational drug candidates or commercialization of our approved drugs.

Our success is highly dependent upon the skills of a limited number of key management personnel. To reach our business objectives, we will need to retain and hire qualified personnel in the areas of manufacturing, commercial operations, research and development, regulatory and legal affairs, business development, clinical trial design, execution and analysis, and pre-clinical testing. There can be no assurance that we will be able to hire or retain such personnel, as we must compete with other companies, academic institutions, government entities and other agencies. The loss of any of our key personnel or

the failure to attract or retain necessary new employees could have an adverse effect on our research programs, investigational drug candidate development, approved drug commercialization efforts and business operations.

We rely on third parties and collaborative partners to manufacture sufficient quantities of compounds within product specifications as required by regulatory agencies for use in our pre-clinical and clinical trials and commercial operations and an interruption to this service may harm our business.

We do not have the ability to manufacture the materials we use in our pre-clinical and clinical trials and commercial operations. Rather, we rely on various third parties to manufacture these materials and there may be long lead times to obtain materials. There can be no assurance that we will be able to identify, 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

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quality standards, and we may not be able to obtain favorable terms in agreements with subcontractors. Our third-party manufacturers, may not be able to operate manufacturing facilities in a cost-effective manner or in a time frame that is consistent with our expected future manufacturing needs. If our third-party manufacturers, cease or interrupt production or if our third-party manufacturers and other service providers fail to supply materials, products or services to us for any reason, such interruption could delay progress on our programs, or interrupt the commercial supply, with the potential for additional costs and lost revenues. If this were to occur, we may also need to seek alternative means to fulfill our manufacturing needs.

For example, Catalent Pharma Solutions, LLC, or Catalent, supplied the product for the Phase 3 program for Qsymia and is our sole source of clinical and commercial supplies for Qsymia. Catalent has been successful in validating the commercial manufacturing process for Qsymia at an initial scale, which has been able to support the launch of Qsymia in the U.S. market. While Catalent has significant experience in commercial scale manufacturing, there is no assurance that Catalent will be successful in increasing the scale of the initial Qsymia manufacturing process, should the market demand for Qsymia expand beyond the level supportable by the current validated manufacturing process. Such a failure by Catalent to further scale up the commercial manufacturing process for Qsymia could have a material adverse impact on our ability to realize commercial success with Qsymia in the U.S. market, and have a material adverse impact on our plan, market price of our common stock and financial condition.

In the case of STENDRA, we currently rely on MTPC to supply the API (avanafil) and the tablets for STENDRA. MTPC is responsible for all aspects of manufacture, including obtaining the starting materials for the production of API. If MTPC is unable to manufacture the API or tablets for STENDRA in sufficient quantities to meet projected demand, future sales of STENDRA could be adversely effected, which in turn could have a detrimental impact on our financial results, our License and Commercialization Agreement and Commercial Supply Agreement with Auxilium, our License and Commercialization Agreement and Commercial Supply Agreement with Menarini, and our ability to enter into a collaboration agreement for the commercialization of STENDRA in territories not covered by our agreements with Auxilium and Menarini.

In August 2012, we entered into an amendment to our agreement with MTPC that permits us to manufacture the API and tablets for STENDRA ourselves or through third parties. According to the amendment, the transition of manufacturing from MTPC must occur on or before June 30, 2015. The transfer of technology to, and qualification of, a new supplier is expensive, time consuming and logistically complicated. The technology transfer needed for this transition is highly dependent on the cooperation of MTPC and its current suppliers. If MTPC, or its current suppliers, are unable to effectively transfer the technology or supply on commercially reasonable terms, partnerability and commercial success of STENDRA could be adversely impacted. On July 31, 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, Latin America and other territories. We intend to submit an amendment to the NDA for avanafil to the FDA, and the MAA for avanafil to the EMA, to include Sanofi Chimie as a qualified supplier of the avanafil API. We cannot be certain we will receive approval by regulatory authorities, and the failure to receive such approval could prevent or delay our ability to establish a reliable supply chain, which could compromise our ability to commercialize avanafil through our relationships with Auxilium, Menarini or otherwise. We currently do not have any manufacturing facilities and intend to continue to rely on third parties for the supply of the starting materials, API and tablets. However, we cannot be certain that we will be successful in entering into such agreements with other suppliers or that we will be able to obtain the necessary regulatory approvals for these suppliers in a timely manner or at all. Any future manufacturing sites would need to be inspected by the U.S. and EU authorities, and any failure of such manufacturing sites to receive approval from FDA or foreign authorities, obtain and maintain ongoing FDA or foreign regulatory compliance, or manufacture avanafil API or tablets in expected quantities could have a detrimental impact on our ability to commercialize STENDRA under our agreements with Auxilium and Menarini and our ability to enter into a collaboration agreement for the commercialization of STENDRA in territories not covered by our agreements with Auxilium and Menarini.

We rely on third parties to maintain appropriate levels of confidentiality of the data compiled during clinical, pre-clinical and retrospective observational studies and trials.

We seek to maintain the confidential nature of our confidential information through contractual provisions in our agreements with third parties, including our agreements with clinical research organizations, or CROs, that manage our clinical studies for our investigational drug candidates. These CROs may fail to comply with their obligations of confidentiality or may be required as a matter of law to disclose our confidential information. As the success of our clinical studies depends in large part on our confidential information remaining confidential prior to, during and after a clinical study,

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any disclosure could have a material adverse effect on the outcome of a clinical study, our business, financial condition and results of operations.

If we fail to comply with applicable healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse are and will be applicable to our business. The 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, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care items or service reimbursable under federal healthcare programs such as Medicare and Medicaid. Further, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations of our products may be subject to scrutiny if they do not qualify for an exemption or safe harbor. 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 False Claims Laws, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the 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 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 federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs;
- numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who prescribe our product and from whom we obtain patient health information are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. We are not a HIPAA covered entity and we do not operate as a business associate to any covered entities. Therefore, these privacy and security requirements do not apply to us. However, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA. We are unable to predict whether our actions could be subject to prosecution in the event of an impermissible disclosure of health information to us. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. These laws could create liability for us or increase our cost of doing business;

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- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the payor. Some state laws also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states prohibit providing meals to prescribers or other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes of conduct. Additional states are considering or recently have considered similar proposals. Foreign governments often have similar regulations which we also will be subject to in those countries where we market and sell products; and
- the federal Physician Payment Sunshine Act requires extensive tracking of physician and teaching hospital payments, maintenance of a payments database, and public reporting of the payment data. Centers for Medicare and Medicaid Services, or CMS, recently issued a final rule implementing the Physician Payment Sunshine Act provisions and clarified the scope of the reporting obligations, as well as that manufacturers must begin tracking on August 1, 2013 and must report payment data to CMS by March 31, 2014.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare programs, like Medicare and Medicaid, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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

The FDA has the authority to impose significant restrictions, including REMS requirements, on approved products through regulations on advertising, promotional and distribution activities. After approval, if products are marketed in contradiction with FDA laws and regulations, the FDA may

issue warning letters that require specific remedial measures to be taken, as well as an immediate cessation of the impermissible conduct resulting in adverse publicity. The FDA may also require that all future promotional materials receive prior agency review and approval before use. Certain states have also adopted regulations and reporting requirements surrounding the promotion of pharmaceuticals. Qsymia and STENDRA are subject to these regulations. Failure to comply with state requirements may affect our ability to promote or sell pharmaceuticals drugs in certain states. This in turn could have a material adverse impact on our financial results and financial condition and could subject us to significant liability, including civil and administrative remedies as well as criminal sanctions.

We are subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our drugs.

We are required to comply with extensive regulations for drug manufacturing, labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion and record keeping in connection with the marketing of Qsymia and STENDRA. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the investigational drug candidates or to whom and how we may distribute our products. Even after FDA approval is obtained, the FDA may still impose significant restrictions on a drug's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. For example, the labeling approved for Qsymia includes restrictions on use, including recommendations for pregnancy testing, level of obesity and duration of treatment. We are subject to ongoing regulatory obligations and restrictions which may result in significant expense and limit our ability to commercialize Qsymia. The FDA has also required the distribution of a Medication Guide to Qsymia patients outlining the increased risk of teratogenicity with fetal exposure and the possibility of suicidal thinking or behavior. In addition, the FDA has required a REMS that may act to limit access to the drug, reduce our revenues and/or increase our costs. The FDA may modify the Qsymia REMS in the future to be more or less restrictive.

Even if we receive FDA 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 may be withdrawn and reformulation of

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our products, additional clinical trials, changes in labeling and additional marketing applications may be required, any of which could harm our business and cause our stock price to decline.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing of our products.

All of those involved in the preparation of a therapeutic drug for clinical trials or commercial sale, including our existing supply contract manufacturers, and clinical trial investigators, are subject to extensive regulation. Components of a finished drug product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with current Good Manufacturing Practices, or cGMP. These regulations govern quality control of the manufacturing processes and documentation policies and procedures, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of our third-party contractors must be inspected routinely for compliance. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulation occurs independent of such an inspection or audit, we or the FDA may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the issuance of a warning letter, temporary or permanent suspension of a clinical trial or commercial sales, recalls, market withdrawals, seizures, or the temporary or permanent closure of a facility. Any such remedial measures would be imposed upon us or third parties with whom we contract until satisfactory cGMP compliance is achieved. The FDA could also impose civil penalties. We must also comply with similar regulatory requirements of foreign regulatory agencies.

We obtain the necessary raw materials and components for the manufacture of Qsymia and STENDRA as well as certain services, such as analytical testing packaging and labeling, from third parties. In particular, we rely on Catalent to supply Qsymia capsules and Packaging Coordinators, Inc., or PCI, for Qsymia packaging services. We and these suppliers and service providers are required to follow cGMP requirements and are subject to routine and unannounced inspections by the FDA and by state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Upon inspection of these facilities, the FDA or foreign regulatory agencies may find the manufacturing process or facilities are not in compliance with cGMP requirements and other regulations. Because manufacturing processes are highly complex and are subject to a lengthy regulatory approval process, alternative qualified supply may not be available on a timely basis or at all. Difficulties, problems or delays in our suppliers and service providers' manufacturing and supply of raw materials, components and services could delay our clinical trials, increase our costs, damage our reputation and cause us to lose revenue or market share if we are unable to timely meet market demands.

In addition, we have an agreement with MTPC to supply the API and the tablets for STENDRA. The MTPC manufacturing sites have been inspected by the U.S. authorities. We do not believe the results of those inspections will have an impact on MTPC's ability to supply STENDRA. However, if MTPC is unable to receive approval from foreign authorities, and maintain ongoing FDA or foreign regulatory compliance, or manufacture avanafil API or STENDRA tablets in sufficient quantities to meet projected demand, the U.S. commercial launch, and future sales of STENDRA will be adversely effected, which in turn could have a detrimental impact on our financial results, our License and Commercialization Agreement and Commercial Supply Agreement with Auxilium, our License and Commercialization Agreement and Commercial Supply Agreement with Menarini, and our ability to enter into additional collaboration agreements for the commercialization of STENDRA in territories not covered by our agreements with Auxilium and Menarini. In August 2012, we entered into an amendment to our agreement with MTPC that permits us to manufacture the API and tablets for STENDRA ourselves or through third parties. According to the amendment, the transition of manufacturing from MTPC must occur on or before June 30, 2015. The technology transfer needed for this transition is highly dependent on the cooperation of MTPC and its current suppliers. If MTPC, or its current suppliers, is unable to effectively transfer the technology or supply on commercially reasonable terms, the partnerability and commercial success of STENDRA could be adversely impacted.

On July 31, 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, Latin America and other territories, subject to approval by regulatory authorities. Enabling Sanofi Chimie to manufacture commercial supply in the future is a critical step in establishing a high quality, reliable supply chain. If Sanofi Chimie is unable to effectively establish the supply chain, our ability to commercialize avanafil through our relationship with Auxilium, Menarini or otherwise could be compromised. Any future manufacturing sites would need to be inspected by the U.S. and EU authorities, and any failure of such manufacturing sites to receive approval from FDA or foreign authorities, obtain and maintain ongoing FDA or foreign regulatory compliance, or

manufacture avanafil API or tablets in expected quantities, could have a detrimental impact on our ability to commercialize STENDRA under our agreements with Auxilium and Menarini, and our ability to enter into a collaboration agreement for the commercialization of STENDRA in territories not covered by our agreements with Auxilium and Menarini.

Any adverse changes in reimbursement procedures by government and other third-party payors may limit our ability to market and sell our approved drugs, or any future drugs, if approved or limit our product revenues and delay profitability.

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.

The healthcare industry in the U.S. and abroad is undergoing fundamental changes that are the result of political, economic and regulatory influences. The levels of revenue and profitability of pharmaceutical companies may be affected by the continuing efforts of governmental and third-party payors to contain or reduce healthcare costs through various means. Reforms that have been and may be considered include mandated basic healthcare benefits, controls on healthcare spending through limitations on the increase in private health insurance premiums and the types of drugs eligible for reimbursement and Medicare and Medicaid spending, the creation of large insurance purchasing groups and fundamental changes to the healthcare delivery system. These proposals include measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide. These changes could impact our ability to maximize revenues in the federal marketplace.

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 March 23, 2010, drug rebates are due on the utilization of Medicaid managed care organizations. This expanded eligibility affects rebate liability for that utilization.
- Effective January 1, 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 funding gap that currently exists in the Medicare Part D prescription drug program. We currently do not anticipate coverage under Medicare Part D, but this could change in the future.
- Effective January 1, 2011, the U.S. Federal government must allocate an annual branded prescription drug fee among pharmaceutical manufacturers of branded prescription drugs based on the dollar value of their branded prescription drug sales to certain federal health care programs identified in the law. The Affordable Care Act determines an individual manufacturer’s market share as the ratio of its aggregate sales of branded prescription drugs during the preceding calendar year as a percentage of the aggregate branded prescription drug sales for all covered manufacturers. Each individual pharmaceutical manufacturer will pay a prorated share of the branded prescription drug fee of \$2.8 billion in 2013 (and set to increase in ensuing years) based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law.
- Changes made by the Affordable Care Act are expected to result in the coverage of 32 million uninsured individuals through an expansion of the Medicaid program, and private sector coverage either through their employer or the new state-based Health Insurance Exchanges effective in 2014. In 2012, the Supreme Court of the United States heard challenges to the constitutionality of the individual mandate and the viability of certain provisions of the Affordable Care Act. The Supreme Court’s decision upheld most of the Affordable Care Act and determined that requiring individuals to maintain “minimum essential” health insurance coverage or pay a penalty to the Internal Revenue Service was within Congress’s constitutional taxing authority. However, the Supreme Court struck down a provision in the Affordable Act that penalized states that choose not to expand their Medicaid programs through an increase in the Medicaid eligibility income limit from a state’s current eligibility levels to 133% of the federal poverty limit. As a result of the Supreme Court’s ruling, it is unclear whether states will expand their Medicaid programs by raising the income limit to 133% of the federal poverty level and whether there will be more uninsured patients in 2014 than anticipated when Congress passed the

Affordable Care Act. For each state that does not choose to expand its Medicaid program, there will 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.

Presently, uncertainty exists as many of the specific determinations necessary to implement the Affordable Care Act have yet to be decided and communicated to industry participants. At this time, we cannot predict the full impact of the Affordable Care Act, or the timing and impact of any future rules or regulations promulgated to implement the Affordable Care Act.

There can be no assurance that future healthcare legislation or other changes in the administration or interpretation of government healthcare or third-party reimbursement programs will not have a material adverse effect on us. Healthcare reform is also under consideration in other countries where we intend to market Qsymia.

We expect to experience pricing and reimbursement pressures in connection with the sale of Qsymia, STENDRA and our investigational drug candidates, if approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. In addition, we may confront limitations in insurance coverage for Qsymia, STENDRA and our investigational drug candidates. For example, the Medicare program generally does not provide coverage for drugs used to treat erectile dysfunction or drugs used to treat obesity. Similarly, other insurers may determine that such products are not covered under their programs. If we fail to successfully secure and maintain reimbursement coverage for our approved drugs and investigational drug candidates or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our approved drugs and investigational drug candidates and our business will be harmed. Congress has enacted healthcare reform and may enact further reform, which could adversely affect the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business.

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

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.

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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 and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our investigational drug candidates, or commercialization of our approved drugs, could be delayed. If we are unable to restore our information systems in the event of a systems failure, our communications, daily operations and the ability to develop our investigational drug candidates and approved drug commercialization efforts would be severely affected.

Natural disasters or resource shortages could disrupt our investigational drug candidate development and approved drug commercialization efforts and adversely affect results.

Our ongoing or planned clinical trials and approved drug commercialization efforts could be delayed or disrupted indefinitely upon the occurrence of a natural disaster. For example, Hurricane Sandy in October 2012 hindered our Qsymia sales efforts. In 2005, our clinical trials in the New Orleans area were interrupted by Hurricane Katrina. In addition, our offices are located in the San Francisco Bay Area near known earthquake fault zones and are therefore vulnerable to damage from earthquakes. In October 1989, a major earthquake in our area caused significant property damage and a number of fatalities. Our current supplier of STENDRA is located in Japan near known earthquake fault zones and is vulnerable to damage from earthquakes and tsunamis. We are also vulnerable to damage from other disasters, such as power loss, fire, floods and similar events. If a significant disaster occurs, our ability to continue our operations could be seriously impaired and we may not have adequate insurance to cover any resulting losses. Any significant unrecoverable losses could seriously impair our operations and financial conditions.

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. We have received notices of allowance from the USPTO for two of our pending patent applications related to obesity, and barring unforeseen delays both are expected to issue as patents in November 2013,

with patent terms extending into 2029. There can, however, be no assurances that the patents will issue or that the scope of the claims will provide sufficient protection for our products.

In addition, even if our patent applications issue as patents, we cannot make assurances as to how much protection, if any, will be provided by these patents. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Others may independently develop similar or alternative technologies or design around our patented technologies or products. These companies would then be able to develop, manufacture and sell products that compete directly with our products. In that case, our revenues and operating results could decline.

Other entities may also challenge the validity or enforceability of our patents and patent applications in litigation or administrative proceedings. The sponsor of a generic application seeking to rely on one of our approved drug products as the reference listed drug must make one of several certifications regarding each listed patent. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is a challenge to the patent; it is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product. Once the FDA accepts for filing a generic application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the reference listed drug, or RLD, NDA holder and patent owner that the application with patent challenge

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has been submitted, and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner file suit against the generic applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the generic application for a period of 30 months from the date of receipt of the notice. If the RLD has new chemical entity exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the 30-month stay does not begin until five years after the RLD approval. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation. If a competitor or a generic pharmaceutical provider successfully challenges our patents, the protection provided by these patents could be reduced or eliminated and our ability to commercialize any approved drugs would be at risk. In addition, if a competitor or generic manufacturer were to receive approval to sell a generic or follow-on version of one of our products, our approved product would become subject to increased competition and our revenues for that product would be adversely affected.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The U.S. Patent Office has recently developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act have only recently become effective. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We also may rely on trade secrets and other unpatented confidential information to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We seek to protect our trade secrets and other confidential information by entering into confidentiality agreements with employees, collaborators, vendors (including CROs and our CSO), consultants and, at times, with potential investors. Nevertheless, employees, collaborators, vendors, consultants or potential investors may still disclose or misuse our trade secrets and other confidential information, and we may not be able to meaningfully protect our trade secrets. In addition, others may independently develop substantially equivalent information or techniques or otherwise gain access to our trade secrets. Disclosure or misuse of our confidential information would harm our competitive position and could cause our revenues and operating results to decline.

If we believe that others have infringed or misappropriated our proprietary rights, we may need to institute legal action to protect our intellectual property rights. Such legal action may be expensive, and we may not be able to afford the costs of enforcing or defending our intellectual property rights against others.

We 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.

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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 infringes 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 makes it difficult for us to stop the infringement of our patents. Even if we have patents issued in these jurisdictions, there can be no assurance that our patent rights will be sufficient to prevent generic competition or unauthorized use.

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

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Risks Relating to our Financial Position and Need for Financing

We may require additional capital for our future operating plans, and we may not be able to secure the requisite additional funding on acceptable terms, or at all, which would force us to delay, reduce or eliminate commercialization 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 2014. Should product sales be significantly less than internal expectations, we would need to raise additional capital to support operating activities beyond 2014. However, we anticipate that we will be required to obtain additional financing to fund our commercialization efforts, additional clinical studies for approved products and the development of our research and development pipeline in future periods. Our future capital requirements will depend upon numerous factors, including:

- our ability to expand the use of Qsymia through targeted patient and physician education;
- our ability to find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience on a timely basis;
- our ability to create a pathway for centralized approval of Qsiva in Europe;
- our ability to eliminate expenses that are not essential to expanding the use of Qsymia;
- the substantial cost to expand into certified retail pharmacy locations and the cost required to maintain the REMS program for Qsymia;
- the cost, timing and outcome of the post-approval clinical studies the FDA has required us to perform as part of the approval for STENDRA and Qsymia;
- our ability, along with our collaboration partners, to successfully commercialize STENDRA in the U.S. and Canada and in over 40 European countries plus Australia and New Zealand;
- our ability to successfully commercialize STENDRA in our other territories outside the U.S., EU, Australia and New Zealand through marketing partnerships;
- 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;
- the activities of competitors; and
- maintaining compliance to our agreement with BioPharma and maintaining our ability to receive an additional \$60 million at a secondary closing.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies. We currently have no commitments or agreements relating to any of these types of transactions.

To obtain additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of equity or debt securities, corporate alliances, joint ventures and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all. We are continually evaluating our existing portfolio and we may choose to divest, sell or spin-off one or more of our drugs and/or investigational drug candidates at any

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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.

On May 21, 2013, we closed an offering of \$220.0 million in 4.5% Convertible Senior Notes due May 1, 2020. The Convertible Notes are governed by an indenture, dated as of May 21, 2013 between VIVUS and Deutsche Bank National Trust Company, as trustee. On May 29, 2013, we closed on an additional \$30.0 million of Convertible Notes upon exercise of an option by the initial purchasers of the Convertible Notes. Total net proceeds from the Convertible Notes were approximately \$241.8 million.

The Convertible Notes are senior unsecured obligations of VIVUS and bear interest at a fixed rate of 4.50% per annum, payable semiannually in arrears on May 1 and November 1 of each year, beginning on November 1, 2013, unless earlier purchased or converted.

The Convertible Notes are convertible into approximately 16,826,000 shares of VIVUS's common stock under certain circumstances prior to maturity at a conversion rate of 67.3038 shares per \$1,000 principal amount of Convertible Notes, which represents a conversion price of approximately \$14.858 per share, subject to adjustment under certain conditions. The Convertible Notes are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding November 1, 2019 only under certain conditions. On or after November 1, 2019, holders may convert all or any portion of their Convertible Notes at their option at the conversion rate then in effect at any time, regardless of these conditions. Subject to certain limitations, we will settle conversions of the Convertible Notes by paying or delivering, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The conversion rate of the Convertible Notes, and the corresponding conversion price, will be subject to adjustment for certain events, but will not be adjusted for accrued interest. In addition, following certain corporate transactions that occur on or prior to the maturity date for the Convertible Notes, we will increase the conversion rate for a holder that elects to convert its Convertible Notes in connection with such a corporate transaction. The Convertible Notes were issued to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended, or the Securities Act. Neither the Convertible Notes nor any shares of VIVUS's common stock issuable upon conversion of the Convertible Notes have been or are expected to be registered under the Securities Act or under any state securities laws.

In connection with the issuance of the Convertible Notes, we entered into capped call transactions with certain counterparties affiliated to the underwriters. The capped call transaction is expected generally to reduce the potential dilution and/or offset potential cash payments in excess of the principal amount of converted Convertible Notes upon conversion of the Convertible Notes near maturity in the event that the market price of VIVUS's common stock, as measured under the terms of the capped call transaction, is greater than the strike price of the capped call transaction, which initially corresponds to the

conversion price of the Convertible Notes, and will be subject to anti-dilution adjustments similar (although not identical) to those applicable to the conversion rate of the Convertible Notes. However, if the market price of VIVUS's common stock, as measured under the terms of the capped call transaction, exceeds \$20.00 per share, which is the initial cap price of the capped call transaction, the cash or number of shares of common stock VIVUS expects to receive upon exercise of the capped call transaction will be capped based on the amount by which the cap price exceeds the strike price of the capped call transaction, and thus, the anti-dilutive effect of the capped call transaction will be limited. The capped call transaction provides for exercise upon final conversion under the Convertible Notes and interim conversion dates under the Convertible Notes will not entitle VIVUS to make corresponding exercises under the capped call transaction, but will instead result in a partial early termination of the capped call transaction.

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

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bankruptcy laws. In addition, debt financing typically contains covenants that restrict operating activities. For example, on March 25, 2013, we entered into the Purchase and Sale Agreement with BioPharma, which provides for the purchase of a debt-like instrument. Under the BioPharma Agreement, we received \$50 million, less \$1.1 million in funding and facility payments, on April 9, 2013. To secure our obligations in connection with the BioPharma Agreement, we granted BioPharma a security interest to certain of our assets. During the term of the BioPharma Agreement, we are required to use commercially reasonable efforts to undertake certain obligations and activities to develop, market, promote and commercialize Qsymia and maximize net sales of Qsymia. Additionally, during the term of 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. In addition, under the BioPharma Agreement, we may enter into a licensing, co-promotion, joint venture, partnering or similar agreement or arrangement with a partner for the purpose of securing promotional and/or marketing resources for Qsymia that is expressly subject to the following conditions: (a) we shall continue to receive no less than twenty-five percent (25%) of net Qsymia product sales; and (b) the partner covenants and agrees in writing to provide promotion and marketing efforts of Qsymia in the partnered territory substantially similar to, and in any event no less in scope, degree or scale than, the promotional and marketing efforts undertaken by us. 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 which may cause losses and affect the liquidity of these investments.

At September 30, 2013, we had \$143.1 million in cash and cash equivalents and \$203.3 million in available-for-sale securities. While at September 30, 2013, our excess cash balances were invested in money market and U.S. Treasury securities, our investment policy as approved by our Board of Directors, also provides for investments in debt securities of U.S. government agencies, corporate debt securities and asset-backed securities. Our investment policy has the primary investment objectives of preservation of principal. However, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy. Although the U.S. Congress was able to resolve the debt ceiling issue in time to avoid default, the major credit rating agencies have expressed their ongoing concern about the high levels of debt that the U.S. government has taken on. Standard & Poor's announced that it had revised its outlook on the long-term credit rating of the U.S. to negative, which could affect the trading market for U.S. government securities. These factors could impact the liquidity or valuation of our available-for-sale securities, all of which were invested in U.S. treasury securities as of September 30, 2013. 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 litigation could divert our resources and management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities related class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their investigational drug candidate development programs, the review of marketing applications by regulatory authorities and the commercial launch of newly approved drugs. We are a defendant in federal and consolidated state shareholder derivative lawsuits. These securities related class action lawsuits generally allege that we and our officers misled the investing public regarding the safety and efficacy of Qsymia and the prospects for the FDA's approval of the Qsymia NDA as a treatment for obesity. Securities related class action litigation often is expensive and diverts management's attention and our financial resources, which could adversely affect our business. For example, despite the granting of the prior two motions to dismiss by the U.S.

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

Additionally, certain of our officers and directors are defendants in a shareholder derivative lawsuit captioned *Turberg v. Logan, et al.*, Case No. CV-10-05271-PJH, pending in the same federal court. In the plaintiff's Verified Amended Shareholder Derivative Complaint filed June 3, 2011, the plaintiff

largely restated the allegations of the *Kovtun* action. The same individuals are also named defendants in consolidated shareholder derivative suits pending in the California Superior Court, Santa Clara County under the caption *In re VIVUS, Inc. Derivative Litigation*, Master File No. 11 0 CV188439. The allegations in the state court derivative suits are substantially similar to the other lawsuits. We are named as a nominal defendant in these actions, neither of which seeks any recovery from the Company. The parties have agreed to stay the derivative lawsuits pending the outcome of the appeal of the securities class action.

Furthermore, on July 12, 2013, certain of our current and former officers and directors were named as defendants in a separate shareholder derivative lawsuit filed in the California Superior Court, Santa Clara County and captioned *Ira J. Gaines IRA, et al. v. Leland F. Wilson, et al.*, Case No.1-13-CV-249436. The lawsuit generally alleges breaches of the fiduciary duty of care in connection with the launch of Qsymia, breaches of the duty of loyalty and insider trading by some defendants for selling Company stock while purportedly being aware that the Qsymia launch would be less successful than predicted and corporate waste. Again, we are named as a nominal defendant, and no recovery from the Company is sought. As with the other shareholder litigation, we have certain indemnification obligations to the named defendants, including to advance defense costs to the individuals. On October 21, 2013, the Company filed a demurrer seeking to have the lawsuit dismissed in its entirety for failure to make a pre-suit demand upon our Board of Directors or plead sufficient facts to show that such demand would have been futile.

We have an accumulated deficit of \$643.4 million as of September 30, 2013, and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of \$643.4 million for the period from our inception through September 30, 2013, 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, 2012, we had approximately \$449.0 million and \$118.1 million of net operating loss, or NOL, carryforwards with which to offset our future taxable income for federal and state income tax reporting purposes, respectively. We used \$121.2 million federal and \$32.2 million state NOLs to offset our year ended December 31, 2007 federal and state taxable income, which included the \$150.0 million in gain recognized from our sale of Evamist. Utilization of our net operating loss and tax credit carryforwards, or Tax Attributes, may be subject to substantial annual limitations provided by the Internal Revenue Code and similar state provisions to the extent certain ownership changes are deemed to occur. Such an annual limitation could result in the expiration of the Tax Attributes before utilization. The Tax Attributes reflected above have not been reduced by any limitations. To the extent it is determined upon completion of the analysis that such limitations do apply, we will adjust the Tax Attributes accordingly. We face the risk that our ability to use our Tax Attributes will be substantially restricted if we undergo an “ownership change” as defined in Section 382 of the U.S. Internal Revenue Code, or Section 382. An ownership change under Section 382 would occur if “5-percent shareholders,” within the meaning of Section 382, collectively increased their ownership in the Company by more than fifty percentage points over a rolling three-year period. There can be no assurance that a Section 382 ownership change has not occurred or will not occur in the future.

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

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recorded in our condensed 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 create a pathway for centralized approval of Qsiva in Europe;
- the costs, timing and outcome of post-approval clinical studies which the FDA has required us to perform as part of the approval for Qsymia and STENDRA;
- the substantial cost to expand into certified retail pharmacy locations and the cost required to maintain the REMS program for Qsymia;
- results within the clinical trial programs for Qsymia and STENDRA or other results or decisions affecting the development of our investigational drug candidates;
- announcements of technological innovations or new products by us or our competitors;
- approval of, or announcements of, other anti-obesity compounds in development;
- publication of generic drug combination weight loss data by outside individuals or companies;

- actual or anticipated fluctuations in our financial results;
- our ability to obtain needed financing;
- sales by insiders or major stockholders;
- economic conditions in the U.S. and abroad;
- the volatility and liquidity of the financial markets;
- comments by or changes in assessments of us or financial estimates by security analysts;
- negative reports by the media or industry analysts on various aspects of our products, our performance and our future operations;
- adverse regulatory actions or decisions;
- any loss of key management;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- discussions about us or our stock price by the financial and scientific press and in online investor communities;
- investment activities employed by short sellers of our common stock;
- developments or disputes concerning patents or other proprietary rights;

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- reports of prescription data by us or from independent third parties for our products;
- licensing, product, patent or securities litigation; and
- public concern as to the safety and efficacy of our drugs or future investigational drug candidates developed by us.

These factors and fluctuations, as well as political and other market conditions, may adversely affect the market price of our common stock. Additionally, volatility or a lack of positive performance in our stock price may adversely affect our ability to retain or recruit key employees, all of whom have been or will be granted stock options as an important part of their compensation packages.

Our operating results are unpredictable and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.

Our operating results will likely fluctuate from fiscal quarter to fiscal quarter, and from year to year, and are difficult to predict. Although we have commenced sales of Qsymia, we may never increase these sales or become profitable. In addition, although we have entered into License and Commercialization Agreements with Auxilium and Menarini, to commercialize and promote STENDRA for the treatment of ED in the U.S. and Canada, and to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, plus Australia and New Zealand, respectively, we may not be successful in commercializing these drug products in these territories. Our operating expenses are largely independent of sales in any particular period. We believe that our quarterly and annual results of operations may be negatively affected by a variety of factors. These factors include, but are not limited to, the level of patient demand for Qsymia and STENDRA, the ability of our distribution partners to process and ship product on a timely basis, the success of our third-party's manufacturing efforts to meet customer demand, fluctuations in foreign exchange rates, investments in sales and marketing efforts to support the sales of Qsymia and STENDRA, investments in the research and development efforts, and expenditures we may incur to acquire additional products.

Future sales of our common stock may depress our stock price.

Sales of our stock by our executive officers and directors, or the perception that such sales may occur, could adversely affect the market price of our stock. We have also registered all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws. Some of our executive officers have adopted trading plans under SEC Rule 10b5-1 to dispose of a portion of their stock. Any of our executive officers or directors may adopt such trading plans in the future. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

Our charter documents and Delaware law could make an acquisition of our company difficult, even if an acquisition may benefit our stockholders.

Our Board of Directors has adopted a Preferred Shares Rights Plan. The Preferred Shares Rights Plan has the effect of causing substantial dilution to a person or group that attempts to acquire us on terms not approved by our Board of Directors. The existence of the Preferred Shares Rights Plan could limit the price that certain investors might be willing to pay in the future for shares of our common stock and could discourage, delay or prevent a merger or acquisition that a stockholder may consider favorable.

Some provisions of our Amended and Restated Certificate of Incorporation and 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.

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In addition, we are governed by the provisions of Section 203 of Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These and other provisions in our charter documents could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The following documents are filed as Exhibits to this report:

EXHIBIT NUMBER	DESCRIPTION
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2(2)	Amended and Restated Bylaws of the Registrant.
3.3(3)	Amendment No. 1 to the Amended and Restated Bylaws of the Registrant.
3.4(4)	Amendment No. 2 to the Amended and Restated Bylaws of the Registrant.
3.5(5)	Amendment No. 3 to the Amended and Restated Bylaws of the Registrant.
3.6(6)	Amendment No. 4 to the Amended and Restated Bylaws of the Registrant.
3.7(7)	Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Registrant.
4.1(8)	Specimen Common Stock Certificate of the Registrant.
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SIGNATURES

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

Date: November 7, 2013

VIVUS, Inc.

/s/ SVAI SANFORD

Svai Sanford
Chief Financial Officer

/s/ SETH H. Z. FISCHER

Seth H. Z. Fischer
Chief Executive Officer

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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.
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CONFIDENTIAL
EXECUTION COPY

LICENSE AND COMMERCIALIZATION AGREEMENT

dated as of October 10, 2013

by and between

VIVUS, INC.

and

AUXILIUM PHARMACEUTICALS, INC.

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**CONFIDENTIAL
EXECUTION COPY**

LICENSE AND COMMERCIALIZATION AGREEMENT

THIS LICENSE AND COMMERCIALIZATION AGREEMENT (the “**Agreement**”) is entered into as of the 10th day of October 2013 (the “**Effective Date**”) by and between **VIVUS, INC.**, a Delaware corporation having its principal offices at 351 E. Evelyn Ave., Mountain View, CA 94041 (“**VIVUS**”), and **AUXILIUM PHARMACEUTICALS, INC.**, a Delaware corporation having a place of business at 640 Lee Road, Chesterbrook, PA 19087. (“**Auxilium**”). VIVUS and Auxilium are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

RECITALS

WHEREAS, VIVUS has received a license to certain intellectual property rights from Mitsubishi Tanabe Pharma Corporation (as successor in interest to Tanabe Seiyaku Co., Ltd., “**MTPC**”) relating to a therapeutic drug known as STENDRA™ (avanafil);

WHEREAS, VIVUS has obtained all required regulatory approval from the FDA for the right to market and commercialize STENDRA in the United States;

WHEREAS, VIVUS desires to grant to Auxilium, and Auxilium desires to receive, a license for the commercialization and exploitation of STENDRA in the United States and the rest of the Auxilium Territory (as defined below) upon the terms and conditions set forth in this Agreement.

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

ARTICLE 1 DEFINITIONS

As used in this Agreement, the following initially capitalized terms, whether used in the singular or plural form, shall have the meanings set forth in this Article 1.

1.1 “**Action Date**” means, with respect to a legal action in connection with Product Infringement, the date that is the earlier of (a) *** following notice pursuant to Section 8.4(a) of a Product Infringement and (b) *** before the date after which a legal action would be substantially limited or compromised with respect to the remedies available against the alleged Third Party infringer.

1.2 “**Affiliate**” means, with respect to a Person, any person, firm, trust, corporation, company, partnership, or other entity or combination thereof that directly or indirectly controls,

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is controlled by or is under common control with such Person. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under the common control with”) means (a) ownership of fifty percent (50%) or more of the voting and equity rights of such person, firm, trust, corporation, company, partnership or other entity or combination thereof, or (b) the power to direct the management of such person, firm, trust, corporation, company, partnership, or other entity or combination thereof.

1.3 “**Alliance Manager**” has the meaning set forth in Section 3.7.

1.4 “**Applicable Law**” means any and all laws, statutes, ordinances, regulations, permits, orders, decrees, judgments, directives, rulings or rules of any kind whatsoever that are promulgated by a federal, state, province, or other Governmental Authority, in each case pertaining to any of the activities contemplated by this Agreement, including any regulations promulgated by any Regulatory Authority in the Auxilium Territory, all as amended from time to time.

1.5 “**Auxilium Indemnitees**” has the meaning set forth in Section 10.1.

1.6 “**Auxilium Know-How**” means all Information (excluding any Patents) (a) that is Controlled by Auxilium or its Affiliates as of the Effective Date or during the Term and (b) is reasonably necessary or useful for the research, Development, manufacture, use, importation, sale, or Commercialization of the Product in the Auxilium Territory. For clarity, the Auxilium Know-How does not include the VIVUS Know-How licensed to Auxilium hereunder.

1.7 “**Auxilium Patents**” means all Patents (a) that are Controlled by Auxilium or its Affiliates as of the Effective Date or during the Term and (b) that disclose or claim any Product or the manufacture, use, importation, or sale thereof. For clarity, the Auxilium Patents do not include the VIVUS Patents licensed to Auxilium hereunder.

1.8 “**Auxilium Technology**” means the Auxilium Patents and Auxilium Know-How.

1.9 “**Auxilium Territory**” means the United States of America and Canada, and their respective territories and possessions.

1.10 “**Auxilium Trademarks**” has the meaning set forth in Section 8.6(c).

1.11 “**Bankrupt Party**” has the meaning set forth in Section 12.7.

1.12 “**Business Day**” means each day of the week excluding Saturday, Sunday or a day on which banking institutions in New York, New York, USA are closed.

1.13 “**Chapter 7 Case**” has the meaning set forth in Section 12.4.

1.14 “**Claim**” means all investigations, claims, suits, actions, cross-complaints, demands, rights, requests, arbitrations, mediations, causes of action, obligations, settlements or orders, whether at law, equity or otherwise, or whether sounding in tort, contract, equity, strict liability or any statutory or common law cause of action of any sort.

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1.15 “**Commercialization**” means the marketing, Promotion, sale, offering for sale, importation and/or distribution of the Product, including activities directed to obtaining Pricing Approval. “**Commercialize**” has a correlative meaning.

1.16 “**Commercialization and Medical Affairs Plans**” shall mean the Commercialization Plan and the Medical Affairs Plan as such are defined in Article 4.

1.17 “**Commercially Reasonable Efforts**” means, with respect to a Party’s obligations under this Agreement, the reasonable and good faith efforts normally used by a company in the pharmaceutical industry for a product (regardless of whether the product is owned by the company or the company has obtained rights to such product) having similar commercial potential, stage of development or lifecycle, medical/scientific, technical and regulatory profile, Intellectual Property protection, profitability, market competition, and other relevant factors.

1.18 “**Commercial Supply Agreement**” shall have the meaning set forth in Section 6.1.

1.19 “**Competing Product**” means a PDE-5 Inhibitor other than the Product.

1.20 “**Compound**” means the compound identified by the International Non-Proprietary Name avanafil and chemically known as (S)-4-(3-Chloro-4-methoxybenzylamino)-2-(2-hydroxymethylpyrrolidin-1-yl)-N-pyrimidin-2-ylmethyl-5-pyrimidinecarboxamide, including any metabolites, polymorphs, salts, esters, free acid forms, free base forms, pro-drug forms, racemates and all optically active forms thereof (each, a “**Compound**” and collectively, the “**Compounds**”).

1.21 “**Confidential Information**” means, with respect to a Party (the “**disclosing Party**”), all confidential and proprietary Information of such disclosing Party that is disclosed to or accessed by the other Party (the “**receiving Party**”) under this Agreement.

1.22 “**Control**” means, with respect to any material, Information, or Intellectual Property right, (a) the ownership thereof or the possession or a license or right thereto and (b) the possession by a Party under such material, Information, or Intellectual Property right of the right to grant to the other Party access, a license, or a sublicense (as applicable) to such material, Information, or Intellectual Property right on the terms and conditions set forth herein without violating the terms of any agreement between such Party and any Third Party in existence as of the Effective Date.

1.23 “**Detail**” or “**Detailing**” means each separate face-to-face contact by a professional sales representative with a physician or other professional with authority to write prescriptions during which time the promotional message involving the Product is presented and is a topic of discussion and/or a sample of the Product is left with the physician or such other professional. When used as a verb, “**Detail**” shall mean to engage in a Detail.

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1.24 “**Development**” means all activities that relate to obtaining, maintaining or expanding Regulatory Approval of the Product. This includes (a) research, preclinical testing, toxicology, formulation and clinical studies of Product; (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain, maintain and/or expand Regulatory Approval of Product; and (c) post-Regulatory Approval product support for Product (including laboratory and clinical efforts directed toward the further understanding of the safety and efficacy of Product). For clarity, Development includes phase IV clinical trials of Product. “**Develop**” and “**Developed**” have correlative meanings.

1.25 “**Existing Confidentiality Agreement**” means the Confidentiality Agreement entered into by the Parties, dated January 6, 2012.

1.26 “**FDA**” means the United States Food and Drug Administration or its successor.

1.27 “**FD&C Act**” means the United States Federal Food, Drug and Cosmetic Act.

1.28 “**Federal Arbitration Act**” has the meaning set forth in Section 13.2.

1.29 “**Field**” means the treatment of any urological disease or condition in humans, including male erectile dysfunction.

1.30 “**Filing Party**” has the meaning set forth in Section 11.3(c).

1.31 “**GAAP**” has the meaning set forth in the definition of “Net Sales” in this Article 1.

1.32 “**Generic Product**” means, with respect to a Product in a given country of the Auxilium Territory, any product sold in such country by a Third Party (other than a sublicensee of Auxilium or any other Third Party authorized to sell such product by, or otherwise in the chain of distribution of, Auxilium or a Auxilium Affiliate or sublicensee) that (a) contains the same active ingredient(s) as the Product, or any base form, salt form, prodrug form, isomer, crystalline polymorph, hydrate or solvate of such active ingredients (but no additional pharmaceutically active ingredients beyond what is contained in the Product), and (b) is approved or registered for use in such country pursuant to any drug approval process based on reference to a Regulatory Approval for such Product held by VIVUS, Auxilium or any of their respective Affiliates or sublicensees in such country or in another country.

1.33 “**Governmental Authority**” means any transnational, domestic or foreign federal, provincial, state or local governmental, regulatory or administrative authority (including any Regulatory Authority), department, court, agency or official, including any political subdivision thereof.

1.34 “**IND**” means an Investigational New Drug Application, as defined in the FD&C Act.

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1.35 “**Indemnified Claim**” has the meaning set forth in Section 10.3.

1.36 “**Indemnified Party**” has the meaning set forth in Section 10.3.

1.37 “**Indemnifying Party**” has the meaning set forth in Section 10.3.

1.38 “**Information**” means any data, results, and information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, procedures, inventions, developments, specifications, formulations, formulae, software, algorithms, marketing reports, expertise, stability, technology, pharmacological, biological, chemical, biochemical, toxicological, and clinical test data, analytical and quality control data, and stability data.

1.39 “**Intellectual Property**” means (a) United States or foreign issued patents or pending patent applications, and any and all divisionals, continuations, continuations-in-part, reissues, renewals, reexaminations, and extensions thereof, any counterparts claiming priority therefrom, utility models, patents of importation/confirmation, supplementary protection certificates, certificates of invention, national and multinational statutory invention registrations and similar statutory rights (“**Patents**”); (b) trademarks, service marks, certification marks, logos, trade names, trade dress, including all registrations and applications for registration of, and all goodwill associated with, the foregoing; (c) copyrights and registrations and applications for registration thereof; (d) confidential and proprietary methods, processes, techniques, devices, technology, assays, materials, trade secrets, inventions, ideas, designs, compositions, formulae, know-how, data, specifications, technical information, instructions, and other similar types of confidential and proprietary documentation, materials and information; and (e) any similar intellectual property or proprietary rights.

1.40 “**JAMS Rules**” has the meaning set forth in Section 13.2.

- 1.41 “**Joint Invention**” has the meaning set forth in Section 8.1.
- 1.42 “**Joint Patent**” has the meaning set forth in Section 8.3(b).
- 1.43 “**JSC**” has the meaning set forth in Section 3.1.
- 1.44 “**Label Expansion Filing**” has the meaning set forth in Section 4.1(a).
- 1.45 “**Licensed Party**” means a Party in its capacity as licensee under the applicable licenses set forth in Article 2.
- 1.46 “**Licensing Party**” means a Party in its capacity as licensor under the applicable licenses set forth in Article 2.
- 1.47 “**Losses**” means (a) all damages, judgments, or settlements payable to Third Parties; and (b) all legal expenses (including reasonable attorneys’ fees and disbursements,

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reasonable expert and witness fees, reasonable fees and costs associated with any investigations, court costs and appeal bonds).

1.48 “**Manufacturing Territory**” means all the countries in the world excluding Democratic People’s Republic of Korea (North Korea), Republic of Korea (South Korea), Singapore, Malaysia, Thailand, Vietnam, and the Philippines.

1.49 “**MTPC**” means Mitsubishi Tanabe Pharma Corporation.

1.50 “**MTPC Agreement**” means that certain Agreement between VIVUS and MTPC (as successor in interest to Tanabe Seiyaku Co., Ltd.), effective as of December 28, 2000, as amended pursuant to the Amendment No. 1 to Agreement dated as of January 9, 2004, the Second Amendment to Agreement dated as of August 1, 2012, the Third Amendment to Agreement dated as of February 21, 2013, and the Fourth Amendment to Agreement, dated as of July 1, 2013, and as otherwise amended from time to time.

1.51 “**MTPC Agreement Net Sales**” means “Net Sales,” as defined in the MTPC Agreement, but only to the extent that they relate to the Auxilium Territory.

1.52 “**MTPC Milestone**” has the meaning set forth in Exhibit C.

1.53 “**MTPC Royalty Period**” means the “Royalty Period,” as defined in the MTPC Agreement.

1.54 “**NDA**” means a New Drug Application, as defined in the FD&C Act.

1.55 “**Net Sales**” for purposes of this Agreement means the amount invoiced or otherwise billed by Auxilium or its Affiliates or sublicensees (“**Selling Party**”) for sales of a Product to a Third Party purchaser, less the following (collectively, “**Net Sales Deductions**”):

(a) discounts actually given on Product, including cash, trade and quantity discounts, price reduction or incentive programs (including sales coupons and co-payment programs), retroactive price adjustments with respect to sales of such Product, and charge-back payments;

(b) credits, refunds, returns or allowances actually allowed, paid, received or given, including credits, allowances, discounts and rebates to, and chargebacks from the account of customers for nonconforming, damaged, rejected, out-dated and returned, withdrawn or recalled Product or on account of retroactive price reductions affecting the Product;

(c) rebates, reimbursements, administrative fees or similar allowances actually granted to managed health care organizations or to federal, state and local governments in the Auxilium Territory or any other organization that utilizes any governmental discount program with respect to the Product;

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(d) inventory management agreement (IMA) fees, wholesaler fees, and specialty pharmacy charges, in each case, to the extent specifically attributable to the applicable Product;

(e) freight, postage, shipping and insurance charges actually allowed or paid for delivery of Product, to the extent billed as a separate line item by the Selling Party to the Third Party purchaser;

(f) taxes, duties or other governmental charges imposed on the sale of Product and actually paid by the Selling Party (as adjusted for rebates and refunds, but specifically excluding taxes based on net income of the Selling Party), to the extent billed as a separate line item by the Selling Party to the Third Party purchaser;

provided that all of the foregoing deductions shall be calculated in accordance with then-current generally accepted accounting principles in the United States, consistently applied during the applicable calculation period throughout the Selling Party’s organization (“**GAAP**”). To the extent that Net Sales Deductions are based on estimates, such estimates will be adjusted to actual on a periodic basis.

A sale of a Product is deemed to occur in accordance with GAAP.

For sake of clarity and avoidance of doubt, the transfer of Product by a Selling Party or one of its Affiliates to another Affiliate of such Selling Party or to a sublicensee of such Selling Party for resale shall not be considered a sale; in such cases, Net Sales shall be determined based on the amount invoiced or otherwise billed by such Affiliate or sublicensee to an independent Third Party, less the Net Sales Deductions allowed under this Section.

1.56 “**Net Sales Deductions**” has the meaning set forth in the definition of “Net Sales” in this Article 1.

1.57 “**Orange Book**” means the FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” or any replacement thereof established or approved by the FDA.

1.58 “**PDE-5 Inhibitor**” means any product that operates as a phosphodiesterase type-5 inhibitor.

1.59 “**Person**” means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.

1.60 “**Pricing Approval**” means the approval, agreement, determination, or governmental decision establishing the price or level of reimbursement for the Product, as required in a given jurisdiction.

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1.61 “**Product**” means pharmaceutical compositions containing the Compound, including but not limited to that drug product known as STENDRA™, in the form, formulation, and dosage strength(s) as defined in the NDA approved by the FDA as of the Effective Date and any other improvements, line extensions, delivery mechanisms, dosage strengths, formulations, or forms as may be approved in the future by the FDA or Health Canada that, in each case, contain a Compound.

1.62 “**Product Infringement**” has the meaning set forth in Section 8.4(a).

1.63 “**Product Launch**” means the first commercial sale of the Product by Auxilium or its Affiliate or sublicensee after the Effective Date to an unrelated Third Party in a bona fide arms-length transaction for use, consumption, or commercial distribution in the Field in the Auxilium Territory, excluding any transfer of Product for research, test marketing, clinical trial purposes, compassionate use, or named patient arrangements.

1.64 “**Product Marketing Authorization**” has the meaning set forth in Section 5.1(a).

1.65 “**Promotion**” means those activities, including advertising, Detailing, and distributing samples of a product, normally undertaken by a pharmaceutical company that are aimed at legally marketing and promoting, and encouraging the appropriate use of, a particular prescription pharmaceutical product. “**Promote**” and “**Promotional**” have correlative meanings.

1.66 “**Promotional Materials**” means all training materials and all written, printed, graphic, electronic, audio or video matter, including journal advertisements, sales visual aids, leave items, formulary binders, reprints, direct mail, direct-to-consumer (“**DTC**”) advertising, Internet postings and broadcast advertisements, in each case created by Auxilium or its Affiliates or on its behalf, and used or intended for use in connection with any Promotion of the Product in the Auxilium Territory under this Agreement.

1.67 “**Prosecuting Party**” has the meaning set forth in Section 8.3(b).

1.68 “**PV Agreement**” has the meaning set forth in Section 5.7.

1.69 “**Quality Agreement**” has the meaning set forth in Section 6.1.

1.70 “**Regulatory Approval**” means all approvals necessary for the manufacture, marketing, importation and sale of the Product for one or more indications in a country or regulatory jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements, but which shall exclude any Pricing Approval.

1.71 “**Regulatory Authority**” means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval and/or, to the extent required in such country or regulatory jurisdiction, Pricing Approval, including FDA in the case of the Auxilium Territory.

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1.72 “**Regulatory Materials**” means regulatory applications, submissions, notifications, registrations, and/or other filings made to or with a Regulatory Authority that are necessary or reasonably desirable in order to Develop, use, import, sell, offer to sell, register, market, manufacture, or otherwise Commercialize the Product in the Field for the Auxilium Territory, along with any documents related to Regulatory Approval and Pricing Approvals issued

by a Regulatory Authority for the Auxilium Territory. Regulatory Materials include, but are not limited to, INDs, NDAs, post-marketing reports submitted to a Regulatory Authority such as those described in 21 CFR 314.81, supplemental applications, and all correspondence to or from a Regulatory Authority which reference an IND or NDA.

1.73 “**Royalty Term**” has the meaning as set forth in Section 7.3(b).

1.74 “**Sales Force**” means Auxilium’s sales personnel Detailing the Product in the Auxilium Territory including employees of, and contract sales organizations engaged by, Auxilium who are qualified to do so pursuant to the terms and conditions of this Agreement.

1.75 “**SEC**” means the United States Securities and Exchange Commission or any successor.

1.76 “**Selling Party**” has the meaning set forth in the definition of “Net Sales” in this Article 1.

1.77 “**Sole Inventions**” has the meaning set forth in Section 8.1.

1.78 “**SOPs**” has the meaning set forth in Section 5.6(c).

1.79 “**Supply Chain Transfer**” has the meaning set forth in Section 6.2.

1.80 “**Supply Chain Transfer Plan**” has the meaning set forth in Section 6.2.

1.81 “**Taxes**” has the meaning set forth in Section 7.6.

1.82 “**Term**” has the meaning set forth in Section 12.1.

1.83 “**Territory**” means the VIVUS Territory and the Auxilium Territory, respectively.

1.84 “**Third Party**” means any legal person, entity or organization other than VIVUS, Auxilium or an Affiliate of either Party, including any Governmental Authority.

1.85 “**Time of Onset Claim**” means a new claim on the label of the Product (a) referencing a specific time of onset (or erectogenic effect) of 15 minutes or less or (b) referencing the time of onset (or erectogenic effect) by using the phrase “approximately 15 minutes.”

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1.86 “**Time of Onset Study**” means a clinical study conducted for the purpose of supporting a Time of Onset Claim.

1.87 “**VIVUS Indemnitees**” has the meaning set forth in Section 10.2.

1.88 “**VIVUS Know-How**” means all Information (excluding any Patents) that (a) is Controlled as of the Effective Date or during the Term by VIVUS or its Affiliates and (b) relates to any Product in the Field or the research, development, manufacture, use or sale of the Product in the Field in the Auxilium Territory.

1.89 “**VIVUS Patents**” means (a) United States Patent Nos. 6,656,935 and 7,501,409, (b) Canadian Patent Nos. 2,383,466 and 2,420,461, and (c) any reissues, renewals, re-examinations, extensions, continuations, divisions, or continuations in part of any of the foregoing.

1.90 “**VIVUS Technology**” means the VIVUS Patents and VIVUS Know-How.

1.91 “**VIVUS Territory**” means the entire world other than the Auxilium Territory.

1.92 “**VIVUS Trademarks**” means the mark STENDRA, together with any registrations or applications for registration therefor, in each case that are owned by VIVUS in the Auxilium Territory as of the Effective Date or during the Term, including United States Trademark Application Serial No. 85/565,411, filed March 9, 2012, and Canadian Trademark Application No. 1592942, filed September 5, 2012.

ARTICLE 2 LICENSES

2.1 License to Auxilium. Subject to the terms and conditions of this Agreement, VIVUS hereby grants to Auxilium (the “**Auxilium License**”):

(a) an exclusive (even as to VIVUS), royalty-bearing, sublicensable (subject to Section 6) license under the VIVUS Technology, (i) to use, distribute, import, Promote, market, sell, offer for sale, and otherwise Commercialize Products in the Field in the Auxilium Territory; (ii) make and have made Products in the Manufacturing Territory, where such Product is solely for use or sale in the Field in the Auxilium Territory (subject to Section 2.2), and (iii) to conduct certain Development activities on the Product in the Field pursuant to Article 4 solely in support of Regulatory Approval in the Auxilium Territory; and

(b) an exclusive (even as to VIVUS), royalty-bearing, sublicensable (subject to Section 6) license to use the VIVUS Trademarks solely in connection with the Commercialization of the Product in the Field in the Auxilium Territory.

2.2 Clarifications Regarding Manufacturing Rights. The rights granted to Auxilium to make and have made Product under Section 2.1(a) shall be subject to the following clarifications and/or limitations:

(a) As of the Effective Date and until the completion of the Supply Chain Transfer, Auxilium is not being granted any right to manufacture the Compound or bulk tablets of the Product, and instead Auxilium's rights to make or have made Product shall be limited to the filling, packaging, and labeling of bulk tablets of Product supplied under the Commercial Supply Agreement, along with the limited manufacturing rights granted to Auxilium in the Commercial Supply Agreement (which are solely intended to address failure to supply situations).

(b) In the event of a Supply Chain Transfer pursuant to Section 6.2, Auxilium's rights to make or have made Product shall be subject to any exclusive manufacturing rights granted to the Third Party manufacturers in the supply chain (which exclusive manufacturing rights shall be disclosed by VIVUS to Auxilium, from time to time, until the completion of the Supply Chain Transfer pursuant to Section 6.2), in any event in accordance with and subject to the terms of the Supply Agreement.

(c) As between the Parties, VIVUS retains the sole right to make and have made Product anywhere in the world, where such Product is for use or sale solely outside the Auxilium Territory, including the right to license Third Parties to do the same.

2.3 License to VIVUS.

Subject to the terms and conditions of this Agreement, Auxilium hereby grants to VIVUS a non-exclusive, royalty-free, sublicensable (subject to Section 6) license under the Auxilium Technology, but solely to the extent necessary to (a) fulfill its obligations under this Agreement, including its manufacturing and supply obligations under Article 6; (b) conduct research, Development and manufacturing activities in the Auxilium Territory solely in support of the Regulatory Approval of the Product in the VIVUS Territory provided that any such activities in the Auxilium Territory do not have, and are not reasonably expected to have, an adverse impact on the Commercialization of the Product in the Field in the Auxilium Territory; (c) use, distribute, import, promote, market, sell, offer for sale, and otherwise Commercialize Products solely in the VIVUS Territory; and (d) make and have made the Product anywhere in the world for use or sale solely in the VIVUS Territory (the "VIVUS License").

2.4 **VIVUS Retained Rights.** Notwithstanding the rights granted to Auxilium under the Auxilium License, VIVUS shall retain its rights under the VIVUS Technology within the Field in the Auxilium Territory, but solely to the extent necessary to (a) fulfill its obligations under this Agreement, including its manufacturing and supply obligations under Article 6 and (b) conduct research, Development, and manufacturing activities in the Auxilium Territory solely in support of the Regulatory Approval, Pricing Approval, or Commercialization of the Product in the VIVUS Territory (including the right to grant licenses to Affiliates or Third Parties with respect to such activities); provided that any such activities in the Auxilium Territory do not have, and are not reasonably expected to have, an adverse impact on the Commercialization of the Product in the Field in the Auxilium Territory. VIVUS retains all rights to the VIVUS Technology outside the Field.

2.5 **No Other Licenses.** Neither Party grants to the other Party any rights, licenses or covenants in or to any Intellectual Property, whether by implication, estoppel, or otherwise, other than the license rights that are expressly granted under this Agreement.

2.6 Sublicense Agreements.

(a) **Sublicensing by Auxilium.** Auxilium acknowledges that the Auxilium License includes sublicenses under the rights licensed to VIVUS under the MTPC Agreement and that VIVUS is required to notify and consult with MTPC with respect to the selection of sublicensees. Consequently, the Auxilium License may be further sublicensed by Auxilium only with the prior written consent of VIVUS, which shall not be unreasonably withheld, conditioned or delayed. At Auxilium's request, VIVUS shall use Commercially Reasonable Efforts to obtain any consents or approvals from MTPC that are required for Auxilium to grant such a sublicense, it being understood that, so long as VIVUS uses such Commercially Reasonable Efforts, VIVUS shall not be responsible for any denials or delays resulting from MTPC's action or inaction. Any agreement granting a sublicense under the Auxilium License shall be consistent with the terms of this Agreement and shall include confidentiality and non-use obligations no less stringent than those set forth in Article 11. Notwithstanding any sublicenses granted by Auxilium hereunder, Auxilium shall remain responsible for and guarantee the performance of its obligations under this Agreement.

(b) **Sublicensing by VIVUS.** The portion of the VIVUS License in Section 2.3(a) may be sublicensed by VIVUS to VIVUS's Affiliates or to any of VIVUS's subcontractors or manufacturers existing on the Effective Date or any other Third Party approved by the JSC. The portion of the VIVUS License in Section 2.3(b), 2.3(c), or 2.3(d) may be freely sublicensed by VIVUS through multiple tiers. Any agreement granting a sublicense under the VIVUS License shall be consistent with the terms of this Agreement and shall include confidentiality and non-use obligations no less stringent than those set forth in Article 11. Notwithstanding any sublicenses granted by VIVUS hereunder, VIVUS shall remain responsible for and guarantee the performance of its obligations under this Agreement.

2.7 **Third Party Agreements.** Subject to Section 7.10, Auxilium shall be solely responsible for obtaining, at its sole expense, any agreements with Third Parties required in order to lawfully perform its Commercialization responsibilities under this Agreement, other than manufacturing and other related responsibilities that are subject to the Commercial Supply Agreement.

2.8 Exclusivity.

(a) Auxilium hereby covenants that for a period of five (5) years from the Effective Date, neither it nor its Affiliates will, directly or indirectly (including via a license to a Third Party), develop, commercialize or in-license any Competing Product in the Auxilium Territory. VIVUS hereby

covenants that for a period of five (5) years from the Effective Date, neither it nor its Affiliates will, directly or indirectly (including via a license to a Third Party), develop, commercialize, or in-license any Competing Product in the Auxilium Territory.

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(b) In the event that, during the Term, either Party or any of such Party's Affiliates experiences a change in control that results in a Third Party either (i) becoming an Affiliate of such Party or (ii) become such Party's successor under this Agreement (such Third Party, an "**Acquirer**"), and the Acquirer or any of such Acquirer's Affiliates, immediately prior to such acquisition, owns or has a license or other right to a Competing Product, then the Acquirer and its Affiliates (including for the avoidance of doubt, the acquired Party and its Affiliates) shall not be prohibited from developing or commercializing such Competing Product, provided that the Acquirer does not use any Confidential Information of the other Party in connection with the development or commercialization of such Competing Product.

2.9 Covenant Not To Sue. VIVUS hereby grants to Auxilium a covenant not to sue on any VIVUS Technology on account of the Development, manufacture, or Commercialization of the Product in the Field in the Auxilium Territory by or on behalf of Auxilium, its Affiliates or sublicensees during the Term.

2.10 Letter Agreement. A letter, signed by ***, addressing *** is attached hereto as Exhibit E to this Agreement (the "**Letter Agreement**"). No further consent of VIVUS shall be required for Auxilium to receive the benefit of the Letter Agreement, and Auxilium shall have the right to *** as a consequence of *** in the Letter Agreement being ***.

2.11 Notice Right. VIVUS shall provide Auxilium with prompt written notice of any breach or alleged breach, including without limitation any notice of such breach or alleged breach provided by MTPC or its successor under the MTPC Agreement, of the MTPC Agreement, or by any Third Party manufacturer under any manufacturing agreement between such Third Party manufacturer and VIVUS, and shall provide Auxilium with copies of any documentation and correspondence between MTPC or such Third Party manufacturer and VIVUS regarding such breach including written summaries of any oral discussions. In the event that VIVUS is in breach of the MTPC Agreement or such manufacturing agreement, it shall promptly provide to Auxilium a written plan of action to remedy or cure such breach and shall keep Auxilium promptly informed of its progress or any changes to such plan of action. VIVUS may condition disclosure of attorney-client privileged information or attorney work product on the Parties' execution of a joint defense agreement, common interest agreement, or similar agreement intended to preserve attorney-client and attorney work product privileges under Applicable Law, in a form reasonably acceptable to VIVUS.

ARTICLE 3 GOVERNANCE

3.1 Joint Steering Committee. Within *** after the Effective Date, VIVUS and Auxilium shall form a Joint Steering Committee ("**JSC**") consisting of *** representatives from VIVUS and *** representatives from Auxilium. Each Party may replace any of its JSC representatives at any time upon prior written notice to the other Party.

3.2 Meetings of the JSC. The JSC shall meet at least ***, unless a particular meeting is waived by mutual consent. In addition, each Party shall have the right to call a

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meeting of the JSC on reasonable written notice to the other Party. Subject to the foregoing, the JSC shall meet on such dates and at such times as agreed by the JSC and shall meet via teleconference or videoconference or, if mutually agreed by the Parties, at a location determined by the JSC. Upon prior written notice to, and approval of, the JSC, each Party may permit visitors to attend meetings of the JSC, provided that any approved visitor shall be subject to confidentiality and non-use obligations no less stringent than the terms of Article 11. Each Party shall be responsible for its own expenses for participating in the JSC. Meetings of the JSC shall be effective only if at least (1) representative of each Party is present or participating, subject to the following sentence. The Parties acknowledge and agree that VIVUS shall have the right to opt out of its participation in the JSC, which shall only be effective if done in writing with specific reference to this subsection, at any time, in which case Auxilium shall have the right to make the decisions and take the actions previously reserved to the JSC, and shall keep VIVUS reasonably informed of its plans and activities on at least a semi-annual basis.

3.3 Responsibilities of the JSC. The JSC shall have the responsibility and authority to:

- (a) review and comment on any Development being conducted by either Party;
- (b) provide a forum for discussing any development relating to the Product being conducted by VIVUS (or its sublicensees) outside the Auxilium Territory;
- (c) review and comment on marketing and sales activities being carried out by Auxilium in the Auxilium Territory, including review of the Commercialization and Medical Affairs Plans;
- (d) provide a forum for discussing marketing and sales activities being conducted by VIVUS (or its sublicensees) outside the Auxilium Territory;
- (e) review and discuss any manufacturing or supply issues that may arise;

- (f) coordinate the efforts of the Parties with respect to the Label Expansion Filing;
- (g) Establish subcommittees pursuant to Section 3.6 on an as-needed basis, oversee the activities of all subcommittees so established, and address disputes or disagreements arising in all such subcommittees; and
- (h) Perform such other functions as the Parties may agree in writing.

3.4 Areas Outside the JSC's Authority. The JSC shall not have any authority other than that expressly set forth in Section 3.3 and, specifically, shall have no authority to (a) amend or interpret this Agreement, or (b) determine whether or not a breach of this Agreement has occurred.

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3.5 JSC Decisions.

(a) **Consensus; Good Faith; Action Without Meeting.** The JSC shall decide all matters by consensus, with each Party having one (1) collective vote. The members of the JSC shall act in good faith to cooperate with one another and to reach agreement with respect to issues to be decided by the JSC. Action that may be taken at a meeting of the JSC also may be taken without a meeting if a written consent setting forth the action so taken is signed by one (1) duly authorized representative of each Party.

(b) **Failure to Reach Consensus.** In the event that the members of the JSC cannot come to consensus within *** with respect to any matter over which the JSC has authority and responsibility as set forth in Section 3.3, the JSC shall submit the respective positions of the Parties with respect to such matter for discussion in good faith to the respective chief executive officers of VIVUS and Auxilium for resolution. If such chief executive officers are not able to mutually agree upon the resolution to such matter within *** after submission to them, then, subject to the limitations of Section 3.4, (a) the chief executive officer of VIVUS shall have the right to decide matters relating to a regulatory issue or the Label Expansion Filing, in each case, prior to transfer of the Product Marketing Authorization to Auxilium, except that in no event can the chief executive officer of VIVUS unilaterally decide such matter in a manner that (i) creates or would reasonably be expected to create ***, (ii) *** or would reasonably be expected to *** the ***, (iii) impedes or may impede in any way the supply of Product to Auxilium, or (iv) is contrary to the terms of this Agreement or any other written agreement between the Parties; and (b) to the extent such matter relates to a Development or Commercialization issue, or relates to a regulatory issue (after transfer of the Product Marketing Authorization to Auxilium), the chief executive officer of Auxilium shall have the right to decide such matter, except that in no event can the chief executive officer of Auxilium unilaterally decide such matter in a manner that (i) creates or would reasonably be expected to create ***, (ii) *** or would reasonably be expected to *** the ***, or (iii) is contrary to the terms of this Agreement or any other written agreement between the Parties.

3.6 Subcommittees. The JSC shall have the right to establish one (1) or more subcommittees and to delegate certain of its powers and responsibilities thereto. Subcommittees established by the JSC shall operate under the same rules as the JSC, except that any disputes that cannot be resolved by a subcommittee in a reasonable time period shall be submitted to the JSC for resolution in accordance with Section 3.5.

3.7 Alliance Manager. Each Party shall appoint one (1) employee representative who possesses a general understanding of regulatory, manufacturing, and marketing issues to act as its respective alliance manager for this relationship ("**Alliance Manager**"). The Alliance Manager shall be one of the *** representatives on the JSC for each Party.

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ARTICLE 4 DEVELOPMENT AND COMMERCIALIZATION

4.1 Development Obligations.

(a) **Time of Onset Study.** VIVUS shall finalize the reports from the Time of Onset Study, at VIVUS's sole cost and expense. At VIVUS's sole cost and expense, VIVUS shall prepare and file with the FDA appropriate Regulatory Materials designed to use the results of the Time of Onset Study to obtain a Time of Onset Claim for the Product in the Auxilium Territory (the "**Label Expansion Filing**"), and VIVUS shall use its Commercially Reasonable Efforts to obtain approval of the Lab12el Expansion Filing; provided however that in no event shall VIVUS be required to conduct any additional Development to support the Label Expansion Filing. Auxilium shall provide VIVUS with all reasonable assistance necessary for such preparation and filing, including without limitation access to all data from the Time of Onset Study. Data or results from the Time of Onset Study shall be owned by VIVUS and shall be licensed to Auxilium hereunder as VIVUS Know-How pursuant to Section 2.2.

(b) **Post-Approval Studies.** VIVUS shall be responsible for conducting any post-Regulatory Approval studies of Product that are required by the FDA in the Auxilium Territory ("**FDA-Required Studies**"). The costs of conducting any FDA-Required Studies shall be borne by the Parties equally, up to a maximum aggregate payment by Auxilium of ***, and once this maximum is reached, VIVUS shall be solely responsible for the remainder of such costs. VIVUS shall conduct such studies using Commercially Reasonable Efforts. Any additional post-Regulatory Approval studies of Product that Auxilium determines to conduct with respect to the Product in the Field in the Auxilium Territory shall be conducted by Auxilium as its sole expense. Auxilium shall not be under any obligation to conduct any such additional post-Regulatory Approval studies of Product.

(c) **Use of Data.** Each Party shall have the right, without any additional payment, to use any clinical or non-clinical data developed by or on behalf of the other Party or its Affiliates relating to the Product solely (i) to support the Regulatory Approval of Products in its territory (i.e., the Auxilium Territory for Auxilium and the VIVUS Territory for VIVUS) and (iii) for Promotional, marketing, and medical education purposes in support of the Commercialization of the Product in its territory. The rights set forth in this section may be sublicensed by each Party to any Third Party collaborator or

licensee in such Party's territory (or a portion thereof) who also holds Development or Commercialization rights to the Product in the Party's respective Territory.

(d) **Other Development.** As between the Parties, except for the responsibilities assigned to VIVUS pursuant to Section 4.1(a), Auxilium shall have the sole right to conduct any further Development work (including clinical trials) on the Product in the Field in the Auxilium Territory, at its sole discretion. Auxilium shall be responsible for all of its costs in connection with any further Development activities that it conducts, unless otherwise mutually agreed in writing by the Parties.

4.2 Commercialization — General. Subject to the terms of this Agreement, Auxilium shall have sole responsibility and decision-making authority for Commercialization activities for the Auxilium Territory. Auxilium shall be solely responsible for all costs and expenses associated with such Commercialization activities. The Commercialization activities shall comply in all material respects with Applicable Law. Notwithstanding the foregoing,

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Auxilium acknowledges and agrees that, under the MTPC Agreement, MTPC retains certain co-promotion rights in the Auxilium Territory with respect to the Product outside the field of male erectile dysfunction. Each of Auxilium and VIVUS agree to cooperate in good faith should a co-promotion agreement need to be negotiated with MTPC.

4.3 Commercialization Plan.

(a) Without limiting the generality of Auxilium's sole responsibility and decision-making authority for Commercializing the Product in the Field in the Auxilium Territory as set forth in Section 4.2, Auxilium will use its Commercially Reasonable Efforts to carry out the Commercialization of the Product in accordance with a written Commercialization Plan, as such may be amended or revised by Auxilium from time to time, that describes the anticipated Commercialization activities to be performed with respect to Product in the Auxilium Territory by Auxilium or on its behalf by permitted Third Parties (the "**Commercialization Plan**"). Each Commercialization Plan shall address, in reasonable detail, to the extent applicable, call plans for Detailing of Product, Sales Force training, Product sampling strategies and quantities, Product positioning and scientific communication strategy, and DTC and non-DTC advertising.

(b) Attached hereto as Exhibit A is a Commercialization Plan covering activities to be conducted in preparation of Product Launch in the Auxilium Territory and during the first full calendar year following the Product Launch.

(c) Auxilium shall thereafter update the Commercialization Plan (together with the Medical Affairs Plan described in Section 4.7) on an annual basis as follows: Auxilium shall provide the JSC with preliminary drafts of the Commercialization Plan and Medical Affairs Plan no later than *** of each year for the JSC's review and comment and Auxilium shall provide the JSC with the final Commercialization Plan and Medical Affairs Plan no later than *** of the year immediately following such year. In preparing the updated versions of the Commercialization Plan and Medical Affairs Plan, Auxilium shall analyze the effectiveness of the elements of the prior year Commercialization Plan and Medical Affairs Plan and shall use updated sales forecasts to develop the new Commercialization Plan. Auxilium agrees to give due consideration to the input provided by the JSC but Auxilium at all times will retain responsibility and decision-making authority for the Commercialization of the Product in the Field in the Auxilium Territory. Auxilium may, at its election, update the Commercialization Plan and Medical Affairs Plan between annual updates by following this same procedure.

(d) Each Party shall use Commercially Reasonable Efforts in performing its obligations under this Section 4.3 concerning (as applicable) the Commercialization Plan and Medical Affairs Plan.

(e) In the event of any inconsistency between, on the one hand, the Commercialization Plan or Medical Affairs Plan and, on the other hand, this Agreement, the terms of this Agreement shall prevail.

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4.4 Commercialization by Auxilium. Auxilium, itself or through its Affiliates or sublicensees, shall use Commercially Reasonable Efforts to Commercialize the Product in the Field in the Auxilium Territory. Without limiting the generality of the foregoing, Auxilium shall commence a Product Launch in the United States no later than ***. Notwithstanding the foregoing or any other provision of this Agreement, in the event that Auxilium, due solely to reasons outside of its reasonable control, is unable to commence a Product Launch in the United States no later than ***, due to VIVUS, or any supplier or subcontractor of VIVUS, failing to ship to Auxilium Product for sale reasonably in advance of such date, and ***, then, in addition to any other rights or remedies of Auxilium under this Agreement, Auxilium shall have the right to terminate this Agreement and promptly receive a return of the license fee paid by Auxilium under Section 7.1. If VIVUS has complied with the terms of the above and in the event Auxilium fails to commence a Product Launch in the United States by *** and as a result of the failure to launch, ***, VIVUS shall, in addition to any other rights or remedies of VIVUS under this Agreement, have the right to retain the license fee paid by Auxilium under Section 7.1, and VIVUS shall have no liability to Auxilium as a result of ***.

4.5 Sales Force.

(a) **General.** Auxilium shall at all times during the Term maintain a Sales Force containing a reasonable number of sales representatives in order to meet Auxilium's obligations under Section 4.4 with respect to the United States. The Sales Force may consist of employees of Auxilium or a contract sales force (or a combination thereof); provided that Auxilium shall remain responsible for the management, supervision, and performance of such contract sales force.

(b) **Qualifications.** Unless otherwise agreed by the Parties, Auxilium shall subject the members of its Sales Force to substantially the same minimum qualifications that it applies to its sales forces for its other products in the Auxilium Territory.

(c) **Compensation.** Auxilium shall be solely responsible for all costs and expenses of recruiting, hiring, maintaining and compensating its Sales Force, including salaries, benefits and incentive compensation.

4.6 Promotional Materials.

(a) Auxilium shall be responsible, at its expense, for preparing and producing the then current Promotional Materials. Up to two times per year Auxilium shall make its core Promotional Materials available to the JSC for its review. The Promotional Materials used by Auxilium or its Affiliates or sublicensees in a particular market in the Auxilium Territory shall be consistent with the Regulatory Approval in the Auxilium Territory and shall in any event comply in all material respects with Applicable Law. Auxilium shall use and distribute the Promotional Materials in accordance with the terms of this Agreement. To the extent that VIVUS disagrees with Promotional message or tactics proposed by Auxilium for Product in the Auxilium Territory, it may raise such issues with the JSC for discussion. Auxilium shall be solely responsible for timely submitting, as applicable, any Promotional Materials to the FDA's

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Office of Prescription Drug Promotion ("OPDP"), or to any equivalent Regulatory Authority elsewhere in the Auxilium Territory (including to any applicable state governmental authorities therein). Promptly following the Effective Date, VIVUS will take such actions necessary to confirm with OPDP that Auxilium is responsible for such submissions on behalf of VIVUS.

(b) Auxilium shall not use or distribute in connection with Promotion of the Product any materials bearing VIVUS's name or trademarks without VIVUS's prior written approval. Notwithstanding the foregoing, Auxilium shall be permitted to use the VIVUS Trademarks in accordance with the license granted in Section 2.1(b).

(c) All Promotional Materials shall include MTPC's name in a form that references MTPC as the licensor, to the extent permitted by Applicable Law and is customary for such materials in the Auxilium Territory. Auxilium shall directly provide MTPC with copies of all Promotional Materials as soon as reasonably practicable after such Promotional Materials are first used.

4.7 **Medical Affairs Activities.** Without limiting the generality of Auxilium's sole responsibility and decision-making authority for Commercializing the Product in the Field in the Auxilium Territory as set forth in Section 4.2, Auxilium will use its Commercially Reasonable Efforts to carry out medical affairs activities for the Product in accordance with a written Medical Affairs Plan, as such may be amended or revised by Auxilium from time to time, that describes the anticipated medical affairs activities to be performed with respect to Product in the Auxilium Territory by Auxilium or on its behalf by permitted Third Parties (the "**Medical Affairs Plan**"). Each Medical Affairs Plan shall address, in reasonable detail and to the extent applicable, grants to support continuing medical education, medical information services, the support of investigator-initiated trials, and phase IV clinical trials (in each case, with respect to Product in the Field in the Auxilium Territory). Attached hereto as Exhibit A is a Medical Affairs Plan covering those medical affairs activities anticipated to be conducted in preparation of Product Launch in the Auxilium Territory and during the first full calendar year following the Product Launch.

4.8 **Compliance.** In performing its duties hereunder, Auxilium shall, and shall use its Commercially Reasonable Efforts to cause its Sales Force to, comply with all Applicable Laws in all material respects, including all laws and regulations and other guidelines concerning the sale, promotion, and advertising of prescription drug products that are applicable to the Auxilium Territory, such as the AMA's Guidelines on Gifts to Physicians, the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, and the standards promulgated by the Accreditation Council for Continuing Medical Education, each as amended from time to time. Further, Auxilium shall use its Commercially Reasonable Efforts to cause its Sales Force to comply with all Auxilium compliance policies as in effect from time to time while selling or marketing the Product.

4.9 **Re-Sale Price.** Auxilium shall have the sole discretion and authority to determine the price(s) (including discounts) at which it sells Products in the Auxilium Territory, subject to Auxilium's compliance with Applicable Law.

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4.10 **Commercialization Reports.** Auxilium shall keep the JSC (or VIVUS in the absence of a JSC) reasonably informed regarding the material progress and results of Auxilium's Commercialization activities and those of its Affiliates and sublicensees, including providing the following:

(a) On a quarterly basis during the Term, Auxilium shall provide VIVUS with an email report of gross sales and Net Sales of the Products in the Auxilium Territory during said period and on a calendar year-to-date basis. Any such report shall be in a reasonable format, as determined by Auxilium in its discretion. Each such report shall be deemed to constitute Confidential Information of Auxilium for purposes of this Agreement.

4.11 **Cross-Territory Sales.** Neither Party shall Commercialize or authorize the Commercialization of any Product in the other Party's Territory. Except as authorized under Sections 2.1 and 2.2, neither Party shall, itself or through other Persons, directly solicit, advertise, sell, distribute, ship, consign, or otherwise transfer any Product outside such Party's Territory. Each Party shall use Commercially Reasonable Efforts to ensure that Products sold in its Territory are not used outside such Territory. Without limiting the generality of the foregoing, neither Party shall sell any Product to a purchaser if such Party knows, or has reason to believe, that such purchaser intends to remove such Product from such Party's Territory or otherwise intends to facilitate the use of such Product outside such Party's Territory. Each Party shall use Commercially Reasonable Efforts to ensure that its Affiliates, sublicensees, distributors, and wholesalers comply with all of the foregoing obligations.

ARTICLE 5
REGULATORY

5.1 Transfer of Marketing Authorization.

(a) **Transfer.** VIVUS shall, as soon as practicable following the later of (i) *** that *** is approved, and (ii) the approval of *** as a *** by ***, notify the FDA of the transfer to Auxilium of NDA #202276 (the “**Product Marketing Authorization**”), and shall promptly provide a correct and complete copy of such notice of transfer to Auxilium. Promptly following the Effective Date, VIVUS shall provide Auxilium with a complete copy of NDA #202276 and all related correspondence with the FDA. VIVUS shall use Commercially Reasonable Efforts to complete any and all other regulatory requirements necessary for such transfer in accordance with Applicable Laws. Auxilium shall assist and cooperate with VIVUS in connection with such transfer. Auxilium shall be responsible for out of pocket costs and expenses incurred by either Auxilium or VIVUS or their Affiliates in connection with the transfer of the Product Marketing Authorization. Such payments shall be based on written invoices submitted to Auxilium by VIVUS from time to time. For clarity, only the Product Marketing Authorization will be transferred to Auxilium, and no patents, patent applications, or other intellectual property of VIVUS shall be transferred.

(b) **Post-Transfer Responsibilities.** Following completion of the transfer of the Product Marketing Authorization to Auxilium, the obligation set forth in this Section 5.1(b)

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shall apply. Auxilium shall use its Commercially Reasonable Efforts to comply with all requirements imposed on Auxilium as the holder of the Product Marketing Authorization by Applicable Law and for maintaining the on-going validity of the Product Marketing Authorization. Auxilium shall not take any actions, other than to the extent required by Applicable Law, that would reasonably be expected to cause the Product Marketing Authorization to be withdrawn by the FDA. Auxilium shall be responsible for collecting and maintaining any safety-related information required by Applicable Law in the Auxilium Territory and will coordinate with VIVUS (or at VIVUS’s request, with VIVUS’s licensees of the Product in the VIVUS Territory) to provide any portion of such information that is necessary or useful to support safety documentation/reporting in the VIVUS Territory.

(c) **Restriction on Further Transfer.** Auxilium shall in no circumstances transfer, or permit any Affiliates to transfer, the Product Marketing Authorization to any Third Party without the prior written consent of VIVUS; provided that the foregoing shall not limit or otherwise restrict in any way a change in control of Auxilium. Auxilium acknowledges that a breach of this Section 5.1(c) by Auxilium would constitute a material breach of this Agreement.

(d) **VIVUS Retained Rights.** Notwithstanding the transfer of the Product Marketing Authorization by VIVUS to Auxilium as provided in Section 5.1, VIVUS shall, in all circumstances, retain the following rights after such transfer: (i) VIVUS shall exercise control over the selection of the manufacturer of the Product for sale in the Auxilium Territory unless and until the Supply Chain Transfer occurs pursuant to Section 6.2; and (ii) VIVUS shall remain the owner of all data filed with Regulatory Authorities in connection with the Product Marketing Authorization and the Label Expansion Filing and shall retain the right, with prior written notice to Auxilium, to grant access to this data to Third Parties who are collaborating with or otherwise assisting VIVUS in connection with the Development or Commercialization of the Product for use in the Field outside the Auxilium Territory, or manufacturing of the Product and/or the development, commercialization, or manufacturing of any other VIVUS product; and (iii) VIVUS shall, in accordance with Section 5.2(c), retain final decision-making right with respect to the content of any communications with Regulatory Authorities in the Auxilium Territory in connection with the qualification of Product manufacturers unless and until a Supply Chain Transfer occurs pursuant to Section 6.2.

5.2 Regulatory Materials and Regulatory Approvals.

(a) **Product Marketing Authorization.** Upon transfer of the Product Marketing Authorization to Auxilium in accordance with Section 5.1, (i) Auxilium shall be the legal and beneficial owner of the Product Marketing Authorization and any other Regulatory Approval granted by the FDA or other Regulatory Authority in the Auxilium Territory with respect to the Product, and (ii) Auxilium shall be solely responsible for all communications and other dealings with the FDA and any other Regulatory Authorities in the Auxilium Territory relating to the Product or the Product Marketing Authorization, subject to Section 5.1(d).

(b) **Costs.** Except as otherwise provided in this Agreement, each Party shall bear its own costs in connection with its performance of regulatory activities hereunder.

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Notwithstanding the foregoing, VIVUS shall be responsible for any fees payable to the FDA or any other Regulatory Authority in the Auxilium Territory with respect to the Product prior to the transfer of the Product Marketing Authorization to Auxilium, and Auxilium shall be responsible for any fees payable to the FDA or any other Regulatory Authority in the Auxilium Territory with respect to the Product after the transfer of the Product Marketing Authorization to Auxilium. With respect to any fees paid by VIVUS prior to the transfer of the Product Marketing Authorization to Auxilium as prepayments to the FDA or any other Regulatory Authority in the Auxilium Territory with respect to the Product, Auxilium shall reimburse VIVUS for the pro rata portion of such fees that are allocable to the Term of this Agreement.

(c) **Notifications; Communications with Regulatory Authorities.** During the Term, each Party shall keep the other reasonably and regularly informed of such Party’s submission to Regulatory Authorities of all material Regulatory Materials, meetings with Regulatory Authorities, and receipt of, or any material changes to existing, Regulatory Approvals, in each case for the Product in the Auxilium Territory, pursuant to procedures to be

developed by the JSC. Prior to completion of the transfer of the Product Marketing Authorization to Auxilium in accordance with Section 5.1, VIVUS and Auxilium shall jointly make decisions with respect to the content of any communications that VIVUS makes to Regulatory Authorities regarding the Product. Following completion of transfer of the Product Marketing Authorization to Auxilium in accordance with Section 5.1, Auxilium shall have the right to make any final decisions with respect to the content of any communications that it makes to Regulatory Authorities regarding the Product; provided, however, that (i) any commitments to a Regulatory Authority in the Auxilium Territory that would reasonably be expected to have a material impact on the Commercialization of the Product in the VIVUS Territory shall require VIVUS's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed.

5.3 Other Regulatory Obligations.

(a) Auxilium shall comply with all pharmacovigilance obligations imposed by Applicable Law in relation to the Product. Each Party shall keep the other informed in a timely manner of any Information that such Party receives (directly or indirectly) that (i) raises any material concerns regarding the safety or efficacy of the Product; (ii) reasonably indicates or suggests a potential material liability of either Party to Third Parties in connection with the Product; (iii) is reasonably likely to lead to a recall or market withdrawal of the Product in any jurisdiction; or (iv) relates to the Product and is reasonably likely to have a material impact on a Regulatory Approval, Pricing Approval, or the Commercialization of the Product in the Field in the Auxilium Territory.

(b) Each Party shall fully cooperate with and assist the other Party in complying with any regulatory obligations with respect to the Product in the Auxilium Territory.

(c) Prior to the completion of the transfer of the Product Marketing Authorization to Auxilium, Auxilium shall not communicate with any Regulatory Authority in the Auxilium Territory regarding any Product unless explicitly requested or permitted in writing

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to do so by VIVUS. Following the completion of transfer of the Product Marketing Authorization to Auxilium, (i) Auxilium's communications with Regulatory Authorities in the Auxilium Territory regarding the Product shall comply with Section 5.2(c) and Section 5.3(a), and (ii) except to the extent required by Applicable Law, VIVUS shall not communicate with any Regulatory Authority in the Auxilium Territory regarding any Product unless explicitly requested or permitted in writing to do so by Auxilium. Except to the extent required by Applicable Law, in no event shall Auxilium communicate with any Regulatory Authority in the VIVUS Territory regarding any Product unless explicitly requested or permitted in writing to do so by VIVUS.

5.4 Intentionally Omitted.

5.5 Rights of Reference. VIVUS hereby grants to Auxilium an exclusive right of reference to all Regulatory Materials and Regulatory Approvals owned or Controlled by VIVUS solely for the purpose of obtaining or maintaining, during the Term, the Product Marketing Authorization, in each case subject to Section 4.1(a). Auxilium hereby grants to VIVUS an exclusive right of reference to all Regulatory Materials, Regulatory Approvals, and Pricing Approvals owned or Controlled by Auxilium solely for the purpose of obtaining or maintaining Regulatory Approval for Product in the VIVUS Territory during the Term.

5.6 Regulatory Actions.

(a) **Notice of Non-Compliance.** Each Party shall promptly disclose to the other Party any information that it receives pertaining to notices from Regulatory Authorities of non-compliance with Applicable Laws that might reasonably be expected to have an impact on the Commercialization of the Product in the Territory, including any notices relating to the manufacture of the Product.

(b) **Inspection or Audit.** If a Regulatory Authority desires to conduct an inspection or audit of either Party's facility or a facility under contract with either Party with regard to the Product, such Party shall cooperate and cause the contract facility to cooperate with such Regulatory Authority during such inspection or audit. Each Party shall use its Commercially Reasonable Efforts to segregate, and not disclose, any Confidential Information of the other Party or other materials, correspondence and documents that are not required to be disclosed during an audit or inspection by a Regulatory Authority. To the extent that either Party receives the inspection or audit observations of such Regulatory Authority, such Party shall promptly provide the other Party with a copy of the inspection or audit observations of such Regulatory Authority. The Party holding the Product Marketing Authorization shall prepare the response to any such observations, but the submission of the response to the applicable Regulatory Authority shall be subject to the other Party's review, and the Party holding the Product Marketing Authorization shall give due consideration to such other Party's comments. Each Party shall implement at its own cost the actions to correct any material deficiencies with such Party's facility or facility under contract found by the Regulatory Authority during the audit or inspection, in accordance with the requirements of the Regulatory Authority and Applicable Law. In the case of any audit or inspection of a Party's facility or a facility under contract with

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such Party where such audit or inspection is not related to the Product, such Party shall promptly notify the other Party of any findings of such an audit or inspection that may have an effect on the other Party's ability to assume its obligation and responsibilities imposed by this Agreement or the Commercialization of the Product in the Auxilium Territory.

(c) **Product Withdrawals and Recalls.** The Parties shall exchange their internal standard operating procedures ("SOPs") for conducting product recalls reasonably in advance of Product Launch, and shall discuss and resolve any conflicts between such SOPs and issues relating thereto promptly after such exchange. In the event of any disagreement as to how to resolve any such conflicts with respect to the Product, VIVUS's SOP

shall control unless and until VIVUS transfers ownership of the Product Marketing Authorization to Auxilium, and Auxilium’s SOP shall control thereafter. If either Party becomes aware of information relating to the Product that indicates that a unit or batch of such Product may not conform to the specifications therefor, or that potential adulteration, misbranding, and/or other issues have arisen that relate to the safety or efficacy of Products, it shall promptly so notify the other Party. To the extent practicable, the Parties shall discuss the circumstances of any potential product recall, field correction, or withdrawal of any Product and possible appropriate courses of action. If Auxilium decides to initiate a recall, field correction, or withdrawal of Product in the Auxilium Territory, Auxilium shall have the right and responsibility, at its expense but without limiting any claims Auxilium may have against VIVUS or any other Person, to control such recall, field correction, or withdrawal in a manner consistent with its internal SOPs (as revised pursuant to the first sentence of this Section 5.6(c), if applicable); provided, however, Auxilium shall consider in good faith the views of VIVUS as to whether a recall, field correction, or withdrawal is necessary or appropriate. For clarity, as between the Parties, VIVUS shall have the right, at its expense, to control all recalls, field corrections, and withdrawals of any Product in the VIVUS Territory. Each Party shall maintain complete and accurate records of any recall, field correction, or withdrawal in its territory for such periods as may be required by Applicable Laws, but in no event for less than ***. For purposes of clarity, for Product supplied by VIVUS under the Commercial Supply Agreement, the Parties’ respective responsibilities for the costs of any Product recall, field correction, or withdrawal of such Product shall be as set forth in the Commercial Supply Agreement.

5.7 **PV Agreement.** Not later than *** after the Effective Date, the Parties shall use commercially reasonable efforts to enter into a separate pharmacovigilance agreement (the “PV Agreement”) containing the specific terms, conditions and obligations of the Parties with respect to the collection, reporting and monitoring of all adverse drug reactions, adverse events, medical inquires with safety concerns, and other relevant drug safety matters with respect to Products during the Term.

ARTICLE 6
MANUFACTURING

6.1 **Commercial Supply Agreement.** Concurrent with the execution of this Agreement, the Parties have executed the manufacturing and supply agreement (the “Commercial Supply Agreement”) attached hereto as Exhibit B, under which VIVUS has

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agreed to supply, itself or through *** Third Party manufacturers, bulk tablets of Product to Auxilium, its Affiliates, and/or its sublicensees for Commercialization in the Field in the Auxilium Territory. Not later than *** after the Effective Date, the Parties shall use commercially reasonable efforts to enter into a separate quality agreement governing the agreed-upon specifications and other technical aspects of supply of such Product for Commercialization in the Field in the Auxilium Territory (the “Quality Agreement”). For the avoidance of doubt, none of VIVUS’s agreements with Third Party manufacturers and suppliers for the Product shall be assigned to Auxilium on the Effective Date.

6.2 **Transition of Supply Chain.** At a time selected by Auxilium, but in any event no later than the third (3rd) anniversary of the Effective Date, Auxilium may elect to have VIVUS transfer control of the supply chain for the Product to Auxilium or its designee for the supply of Product for the Auxilium Territory by assigning to Auxilium VIVUS’s agreement(s) with the contract manufacturer(s) in such supply chain (the “Supply Chain Transfer”). As promptly as practicable following written notice from Auxilium that it will exercise its right to a Supply Chain Transfer, the Parties shall discuss and agree on a written plan for the Supply Chain Transfer (the “Supply Chain Transfer Plan”). Following agreement on such Supply Chain Transfer Plan, the Parties shall each use Commercially Reasonable Efforts to carry out their respective obligations thereunder in a timely fashion; provided, however, the Supply Chain Transfer shall only occur if and when Auxilium makes the applicable election. Following the Supply Chain Transfer, Auxilium shall pay the Third Party manufacturer of Product directly for such supply.

ARTICLE 7
FINANCIALS

7.1 **License Fee.** No later than *** after the Effective Date, Auxilium shall pay to VIVUS a one-time, non-refundable, non-creditable license fee of thirty million dollars (\$30,000,000) by wire transfer of immediately available funds into an account designated in writing by VIVUS.

7.2 **Milestone Payments.** Auxilium shall make each of the milestone payments indicated below to VIVUS upon the achievement of the corresponding milestone event, and in each case as adjusted pursuant to Section 7.4:

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Milestone Event	Payment
Approval by FDA of a Time of Onset Claim for the Product in the Auxilium Territory	\$15 Million
Aggregate Net Sales of Product in any calendar year in the Auxilium Territory first reach ***	***
Aggregate Net Sales of Product in any calendar year in the Auxilium Territory first reach ***	***
Aggregate Net Sales of Product in any calendar year in the Auxilium Territory first reach ***	***
Aggregate Net Sales of Product in any calendar year in the Auxilium Territory first reach ***	***
Aggregate Net Sales of Product in any calendar year in the Auxilium Territory first reach ***	***
Aggregate Net Sales of Product in any calendar year in the Auxilium Territory first reach ***	***
Aggregate Net Sales of Product in any calendar year in the Auxilium Territory first reach ***	***

Each milestone payment in this Section 7.2 shall be paid only once. The maximum total amount of payment to VIVUS pursuant to this Section 7.2 shall be two hundred seventy million dollars (\$270,000,000). For the Time of Onset Claim milestone payment above, Auxilium shall pay VIVUS the applicable milestone payment within *** after the achievement of the corresponding milestone event. For the other milestone payments, Auxilium shall notify and pay

to VIVUS the applicable milestone payment together with the delivery of the quarterly report pursuant to Section 7.5 for the calendar quarter in which the applicable event was achieved. For clarity, in the event that more than one (1) of the aggregate Net Sales thresholds is achieved in a calendar year, Auxilium shall owe each of the corresponding payments. Each milestone payment hereunder shall be made by wire transfer of immediately available funds into an account designated in writing by VIVUS. Each such milestone payment is non-refundable and non-creditable against any other payments due hereunder.

7.3 Royalty Payments to VIVUS.

(a) **Royalty Payments to VIVUS.** During the Royalty Term, on a calendar quarter basis, Auxilium shall pay to VIVUS royalties calculated as a percentage of Net Sales of Products in the Auxilium Territory as follows (“**Royalty Payments**”):

Aggregate Net Sales of Products in a calendar year in the Auxilium Territory	Royalty Rate
Portion of Net Sales less than or equal to US\$***	*** %
Portion of Net Sales greater than US\$*** and less than or equal to US\$***	*** %
Portion of Net Sales greater than US\$***	*** %

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For purposes of illustration only, if Net Sales in the Auxilium Territory for each of the four calendar quarters in 2014 was \$***, the royalties due to VIVUS hereunder would be as follows: ***.

(b) **Duration.** Royalty payments shall be payable under this Section 7.3 during the period commencing with the Effective Date and continuing on a country-by-country basis until the later of: (i) ten (10) years after the Product Launch in such country, or (ii) expiration of the last to expire Patents within the VIVUS Patents covering the Product in such country (the “**Royalty Term**”).

7.4 **Royalties under MTPC Agreement.** In addition to the royalties owed to VIVUS pursuant to Section 7.3, Auxilium shall be responsible for paying the amounts and payments set forth on Exhibit C owed by VIVUS to MTPC under the MTPC Agreement on account of Net Sales of Auxilium or its Affiliates or sublicensees, including the royalties on net sales owed to MTPC during the MTPC Royalty Period, trademark royalties owed to MTPC after the end of the MTPC Royalty Period, and Auxilium’s pro-rata share of the sales milestone, all of which are set forth in Exhibit C (the “**MTPC Payments**”). For the avoidance of doubt, the Parties acknowledge that such payments to VIVUS are intended to match payments owed by VIVUS to MTPC under the MTPC Agreement, that the definition of “net sales” under the MTPC Agreement is different than the definition of Net Sales hereunder, and that, as a result, Auxilium’s payment obligations under this Section 7.4 and Exhibit C that are based on net sales shall be determined using the definition of MTPC Agreement Net Sales contained in the MTPC Agreement.

7.5 **Royalty Payments and Reports.** Within *** after the end of each calendar quarter, Auxilium shall provide VIVUS with a statement of (a) the amount of gross sales of Products during the applicable calendar quarter, (b) an itemized calculation of Net Sales showing Net Sales Deductions during such calendar quarter, and (c) the calculation of the amount of royalty payment due on such sales for such calendar quarter pursuant to Section 7.3, any Net Sales milestone payment due pursuant to Section 7.2, and any payment due pursuant to Section 7.4. In addition, within *** after the end of each calendar month, Auxilium shall provide VIVUS with its best estimate of the items in subsections (a) and (b) above for such month. Together with each quarterly statement provided pursuant to this Section 7.5, Auxilium shall provide VIVUS with any payments due. All amounts payable to VIVUS under this Section 7.5 shall be paid by wire transfer of immediately available funds into an account designated in writing by VIVUS.

7.6 **Taxes.** All payments made under this Agreement shall be made free and clear of withholding for Taxes (“**Withholding Taxes**”) unless such withholding is otherwise required under Applicable Law. To the extent such withholding is required under Applicable Law, Auxilium shall pay such Taxes to the applicable taxing authority and shall be permitted to deduct such Taxes from applicable payments under this Agreement. Auxilium will timely provide VIVUS with reasonable documentation evidencing the payment of any such Taxes to the applicable taxing authority and shall comply with any tax reporting obligations that are required under Applicable Law so as to enable VIVUS to obtain a credit of any such Tax.

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Notwithstanding the foregoing, to the extent that a deduction or withholding of Taxes hereunder arises as a result of any action taken by Auxilium after the Effective Date that has at the time of such action the effect of modifying the Tax treatment of, or increasing the Taxes applicable to, payments hereunder, in each case relative to the Tax treatment existing as of the Effective Date (a “**Auxilium Withholding Tax Action**”), including without limitation an assignment of this Agreement by Auxilium or any failure on the part of Auxilium to comply with Applicable Law, then, and only to the extent VIVUS is not eligible to obtain a credit of any such withholding taxes, (a) the payment by Auxilium shall be increased by the amount necessary (the “**Additional Tax**”) to ensure that VIVUS receives an amount equal to the amount that it would have received had no such Auxilium Withholding Tax Action occurred, and (b) obligations set forth above with respect to making payments to the applicable taxing authority and reporting such payments to VIVUS shall apply with respect to such Additional Tax; provided that, to the extent any Additional Tax is attributable in whole or in part to any action taken by VIVUS after the Effective Date, the payment increase in subsection (a) shall be proportionately reduced to reflect the relative responsibilities of the Parties for causing the deduction or withholding of Taxes. Solely for purposes of this Section 7.8, “**Taxes**” means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including interest, penalties and additions thereto) that are imposed by the applicable government or other taxing authority.

7.7 **Late Payments.** In the event any payment due hereunder is not made when due, the payment shall accrue interest (beginning on the date such payment is due) calculated at the rate of *** percent (***) per month or the maximum rate allowable by Applicable Law, whichever is less Such payment when made shall be accompanied by all interest so accrued.

7.8 Records; Audits. Auxilium shall maintain complete and accurate books and records in accordance with GAAP in sufficient detail to permit VIVUS to confirm the accuracy of milestone payments, royalty payments, and any other compensation payable under this Agreement, for a period of *** from the creation of individual records or any longer period required by Applicable Law. At VIVUS's request, such records shall be available for review at a location in the Auxilium Territory determined by Auxilium not more than once each calendar year covering the two immediately preceding calendar years (during normal business hours on a mutually agreed date with reasonable advance notice) by an independent Third Party auditor selected by VIVUS and approved by Auxilium (such approval not to be unreasonably withheld, conditioned, or delayed) and subject to confidentiality and non-use obligations no less stringent than those set forth in Article 11 for the sole purpose of verifying for VIVUS the accuracy of the financial reports furnished by Auxilium pursuant to this Agreement or of any payments made by Auxilium to VIVUS pursuant to this Agreement. Any such auditor shall not disclose Auxilium's Confidential Information to VIVUS, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Auxilium or the amount of payments due by Auxilium under this Agreement. Any undisputed amounts finally determined to be owed but unpaid shall be paid within *** from the accountant's report, plus interest (as set forth in Section 7.7) from the original due date. Any amounts finally determined to have been overpaid may be credited by Auxilium against future payments to VIVUS hereunder. Auxilium may carry forward any unused credits to future calendar quarters; provided, that in the event there are

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unused credit amounts upon the termination of this Agreement or expiration of the Royalty Term, VIVUS shall promptly pay to Auxilium such amounts. VIVUS shall bear the full cost of such audit unless such audit reveals an underpayment or under-reporting error of *** percent (***) or more during the applicable audit period, in which case Auxilium shall bear the full cost of such audit.

7.9 Currency. All amounts specified or payable in this Agreement shall be in United States dollars.

7.10 Royalty Reduction.

(a) In the event the manufacture or Commercialization of the Product in the Auxilium Territory would necessarily infringe the issued patents of any Third Party absent a license thereunder (but excluding any infringement to the extent resulting from changes to the Product made by Auxilium or its Affiliates or sublicensees) and Auxilium must obtain a royalty-bearing license under such patents, then Auxilium may deduct from the Royalty Payments due to VIVUS pursuant to Section 7.3 with respect to a particular Product in a particular country in the Auxilium Territory, an amount equal to *** percent (***) of the royalties actually paid to any such Third Party with respect to such Product in such country as consideration for any such license.

(b) In the event that, at any time during the Royalty Term, a Generic Product is sold in a country of the Auxilium Territory and Auxilium's Net Sales of the Product in such country during any quarter following such sales of Generic Product is reduced (a "**Net Sales Reduction**") by at least *** percent (***) from the Net Sales of the Product in such country in ***, then the Royalty Payments with respect to any Net Sales of Product in such country shall be reduced by *** percent (***). In the event that the Net Sales Reduction equals or exceeds *** percent (***) from the Net Sales of the Product in such country in ***, then the Royalty Payments shall be reduced by *** (***). For clarity, regardless of any Net Sales Reduction, the MTPC Payments will remain unchanged, and Auxilium shall continue to be required to make any required MTPC Payments with respect to Net Sales.

(c) In the event that all of the claims of the VIVUS Patents within any country of the Auxilium Territory expire or are invalidated prior to the end of the applicable Royalty Term, then, to the extent that none of the reductions set forth in Section 7.10(b) apply, thereafter until the end of the Term the Royalty Payments owed with respect to any Net Sales of Product in such country shall be reduced by *** percent (***). For the avoidance of doubt, if any of the reductions set forth in Section 7.10(b) apply to a particular Product in a particular country, this Section 7.10(c) shall not cause any further reductions in payments owed by Auxilium hereunder with respect to such Product in such country.

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ARTICLE 8 INTELLECTUAL PROPERTY

8.1 Ownership of Inventions. Each Party shall own all inventions and Information made solely by its respective employees, agents, and independent contractors and its Affiliates in the course of conducting such Party's activities under this Agreement (collectively, "**Sole Inventions**"), along with any Patents covering such Sole Inventions. All inventions and Information that are made jointly by employees, Affiliates, agents, or independent contractors of both Parties in the course of performing activities under this Agreement (collectively, "**Joint Inventions**"), along with any Joint Patents, shall be owned jointly by the Parties. Subject to the licenses granted pursuant to Section 2.1 or 2.3, each Party shall have the right to practice, license and exploit the Joint Inventions and Joint Patents worldwide, without consent of the other Party (and where consent is required by Applicable Law, such consent is hereby deemed granted) and without a duty of accounting to the other Party. For the avoidance of doubt and for purposes of this Agreement, to the extent that any Joint Inventions relate to any Product, such Joint Inventions shall be deemed to constitute VIVUS Know-How and Auxilium Know-How, and to the extent that any Joint Patents relate to any Product, such Joint Patents shall be deemed to constitute VIVUS Patents and Auxilium Patents.

8.2 Disclosure of Inventions. Each Party shall promptly disclose to the other all Sole Inventions or Joint Inventions relating to any Product or its composition, formulation, manufacture, or use, including all invention disclosures or other similar documents submitted to such Party by its, or its Affiliates', employees, agents or independent contractors describing such Sole Inventions or Joint Inventions. Such Party shall also respond promptly to reasonable requests from the other Party for more Information relating to such inventions.

8.3 Prosecution of Patents.

(a) **VIVUS Patents.** Auxilium acknowledges that, under the terms of the MTPC Agreement, MTPC has the sole right to prosecute and maintain the VIVUS Patents.

(b) **Joint Patents.** With respect to any potentially patentable Joint Invention, the Parties shall meet and agree upon which Party, if any, shall prepare, file, prosecute (including any interferences, reissue proceedings and reexaminations) and maintain patent applications covering such Joint Invention (any such patent application and any patents issuing therefrom a “**Joint Patent**”) in any jurisdictions throughout the world, as well as the manner in which patent expense for such Joint Patent will be shared by the Parties. The Party that prosecutes a patent application in the Joint Patents (the “**Prosecuting Party**”) shall provide the other Party reasonable opportunity to review and comment on such prosecution efforts regarding the applicable Joint Patents in the particular jurisdictions, and such other Party shall provide the Prosecuting Party reasonable assistance in such efforts. The Prosecuting Party shall provide the other Party with a copy of all material communications from any patent authority in the applicable jurisdictions regarding the Joint Patent being prosecuted by such Party, and shall provide drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. In particular, each Party agrees to provide the other Party with all information necessary or desirable to enable the other Party to comply with the duty of candor/duty of disclosure requirements of any patent authority. Either Party may determine that it is no longer interested in supporting the continued

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prosecution or maintenance of a particular Joint Patent in a country or jurisdiction, in which case the disclaiming Party shall provide the other Party with written notice of such determination at least *** before any deadline for taking action to avoid abandonment and shall provide the other Party with the opportunity to have the disclaiming Party’s interest in such Joint Patent in such country or jurisdiction assigned to the other Party, at no cost to the other Party.

(c) **Cooperation in Prosecution.** Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts provided above in this Section 8.3, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

8.4 Enforcement of Patents.

(a) **Notification.** If a Party becomes aware of any infringement, threatened infringement, or alleged infringement of the VIVUS Patents or Joint Patents on account of a Third Party’s manufacture, use or sale of a product that includes the Compound as the sole active ingredient in the Field in the Auxilium Territory (in each case, a “**Product Infringement**”), then such Party shall promptly notify the other Party in writing of such Product Infringement, including any evidence in such Party’s possession demonstrating such Product Infringement. Any “patent certification” filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) (or similar provisions in other jurisdictions) that asserts that infringement of a VIVUS Patent or Joint Patent will not arise from the manufacture, use or sale of a product that includes the Compound as the sole active ingredient in the Field in the Auxilium Territory by a Third Party or that asserts that any claims of a VIVUS Patent or Joint Patent covering product that includes the Compound as the sole active ingredient in the Field in the Auxilium Territory is invalid or unenforceable shall be deemed to be a Product Infringement hereunder, and each Party shall provide written notice to other Party of any such filed certification within *** of becoming aware thereof.

(b) **Enforcement.** During the Term and subject to the remainder of this Section 8.4(b), Auxilium shall have the first right to initiate, prosecute and control legal proceedings against any person or entity engaged in a Product Infringement of the VIVUS Patents in the Auxilium Territory, all at Auxilium’s sole expense. If Auxilium decides not to bring such legal action, or if Auxilium fails to initiate such legal action by the Action Date, VIVUS (and/or MTPC) shall have the right, but not the obligation, to commence a suit or take action to enforce the applicable VIVUS Patents with respect to such Product Infringement in the Auxilium Territory, at its own expense.

(c) **Cooperation.** Each Party shall provide to the Party enforcing any rights under Section 8.4(b) reasonable assistance in such enforcement, including joining such action as a party plaintiff if required by Applicable Law to pursue such action. Additionally, to the extent requested by Auxilium, VIVUS agrees to exercise its right under the MTPC Agreement to require MTPC to cooperate in any enforcement by or on behalf of Auxilium pursuant to Section 8.4(b), including being joined as a party to such action if necessary. The enforcing Party shall keep the other Party reasonably and regularly informed of the status and progress of such

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enforcement efforts, and shall reasonably consider the other Party’s comments on any such efforts. The non-enforcing Party shall have the right to be represented in any action brought under Section 8.4(b) by counsel of its choice and at its own expense. For clarity, as between the Parties, VIVUS (or MTPC or a VIVUS designee) shall have the exclusive right to bring and control any legal action in connection with any actual, alleged, or threatened infringement of a VIVUS Patent that is not a Product Infringement at its own expense as it reasonably determines appropriate.

(d) **Settlement.** Without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, neither Party shall settle any claim, suit or action brought under Section 8.4 involving VIVUS Patents in any manner that (i) admits the invalidity of, or otherwise impairs the other Party’s rights in, the VIVUS Patents or (ii) limits, or would reasonably be expected to limit, the ability of the other Party or its licensees to sell or manufacture Products in its territory (i.e., the Auxilium Territory in the case of Auxilium or the VIVUS Territory in the case of VIVUS). Notwithstanding the foregoing, in the event that (A) Auxilium decides not to bring a legal action against Product Infringement in the Auxilium Territory, or if Auxilium fails to initiate such legal action by the Action Date, and (B) thereafter MTPC (or a licensee or designee of MTPC other than VIVUS) brings an action under the VIVUS Patents in the Auxilium Territory or the VIVUS Territory, settlement of such action shall be at MTPC’s sole discretion and shall not require the consent of Auxilium.

(e) **Recoveries.** Any recoveries resulting from an action brought by a Party under Section 8.4(b) relating to a claim of Product Infringement of a VIVUS Patent shall be first applied against payment of each Party's costs and expenses in connection therewith. Any such recoveries in excess of such costs and expenses (the "**Remainder**") will be retained by the enforcing Party; *provided* that if Auxilium is the enforcing Party, the Remainder shall be included in Net Sales for purposes of calculating royalties owed to VIVUS hereunder.

(f) **Joint Patents.** If a Third Party infringes any Joint Patent, the Parties shall discuss such infringement and the Parties shall each have the right, but neither Party shall be obligated, to bring an appropriate suit or other action under such Joint Patent against any Person engaged in such infringement. If both Parties agree to so enforce such Joint Patents, they shall be jointly responsible for, and share equally, all the costs and expenses of any suit brought by them and shall equally share all recoveries with respect thereto. If one Party elects not to enforce such Joint Patents against such infringement, then the other Party shall have the right, but not the obligation, to take action to enforce such Joint Patents against such infringement at its own cost and expense and such other Party may retain all recoveries with respect thereto.

8.5 Patent Marking. Auxilium shall, and shall require its Affiliates and sublicensees, to mark Products sold by it hereunder with appropriate patent numbers or indicia to the extent permitted by Applicable Law.

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8.6 Trademarks.

(a) **General.** All uses of the VIVUS Trademarks and Auxilium Trademarks shall comply with all Applicable Laws in the Auxilium Territory. Unless otherwise agreed by the Parties or required by the FDA, Auxilium shall sell the Product in the Auxilium Territory under the VIVUS Trademark STENDRA. Auxilium may include its company name and associated logos on all Product packaging and Promotional Materials for the Auxilium Territory.

(b) **VIVUS Trademarks.** Auxilium's use of the VIVUS Trademarks shall be limited to the marketing, sale and distribution of the Product in the Auxilium Territory. Auxilium shall not at any time register or cause to be registered any other trademark, name or design confusingly similar to any of the VIVUS Trademarks without the express consent of VIVUS, which consent shall not be unreasonably withheld, conditioned or delayed. Auxilium shall properly designate the VIVUS Trademarks on the packaging of the final Product, to the extent required or permissible by the applicable Regulatory Approvals. All rights arising from the use of the VIVUS Trademarks in the Auxilium Territory during the Term shall inure to VIVUS's benefit. Auxilium agrees that the Product with which the VIVUS Trademarks are used shall conform to all requirements of the Regulatory Authority in the Auxilium Territory. Auxilium shall, as soon as practicable after receiving notice of any potential infringement of the VIVUS Trademarks in the Auxilium Territory, inform VIVUS of any such potential infringement. VIVUS shall have the sole right and discretion to bring infringement or unfair competition proceedings involving the VIVUS Trademarks. In order to further the development of a consistent worldwide brand for the Product, Auxilium shall, in consultation with VIVUS, develop appropriate trademark usage guidelines for the VIVUS Trademarks that can be communicated by VIVUS to licensees outside the Auxilium Territory from time to time.

(c) **Auxilium Trademarks.** To the extent that Auxilium elects to use other trademarks in addition to the VIVUS Licensed Trademarks in connection with the sale or marketing of Products in the Auxilium Territory (such other trademarks, if any, the "**Auxilium Trademarks**"), Auxilium shall be responsible for the selection, adoption, registration, maintenance and defense of such Auxilium Trademarks, as well as all expenses associated therewith. Auxilium shall own all Auxilium Trademarks.

8.7 Regulatory Data Protection. As between the Parties, VIVUS shall be solely responsible for deciding which of the VIVUS Patents to submit to FDA for listing in the Orange Book for any Product and for maintaining with FDA correct and complete listings of applicable patents for such Product; provided that VIVUS shall not unreasonably fail to include any VIVUS Patents requested by Auxilium to be submitted to FDA for listing in the Orange Book.

8.8 Infringement of Third Party IP. Each Party shall promptly notify the other Party in writing of any allegation, claim or suit that the manufacture, use or sale of any Product infringes or misappropriates a Third Party's Patent or other Intellectual Property. Subject to Article 10, each Party shall have the sole right to control any defense of any such claim involving alleged infringement of Third Party rights by such Party's activities, at its own expense and by counsel of its own choice.

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ARTICLE 9 REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Mutual Representations and Warranties. Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows, as of the Effective Date:

(a) **Corporate Existence and Power.** It is a corporation, duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated or formed, and has all requisite power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder.

(b) **Authority and Binding Agreement.** It has the requisite power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and this Agreement has been duly executed and delivered on its behalf, and constitutes a legal, valid, and binding

obligation of such Party that is enforceable against it in accordance with its terms, subject as to enforcement of remedies to applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting generally the enforcement of creditors' rights and subject to a court's discretionary authority with respect to the granting of a decree ordering specific performance or other equitable remedies.

(c) **Consents.** All necessary consents, approvals and authorizations of all governmental authorities and other Third Parties required to be obtained by it in connection with the execution, delivery and performance of this Agreement have been obtained by it.

(d) **No Conflict.** The execution and delivery of this Agreement, the performance of such Party's obligations hereunder and the licenses and sublicenses to be granted pursuant to this Agreement (i) do not and will not conflict with or violate any requirement of Applicable Law existing as of the Effective Date, (ii) do not and will not conflict with or violate the certificate of incorporation, certificate of formation, by-laws, limited partnership agreement or other organizational documents of such Party, and (iii) do not and will not conflict with, violate, breach, constitute a default or give rise to any right of termination under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date.

9.2 VIVUS Representations, Warranties and Covenants. VIVUS hereby represents, warrants, and covenants to Auxilium as of the Effective Date that:

(a) VIVUS is the exclusive licensee of the VIVUS Patents in the Field in the Auxilium Territory;

(b) VIVUS has granted no rights to a Third Party under the VIVUS Technology with respect to the Commercialization of Product in the Field in the Auxilium

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Territory, and as of the Effective Date, no Third Party has any right or license to clinically develop Product in the Field in the Territory at any time during the Term;

(c) to the knowledge of VIVUS as of the Effective Date, the manufacture, Development, and Commercialization of the Product in the Field in the Auxilium Territory does not infringe any issued Third Party patents or any claims of any pending patent applications in the Auxilium Territory that are reasonably likely to issue as filed. VIVUS has no knowledge of any Third Party infringement of the VIVUS Patents. VIVUS has not received any written notice from any Third Party asserting that the VIVUS Patents are invalid, unenforceable, or not infringed. VIVUS has not, and to VIVUS's knowledge MTPC has not, alleged that any Third Party infringes or has infringed the VIVUS Patents or misappropriated or used without authorization the VIVUS Know-How;

(d) there are no liens, encumbrances, charges, security interests, mortgages or other similar restrictions currently existing on or to the VIVUS Technology;

(e) to the knowledge of VIVUS, all of the clinical trials of the Product conducted prior to, or being conducted as of, the Effective Date were conducted, or are being conducted, in accordance with Applicable Laws, and in the case of clinical trials, the then valid cGCP. "cGCP" shall mean the current standards for Clinical Trials for drugs, as set forth in the FDC Act and applicable FDA regulations (including without limitation 21 C.F.R. Parts 50, 54 and 56) and guidances promulgated thereunder, as amended from time to time;

(f) VIVUS has disclosed, shown or made available (e.g., through the electronic data room) to Auxilium all material information and data (including without limitation all communications with or from the FDA or any other Regulatory Authority) relating to the results of all preclinical studies and clinical trials of the Product, including without limitation the Time of Onset Study, conducted by or on behalf of VIVUS including, without limitation, with respect to the status and results of clinical trials and preclinical studies and Regulatory Approval activities;

(g) VIVUS has provided to, or made available for review by, Auxilium all reports and data collections containing information about adverse safety issues (including adverse drug experiences) related to the Product of which VIVUS has knowledge; and

(h) VIVUS has not received any written notice from any Third Party asserting or alleging that the research, Development, making or using of the Product by VIVUS prior to the Effective Date has infringed or otherwise violated, or that the Commercialization of the Product in the Field in the Auxilium Territory will infringe or otherwise violate, the intellectual property rights of such Third Party.

(i) VIVUS has obtained all Regulatory Approvals required by the FDA necessary for the Commercialization of the Product. True and complete copies of such Regulatory Approvals and all correspondence with the FDA and any other Regulatory Authority relating to the Regulatory Approvals for the Product, including without limitation post-approval

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communication or those regarding any label extension studies, have been provided to Auxilium. All of the Regulatory Approvals held by or issued to VIVUS are in full force and effect, and VIVUS is in compliance with each such Regulatory Approval. VIVUS is the sole and exclusive holder of such Regulatory Approvals and the associated filings and applications with the FDA, including any NDAs or INDs and any comparable regulatory applications or filings made or held by or issued to VIVUS and holds all right, title and interest in and to all such Regulatory Approvals free and clear of any liens, encumbrances, charges, security interests, mortgages or other similar restrictions. Other than as set forth in the letter from the FDA granting Regulatory Approval, VIVUS has conducted all necessary preclinical and clinical trials required by the FDA necessary for the Commercialization of the Product and is not aware of or has received any notice from any Regulatory Authority that any additional trials are required to Commercialize the Product.

(j) the MTPC Agreement is valid, binding and in full force and effect and is enforceable by VIVUS in accordance with its terms.

VIVUS has performed all obligations required to be performed by it to date under the MTPC Agreement and is not in breach of or in default under the MTPC Agreement, and no event has occurred which with the passage of time or giving of notice or both would constitute such a breach or default, and to VIVUS's knowledge, there is no existing breach or default by MTPC and to VIVUS's knowledge, no event has occurred which with the passage of time or giving notice of or both would constitute such a breach or default by MTPC. VIVUS has not received any notice of breach under the MTPC Agreement, whether or not cured or disputed. MTPC has not exercised its rights under Section 2.4 of the MTPC Agreement. To the knowledge of VIVUS, VIVUS's rights under the VIVUS Technology with respect to the Development, manufacture or Commercialization of the Product in the Field for the Auxilium Territory are exclusive as to MTPC. VIVUS has provided to Auxilium a complete and accurate copy of the MTPC Agreement as of the Effective Date.

(k) With respect to the Product covered by the Product Marketing Authorization, VIVUS has paid in full the milestones set forth in Section 10(a) of the MTPC Agreement and the only milestones or consideration to be paid to MTPC under the MTPC Agreement are those set forth in Section 10(e) and Article 11 of the MTPC Agreement.

(l) VIVUS will not at any time during the Term take any action that it knows or should know, will result in a breach of the MTPC Agreement and will throughout the Term comply with the terms and provisions of the MTPC Agreement in all material respects. VIVUS will not at any time during the Term terminate the MTPC Agreement without the prior written consent of Auxilium. VIVUS will not agree to any amendment, waiver of rights, or modification of the MTPC Agreement that has, or would reasonably be expected to have, a material negative effect on the rights granted to Auxilium under this Agreement or the obligations imposed on Auxilium under this Agreement without the prior written consent of Auxilium.

(m) As of the Effective Date, VIVUS represents that it has not failed to furnish Auxilium with any information requested by Auxilium, or intentionally concealed from Auxilium any information in VIVUS's possession which would be reasonably likely to be

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material to Auxilium's decision to enter into this Agreement and undertake the commitments and obligations set forth herein.

(n) As of the Effective Date, VIVUS represents and warrants that (i) there is no actual, pending, alleged or, to the knowledge of VIVUS, threatened product liability action with respect to any Product anywhere in the United States or the European Union; (ii) to the knowledge of VIVUS, there is no actual, pending, alleged or threatened product liability action with respect to any Product anywhere else the world; and (iii) VIVUS is not aware of any facts or circumstances that would cause VIVUS to believe that there is a basis for such a product liability claim.

9.3 VIVUS Trademark Representations and Warranties. VIVUS hereby represents and warrants to Auxilium as of the Effective Date that:

(a) to the knowledge of VIVUS, there is no Third Party using or infringing any of the VIVUS Trademarks in the Auxilium Territory in derogation of the rights granted to Auxilium in this Agreement;

(b) VIVUS has not received notice of any opposition or cancellation action or litigation pending or any communication which expressly threatens an opposition or cancellation action, or other litigation, before any trademark office, court or any other governmental entity in the Auxilium Territory with respect to any of the VIVUS Trademarks;

(c) the VIVUS Trademarks are the only trademarks owned, held, Controlled, licensed or otherwise used (or intended to be used) by VIVUS or its Affiliates with respect to the Product in the Field in the Auxilium Territory (other than VIVUS's corporate name and/or logo); and

(d) to the knowledge of VIVUS, it has all rights necessary to use the VIVUS Trademarks with respect to the Product in the Auxilium Territory and to license to Auxilium the VIVUS Trademarks as set forth above; and

(e) to the knowledge of VIVUS, it has not infringed, misappropriated, diluted or otherwise violated any trademark of any Third Parties by registering or using the VIVUS Trademarks in the Auxilium Territory.

9.4 Compliance with Law. Each Party shall, and shall use Commercially Reasonable Efforts to ensure that its Affiliates and sublicensees shall, comply in all material respects with all Applicable Laws in exercising their rights and fulfilling their obligations under this Agreement. If the exercise by Auxilium of any of its rights under the Agreement requires the making of filings under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, then each Party agrees to diligently make any such filings and respond to any request for information to expedite review of such transaction.

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9.5 Representations Regarding Debarment and Compliance.

(a) Each Party represents, warrants and covenants that as of the Effective Date and during the Term, neither it nor any of its Affiliates nor any of their respective directors, officers, employees, or consultants, and, to its knowledge based upon reasonable inquiry, any Third Party (and its directors, officers, employees and consultants), in each case who were responsible for the development or whose responsibilities involve the Development or Commercialization of the Product as authorized by this Agreement:

(i) are debarred under Section 306(a) or 306(b) of the FD&C Act;

(ii) have been charged with, or convicted of, any felony or misdemeanor under Applicable Laws related to any of the following: (A) the development or approval of any drug product or the regulation of any drug product under the FD&C Act; (B) a conspiracy to commit, aid or abet the development or approval of any drug product or regulation of any drug product; (C) health care program-related crimes (involving Medicare or any state health care program); (D) patient abuse, controlled substances, bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records; (E) interference with, obstruction of an investigation into, or prosecution of, any criminal offense; or (F) a conspiracy to commit, aid or abet any of these listed felonies or misdemeanors; and

(iii) is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any United States federal or state health care programs (including convicted of a criminal offense that falls within the scope of 42 U.S.C. §1320a-7 but not yet excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any United States federal procurement or nonprocurement programs.

(b) Each Party will notify the other Party promptly, but in no event later than ***, after knowledge of any exclusion, debarment, suspension or other ineligibility set forth in Section 9.5(a)(iii) occurring during the Term, or if such Party concludes based on its good faith business judgment that a pending action or investigation is likely to lead to the exclusion, debarment, suspension or other ineligibility of such Party.

9.6 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 9, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

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ARTICLE 10 Indemnification

10.1 Indemnification by VIVUS. VIVUS shall defend, indemnify, and hold harmless Auxilium, its Affiliates, and their respective officers, directors, employees, consultants and authorized agents and their respective successors and assigns or heirs, as the case may be (the “**Auxilium Indemnitees**”) from and against any and all Losses incurred by such Auxilium Indemnitee based on or arising out of:

- (a) any misrepresentation or breach of any of VIVUS’s representations, warranties, covenants or obligations under this Agreement;
- (b) the negligence or willful misconduct of, or violation of Applicable Law by, VIVUS, its Affiliates, licensees, distributors or their respective officers, directors, employees, consultants or authorized agents under this Agreement; or
- (c) the Commercialization of any Product by VIVUS, its Affiliates, and sublicensees.

The foregoing indemnity obligations shall not apply to the extent that the Losses of such Auxilium Indemnitee were caused by: (i) a breach of any of Auxilium’s representations, warranties, covenants, or obligations under this Agreement; or (ii) the negligence or willful misconduct of, or violation of Applicable Law by, such Auxilium Indemnitee.

10.2 Indemnification by Auxilium. Auxilium shall defend, indemnify and hold harmless VIVUS, its Affiliates, and their respective officers, directors, employees, consultants and authorized agents and their respective successors and assigns or heirs, as the case may be (the “**VIVUS Indemnitees**”) from and against any and all Losses incurred by such VIVUS Indemnitee based on or arising out of:

- (a) any misrepresentation or breach of any of Auxilium’s representations, warranties, covenants or obligations under this Agreement;
- (b) the negligence or willful misconduct of, or violation of Applicable Law by, Auxilium, its Affiliates, licensees, distributors or their respective officers, directors, employees, consultants or authorized agents under this Agreement; or
- (c) the Commercialization of any Product by Auxilium, its Affiliates, and sublicensees.

The foregoing indemnity obligation shall not apply to the extent that the Losses of such VIVUS Indemnitee were caused by: (i) a breach of any of VIVUS’s representations, warranties, covenants, or obligations under the Agreement; or (ii) the negligence or willful misconduct of, or violation of Applicable Law by, such VIVUS Indemnitee.

10.3 Indemnification Procedures. The Party claiming indemnity under this Article 10 (the “**Indemnified Party**”) shall give written notice to the Party from whom indemnity is being sought (the “**Indemnifying Party**”) promptly and in no event later than *** after learning of a written Claim (“**Indemnified Claim**”). Failure by an Indemnified Party to give notice of an

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Indemnified Claim within *** of receiving a writing reflecting such Claim shall not relieve the Indemnifying Party of its indemnification obligations hereunder except and solely to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give such notice. The Indemnifying Party shall have the right to assume and control the defense of the Indemnified Claim with counsel of its choice so long as the Indemnifying Party is

conducting a good faith and diligent defense. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance in connection with the defense of the Indemnified Claim. The Indemnified Party may monitor such defense with counsel of its own choosing at its sole expense; provided, that if under applicable standards of professional conduct a conflict of interest exists between the Indemnifying Party and the Indemnified Party in respect of such claim, such Indemnified Party shall have the right to employ separate counsel to represent such Indemnified Party with respect to the matters as to which a conflict of interest exists and in that event the reasonable fees and expenses of such separate counsel shall be paid by the Indemnifying Party. The Indemnifying Party may not settle the Indemnified Claim without the prior written consent of the Indemnified Party, such consent shall not be unreasonably withheld, delayed or conditioned. If the Indemnifying Party does not assume and conduct the defense of the Indemnified Claim as provided above: (a) the Indemnified Party may assume and conduct the defense of the Indemnified claim at the Indemnifying Party's expense; (b) the Indemnified Party may consent to the entry of any judgment or enter into any settlement with respect to the Indemnified Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith); and (c) the Indemnifying Party will remain responsible to indemnify the Indemnified Party for Losses as provided in this Article 10.

10.4 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY EXEMPLARY, SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES, COSTS OR EXPENSES (INCLUDING LOST PROFITS, LOST REVENUES AND/OR LOST SAVINGS) ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY IN CONNECTION WITH THIRD PARTY CLAIMS UNDER SECTION 10.1 OR 10.2, (B) DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ARTICLE 11, OR (C) DAMAGES TO THE EXTENT ARISING FROM OR RELATING TO WILLFUL MISCONDUCT OR FRAUDULENT ACTS OR OMISSIONS OF A PARTY.

10.5 Insurance. Auxilium shall procure and maintain insurance during the Term of this Agreement and for a period of *** following the termination or expiration of this Agreement, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Such insurance shall be written by insurance companies with a rating of at least an "A-" in the latest addition of A.M. Best or its equivalent. Without limiting the generality of the foregoing, Auxilium's insurance shall include, at minimum, the following coverages:

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(a) commercial general liability coverage with minimum per claim limits of at least \$*** per occurrence and \$*** annual aggregate, the policy(ies) for which shall (A) name VIVUS as an additional insured, and (B) be primary and non-contributory;

(b) automobile liability coverage covering all owned, hired and non-owned automobile equipment with minimum per claim limits of \$*** per occurrence and annual aggregate, the policy(ies) for which shall name VIVUS as an additional insured;

(c) excess liability/umbrella coverage with minimum per claim limits of at least \$*** per occurrence and annual aggregate;

(d) products liability coverage with minimum per claim limits of at least \$*** per occurrence and annual aggregate with a *** extended reporting period endorsement; and

(e) property coverage having limits adequate for Product inventory in Auxilium's care, custody, and/or control and for Product in transit to and from Auxilium.

It is understood that the insurance requirements above shall not be construed to create a limit of Auxilium's liability with respect to its indemnification obligations under this Article 10. Auxilium shall provide VIVUS with written evidence of such insurance upon written request. Auxilium shall provide VIVUS with written notice at least *** prior to the cancellation, non-renewal or material change in such insurance or self-insurance that materially adversely affects the rights of VIVUS hereunder.

ARTICLE 11

Confidentiality

11.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the receiving Party agrees that, for the Term and for *** thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement any Confidential Information of the disclosing Party except for that portion of such information or materials that the receiving Party can demonstrate by competent proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) is subsequently disclosed to the receiving Party or its Affiliate by a Third Party without obligations of confidentiality with respect thereto; or

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(e) is subsequently independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of Confidential Information.

Notwithstanding the foregoing, the receiving Party may disclose without violation of this Agreement such portion of the Confidential Information as is required or permitted to be disclosed if, on the advice of counsel, it is required under Applicable Law or pursuant to legal process to disclose such Confidential Information of the disclosing Party; *provided* that unless otherwise prohibited by Applicable Law, the receiving Party first advises the disclosing Party of such intended disclosure and provides the disclosing Party with the opportunity to seek appropriate judicial or administrative relief to avoid, or obtain confidential treatment of, such disclosure at the disclosing Party's sole cost and expense.

The confidentiality provisions set forth herein shall supersede and replace the Existing Confidentiality Agreement and shall be deemed to cover all confidential information disclosed or obtained under the Existing Confidentiality Agreement.

11.2 Authorized Disclosure. The receiving Party may disclose Confidential Information belonging to the disclosing Party to the extent the receiving Party determines such disclosure is reasonably necessary in the following situations:

(a) prosecuting or defending litigation relating to this Agreement;

(b) in the case of VIVUS as the receiving Party, subject to prior written notice to Auxilium, disclosure to MTPC as required pursuant to the MTPC Agreement;

(c) in the case of VIVUS as the receiving Party, disclosure to its licensees, sublicensees, and collaborators with respect to the Product outside the Territory or outside the Field, but solely to the extent that such Confidential Information (i) raises any material concerns regarding the safety or efficacy of any Product; (ii) indicates or suggests a potential material liability of either VIVUS or the applicable licensee, sublicensee, or collaborator to Third Parties in connection with any Product; (iii) is reasonably likely to lead to a recall or market withdrawal of any Product; or (iv) relates to any Product and is reasonably likely to have a material impact on a Regulatory Approval, Pricing Approval, or the Commercialization of any Product in such licensee's, sublicensee's, or collaborator's territory; *provided* that each such Person must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Sections 11.1 prior to any such disclosure (it being understood that receiving Party shall be liable for any breach of such confidentiality and non-use obligations by any such Person);

(d) disclosure to the receiving Party's Affiliates' and their respective directors, officers, employees, consultants, attorneys, professional advisors, bankers, lenders, insurers, sublicensees, suppliers and distributors only on a need-to-know basis and solely as necessary in connection with this Agreement; *provided* that each such Person must be bound by obligations of confidentiality and non-use on substantially similar terms as those set forth in Sections 11.1 prior to any such disclosure (it being understood that receiving Party shall be liable for any breach of such confidentiality and non-use obligations by any such Person); and

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(e) disclosure to any bona fide potential or actual investor, acquirer, merger partner, or other potential or actual financial partner (and/or their respective consultants, attorneys, professional advisors) on a need-to-know basis and solely for the purpose of evaluating a potential investment, acquisition, merger, or similar transaction; *provided* that each such Person must be bound by obligations of confidentiality and non-use on substantially similar terms as those set forth in Sections 11.1 prior to any such disclosure (it being understood that the receiving Party shall be liable for any breach of such confidentiality and non-use obligations by any such Person).

11.3 Publicity; Terms of Agreement.

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the authorized disclosure provisions set forth in Section 11.2 and this Section 11.3.

(b) The Parties have agreed to make a joint public announcement of the execution of this Agreement substantially in the form of the press release attached as Exhibit D on or after the Effective Date. After release of such press release announcing this Agreement, if either Party desires to make a public announcement concerning the material terms of this Agreement, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval, such approval not to be unreasonably withheld, conditioned or delayed. A Party commenting on such a proposed press release shall provide its comments, if any, within *** after receiving the press release for review. Neither Party shall be required to seek the permission of the other Party to disclose any information already disclosed or otherwise in the public domain, provided such information remains accurate.

(c) Either Party or any of its Affiliates (the "Filing Party") may publicly disclose without violation of this Agreement, such terms of this Agreement as are, on the advice of such Filing Party's counsel, required by the rules and regulations of the SEC or any other applicable entity having regulatory authority over such Filing Party's securities; *provided* that such Filing Party shall advise the other Party of such intended disclosure and request confidential treatment of certain commercial terms and technical terms hereof to the extent such confidential treatment is reasonably available to such Filing Party. In the event of any such filing, such Filing Party will provide such other Party, a reasonable time prior to filing, with a copy of the Agreement marked to show provisions for which such Filing Party intends to seek confidential treatment and shall reasonably consider and incorporate such other Party's comments thereon to the extent consistent with the legal requirements applicable to such Filing Party and that govern redaction of information from material agreements that must be publicly filed. Such other Party shall provide the Filing Party any such comments as promptly as practicable. The intention of the Parties is to agree upon a single redacted version of the Agreement to be filed with the SEC or any other applicable entity.

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ARTICLE 12
Term and Termination

12.1 Term. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 12, shall remain in effect until the expiration of the last-to-expire payment obligation in Article 7 (the “Term”). Upon the expiration of the Term, the licenses and covenant in Sections 2.1 and 2.9 shall become fully paid-up, royalty-free, perpetual and irrevocable.

12.2 Termination For Cause, Convenience, or Generic Entry.

(a) **Material Breach.** Either Party shall have the right to terminate this Agreement upon written notice to the other Party if such other Party, after receiving written notice from the terminating Party identifying a material breach by such other Party of its obligations under this Agreement, fails to cure (or if not curable within such time period, adopt a plan for cure during such time period) such material breach within *** from the date of such notice (or, in the case of payment obligations, *** from the date of such notice). For the avoidance of doubt (and without limiting VIVUS’s remedies for any other breaches by Auxilium), Auxilium’s uncured failure to pay the amounts set forth in Section 7.1 and 7.2 by the deadlines set forth therein shall each be deemed to be a material breach of this Agreement.

(b) **Government Action.** VIVUS shall have the right to terminate this Agreement immediately upon written notice to Auxilium if Auxilium is excluded from participation in United States federal healthcare programs and fails to cure such exclusion within one hundred twenty (120) days.

(c) **Auxilium Termination for Convenience.** At any time following the one (1) year anniversary of the Product Launch in the United States, Auxilium shall have the right to terminate this Agreement for any reason upon one hundred eighty (180) days prior written notice to VIVUS.

(d) **Auxilium Termination Upon Generic Entry.** Auxilium shall have the right to terminate this Agreement upon a Generic Entry after providing thirty (30) days written notice. Within *** after receipt of an invoice from VIVUS, Auxilium shall reimburse VIVUS for any cancellation fees, penalties, or other payments owed by VIVUS to a Third Party as a direct result of such termination, as well as any other non-cancelable expenses reasonably incurred by VIVUS in connection with its obligations under this Agreement or the Commercial Supply Agreement prior to the effective date of termination.

12.3 Termination for Patent Challenge. VIVUS may terminate this Agreement in its entirety upon written notice to Auxilium if Auxilium or any Affiliate, directly or indirectly, individually or in association with any other person or entity, commences any action or proceeding that challenges the validity or enforceability of any VIVUS Patent in the Auxilium Territory, except if such action or proceeding is commenced in response to a claim asserted by VIVUS against Auxilium or the Auxilium Affiliate for infringement of such VIVUS Patent. In the event Auxilium is aware that a sublicensee of its license rights hereunder, directly or indirectly, individually or in association with any other person or entity, commences any action or proceeding that challenges the validity, enforceability or scope of any VIVUS Patent in the

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Auxilium Territory, Auxilium shall promptly terminate the applicable sublicense. If Auxilium does not terminate such sublicense within *** of Auxilium being made aware of such challenge by VIVUS, VIVUS may terminate this Agreement in its entirety upon written notice to Auxilium.

12.4 Termination Upon Bankruptcy. Either Party shall have the right to terminate this Agreement immediately by providing written notice, if: (a) the other Party applies for or consents to the appointment of a receiver, trustee, liquidator or custodian of itself or of all or a substantial part of its assets, (b) the other Party makes a general assignment for the benefit of its creditors, (c) the other Party is dissolved or liquidated in full or in substantial part, (d) the other Party commences a voluntary case under Chapter 7 (or “**Chapter 7 Case**”) of the United States Bankruptcy Code or consents to any such relief or to the appointment of or taking possession of its property by any official in such an involuntary case or such other proceeding commenced against it, (e) the other Party takes any corporate action for the purpose of effecting any of the foregoing, (f) a case under Chapter 11 of the Bankruptcy Code in respect of such Party is converted to a Chapter 7 Case, or (g) the other Party becomes the subject of an involuntary Chapter 7 Case or other proceeding seeking liquidation with respect to itself or its debts under any bankruptcy, insolvency or other similar law now or hereafter in effect that is not dismissed within *** after commencement.

12.5 Effect of Termination of the Agreement. Except as provided in this Section 12.5 upon any termination of this Agreement other than the expiration of the Term, the following shall apply (in addition to any other rights and obligations under Section 12.6 or otherwise under this Agreement with respect to such termination):

(a) **Auxilium License.** The Auxilium License shall terminate (and, as between the Parties, all rights in the VIVUS Technology shall revert to VIVUS); *provided* that in the event that Auxilium terminates this Agreement pursuant to Section 12.2(a) or 12.4, the Auxilium License shall remain in full force and effect (but on a non-exclusive basis), solely to the extent necessary to permit Auxilium, its Affiliates, or its sublicensees to sell any inventories of Products in the Auxilium Territory pursuant to Section 12.5(f). For the avoidance of doubt, Section 2.9 shall not apply to any activities after the effective date of termination, except for those activities permitted by Section 12.5(f).

(b) **VIVUS License.** The VIVUS License (other than Section 2.3(a)) shall survive any termination of this Agreement. In addition, in the event of any termination of this Agreement other than by Auxilium pursuant to Section 12.2(a) or 12.4, Auxilium shall automatically grant to VIVUS a non-exclusive, royalty-free, sublicensable (through multiple tiers) license under the Auxilium Technology, to use, make, have made, distribute, import, Develop, Promote, market, sell, offer for sale, and otherwise Commercialize Products in the Field in the Auxilium Territory.

(c) **Marks.** All rights in the VIVUS Trademarks shall return to VIVUS, and Auxilium shall assign to VIVUS any Auxilium Trademarks incorporating the mark STENDRA that are Controlled by Auxilium and then being used to Commercialize Product in the Auxilium

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Territory, but expressly excluding (i) Auxilium's corporate name, (ii) any other mark that incorporates or is derived from Auxilium's corporate names, and (iii) any other proprietary mark of Auxilium that is used by Auxilium independently of the Product.

(d) **Regulatory Materials.** To the extent permitted by Applicable Law, Auxilium shall transfer and assign to VIVUS all Regulatory Materials, Regulatory Approvals, and Pricing Approvals with respect to Product that are Controlled by Auxilium or its Affiliates, if any; *provided* that in the event that Auxilium terminates this Agreement pursuant to Section 12.2(a) or 12.4, Auxilium shall be permitted (on a non-exclusive basis) to sell under such Regulatory Materials, Regulatory Approvals, and Pricing Approvals any inventories of Products in the Auxilium Territory to the extent permitted pursuant to Section 12.5(f). The Parties agree that any failure by Auxilium to perform its obligation to transfer and assign the Product Marketing Authorization to VIVUS following termination in accordance with this section may cause irreparable harm to VIVUS, for which damages may not be an adequate remedy. Therefore, in addition to its rights and remedies otherwise available at law, including, without limitation, the recovery of damages for breach of this Agreement, VIVUS shall be entitled to seek specific performance of such obligation, along with such other and further equitable relief as a court may deem proper under the circumstances.

(e) **Transition Assistance.** In the event of any termination of this Agreement other than termination by Auxilium pursuant to Section 12.2(a) or 12.4, Auxilium shall provide reasonable assistance, at no cost to VIVUS, as may be reasonably necessary for VIVUS to commence or continue Developing, manufacturing and Commercializing the Products in the Auxilium Territory, including without limitation, upon request of VIVUS, using commercially reasonable efforts to transfer any agreements or arrangements with distributors that apply solely to the sale or supply of Product in the Auxilium Territory.

(f) **Sell-Through of Inventory.** For a period of *** following the effective date of termination, Auxilium, its Affiliates, and its sublicensees may sell or otherwise dispose of the inventory of Product then on hand or in production or for which substantial preparation for manufacture has been made or which they are legally obligated to supply.

(g) **Sublicense Agreements.** The Parties agree that upon termination of this Agreement for any reason, all sublicenses granted by Auxilium to Affiliates or Third Parties under the VIVUS Technology shall immediately terminate.

(h) **Certain Pre-Termination Liabilities.** Following termination of this Agreement, Auxilium shall retain liability for payment of all gross to net sales deductions (including returns, rebates and chargeback) of Products that were sold prior to the effective date of termination. To the extent that any such deductions are charged to or otherwise borne by VIVUS, Auxilium shall reimburse VIVUS promptly (but in any event no later than ***) following Auxilium's receipt of an invoice therefor. For the avoidance of doubt, the foregoing is not intended to prevent Auxilium from properly deducting the Net Sales Deductions when calculating Net Sales.

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(i) **Sales Volume.** Auxilium shall use Commercially Reasonable Efforts to ensure that the average monthly sales volume of each Product leading up to the effective date of termination does not substantially exceed the average monthly sales volume of such Product for the *** period prior to date of the notice of termination, and in any event Auxilium shall not take any affirmative action to cause such outcome.

12.6 Accrued Liabilities; Other Remedies. Termination or expiration of this Agreement for any reason shall not release either Party from any liability or obligation that already has accrued prior to such expiration or termination (including any milestone or other payment that has been triggered by an event occurring prior to the effective date of termination or expiration), nor affect the survival of any provision hereof to the extent it is expressly stated to survive such termination. Termination or expiration of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.

12.7 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by VIVUS and Auxilium are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the United States Bankruptcy Code. The Parties agree that each Party, as licensee of certain rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the United States Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party (such Party, the "**Bankrupt Party**") under the United States Bankruptcy Code, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed to such other Party and all embodiments of such intellectual property, which, if not already in such other Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon such other Party's written request therefor, unless the Bankrupt Party elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a), following the rejection of this Agreement by the Bankrupt Party upon written request therefor by the other Party.

12.8 Survival. The following provisions shall survive any expiration or termination of this Agreement: Articles 10, 11, 13 and 14 and Sections 7.8, 8.1, 12.5, 12.6, 12.7, and 12.8.

ARTICLE 13 Dispute Resolution

13.1 Disputes. The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this

Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 13 if and when a dispute arises under this Agreement.

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(a) **Referred from Committee.** Any disputes, controversies or differences which may arise from the JSC pursuant to Article 3 shall be resolved in accordance with Section 3.5.

(b) **Good Faith Resolution.** Any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement, including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, then upon the request of either Party, the Parties agree to meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting between the chief executive officers of each Party. If the matter is not resolved within *** following the request for discussions, either Party may then invoke the provisions of Section 13.2.

13.2 Arbitration. Any dispute, controversy or claim arising out of or relating to the validity, construction, interpretation, enforceability, breach, performance, application or termination of this Agreement that is not resolved pursuant to Section 13.1, except for a dispute, claim or controversy under Section 13.10, shall be settled by binding arbitration administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures of JAMS then in effect (the “**JAMS Rules**”), except as otherwise provided herein. The arbitration shall be governed by the United States Federal Arbitration Act, 9 U.S.C. §§ 1-16 (the “**Federal Arbitration Act**”), to the exclusion of any inconsistent state laws. The United States Federal Rules of Civil Procedure shall govern discovery and the rules of evidence for the arbitration. The arbitration will be conducted in New York, New York and the Parties consent to the personal jurisdiction of the United States federal courts, for any case arising out of or otherwise related to this arbitration, its conduct and its enforcement. Any situation not expressly covered by this Agreement shall be decided in accordance with the JAMS Rules.

13.3 Arbitrator. The arbitrator shall be one (1) neutral, independent and impartial arbitrator selected from a pool of retired federal judges or magistrates to be presented to the Parties by JAMS. Failing the agreement of the Parties as to the selection of the arbitrator within ***, the arbitrator shall be appointed by JAMS in accordance with the JAMS Rules.

13.4 Decision. The power of the arbitrator to fashion procedures and remedies within the scope of this Agreement is recognized by the Parties as essential to the success of the arbitration process. The arbitrator shall not have the authority to fashion remedies which would not be available to a federal judge hearing the same dispute. The arbitrator is encouraged to operate on this premise in an effort to reach a fair and just decision. Reasons for the arbitrator’s decisions should be set forth in accordance with the JAMS Rules. Such a written decision shall be rendered by the arbitrator following a full comprehensive hearing, no later than *** following the selection of the arbitrator as provided for in Section 13.3.

13.5 Award. Any award shall be promptly paid in United States dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by Applicable Law, be charged against the Party resisting enforcement. Each Party agrees to abide by the award rendered in any arbitration conducted

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pursuant to this Article 13, and agrees that, subject to the Federal Arbitration Act, judgment may be entered upon the final award in any court of competent jurisdiction and that other courts may award full faith and credit to such judgment in order to enforce such award. The award shall include interest from the date of the award until paid in full, at a rate fixed by the arbitrator and the arbitrator may, in his or her discretion, award pre-judgment interest. With respect to money damages, nothing contained herein shall be construed to permit the arbitrator or any court or any other forum to award punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for punitive or exemplary damages.

13.6 Costs. Each Party shall bear its own legal fees. The arbitrator shall assess his or her costs, fees and expenses against the Party losing the arbitration and shall require such losing Party to reimburse the other Party for all of its reasonable attorneys’ fees, costs, and disbursements arising out of the arbitration (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, and so on). Notwithstanding the foregoing, if the arbitrator believes that neither Party is the clear loser, the arbitrator shall divide his or her costs, fees, and expenses according to his or her sole discretion, and each Party shall bear its own attorney’s fees, costs, and disbursements arising out of the arbitration.

13.7 Injunctive Relief. Provided a Party has made a sufficient showing under the rules and standards set forth in the Federal Rules of Civil Procedure and applicable case law, the arbitrator shall have the freedom to invoke, and the Parties agree to abide by, injunctive measures after either Party submits in writing for arbitration claims requiring immediate relief. Additionally, nothing in this Article 13 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

13.8 Confidentiality. The arbitration proceeding shall be confidential and the arbitrator shall issue appropriate protective orders to safeguard each Party’s Confidential Information. Except as required to comply with Applicable Laws, including rules and regulations promulgated by the SEC, The NASDAQ Stock Market or any securities exchanges, no Party shall make (or instruct the arbitrator to make) any public announcement with respect to the proceedings or decision of the arbitrator without prior written consent of the other Party. The existence of any dispute submitted to arbitration, and the award, shall be kept in confidence by the Parties and the arbitrator, except as required in connection with the enforcement of such award or as otherwise required by Applicable Law.

13.9 Survivability. Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.

13.10 Patent and Trademark Disputes. Notwithstanding anything to the contrary in this Article 13, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of the VIVUS Patents, VIVUS Trademarks, Auxilium Patents, Auxilium

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Trademarks or Joint Patents shall be submitted to a court of competent jurisdiction in the country in which such patent or trademark rights were granted or arose.

ARTICLE 14 Miscellaneous

14.1 Entire Agreement; Amendment. This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof, including, the Existing Confidentiality Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations pursuant the Existing Confidentiality Agreement. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

14.2 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall mean conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party.

14.3 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 14.3, and shall be deemed to have been given for all purposes when received, if hand-delivered or by means of facsimile, or one Business Day after being sent by a reputable overnight delivery service.

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If to VIVUS:	VIVUS, Inc. 351 E. Evelyn Ave. Mountain View, CA 94041 Attention: General Counsel Fax: (650) 934-5320
With a copy to:	Hogan Lovells US LLP 525 University Avenue 3rd Floor Palo Alto, CA 94301 Attention: Shane Albright, Partner Fax: (650) 463-4199
If to Auxilium:	Auxilium Pharmaceuticals, Inc. 640 Lee Road Chesterbrook, Pennsylvania 19087 Attention: Adrian Adams, Chief Executive Officer Attention: Andrew I. Koven, Chief Administrative Officer & General Counsel Fax: 1-484-321-5996
With a copy to:	Holland & Knight LLP 701 Brickell Avenue, Suite 3000 Miami, FL 33131 Attention: Rodney H. Bell Fax: (305) 789-7799

14.4 No Strict Construction; Headings; Interpretation. This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. The definitions of the terms herein apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The words “include”, “includes” and “including” will be deemed to be followed by the phrase “without limitation.” Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any laws herein will be construed as referring to such laws and any rules or regulations promulgated thereunder as from time to time enacted, repealed or amended, (c) any reference herein to any Person will be construed to include such Person’s successors and assigns, (d) the words “herein”,

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“hereof” and “hereunder”, and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) any reference herein to the words “mutually agree” or “mutual written agreement” will not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as such Party may determine in such Party’s sole discretion, except as expressly provided in this Agreement, (f) as applied to a Party, the word “will” shall be construed to have the same meaning and effect as the word “shall,” and (g) all references herein without a reference to any other agreement to Articles, Sections, or Exhibits will be construed to refer to Articles, Sections, and Exhibits of or to this Agreement.

14.5 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment without the other Party’s consent to such Party’s Affiliate or to a successor to all or substantially all of the assets or business of such Party to which this Agreement pertains. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Any assignment or attempted assignment by either Party in violation of the terms of this Section 14.5 shall be null, void and of no legal effect. The VIVUS Technology shall exclude any intellectual property held or developed by a permitted successor of VIVUS prior to the transaction in which it became a successor of such Party, and the Auxilium Technology shall exclude any intellectual property held or developed by a permitted successor of Auxilium prior to the transaction in which it became a successor of such Party.

14.6 Records Retention. Each of VIVUS and Auxilium will maintain complete and accurate records pertaining to its activities under this Agreement, including records pertaining to Development or Commercialization of any Products and reports and information provided to any Regulatory Authority or other Governmental Authority, in accordance with Applicable Law. Each of VIVUS and Auxilium will retain such records for a duration prescribed by Applicable Law, but not in any event for less than *** after the Effective Date (or longer if a Party is notified, ordered or otherwise required to maintain such records for a longer period in connection with a legal proceeding or government investigation).

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

14.8 Successors and Assigns; No Third Party Beneficiaries. This Agreement will be binding upon and inure to the benefit of the Parties and their successors and permitted assigns. No provision of this Agreement, express or implied, is intended to or will be deemed to confer upon Third Parties any right, benefit, remedy, claim, liability, reimbursement, claim of action or other right of any nature whatsoever under or by reason of this Agreement other than the Parties and, to the extent provided in Sections 10.1 and 10.2, the Indemnified Parties. Without

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limitation, this Agreement will not be construed so as to grant employees of either Party in any country any rights against the other Party pursuant to the laws of such country.

14.9 Performance by Affiliates. Any obligation of VIVUS under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at VIVUS’s sole and exclusive option, either by VIVUS directly or by any Affiliate of VIVUS that VIVUS causes to satisfy, meet or fulfill such obligation, in whole or in part. Any obligation of Auxilium under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at Auxilium’s sole and exclusive option, either by Auxilium directly or by any Affiliate of Auxilium that Auxilium causes to satisfy, meet or fulfill such obligation, in whole or in part. Each of the Parties guarantees the performance of all actions, agreements and obligations to be performed by any Affiliates of such Party under the terms and conditions of this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party’s Affiliate of any of such Party’s obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party’s Affiliate.

14.10 Further Assurances and Actions. Each Party, upon the request of the other Party, without further consideration, will do, execute, acknowledge, and deliver or cause to be done, executed, acknowledged or delivered all such further acts, deeds, documents, assignments, transfers, conveyances, powers of attorney, instruments and assurances as may be reasonably necessary to effect complete consummation of the transactions contemplated by this Agreement, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this

Agreement. The Parties agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to consummate or implement expeditiously the transactions contemplated by this Agreement.

14.11 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

14.12 No Waiver. Any provision of this Agreement may waived if, but only if, such waiver is in writing and is signed by the Party against whom the waiver is to be effective. No failure or delay by any Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by Applicable Law.

14.13 Independent Contractors. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or

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authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

14.14 Counterparts. This Agreement may be executed in one (1) or more counterparts, including by facsimile or other electronic transmission, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

Signature Page to Follow

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IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their duly authorized officers as of the Effective Date.

VIVUS, INC.

AUXILIUM PHARMACEUTICALS, INC.

By: /s/ John L. Slebir
Name: John L. Slebir
Title: Vice President, General Counsel

By: /s/ Adrian Adams
Name: Adrian Adams
Title: CEO & President

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EXHIBITS

- Exhibit A Commercialization and Medical Affairs Plans
- Exhibit B Commercial Supply Agreement
- Exhibit C Additional Financial Terms
- Exhibit D Press Release
- Exhibit E Letter Agreement

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**EXHIBIT B
COMMERCIAL SUPPLY AGREEMENT**

[A COPY OF THE COMMERCIAL SUPPLY AGREEMENT HAS BEEN SEPARATELY FILED WITH THE SECURITIES AND EXCHANGE COMMISSION]

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**EXHIBIT C
ADDITIONAL FINANCIAL TERMS**

Additional Royalty Payments for Product (solely during MTPC Royalty Period):

Annual Total MTPC Agreement Net Sales	Royalty Percentage
Portion up to US\$***	***% of such MTPC Agreement Net Sales
Portion in excess of US\$***	***% of such MTPC Agreement Net Sales

Additional Milestone Payments:

- A pro-rata share of US \$6,000,000 sales milestone, due when for the first time the total MTPC Agreement Net Sales during any calendar year of Product sold by VIVUS, its Affiliates, and sublicensees exceed US \$*** (the “**MTPC Milestone**”). The pro-rata share owed by Auxilium will be calculated based on the relative Net Sales (as defined in the MTPC Agreement) of the Product sold by Auxilium or its Affiliates or sublicensees in the Auxilium Territory during the calendar year for which such milestone payment is owed compared to the Net Sales (as defined in the MTPC Agreement) of Product sold in the VIVUS Territory during such calendar year.

Trademark Royalty Payments:

In consideration for the trademark license granted in Section 2.1(b) and the use of the trademarks associated with the Product and the VIVUS Technology, Auxilium shall (a) during *** following the expiration of the MTPC Royalty Period in a particular country in the Auxilium Territory, pay to VIVUS a royalty equal to *** percent (***) of the MTPC Agreement Net Sales of Products in such country; and (b) following *** following the end of the Royalty Term in such country, pay to VIVUS a royalty equal to *** percent (***) of the MTPC Agreement Net Sales of Products in such country. Thereafter, *** royalties shall be owed with respect to MTPC Agreement Net Sales of Product in such country. For the avoidance of doubt, the foregoing royalty shall be owed on MTPC Agreement Net Sales of all Products, regardless of whether such Products are sold under the VIVUS Trademarks.

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**EXHIBIT D
PRESS RELEASE**



**AUXILIUM PHARMACEUTICALS, INC. ANNOUNCES LICENSE AGREEMENT FOR
THE MARKETING RIGHTS TO STENDRA™ IN THE UNITED STATES AND CANADA**

*- STENDRA Broadens Auxilium's Presence in Men's Health Care
With a Projected 2013 Launch into the Multi-Billion Dollar Erectile Dysfunction Market -*

CHESTERBROOK, PA (October 11, 2013) - Auxilium Pharmaceuticals, Inc. (NASDAQ: AUXL), a specialty biopharmaceutical company, announced today the signing of an agreement with VIVUS, Inc. (NASDAQ: VVUS) providing Auxilium with the exclusive right to market VIVUS's product, STENDRA (avanafil), in the United States and Canada. The parties also simultaneously signed a Commercial Supply Agreement pursuant to which VIVUS will be initially responsible for the manufacture and supply of STENDRA to Auxilium.

STENDRA is an oral therapy approved by the U.S. Food and Drug Administration (FDA) for the treatment of erectile dysfunction (ED).

Under the license, Auxilium will pay VIVUS a one-time license fee of \$30 million. Auxilium may make a \$15 million regulatory milestone payment to VIVUS if the FDA approves the STENDRA label to reflect a 15 minute or less onset of action efficacy claim and up to \$255 million in potential milestone payments based on the achievement of certain sales targets. VIVUS will also receive royalties on product sales.

It is estimated that more than 50 percent of men over 40 years of age experience some degree of ED(1). Prevalence of the condition increases with age and can be caused by a variety of factors, including medications (anti-hypertensives, histamine receptor antagonists); lifestyle (tobacco, alcohol use); diseases (diabetes, cardiovascular conditions, prostate cancer); prostatectomy, and spinal cord injuries. The market opportunity for ED medical treatments continues to grow, with U.S. sales exceeding \$2.9 billion in 2012(2). About one half of men being treated with currently available PDE5 inhibitors are dissatisfied with the results of that treatment and tend to switch among the products in pursuit of better efficacy or less side effects(3).

Auxilium expects to begin its commercial launch of STENDRA by the end of 2013, first with shipments of STENDRA in December 2013, followed by promotional activities in early January 2014 by its PRIMERA sales force, which consists of 150 representatives currently devoted to strategic targeting of urologists, endocrinologists, and certain high prescribing primary care physicians. The Company also plans to leverage digital media to reach a broader audience online. Auxilium believes that the transaction will be accretive in 2015.

“We believe STENDRA complements our current portfolio of testosterone replacement therapy and ED products, further broadening our men’s health care franchise in a very large market segment consisting of patients that tend to switch among products,” said Adrian Adams, Chief Executive Officer and President of Auxilium. “We believe the unique features of STENDRA, including its dosing interval (30 minutes prior to sexual activity), ability to take with or without food, modest alcohol consumption requirements and a favorable side effect profile make it an exciting entrant into the category.”

“Auxilium is the ideal partner for STENDRA, with an established sales force and excellent relationships with

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physicians responsible for men’s health care,” stated Timothy E Morris, Senior Vice President, Finance and Global Commercial Development, Chief Financial Officer for VIVUS, Inc. “We look forward to working with Auxilium as they prepare for launch later this year.”

VIVUS will retain commercial rights to STENDRA outside the U.S. and Canada and will continue to be responsible for the product’s development and regulatory approval in the U.S. to support a potential label amendment for a 15 minute or less onset of action efficacy claim, if approved by the FDA.

About STENDRA

STENDRA (avanafil) is approved by the FDA for the treatment of erectile dysfunction in the U.S. Auxilium intends to market and sell STENDRA in the U.S. VIVUS, through a collaboration arrangement with Menarini and its wholly-owned subsidiary BERLIN-CHEMIE AG/MENARINI, intends to market and sell avanafil under the trade name SPEDRA™ in the European Union plus Australia and New Zealand. VIVUS licensed avanafil from Mitsubishi Tanabe Pharma Corporation (MTPC).

STENDRA will be available through retail and mail order pharmacies. The Company plans to offer programs that will help with patients’ out-of-pocket costs.

STENDRA is rapidly absorbed and can be taken 30 minutes before sexual activity on an as-needed basis. STENDRA should not be taken more than once per day and can be taken without regard to food and has modest alcohol consumption requirements. For more information about STENDRA, please visit www.stendra.com.

About Auxilium

Auxilium Pharmaceuticals, Inc. is a specialty biopharmaceutical company with a focus on developing and marketing products to predominantly specialist audiences. Auxilium markets Testim® (testosterone gel) for the topical treatment of hypogonadism in the U.S. and XIAFLEX® (collagenase clostridium histolyticum (CCH)) for the treatment of adult Dupuytren’s contracture patients with a palpable cord in the U.S. Ferring International Center S.A. markets Testim in certain countries of the EU and Paladin Labs Inc. markets Testim in Canada. Swedish Orphan Biovitrium AB has marketing rights for XIAPEX® (the EU tradename for collagenase clostridium histolyticum) in 71 Eurasian and African countries. Asahi Kasei Pharma Corporation has development and commercial rights for XIAFLEX in Japan and Actelion Pharmaceuticals Ltd has development and commercial rights for XIAFLEX in Canada, Australia, Brazil and Mexico. Auxilium also markets TESTOPEL®, a long-acting implantable testosterone replacement therapy, Edex®, the leading branded non-oral drug for erectile dysfunction, Striant®, a buccal system for testosterone delivery, Osbon ErecAid®, the leading device for aiding erectile dysfunction, and also has a non-promoted respiratory franchise, including Theo-24® and Semprex®-D, along with three other non-promoted products, in the U.S. Auxilium has three projects in clinical development. XIAFLEX is currently under regulatory review by the U.S. FDA for the treatment of Peyronie’s disease. CCH is in phase II of development for the treatment of Frozen Shoulder syndrome (adhesive capsulitis) and phase II of development for the treatment of cellulite (edematous fibrosclerotic panniculopathy). Auxilium also has rights to pursue additional indications for XIAFLEX. For additional information, visit <http://www.auxilium.com>.

SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

This news release contains forward-looking statements as defined by the Private Securities Litigation Reform Act of 1995, which discuss matters that are not facts, and may include words to indicate their uncertain nature such as “believe,” “expect,” “anticipate,” “intend,” “plan,” “could,” “estimate,” “project,” “will,” and “target.” Our forward-looking statements convey management’s expectations, beliefs, plans and objectives regarding future performance of the Company and are based upon preliminary information and management assumptions. No specific assurances can be given regarding the timing, nature or success of the Company’s launch of STENDRA in the U.S. or Canada, and related promotional activities and product shipments; whether and when the Company will use digital media to

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reach a broader audience online; whether or when the Company's license to promote STENDRA will be accretive; the achievement of certain sales milestones for STENDRA and any potential Auxilium milestone payment obligations; STENDRA's promotion by the PRIMERA sales force; whether STENDRA complements the Company's current portfolio of testosterone replacement therapy and ED products; whether STENDRA will help the Company expand its men's health franchise and whether STENDRA will receive label expansion for a rapid onset of action in 15 minutes or less; whether the Company will offer programs to assist with patients' out-of-pocket costs for STENDRA, or the Company's ability to successfully develop its product candidates. While the Company may elect to update the forward-looking statements made in this news release in the future, the Company specifically disclaims any obligation to do so. Such forward-looking statements are subject to a wide range of risks and uncertainties that could cause results to differ in material respects, including those relating to product development, revenue, expense and earnings expectations, intellectual property rights, results and timing of clinical trials, success of marketing efforts, the need for additional research and testing, and the timing and content of decisions made by regulatory authorities, including the U.S. Food and Drug Administration, and those risks discussed in our reports on file with the Securities and Exchange Commission (the "SEC"). Our SEC filings may be accessed electronically by means of the SEC's home page on the Internet at <http://www.sec.gov> or by means of the Company's home page on the Internet at <http://www.auxilium.com> under the heading "For Investors - SEC Filings." There may be additional risks that the Company does not presently know or that the Company currently believes are immaterial which could also cause actual results to differ from those contained in the forward-looking statements.

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(1) Andre B. Prevalence and Incidence of Androgen Deficiency in Middle-Aged and Older Men: Estimates from The Massachusetts Male Ageing Study. *The Journal of Clinical Endocrinology & Metabolism*. 2004; 89(12):5920-5926.

(2) US TRx revenues per Symphony Health

(3) Impact CR Consumer Segmentation, Feb. 2013; Qualitative Market Interviews (n= 722); HCP Research, Primary Interviews, Life Science Strategy Group LLC n= 64, June 2010.

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October 11, 2013

VIVUS, Inc. Announces License Agreement for the Marketing Rights to STENDRA in the United States and Canada

MOUNTAIN VIEW, Calif., Oct. 11, 2013 (GLOBE NEWSWIRE) — VIVUS, Inc. (Nasdaq:VVUS) today announced the signing of an agreement providing Auxilium Pharmaceuticals, Inc. (Nasdaq:AUXL) the exclusive rights to market STENDRA™ (avanafil) in the United States and Canada. The parties also simultaneously signed a Commercial Supply Agreement pursuant to which VIVUS will be responsible for the manufacture and supply of STENDRA to Auxilium for a mutually agreed term. STENDRA is an oral therapy approved by the U.S. Food and Drug Administration (FDA) for the treatment of erectile dysfunction (ED). Under the license agreement, VIVUS is eligible to receive up to \$300 million based on certain regulatory and sales milestones, including an upfront licensing fee of \$30 million and a \$15 million payment contingent upon a potential label amendment regarding onset-of-action, in addition to royalties on product sales.

"Auxilium is the ideal partner for STENDRA, with an established sales force and excellent relationships with physicians responsible for men's health," stated Seth H.Z. Fischer, CEO of VIVUS. "We look forward to working with Auxilium as they prepare for launch later this year."

It is estimated that more than 50 percent of men over 40 years of age experience some degree of ED(i). Prevalence of the condition increases with age and can be caused by a variety of factors, including medications (anti-hypertensives, histamine receptor antagonists); lifestyle (tobacco, alcohol use); diseases (diabetes, cardiovascular conditions, prostate cancer); prostatectomy, and spinal cord injuries. The market opportunity for ED medical treatments continues to grow, with U.S. sales exceeding \$2.9 billion in 2012(ii). About one half of men being treated with currently available PDE5 inhibitors are dissatisfied with the results of that treatment and tend to switch among the products in pursuit of better efficacy or less side effects(iii).

"We believe STENDRA complements our current portfolio of testosterone replacement therapy and ED products, further broadening our men's health care franchise in a very large market segment consisting of patients that tend to switch among products," said Adrian Adams, chief executive officer and president of Auxilium. "The rapid onset of action of STENDRA and its favorable side effect profile make it an exciting new entrant into the category."

Auxilium expects to begin its commercial launch of STENDRA by the end of 2013, first with shipments of STENDRA in December 2013, followed by promotional activities in early January 2014 with its PRIMERA sales force, which consists of 150 representatives currently devoted to strategic targeting of urologists, endocrinologists, and certain high prescribing primary care physicians. Auxilium will also leverage digital media to reach a broader audience online.

“The Agreement with Auxilium in the U.S. and Canada, along with the previously-announced license agreement with Menarini for Europe and abroad, fulfills significantly our objective of monetizing avanafil,” stated Timothy E. Morris, senior vice president, finance and global commercial development, chief financial officer for VIVUS. “Both deals combined have the potential to generate over \$95 million in cash to VIVUS within the first year, in addition to royalties earned on sales of avanafil.”

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VIVUS will continue to be responsible for the product’s post-approval requirements in the U.S., including a potential label amendment based on the results of the TA-501 study designed to assess the efficacy of STENDRA in approximately 15 minutes. In the study, STENDRA patients achieved statistically significant improvement over placebo, in the mean proportion of attempts that resulted in erections sufficient for successful intercourse, as early as 10 minutes for the 200 mg dose and 12 minutes for the 100 mg dose after being taken.

Aquilo Partners, L.P. acted as the exclusive advisor to VIVUS on the transaction.

About Avanafil

STENDRA (avanafil) is approved in the U.S. by the FDA for the treatment of erectile dysfunction. Auxilium Pharmaceuticals, Inc. has exclusive marketing rights to STENDRA in the U.S. and Canada.

STENDRA will be available through retail and mail order pharmacies. Auxilium plans to offer programs that will help patients with out-of-pocket costs.

SPEDRA, the trade name for avanafil in the EU, is approved by the EMA for the treatment of erectile dysfunction in the EU. VIVUS has granted an exclusive license to the Menarini Group through its subsidiary Berlin-Chemie AG to commercialize and promote SPEDRA for the treatment of erectile dysfunction in over 40 European countries plus Australia and New Zealand.

Avanafil is licensed from Mitsubishi Tanabe Pharma Corporation (MTPC). VIVUS owns worldwide development and commercial rights to avanafil for the treatment of sexual dysfunction, with the exception of certain Asian-Pacific Rim countries. VIVUS is in discussions with other parties for the commercialization rights to its remaining territories.

For more information about STENDRA, please visit www.Stendra.com.

Important Safety Information

STENDRA™ (avanafil) is prescribed to treat erectile dysfunction (ED).

Do not take STENDRA if you take nitrates, often prescribed for chest pain, as this may cause a sudden, unsafe drop in blood pressure.

Discuss your general health status with your healthcare provider to ensure that you are healthy enough to engage in sexual activity. If you experience chest pain, nausea, or any other discomforts during sex, seek immediate medical help.

STENDRA may affect the way other medicines work. Tell your healthcare provider if you take any of the following; medicines called HIV protease inhibitors, such as ritonavir (Norvir®), indinavir (Crixivan®), saquinavir (Fortavase® or Invirase®) or atazanavir (Reyataz®); some types of oral antifungal medicines, such as ketoconazole (Nizoral®), and itraconazole (Sporanox®); or some types of antibiotics, such as clarithromycin (Biaxin®), telithromycin (Ketek®), or erythromycin.

In the rare event of an erection lasting more than 4 hours, seek immediate medical help to avoid long-term injury.

In rare instances, men taking PDE5 inhibitors (oral erectile dysfunction medicines, including STENDRA) reported a sudden decrease or loss of vision. It is not possible to determine whether these events are

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related directly to these medicines or to other factors. If you experience sudden decrease or loss of vision, stop taking PDE5 inhibitors, including STENDRA, and call a doctor right away.

Sudden decrease or loss of hearing has been rarely reported in people taking PDE5 inhibitors, including STENDRA. It is not possible to determine whether these events are related directly to the PDE5 inhibitors or to other factors. If you experience sudden decrease or loss of hearing, stop taking STENDRA and contact a doctor right away. If you have prostate problems or high blood pressure for which you take medicines called alpha blockers or other anti-hypertensives, your doctor may start you on a lower dose of STENDRA.

Drinking too much alcohol when taking STENDRA may lead to headache, dizziness, and lower blood pressure.

STENDRA in combination with other treatments for ED is not recommended.

STENDRA does not protect against sexually transmitted diseases, including HIV.

The most common side effects of STENDRA are headache, flushing, runny nose and congestion.

Please see full patient prescribing information for STENDRA (50 mg, 100 mg, 200 mg) tablets.

About VIVUS

VIVUS is a biopharmaceutical company commercializing and developing innovative, next-generation therapies to address unmet needs in obesity, sleep apnea, diabetes and sexual health. For more information about VIVUS, please visit www.vivus.com.

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 and are subject to risks, uncertainties and other factors, including risks and uncertainties related to regulatory approval of certain avanafil claims within the Auxilium exclusive territories and the timing, strategy, tactics and success of avanafil commercialization by Auxilium in the U.S. or Canada. These risks and uncertainties could cause actual results to differ materially from those referred to in these forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. Investors should read the risk factors set forth in VIVUS's Form 10-K for the year ending December 31, 2012, as amended by the Form 10-K/A filed on April 30, 2013, and as amended by the Form 10-K/A filed on June 12, 2013, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

(i) The Massachusetts Male Aging Study

(ii) US TRx revenues per Symphony Health

(iii) 1- Impact CR Consumer Segmentation, Feb 2013; Qualitative Market Interviews (n= 722)

2- HCP Research, Primary Interviews; LSSG, LLC n= 64

CONTACT: VIVUS, Inc.

Timothy E. Morris

Chief Financial Officer

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News Provided by Acquire Media

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EXHIBIT E LETTER AGREEMENT

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CONFIDENTIAL
EXECUTION COPY

COMMERCIAL SUPPLY AGREEMENT

THIS COMMERCIAL SUPPLY AGREEMENT (this “**Agreement**”) is entered into and effective as of October 10, 2013 (the “**Effective Date**”) by and between VIVUS, Inc., a Delaware corporation with its principal place of business at 351 E. Evelyn Avenue, Mountain View, CA 94041 (“**VIVUS**”), and Auxilium Pharmaceuticals, Inc., a Delaware corporation having its principal place of business at 640 Lee Road, Chesterbrook, PA 19087 (“**Purchaser**”). VIVUS and Purchaser are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

WHEREAS, VIVUS and Purchaser have entered into a separate License and Commercialization Agreement, effective as of the date of this Agreement (the “**License Agreement**”), pursuant to which VIVUS granted to Purchaser an exclusive license in the Purchaser Territory for, among other things, the development and commercialization of the therapeutic drug known as Stendra® (avanafil);

WHEREAS, Purchaser desires to purchase the Product from VIVUS, and VIVUS desires to supply the Product to Purchaser, on the terms and subject to the conditions of this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and promises set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. DEFINITIONS

Capitalized terms not expressly defined herein shall have the same meaning as set forth in the License Agreement.

“**API**” has the meaning set forth in Section 2.10.

“**Binding Forecast**” has the meaning set forth in Section 2.3.

“**cGMP**” means current Good Manufacturing Practices, that is, the current standards for the manufacture, processing, packing, testing, shipping, and holding of drug active ingredients in the United States, as set forth in the Act and applicable regulations promulgated thereunder (including without limitation 21 C.F.R. Parts 210 and 211), as amended from time to time, and the equivalent laws in Canada or any other jurisdiction that may be applicable to the conduct of such activities in relation to the Product.

“**Current Inventory**” means VIVUS’s inventory of Product on hand as of the Effective Date, as specified on Exhibit D to this Agreement.

“**Finished Product**” means Product that is fully packaged and labeled in accordance with the FDA-approved NDA (or Canadian equivalent).

“**Forecast**” has the meaning set forth in Section 2.2.

“**GAAP**” means then-current generally accepted accounting principles in the United States, consistently applied during the applicable calculation period by the applicable Party.

“**License Agreement**” has the meaning set forth in the recitals above.

“**Manufacturing Cost**” means VIVUS’s actual out-of-pocket costs in obtaining, transporting, and storing raw materials for manufacturing Product and in having the Product manufactured, tested, and supplied to Purchaser hereunder, including transfer prices paid to MTPC and other Third Party manufacturers. The Manufacturing Cost for Product manufactured by MTPC shall be calculated as set forth in Exhibit B. Manufacturing Cost may be calculated based on estimated costs, as determined by VIVUS in good faith and in accordance with its standard procedures, with appropriate adjustments being made on a periodic basis (at least annually) to reflect variances between actual and estimated costs.

“**Minimum Purchase Obligation**” means the quantities of Product described in Exhibit C.

“**New Third Party Manufacturer**” has the meaning set forth in Section 2.1(a).

“**Person**” means an individual, corporation, partnership, limited liability company, trust, association, joint venture, sole proprietorship, unincorporated organization, governmental authority, or any other form of entity not specifically listed herein.

“**Price**” means Manufacturing Cost plus *** percent (***) to cover VIVUS’s internal costs to manage and coordinate the supply chain; provided, however, that such *** percent (***) markup shall not apply to the Net Sales Manufacturing Cost (as defined in Exhibit B).

“**Product**” means formulated tablets containing Compound in bulk form which, if appropriately packaged and labeled would constitute the pharmaceutical product known as Stendra®, as described in the FDA-approved NDA for such product (as such NDA may be modified in the future in accordance with this Agreement and/or the License Agreement). Product will initially be ordered and supplied at two different dosage strengths: 100 mg and 200 mg.

“**Product Recall**” means a recall, product withdrawal, or field correction of any Product or Finished Product.

“**Product Shortage**” means a circumstance, whether or not the result of a force majeure, in which VIVUS is unable to supply Product to Purchaser in compliance with the terms and conditions of this Agreement in the quantities sufficient to meet Purchaser’s requirements of Product as set forth in outstanding Purchase Orders and/or the Binding Forecast.

“**Purchase Orders**” has the meaning set forth in Section 2.3.

“**Purchaser Territory**” means the “Auxilium Territory” as defined in the License Agreement.

“**Quality Agreement**” has the meaning set forth in Section 5.4.

“***” has the meaning set forth in Section 2.5(b).

“**Specifications**” means the specifications, standards, limits, criteria and other requirements for or related to the Product provided hereunder, as set forth in Exhibit A or otherwise agreed to by the Parties in writing.

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“**Supply Disruption**” has the meaning set forth in Section 2.8.

“**Term**” has the meaning set forth in Section 9.1.

2. SUPPLY OF PRODUCTS

2.1 Supply of Product.

(a) Supply and Purchase of Product. During the Term, and subject to the provisions herein, VIVUS shall manufacture, test, and supply the Product to Purchaser or its designee, directly or through one or more Third Party subcontractors. Purchaser shall purchase the Product from VIVUS, and VIVUS shall supply Product to Purchaser, pursuant to Purchase Orders submitted to VIVUS by Purchaser, from time to time in accordance with Section 2.3. VIVUS shall ensure that the Product delivered to Purchaser (other than shipments out of the Current Inventory pursuant to Section 2.5) has a minimum remaining shelf life of ***.

(b) VIVUS’s Third Party Supplier. Without limiting or modifying any of VIVUS’s obligations under this Agreement, Purchaser acknowledges that, as of the Effective Date, VIVUS obtains Product solely from MTPC and that VIVUS will continue to obtain Product solely from MTPC unless and until VIVUS is able to qualify with the FDA a Third Party manufacturer with the ability to manufacture Product in accordance with the Specifications, cGMP, and Applicable Law (the “**New Third Party Manufacturer**”) as a manufacturer of Compound and bulk tablets of Product. VIVUS represents to Purchaser that qualification of a New Third Party Manufacturer is in process as of the Effective Date and VIVUS agrees to use its best efforts to qualify such New Third Party Manufacturer as soon as is practicable, but in no event later than ***.

(c) Exclusive Arrangement. Subject to the terms and conditions of this Agreement, Purchaser agrees to purchase from VIVUS, and VIVUS agrees to manufacture and provide to Purchaser, all of Purchaser’s requirements for Product. VIVUS shall be free to supply Product to any Third Party worldwide, subject to the exclusive rights granted to Purchaser and obligations assumed by VIVUS pursuant to the License Agreement.

2.2 **Forecasts**. Purchaser will submit to VIVUS, no later than the *** of the *** preceding the start of every *** during the Term, a rolling forecast (“**Forecast**”) setting forth an estimate of the total quantity of Product that Purchaser reasonably believes it will purchase during the *** commencing with the beginning of the subsequent ***, along with estimated shipment dates.

2.3 **Purchase Orders**. Until such time as a New Third Party Manufacturer has been appointed by VIVUS, Purchaser shall purchase Product by written purchase orders (“**Purchase Orders**”), submitted to VIVUS at least *** in advance of the desired shipment date specified therein. For each ***, Purchaser shall be required to submit Purchase Orders for at least *** percent (***) of the quantities in the Forecast for such calendar quarter submitted by Purchaser to VIVUS *** prior to the start of such *** (the “**Binding Forecast**”), and VIVUS will have no obligation to supply Product in excess of *** percent (***) of the quantity specified in such Binding Forecast. Each Purchase Order shall specify, at a minimum, the applicable volume of each dosage strength of Product ordered, and the requested delivery date. Upon receipt of a Purchase Order, subject to the provisions of Section 2.1, VIVUS shall supply the Product in such quantities and deliver the Product to Purchaser (or Purchaser’s designee) on such delivery dates. VIVUS is not obligated to accept verbal orders of any kind for the supply of Product hereunder.

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To the extent there is any conflict or inconsistency between this Agreement and any Purchase Order, this Agreement shall govern. After a New Third Party Manufacturer has been appointed by VIVUS, if any, then the lead times for Purchase Orders set forth above shall be shortened (but not lengthened) to the extent that VIVUS has shorter lead times in its arrangement with the New Third Party Manufacturer.

2.4 **Minimum Purchase Requirements**. For 2015 and for each subsequent calendar year during the Term, Purchaser shall be required to either (a) purchase no less than the Minimum Purchase Obligation from VIVUS in accordance with the terms of this Agreement or (b) *** as it relates to *** to ***. VIVUS acknowledges and agrees that VIVUS’s sole remedy for Purchaser’s failure to meet its Minimum Purchase Obligation is set forth in this Section 2.4 and that the Minimum Purchase Obligation is not a guarantee by Purchaser that any specific sales level will be obtained with respect to the

Product. Purchaser's orders of Current Inventory (including the order made pursuant to Section 2.5(b) below) shall not be counted towards the satisfaction of the Minimum Purchase Obligation.

2.5 Initial Shipments of Product.

(a) The Current Inventory of Product is, as of the Effective Date, being stored at *** at ***. No later than *** following the Effective Date, VIVUS shall transfer to Purchaser ownership of *** of Product that are in the Current Inventory, at no charge. Purchaser shall distribute such Product solely for sampling purposes and shall complete the distribution of such Product as samples within *** after receipt.

(b) Purchaser hereby submits a binding order for a portion of the Current Inventory in the quantities set forth on Schedule 2.5(b). As set forth in Section 3.1, the transfer price for the quantities of Product ordered pursuant to this Section 2.5(b) shall be the Price. Upon payment in full to VIVUS of the portion of the Price based on the Fixed Manufacturing Cost, such quantities of Product will be sold to Purchaser EXW (Incoterms 2010) *** facilities, and title to such quantities of Product shall automatically pass to Purchaser.

(c) For all Product transferred to Purchaser under this Section 2.5, Purchaser shall be responsible, at Purchaser's sole cost, for transport, packaging, and distribution of such Product. Purchaser may use any Third Party that it designates for Product packaging, but Purchaser shall be responsible for the cost of validation if the packager is any Third Party other than ***, as well as any costs associated with transporting Product to such other packager. Other than Product transferred to Purchaser under Section 2.5(a) for use as samples, VIVUS shall ensure that all Current Inventory delivered to Purchaser under this Agreement has a minimum remaining shelf life of not less than ***.

2.6 **Delivery and Shipping Terms.** Product supplied hereunder shall be shipped EXW (Incoterms 2010) MTPC's manufacturing facility (or, if applicable, the manufacturing facility of any other manufacturer being utilized by VIVUS for manufacturing Product) directly to the packaging facility or other location designated by Purchaser. Title to the Product and risk of loss shall pass to Purchaser at the time of delivery of the Product to the Third Party shipper at the loading dock of the manufacturing facility. Purchaser shall arrange for all shipping, insurance freight, custom duties, and other charges associated with, the shipment, and the cost of the foregoing will be paid by Purchaser. VIVUS shall issue (or shall have its manufacturer issue) to Purchaser in advance of shipment a Certificate of Analysis (each, a "COA") and Certificate of Compliance (each, a "COC") for each shipment of Product (including Current Inventory) delivered to Purchaser. Each COA shall be accompanied by batch documentation for each lot of delivered Product and shall certify that the Product conforms to the Specifications, this Agreement, and the Quality Agreement along with the results of such analysis and any supporting data.

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Purchaser will be under no obligation to accept any shipment of Product for which VIVUS has not provided a COA and/or COC or which Purchaser reasonably believes does not comply with the COA or COC at the time the Product was delivered to Purchaser. VIVUS will be responsible for any out-of-pocket costs incurred by Purchaser with respect to the storage, shipment, return, or at VIVUS's direction, destruction, of such non-conforming shipment.

2.7 **Packaging and Labeling.** VIVUS will supply Product to Purchaser in the form of bulk tablets. Purchaser shall be responsible, at its sole expense, for packaging and labeling the Product for commercial sale. Additionally, Purchaser shall, within *** after receipt of an invoice from VIVUS that includes copies of the relevant invoice(s) from ***, pay VIVUS an amount not to exceed \$*** to reimburse VIVUS for payments made to *** prior to the Effective Date in order to initiate packaging validation work for the Product. Any labels, product inserts, and other packaging for the Product shall be consistent with then-current approved NDA for the Product and with Applicable Law. VIVUS's name will not appear on the label or anywhere else on the commercial packaging of the Product unless: (a) required by any Applicable Laws; or (b) VIVUS consents in writing to the use of its name.

2.8 **Supply Disruption.** If VIVUS is unable to supply confirmed orders to Purchaser with respect to the quantity or the delivery date (a "Supply Disruption"), or if VIVUS believes that a Supply Disruption is reasonably likely to occur based on Purchaser's confirmed and/or forecasted orders, VIVUS shall provide Purchaser with prompt written notice of such inability or belief. In the event of a Supply Disruption, VIVUS shall be obliged to allocate the available Product among Purchaser and any other licensees and/or authorized distributors of Product worldwide, *** based on the volume of Product orders of Purchaser and such other licensees and distributors. The "volume of Product orders" will be calculated based on (a) orders for Product that were delivered during the preceding *** or that are then in transit (excluding in each case any orders where payment therefor is delinquent), and (b) the binding portion of any outstanding purchase orders or forecasts. In the event of a Supply Disruption, notwithstanding Section 2.1(c), Purchaser shall be permitted to obtain from another source the quantities of Product that VIVUS is unable to supply. In the absence of gross negligence or willful misconduct, this Section 2.8 describes Purchaser's sole and exclusive remedy, and VIVUS's sole and exclusive liability, for any Supply Disruption. In the event of any Supply Disruption that results in more than *** percent (***) of ordered Product in any *** period arriving at the delivery location more than *** after the intended delivery date, Purchaser shall be relieved of any further obligation during the Term to purchase the Minimum Purchase Obligation.

2.9 **Post-Delivery Handling and Release.** After delivery of the Product to Purchaser in accordance with the terms of this Agreement and the Quality Agreement, any handling, storage, quality control, quality assurance, and the release of the Product shall be the sole responsibility of Purchaser or its designated Third Party.

2.10 **Stability Testing.** VIVUS shall be responsible for conducting all stability testing required under the NDA with respect to the active pharmaceutical ingredient in the Compound ("API") and the bulk Product, and Purchaser shall be responsible for conducting such stability testing with respect to the Finished Product.

2.11 Technology Transfer.

(a) Cooperation. Upon (i) termination of this Agreement by Purchaser as a result of VIVUS's uncured material breach, (ii) in the event of a Supply Disruption, (iii) upon notice from Purchaser that it intends to exercise its Supply Chain Transfer rights under Section 6.2 of the License

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Agreement, (iv) in the event that VIVUS provides a notice to Auxilium under Section 2.8, or (v) upon an event of Force Majeure preventing the timely supply of Product hereunder for a period anticipated to exceed ***, VIVUS shall provide Purchaser with such assistance and any VIVUS Know-How Controlled by VIVUS, as reasonably necessary for manufacturing, formulating and/or packaging of the Product, as the case may be (a “**Technology Transfer**”). In connection with the foregoing, Purchaser shall be permitted to consult with VIVUS’s technical personnel on the specified manufacturing activities and, to the extent necessary, VIVUS shall use Commercially Reasonable Efforts to permit Purchaser to consult with VIVUS’s Third Party manufacturers.

(b) **Manufacturing Rights.** Notwithstanding any Technology Transfer pursuant to Section 2.11(a), Purchaser’s right to manufacture or have manufactured Product shall be limited to the rights described in Section 2.2 of the License Agreement, plus the additional manufacturing rights described in Section 2.8 in connection with a Supply Disruption.

(c) **Technology Transfer Costs.** In connection with a Technology Transfer pursuant to Section 2.11(a)(iii), Purchaser shall be responsible for paying VIVUS’s actual costs and expenses incurred in connection with such Technology Transfer, including FTE costs, out-of-pocket expenses and any technology transfer fees payable to any other Third Party (collectively, “**Technology Transfer Costs**”). In connection with a Technology Transfer pursuant to Section 2.11(a)(i), (ii), or (v), VIVUS shall be responsible for the Technology Transfer Costs. In connection with a Technology Transfer pursuant to Section 2.11(a)(iv), Auxilium shall be responsible for the Technology Transfer Costs unless and until a Supply Disruption shall have occurred, in which event VIVUS shall be responsible for such Technology Transfer Costs, including reimbursing Auxilium for those already paid by Auxilium.

2.12 Notice Right; Step-In Right. VIVUS shall provide Purchaser with prompt written notice of any breach or alleged breach, including without limitation any notice of such breach or alleged breach provided by any Third Party manufacturer of API or bulk Product and shall provide Purchaser with copies of any documentation and correspondence between any Third Party manufacturer and VIVUS regarding such breach including written summaries of any oral discussions. In the event that VIVUS is in breach of any such manufacturing or supply agreement with a Third Party manufacturer, it shall promptly provide to Purchaser a written plan of action to remedy or cure such breach and shall keep Purchaser promptly informed of its progress or any changes to such plan of action. If VIVUS is unable to cure such breach, then, unless VIVUS is disputing such breach in good faith, at Purchaser’s election VIVUS shall use commercially reasonable efforts to cause such Third Party manufacturer to ***. VIVUS may condition disclosure of attorney-client privileged information or attorney work product on the Parties’ execution of a joint defense agreement, common interest agreement, or similar agreement intended to preserve attorney-client and attorney work product privileges under Applicable Law, in a form reasonably acceptable to VIVUS.

2.13 Adjustments Related to Third Party Manufacturers. VIVUS will not at any time during the Term take any action that could reasonably be expected to result in a breach of any agreement between VIVUS and any Third Party manufacturer or supplier. VIVUS shall provide Auxilium with advance written notice of any material amendment, waiver of rights, termination or modification of any agreement between VIVUS and any Third Party manufacturer or supplier, and VIVUS will not agree to any amendment, waiver of rights, termination or modification of any agreement between VIVUS and any Third Party manufacturer or supplier that has, or would reasonably be expected to have, a material negative effect on Purchaser without the prior written consent of Purchaser, which shall not be unreasonably withheld, conditioned, or delayed.

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3. PRICE; PAYMENT

3.1 Prices for Product. Except for the Products described in Section 2.5(a), which shall be provided to Purchaser at no charge, Purchaser shall pay to VIVUS the Price for the units of Product supplied to Purchaser pursuant to this Agreement. Purchaser shall be solely responsible for determining the price at which it will re-sell the Product.

3.2 Payment. VIVUS shall provide to Purchaser written invoices setting forth the amount payable by Purchaser with respect to quantities of Product sold hereunder, including the Price applied by VIVUS to each dosage strength of Product. Purchaser shall pay VIVUS for Product in the amount invoiced by VIVUS within *** from the date of invoice, which invoice shall be issued at the delivery date. If Purchaser is legally required to withhold any Taxes from payments due hereunder, Purchaser shall (a) deduct such Taxes from the payment made to VIVUS, and (b) timely pay the taxes to the proper taxing authority. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect and shall discuss in good faith how to solve any situation where VIVUS may not deduct such payment for reasons beyond VIVUS’s reasonable control. Solely for purposes of this Section, “**Taxes**” means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including interest, penalties and additions thereto) that are imposed by the applicable government or other taxing authority.

3.3 Records; Audit. VIVUS shall maintain complete and accurate books and records in accordance with GAAP in sufficient detail to permit Purchaser to confirm the accuracy of the Manufacturing Costs, and any other financial measure relating to the Price of the Product payable under this Agreement, for a period of *** from the creation of individual records or any longer period required by Applicable Law. At Purchaser’s request, such records shall be available for review at a location in the Purchaser Territory determined by Purchaser not more than once each calendar year (during normal business hours on a mutually agreed date with reasonable advance notice) by an independent Third Party auditor selected by Purchaser and approved by VIVUS (such approval not to be unreasonably withheld, conditioned, or delayed) and subject to confidentiality and non-use obligations no less stringent than those set forth in Article 11 of the License Agreement for the sole purpose of verifying for Purchaser the accuracy of the Manufacturing Costs and Price paid by Purchaser pursuant to this Agreement or of any payments made by Purchaser to VIVUS pursuant to this Agreement. Any such auditor shall not disclose VIVUS’s Confidential Information to Purchaser, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by VIVUS or the amount of payments due by VIVUS under this Agreement. Any undisputed amounts finally determined to be owed but unpaid shall be paid within *** from the accountant’s report. Any amounts finally determined to have been overpaid may be credited to Purchaser against future payments to VIVUS hereunder. Purchaser shall bear the full cost of such audit unless such audit reveals an underpayment or under-reporting error of *** percent (***) or more during the applicable audit period, in which case VIVUS shall bear the full cost of such audit.

4. REPRESENTATIONS AND WARRANTIES

4.1 **Mutual Representations and Warranties.** Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows, as of the Effective Date:

(a) Corporate Existence and Power. It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has all

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requisite power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement.

(b) Authority and Binding Agreement. It has the requisite power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and this Agreement has been duly executed and delivered on its behalf, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject as to enforcement of remedies to applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting generally the enforcement of creditors' rights and subject to a court's discretionary authority with respect to the granting of a decree ordering specific performance or other equitable remedies.

(c) Consents. All necessary consents, approvals and authorizations of all governmental authorities and other Third Parties required to be obtained by it in connection with the execution, delivery and performance of this Agreement have been obtained by it. For the avoidance of doubt, Purchaser shall be solely responsible for obtaining any product and/or distribution license from the applicable Governmental Authority so as to be able to sell and market the Product in a particular jurisdiction.

4.2 **Product Representations and Warranties of VIVUS.**

(a) Compliance. VIVUS warrants that it will ensure that all Product will be manufactured and tested in conformity with this Agreement, the License Agreement, cGMP, the Specifications, and the Quality Agreement.

(b) Conformity with Specifications. VIVUS warrants that it will and will cause its Third Party suppliers to ensure that all Product manufactured by or on behalf of VIVUS and sold to Purchaser pursuant to this Agreement will at the time of delivery to the common carrier for such Product (i) meet the Specifications and (ii) not be misbranded or adulterated.

(c) No Liens. VIVUS warrants that all Product delivered to Purchaser pursuant to this Agreement will, at the time of such delivery, be free and clear of all liens, encumbrances, security interests and other encumbrances.

VIVUS's obligations as provided in Section 10.1 and Section 6.2 shall be the sole and exclusive remedies available to Purchaser with respect to Product that fails to meet the product warranties set forth in Section 4.2.

4.3 **Other Representations and Warranties of VIVUS.**

(a) Performance. VIVUS will perform its obligations under this Agreement, and will use commercially reasonable efforts to cause any Third Party supplier to perform their manufacturing obligations with respect to the Product, in a professional manner with requisite skill, care and diligence and in accordance with the industry standards. VIVUS will maintain, and will use commercially reasonable efforts to cause its Third Party suppliers to maintain, appropriately qualified and trained personnel, adequate premises and space, suitable equipment, correct materials, containers and labels, suitable storage and the knowledge and experience to carry out satisfactorily the work ordered by Auxilium.

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(b) Compliance with Applicable Laws. During the Term of this Agreement, VIVUS will comply with, and will use commercially reasonable efforts to cause its Third Party suppliers to comply with, all Applicable Laws to the conduct of its business and manufacture of Product in the performance of this Agreement and will hold, or will cause its Third Party manufacturers to hold, all permits and authorizations necessary to fulfill its obligations under this Agreement.

(c) Compliance with Certain Agreements. VIVUS is in compliance in all material respects with, and will at all times remain in compliance in all material respects with, and has not received any notice of breach pursuant to any agreement relating to the manufacture of Product.

(d) Debarment. VIVUS represents and warrants that it has not been debarred, nor is it under consideration to be debarred, and that it will not knowingly use in any capacity in connection with the manufacturing or services hereunder any person (including Third Party manufacturers) who has been debarred, nor is under consideration to be debarred by the FDA and/or TPD, the subject of a pending debarment pursuant to the Act, or who is the subject of a conviction described in such section. VIVUS will inform Auxilium in writing immediately upon becoming aware thereof if it or any person (including Third Party manufacturers) who is performing manufacturing or any services hereunder is debarred or is the subject of a conviction described in section 306 of the Act, or if any action, suit, claim, investigation, or proceeding is pending, or to the best of VIVUS's knowledge, is threatened, relating to the debarment or conviction of VIVUS, or any person performing manufacturing or services pursuant to this Agreement.

4.4 **No Other Representations or Warranties.** EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 4 OR THE LICENSE AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF

MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF VIVUS. ALL OTHER REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

5. QUALITY

5.1 **General.** VIVUS shall be responsible for establishing and maintaining such procedures for implementing corrective and preventive actions with respect to the manufacturing of the Product as required by Applicable Law, cGMP, and the Quality Agreement. VIVUS shall cooperate with Purchaser at VIVUS's expense in determining the cause of any quality problems involving the Product, identifying corrective actions, and ensuring the implementation and effectiveness thereof. VIVUS shall implement such corrective actions with respect to the Product, and shall provide Purchaser with written confirmation upon the completion thereof.

5.2 **Notice of Failure to Meet Specifications.** Each Party shall notify the other Party immediately after the discovery that any lot of Product sold to Purchaser failed to comply with its applicable Specifications at the time of delivery or was not manufactured in accordance with Applicable Laws, including without limitation cGMP. VIVUS will immediately make, at its sole expense, such further internal investigation of any failure to meet these requirements as is reasonable under the circumstances and otherwise consistent with its obligations hereunder and shall use its best efforts to remediate such failure as promptly as possible.

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5.3 Changes to Specifications.

(a) Changes Requested by Purchaser. VIVUS will not be required to implement any requests by Purchaser to change the manufacturing process, Specifications, or any testing method with respect to the Product, but VIVUS shall consider any such requests in good faith.

(b) Changes Requested by VIVUS. VIVUS will provide Auxilium with advance notice of any material changes to procedures, Specifications, methods (including testing methods) or standard operating procedures relating to the manufacture or supply of the Product and VIVUS will not make or permit any such changes without the prior written consent of Purchaser if such change is (i) inconsistent with the then-current approved NDA for the Product, (ii) reasonably likely to have a material adverse effect on VIVUS's ability to comply with the terms of this Agreement, including any Product delivery timelines hereunder, or (iii) otherwise reasonably likely to have an adverse impact on the Commercialization of the Product in the Purchaser Territory.

(c) Changes Required by Applicable Law. VIVUS will promptly, at its own expense, implement any changes to any procedures, Specifications, methods (including testing methods) or standard operating procedures relating to the manufacture or supply of the Product required by Applicable Law or the NDA (collectively, "Required Manufacturing Changes").

(d) Cost of Manufacturing Changes. Prior to a Supply Chain Transfer, VIVUS will be solely responsible for all internal and external costs, including, without limitation, obsolete raw materials, regulatory filings, work-in-process, and Product, (i) associated with Required Manufacturing Changes, and (ii) all costs associated with any other manufacturing changes not requested by Purchaser. Prior to a Supply Chain Transfer, Purchaser shall be responsible for such costs only in the event such manufacturing change is requested by Purchaser and is not otherwise required by Applicable Law or the NDA.

5.4 **Quality Agreement.** The parties will use commercially reasonable efforts to enter into a separate quality agreement governing the agreed-upon Specifications and other technical aspects of supply of Products to Purchaser hereunder no later than *** after the Effective Date (the "Quality Agreement"). In the event of any inconsistency between this Agreement and the Quality Agreement, this Agreement shall control, except with respect to quality assurance matters. VIVUS agrees to use its commercially reasonable efforts to have three-way quality agreements put into place with Purchaser and VIVUS's Third Party manufacturers.

6. ACCEPTANCE AND REJECTION PROCEDURES

6.1 **Inspection.** Purchaser or its designee shall promptly, upon arrival on its site, carefully inspect each shipment of Product for transport damages, losses and shortfalls. Apparent defects, such as, for instance, damaged containers or missing packages of Product, must be notified to the carrier promptly upon arrival of the shipment and the freight documents at Purchaser or its designee and, where possible, countersigned by the carrier's representative. Failure of Purchaser or its designee to notify such visually detectable defects to the carrier promptly upon arrival of the concerned shipment and freight documents shall exclude any liability of VIVUS for such defects. Purchaser shall have *** after receipt of a shipment of Product to determine if there is any defect in the Product or any non-compliance with the Specifications or Applicable Law, including without limitation cGMP, which is discoverable by diligent and customary inspection of the shipment and any accompanying documentation (the "Inspection Period"). Purchaser shall notify VIVUS of any such non-compliance prior to the end of the Inspection

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Period, describing in reasonable detail the non-compliance. Notwithstanding the preceding provisions of this Section 6.1, if with respect to any unexpired Product, the non-compliance could not reasonably be expected to have been found by diligent and customary inspection during the Inspection Period and Purchaser notifies VIVUS of such non-compliance, describing such Latent Defect in detail, within *** of Purchaser's knowledge of the Latent Defect and within the shelf life of the Product, such non-compliance shall be deemed to be a "Latent Defect" hereunder. Purchaser's notification of VIVUS of a non-compliance during the Inspection Period or of a Latent Defect as permitted above shall be referred to herein as a "Claim". For the sole purpose of application

of Section 6.2, Purchaser shall be deemed to have accepted any Product if it fails to give a Claim in the periods permitted above; provided, however, that Purchaser's acceptance of Product shall not limit Purchaser's indemnification rights under Section 10.1 (which, for clarity, shall be fully subject to the exceptions recited therein). At VIVUS's reasonable request, Purchaser shall provide VIVUS with any available documentation or analysis that is reasonably necessary for VIVUS to exercise its rejection rights under its supply agreement with MTPC and/or any other relevant Third Party manufacturer.

6.2 **Remedies.** Except for Claims disputed pursuant to Section 6.2(b) hereof, if Purchaser submits a Claim, then as promptly as practicable after the submission of the Claim to VIVUS (but in no event later than *** after the submission of the Claim), VIVUS shall instruct Purchaser whether to return or destroy the Product in question and provide Purchaser with replacement Product. In the event that:

(a) VIVUS agrees with the Claim, then VIVUS shall pay for all out-of-pocket costs of returning or destroying Product that is the subject of any accepted Claim. VIVUS shall bear the risk of loss for such Product, beginning at such time as such Product is taken at Purchaser's premises for return delivery.

(b) VIVUS does not agree with the Claim, then the Parties agree to submit the Product in question to a mutually agreed independent Third Party that has the capability of testing the Product to determine whether or not it complies with the Quality Agreement, the Specifications and Applicable Law, including cGMP. The losing Party shall bear all costs and expenses related to such testing and pay for all shipping costs of returning the Product and/or sending the replacement Product, as the case may be.

6.3 **Cost of Product Recalls.** With respect to any Product supplied hereunder, VIVUS shall bear all Losses (including without limitation expenses related to communications and meetings with all required regulatory agencies, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those customers) related to any Product Recall in the event that such Product Recall is caused by or results from (a) the breach by VIVUS (including indirectly by any Third Party manufacturer) of any representation or warranty or covenant contained in this Agreement or the License Agreement, or (b) VIVUS's negligence or willful misconduct. Additionally, in the event the Product Recall is caused by or results from (a) or (b) above, VIVUS shall replace the units of recalled Products as promptly as practicable and at no cost to Purchaser. Except as provided above, Purchaser shall bear all Losses related to any Product Recall.

7. REGULATORY MATTERS.

7.1 **Regulatory Responsibilities.** The Parties' respective rights and obligations with respect to Regulatory Approvals in the Purchaser Territory, communications with Regulatory Authorities in the

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Purchaser Territory, and other regulatory matters relating to the Product in the Purchaser Territory are set forth in the License Agreement.

8. RECORD-KEEPING; AUDITS

8.1 **Recordkeeping.** VIVUS (and/or MTPC or the New Third Party Manufacturer) will keep complete and accurate records of the manufacture and testing of Product, and retain samples of bulk Product and the active pharmaceutical ingredient in the Compound as are necessary to comply with Applicable Laws, as well as to assist with resolving Product complaints and other similar investigations. Copies of the records and samples will be retained for a period of *** following the date of Product expiry, or longer if required by Applicable Laws. Purchaser is responsible for retaining samples of the fully packaged Product necessary to comply with the legal/regulatory requirements applicable to Purchaser.

8.2 Audits.

(a) Audit Right; Facility Access. From and after the commencement of supply hereunder directly or through an independent auditor reasonably acceptable to VIVUS, Purchaser shall have the right, upon reasonable advance notice and during regular business hours, to make an annual inspection and audit of the facilities being used by VIVUS or a VIVUS Affiliate for the production, storage, or testing of Product to assure compliance by or on behalf of VIVUS with cGMPs, the Specifications, and Applicable Law. At Purchaser's reasonable request, VIVUS agrees to use commercially reasonable efforts to facilitate a similar inspection and audit of the facilities being used by MTPC and/or any other Third Party manufacturer, such as, solely by way of example, by exercising VIVUS's audit right in its agreement with such manufacturer, at Purchaser's cost, and permitting Purchaser or its designee to attend such audit (subject to approval by the Third Party manufacturer to allow such attendance, which VIVUS shall use commercially reasonable efforts to obtain) and in any event sharing the results of such audit with Purchaser.

(b) Third Party Audits. Without limiting VIVUS's obligations under this Agreement in any respect, Purchaser acknowledges that VIVUS's audit right in the MTPC Agreement is limited to periodic audits to ensure that cGMPs continue to be followed. In the event that VIVUS or any Third Party licensee of VIVUS outside the Purchaser Territory proposes to conduct or conducts an audit of the facilities used by or on behalf of VIVUS or a VIVUS Affiliate or Third Party for the production, storage, or testing of Product to be sold to Purchaser under this Agreement, then VIVUS will provide immediate notice to Purchaser of such audit and VIVUS shall use its commercially reasonable efforts to permit Purchaser to be able to be present for and participate in such audit.

(c) Procedure. The inspection and audit provided for under Section 8.2(a) shall not be carried out by Purchaser more than *** per calendar year, but such inspection and audit shall not preclude Purchaser from conducting any "for cause" inspection or audit permitted under the Quality Agreement or otherwise for cause. Each inspection and audit shall be conducted in a manner so as to minimize disruption of the business operations of VIVUS, MTPC and/or any other Third Party manufacturer. VIVUS representatives will be permitted to participate as observers during any such inspection and audit. To the extent that Purchaser's requests an inspection or audit of the facilities of MTPC and/or any other Third Party manufacturer, Purchaser acknowledges that VIVUS must coordinate the dates and schedule of such inspection and audit with MTPC and/or such other Third Party manufacturer. The independent auditor, if any, shall enter into a written confidentiality agreement with VIVUS containing provisions regarding the disclosure of information obtained during the inspection and

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audit that are at least as restrictive as the provisions of Article 13 of this Agreement; provided that, the independent auditor will be permitted to disclose to Purchaser whether and to what extent VIVUS (or, if applicable, MTPC and/or any other Third Party manufacturer) failed to comply with the requirements of Section 8.1 (and shall not be permitted to disclose to Purchaser any other information). A copy of any such disclosure to Purchaser shall also be provided to VIVUS.

(d) **Results.** If an inspection or audit reveals a failure to comply with cGMP or Applicable Law in any material respect, then Purchaser shall promptly provide to VIVUS written notice of such fact, which notice shall contain in reasonable detail the deficiencies found in the applicable facilities and, if practicable, those steps Purchaser believes should be undertaken in order to remedy such deficiencies. The Parties shall discuss in good faith the deficiencies and VIVUS shall, at its own expense, use its best efforts to remedy such deficiencies, or implement a plan to remedy such deficiencies, as soon as reasonably practical following receipt of the notification thereof. In addition to the audit rights set forth in this Section 8.2, Purchaser will be entitled to perform reasonable follow-up inspections to monitor correction of such deficiencies or the circumstances giving rise to such deficiency, failure or notice.

8.3 **Analytical Method Transfer.** Upon the reasonable prior written request of Purchaser, VIVUS agrees to provide Purchaser or use Commercially Reasonable Efforts to cause its Third Party designee hereunder to provide Purchaser with all required documentation and support for analytical method transfer for the Product in order to enable Purchaser to analyze the Product in order to determine its suitability and stability under this Agreement and according to all applicable requirements of Regulatory Authorities or to ensure that the Products are in line with the Regulatory Approvals (a “**Method Transfer**”). VIVUS agrees to actively participate, or use Commercially Reasonable Efforts to cause its Third Party designee hereunder to participate, in such Method Transfer by, among other things, providing samples and conducting parallel testing. Purchaser shall pay for any out-of-pocket costs incurred by VIVUS in connection with such Method Transfer.

8.4 **Regulatory Compliance.** VIVUS will advise Purchaser promptly if an authorized agent of a Regulatory Authority visits its facilities (or, to its knowledge, its Third Party designee’s manufacturing facilities) where the API or the Product is being manufactured, stored, or tested. VIVUS will provide Purchaser with all material information in VIVUS’s possession pertaining to actions taken by Regulatory Authorities (including any inspections, proposed regulatory actions, investigations or requests for information or a meeting by any Regulatory Authority) whether inside the Purchaser Territory or outside the Purchaser Territory in connection with the API or the Product in the Field, including any notice, audit notice, notice of initiation by Regulatory Authorities of investigations, inspections, detentions, seizures or injunctions concerning the API or the Product in the Field whether inside the Purchaser Territory or outside the Purchaser Territory, notice of violation letter (i.e., an untitled letter), warning letter, service of process or other inquiry; provided, however, that VIVUS shall be entitled to redact those portions thereof to the extent not related to the API or the Product in the Field or to the extent disclosing Third Party confidential information. Without limiting the generality of the foregoing, each Party shall promptly, but in any event within ***, inform the other Party of any material inspections, proposed regulatory actions, investigations or requests for information or a meeting by any Regulatory Authority with respect to the API or the Product in the Field in the Manufacturing Territory. VIVUS or its Third Party designee will furnish to Purchaser all material information supplied to, or supplied by, any Regulatory Authority in the Manufacturing Territory, including the Form 483 observations and responses, to the extent that such information relates to the API or the Product or the ability of VIVUS to supply such API or the Product and could reasonably be expected to have a material negative effect on the Purchaser or the Commercialization of the Product in the Purchaser Territory, within *** of their receipt of such information, in each case to the extent that VIVUS is aware of such information and subject in

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each case to the redaction right described above. VIVUS or its Third Party designee will consult in advance with Purchaser prior to responding to any request from a Regulatory Authority to the extent such response relates to the API or the Product, and VIVUS will use commercially reasonable efforts to permit Purchaser and/or its agents to be present at any inspection by any Regulatory Authority of any manufacturing facility where the API or the Product that is supplied to Purchaser hereunder is being manufactured or quality tested.

9. TERM; TERMINATION

9.1 **Term.** The term of this Agreement (the “**Term**”) will commence on the Effective Date and will continue, unless otherwise agreed between the Parties, until December 31st, 2018.

9.2 **Termination for Default or Bankruptcy.** Either Party may terminate this Agreement (a) for material breach by the other Party if such breach continues uncured for a period of *** after receipt of notice thereof; or (b) if (i) the other Party shall institute bankruptcy, insolvency, liquidation or receivership proceedings or proceedings for reorganization under bankruptcy or comparable laws; or (ii) a petition shall be filed against the other Party for any proceedings described in clause (i) above, the effectiveness of which is not stayed or dismissed within *** after the filing thereof; or (iii) the other Party shall make a general assignment of all or substantially all of its assets for the benefit of creditors. Termination of this Agreement pursuant to this Section 9.2 shall not affect any other rights or remedies which may be available to the non-defaulting Party, including any rights or remedies under the License Agreement.

9.3 **Termination Upon Termination of License Agreement.** In addition to the termination rights expressly provided for elsewhere in this Agreement, either Party may also terminate this Agreement upon written notice to the other Party if the License Agreement is terminated in accordance with its terms.

9.4 **Termination upon Transfer of Control of Supply Chain.** This Agreement shall automatically terminate upon the completion of the Supply Chain Transfer (as defined in the License Agreement).

9.5 **Effects of Termination.** Upon expiration or termination of this Agreement other than termination of this Agreement by Purchaser under Section 9.2(a), VIVUS shall manufacture and supply, and Purchaser shall purchase from VIVUS (a) any and all quantities of Product ordered by Purchaser pursuant to this Agreement prior to the date on which such notice is given, for the applicable Price, and (b) any and all materials held by VIVUS or MTPC (or any other Third Party manufacturer of Product) for exclusive use in the manufacture of Compound or Product based on binding part of the Forecasts provided by Purchaser, for an amount equal to *** with respect to such materials. Termination or expiration of this Agreement will not affect any outstanding obligations due hereunder prior to the termination or expiration. In the event of Purchaser's termination of this Agreement under Section 9.2(a), Purchaser shall not be required to purchase any additional quantities of Product from VIVUS and all orders of Product shall be immediately voided and of no effect with no further obligation of Purchaser to VIVUS with respect to materials held by VIVUS or a Third Party manufacturer for manufacture of the Compound or Product.

9.6 **Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to the effective date of such expiration or termination. The following sections

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shall survive termination or expiration of this Agreement for any reason: Sections 2.11, 3.3, 6.1, 6.3 and 8.1 and Articles 9 through 14 and 16.

10. INDEMNIFICATION

10.1 **Indemnification by VIVUS.** VIVUS shall defend and indemnify and hold Purchaser, its Affiliates and their respective directors, officers and employees (the “**Purchaser Indemnified Parties**”) harmless against any and all Losses resulting from any Claim of a Third Party arising out of, based on, or caused by (i) alleged or actual bodily injury or property damage resulting from the manufacturing, packing, labeling, handling, storage, transportation, use, distribution of Products by or on behalf of VIVUS, its licensees (other than Auxilium) or Affiliates, including any product liability claim; (ii) liabilities arising from clinical trials conducted by or on behalf of VIVUS in connection with any Products; (iii) the breach by VIVUS of any representation or warranty or covenant contained in this Agreement; (iv) the Product supplied by VIVUS to Purchaser hereunder failing to meet the warranties set forth in Section 4.2, or (v) the negligence or willful misconduct of VIVUS or its Affiliates, sublicensees, or any of its agents, directors, officers or employees, except in each case to the extent that such Losses arise directly from the breach by Purchaser of any representation or warranty or covenant contained in this Agreement or any negligence or willful misconduct by a Purchaser Indemnified Party.

10.2 **Indemnification by Purchaser.** Purchaser agrees to defend and indemnify and hold VIVUS, its Affiliates and their respective directors, officers and employees (the “**VIVUS Indemnified Parties**”) harmless against any and all Losses resulting from any Claim of a Third Party arising out of, based on, or caused by (i) the storage, sale, shipment, promotion or distribution of the Product by Purchaser after Purchaser has taken title to the Product, or (ii) the breach by Purchaser of any representation or warranty or covenant contained in this Agreement, except in each case to the extent that such Losses arise directly from the breach by VIVUS of any representation or warranty or covenant contained in this Agreement (including breach of Section 4.2), or any negligence or willful misconduct by a VIVUS Indemnified Party.

10.3 **Indemnification Procedures.** The Party claiming indemnity under this Article 10 (the “**Indemnified Party**”) shall give written notice to the Party from whom indemnity is being sought (the “**Indemnifying Party**”) promptly and in no event later than *** after learning of a written claim (“**Indemnified Claim**”). Failure by an Indemnified Party to give notice of an Indemnified Claim within *** of receiving a writing reflecting such Claim shall not relieve the Indemnifying Party of its indemnification obligations hereunder except and solely to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give such notice. The Indemnifying Party shall have the right to assume the conduct and defense of the Indemnified Claim with counsel of its choice so long as the Indemnifying Party is conducting a good faith and diligent defense; provided that, the Indemnifying Party shall not have the right to assume any Indemnified Claim if (x) the Indemnifying Party fails to provide reasonable evidence of its ability and willingness to satisfy such claim, or (y) such claim involves a criminal or regulatory enforcement action. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance in connection with the defense of the Indemnified Claim. The Indemnified Party may monitor such defense with counsel of its own choosing at its sole expense; provided, that if under applicable standards of professional conduct a conflict of interest exists between the Indemnifying Party and the Indemnified Party in respect of such claim, such Indemnified Party shall have the right to employ separate counsel to represent such Indemnified Party with respect to the matters as to which a conflict of interest exists and in that event the reasonable fees and expenses of such separate counsel shall be paid by the Indemnifying Party. The Indemnifying Party may not settle the Indemnified Claim without the prior written consent of the Indemnified Party, such consent shall not be unreasonably withheld,

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delayed or conditioned. In no event shall the Indemnifying Party settle the Indemnified Claim unless such settlement provides an unconditional and full release of the Indemnified Party. If the Indemnifying Party does not assume and conduct the defense of the Indemnified Claim as provided above: (a) the Indemnified Party may assume and conduct the defense of the Indemnified claim at the Indemnifying Party's expense; (b) the Indemnified Party may consent to the entry of any judgment or enter into any settlement with respect to the Indemnified Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith); and (c) the Indemnifying Party will remain responsible to indemnify the Indemnified Party for Indemnified Amounts as provided in this Article 10.

11. LIMITATION OF LIABILITY

11.1 **Limitation.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY EXEMPLARY, SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES, COSTS OR EXPENSES (INCLUDING LOST PROFITS, LOST REVENUES AND/OR LOST SAVINGS) ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTHING IN THE PRECEDING SENTENCE IS INTENDED TO OR SHALL LIMIT OR

RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY IN CONNECTION WITH THIRD PARTY CLAIMS UNDER ARTICLE 10, (B) DAMAGES OR INJUNCTIVE RELIEF AVAILABLE FOR A PARTY'S BREACH OF ARTICLE 13, (C) DAMAGES TO THE EXTENT ARISING FROM OR RELATING TO WILLFUL MISCONDUCT OR FRAUDULENT ACTS OR OMISSIONS OF A PARTY OR (D) DIRECT DAMAGES. EXCEPT FOR WILLFUL MISCONDUCT OR LOSSES ASSOCIATED WITH PRODUCT RECALLS, IN NO EVENT SHALL VIVUS'S AGGREGATE LIABILITY ARISING OUT OF OR RELATING TO THIS AGREEMENT UNDER ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT, STATUTORY OR OTHERWISE) EXCEED THE SUM OF AMOUNTS ACTUALLY RECEIVED BY VIVUS UNDER THIS AGREEMENT AND THE LICENSE AGREEMENT; PROVIDED, HOWEVER THAT THIS LIMITATION SHALL NOT APPLY TO (I) VIVUS'S OBLIGATIONS IN CONNECTION WITH THIRD PARTY CLAIMS UNDER ARTICLE 10 OR (II) DAMAGES TO THE EXTENT ARISING FROM OR RELATING TO VIVUS'S NEGLIGENT, WILLFUL MISCONDUCT OR FRAUDULENT ACTS OR OMISSIONS. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS AGREEMENT SHALL LIMIT THE LIABILITY OF EITHER PARTY UNDER THE LICENSE AGREEMENT.

11.2 **Duty to Mitigate.** Each Party shall use reasonable efforts to mitigate any damages incurred by such Party hereunder.

12. INSURANCE.

12.1 Each Party shall procure and maintain insurance or self-insure during the Term of this Agreement and for a period of *** following the termination or expiration of this Agreement, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Upon written request, each Party shall provide proof of adequate coverage to the other Party. Either Party may substitute a self-insurance program to satisfy in whole or in part its obligations under this Article 12 on written notice to the other Party with information demonstrating the adequacy of such program.

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12.2 It is understood that the insurance requirements above shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under Article 10. Each Party shall provide the other Party with written evidence of such insurance upon written request. Each Party shall provide the other Party with written notice at least *** prior to the cancellation, non-renewal or material change in such insurance or self-insurance that materially adversely affects the rights of the other Party hereunder.

13. CONFIDENTIALITY; PROPRIETARY RIGHTS

13.1 **Confidentiality.** Each Party will maintain the Confidential Information of the other Party in accordance with Article 11 of the License Agreement. The Parties agree not to disclose any financial terms or conditions of this Agreement to any Third Party without the prior consent of the other Party, except as required by Applicable Law.

13.2 **Proprietary Rights.** This Agreement shall not affect the ownership of any intellectual property owned or developed by or licensed to either Party ("**Intellectual Property**") or any rights granted in the License Agreement with respect to such Intellectual Property.

14. DISPUTE RESOLUTION

14.1 **Disputes.** The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 14 if and when a dispute arises under this Agreement. In the event of any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement, including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, then upon the request of either Party, the Parties agree to meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting between the chief executive officers of each Party; provided that, each Party agrees that any statute of limitation or survival period with respect to such dispute shall be tolled during such discussions. If the matter is not resolved within *** following the request for discussions, either Party may then invoke the provisions of Section 14.2.

14.2 **Arbitration.** Any dispute, controversy or claim arising out of or relating to the validity, construction, interpretation, enforceability, breach, performance, application or termination of this Agreement that is not resolved pursuant to Section 14.1, shall be settled by binding arbitration administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures of JAMS then in effect (the "**JAMS Rules**"), except as otherwise provided herein. The arbitration shall be governed by the United States Federal Arbitration Act, 9 U.S.C. §§ 1-16 (the "**Federal Arbitration Act**"), to the exclusion of any inconsistent state laws. The United States Federal Rules of Civil Procedure shall govern discovery and the rules of evidence for the arbitration. The arbitration will be conducted in New York, New York, and the Parties consent to the personal jurisdiction of the United States federal courts, for any case arising out of or otherwise related to this arbitration, its conduct and its enforcement. Any situation not expressly covered by this Agreement shall be decided in accordance with the JAMS Rules.

14.3 **Arbitrator.** The arbitrator shall be one (1) neutral, independent and impartial arbitrator selected from a pool of retired federal judges or magistrates to be presented to the Parties by JAMS.

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Failing the agreement of the Parties as to the selection of the arbitrator within ***, the arbitrator shall be appointed by JAMS in accordance with the JAMS Rules.

14.4 **Decision.** The power of the arbitrator to fashion procedures and remedies within the scope of this Agreement is recognized by the Parties as essential to the success of the arbitration process. The arbitrator shall not have the authority to fashion remedies which would not be available to a federal judge hearing the same dispute. The arbitrator is encouraged to operate on this premise in an effort to reach a fair and just decision. Reasons for the arbitrator's decisions should be set forth in accordance with the JAMS Rules. Such a written decision shall be rendered by the arbitrator following a full comprehensive hearing, no later than *** following the selection of the arbitrator as provided for in Section 14.3.

14.5 **Award.** Any award shall be promptly paid in United States dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by Applicable Law, be charged against the Party resisting enforcement. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Article 14, and agrees that, subject to the Federal Arbitration Act, judgment may be entered upon the final award in any court of competent jurisdiction and that other courts may award full faith and credit to such judgment in order to enforce such award. The award shall include interest from the date of the award until paid in full, at a rate fixed by the arbitrator and the arbitrator may, in his or her discretion, award pre-judgment interest. With respect to money damages, nothing contained herein shall be construed to permit the arbitrator or any court or any other forum to award punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for punitive or exemplary damages, subject to the exceptions set forth in Article 11.

14.6 **Costs.** The arbitrator shall assess his or her costs, fees and expenses against the Party losing the arbitration and shall require such losing Party to reimburse the other Party for all of its reasonable attorneys' fees, costs, and disbursements arising out of the arbitration (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, and so on). Notwithstanding the foregoing, if the arbitrator believes that neither Party is the clear loser, the arbitrator shall divide his or her costs, fees, and expenses according to his or her sole discretion, and each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration.

14.7 **Injunctive Relief.** Provided a Party has made a sufficient showing under the rules and standards set forth in the Federal Rules of Civil Procedure and applicable case law, the arbitrator shall have the freedom to invoke, and the Parties agree to abide by, injunctive measures after either Party submits in writing for arbitration claims requiring immediate relief. Additionally, nothing in this Article 14 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

14.8 **Confidentiality.** The arbitration proceeding shall be confidential and the arbitrator shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required to comply with Applicable Laws, including rules and regulations promulgated by the SEC, The NASDAQ Stock Market or any securities exchanges, no Party shall make (or instruct the arbitrator to make) any public announcement with respect to the proceedings or decision of the arbitrator without prior written consent of the other Party. The existence of any dispute submitted to arbitration, and the award,

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shall be kept in confidence by the Parties and the arbitrator, except as required in connection with the enforcement of such award or as otherwise required by Applicable Law.

14.9 **Survivability.** Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.

15. PRESS RELEASES; USE OF NAMES

15.1 **Press Releases.** The form and content of any public announcement to be made by one Party regarding this Agreement, or the subject matter contained herein, shall be subject to the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned, or delayed), except as may be required by applicable law in which event the Party required to make such announcement shall, to the extent possible, provide to the other Party a written copy of any such required announcement at least *** prior to disclosure to give the other Party reasonable advance notice and review of any such announcement. Notwithstanding the foregoing, either Party may publicly disclose without violation of this Agreement, such terms of this Agreement as are, on the advice of such Party's counsel, required by the rules and regulations of the SEC or any other applicable entity having regulatory authority over such Party's securities; provided that such Party shall advise Purchaser of such intended disclosures and requests confidential treatment of certain commercial terms and technical terms hereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, such Party will provide the other Party, a reasonable time prior to filing, with a copy of the Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements applicable to such Party and that govern redaction of information from material agreements that must be publicly filed. The other Party shall provide any such comments as promptly as practicable. The intention of the Parties is to agree upon a single redacted version of the Agreement to be filed with the SEC or any other applicable entity.

15.2 **Use of Names.** Except as otherwise required by law or by the terms of this Agreement or the License Agreement, or as mutually agreed upon by the Parties, neither Party shall make any use of the name of the other Party in any advertising or promotional material, or otherwise, without the prior written consent of the other Party, which consent shall not be unreasonably withheld.

16. MISCELLANEOUS

16.1 **Entire Agreement; Amendment.** This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof, including, the Existing Confidentiality Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations pursuant the Existing Confidentiality Agreement. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

16.2 **Relationship of the Parties.** The relationship between VIVUS and Purchaser is that of independent contractors and nothing herein shall be deemed to constitute the relationship of partners, joint

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venturers, or principal and agent between VIVUS and Purchaser. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement, or undertaking with any Third Party.

16.3 **Force Majeure.** Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party.

16.4 **Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 16.4, and shall be deemed to have been given for all purposes when received, if hand-delivered or by means of facsimile or other electronic transmission, or one (1) Business Day after being sent by a reputable overnight delivery service.

If to VIVUS: VIVUS, Inc.
351 E. Evelyn Avenue
Mountain View, CA 94041
Attention: General Counsel
Fax: (650) 934-5320

With a copy to: Hogan Lovells US LLP
525 University Avenue
3rd Floor
Palo Alto, CA 94301
Attention: Shane Albright, Partner
Fax: (650) 463-4199

If to Purchaser: Auxilium Pharmaceuticals, Inc.
640 Lee Road
Chesterbrook, Pennsylvania 19087
Attention: Adrian Adams, Chief Executive Officer
Attention: Andrew I. Koven, Chief Administrative
Officer & General Counsel
Fax: 1-484-321-5996

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With a copy to: Holland & Knight LLP
701 Brickell Avenue, Suite 3000
Miami, FL 33131
Attention: Rodney H. Bell
Fax: (305) 789-7799

16.5 **No Strict Construction; Headings; Interpretation.** This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. The definitions of the terms herein apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The words “include”, “includes” and “including” will be deemed to be followed by the phrase “without limitation.” Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any laws herein will be construed as referring to such laws and any rules or regulations promulgated thereunder as from time to time enacted, repealed or amended, (c) any reference herein to any person will be construed to include the person’s successors and assigns, (d) the words “herein”, “hereof” and “hereunder”, and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) any reference herein to the words “mutually agree” or “mutual written agreement” will not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as such Party may

determine in such Party's sole discretion, except as expressly provided in this Agreement, (f) as applied to a Party, the word "will" shall be construed to have the same meaning and effect as the word "shall," and (g) all references herein without a reference to any other agreement to Articles, Sections, or Exhibits will be construed to refer to Articles, Sections, and Exhibits of or to this Agreement.

16.6 **Assignment.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment without the other Party's consent to such Party's Affiliate or to a successor to all or substantially all of the assets or business of such Party to which this Agreement pertains. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16.6 shall be null, void and of no legal effect.

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

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16.8 **Successors and Assigns; No Third Party Beneficiaries.** This Agreement will be binding upon and inure to the benefit of the Parties and their successors and permitted assigns. No provision of this Agreement, express or implied, is intended to or will be deemed to confer upon Third Parties any right, benefit, remedy, claim, liability, reimbursement, claim of action or other right of any nature whatsoever under or by reason of this Agreement other than the Parties and, to the extent provided in Sections 10.1 and 10.2, the Indemnified Parties. Without limitation of the foregoing, this Agreement will not be construed so as to grant employees of either Party in any country any rights against the other Party pursuant to the laws of such country.

16.9 **Performance by Affiliates and/or Subcontractors.** Any obligation of VIVUS under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at VIVUS's sole and exclusive option, either by VIVUS directly or by any Affiliate or Third Party that VIVUS causes to satisfy, meet or fulfill such obligation, in whole or in part. Any obligation of Purchaser under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at Purchaser's sole and exclusive option, either by Purchaser directly or by any Affiliate of Purchaser or Third Party that Purchaser causes to satisfy, meet or fulfill such obligation, in whole or in part. Each of the Parties guarantees the performance of all actions, agreements and obligations to be performed by any Affiliates of such Party or a Third Party under the terms and conditions of this Agreement, and shall cause its Affiliates or such Third Party to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

16.10 **Counterparts.** This Agreement may be executed in one (1) or more counterparts, including by facsimile or other electronic transmission, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Signature page follows]

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed as of the date first above written.

AUXILIUM PHARMACEUTICALS, INC.

By:	<u>/s/ Adrian Adams</u>
Name:	<u>Adrian Adams</u>
Title:	<u>CEO & President</u>
Date:	<u>10/10/13</u>

VIVUS, INC.

By:	<u>/s/ John L. Slebir</u>
Name:	<u>John L. Slebir</u>
Title:	<u>Vice President, General Counsel</u>
Date:	<u>10/10/13</u>

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EXHIBIT A
Specifications

*** 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 B
Manufacturing Cost for Product Manufactured by MTPC

For Product manufactured by MTPC, the Manufacturing Cost shall be equal to the *** of (a) or (b) below:

- (a) A fixed cost for each dosage form of the Product (the “**Fixed Manufacturing Cost**”) as follows:

<u>Dosage forms</u>	<u>Fixed Manufacturing Cost (per tablet)</u>
50mg tablet	US\$***
100mg tablet	US\$***
200mg tablet	US\$***

- (b) A cost per Product tablet for each dosage form calculated based on a percentage of *** total MTPC Agreement Net Sales in the Purchaser Territory according to the following (the “**Net Sales Manufacturing Cost**”):

<u>Annual Total MTPC Agreement Net Sales in the Purchaser Territory</u>	<u>Net Sales Manufacturing Cost (per tablet)</u>
Portion up to US\$***	***% of the MTPC Agreement Net Sales divided by the quantity of each dosage forms of the Product for commercial sales during such ***
Portion above US\$*** but less than or equal to \$***	***% of the MTPC Agreement Net Sales divided by the quantity of each dosage forms of the Product for commercial sales during such ***
Portion in excess of US\$***	***% of the MTPC Agreement Net Sales divided by the quantity of each dosage forms of the Product for commercial sales during such ***

The Manufacturing Cost for Product manufactured by MTPC shall initially be set at the Fixed Manufacturing Cost, and the Price for Product hereunder will be calculated and invoiced to Purchaser based on such Fixed Manufacturing Cost. In the event the Net Sales Manufacturing Cost in a *** per bulk tablet of Product is *** than the Fixed Manufacturing Cost per bulk tablet of Product, Manufacturing Cost for Product sold by Purchaser, its Affiliates, or its sublicensees to Third Parties during such *** shall automatically be adjusted *** to account for the difference between such costs (the “**Manufacturing Cost Adjustment**”). The formula for calculation of such Manufacturing Cost Adjustment is as follows:

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“**Manufacturing Cost Adjustment**” = ***.

No later than *** after the end of each ***, VIVUS shall notify Purchaser whether there is a Manufacturing Cost Adjustment with respect to such *** and if there is such a Manufacturing Cost Adjustment, shall invoice Purchaser for Product sold during such *** at a new Price calculated based on the Manufacturing Cost Adjustment, net of payments already made by Purchaser for such Product.

After transition of manufacturing from MTPC to the New Third Party Manufacturer, it is anticipated that there will be a final reconciliation between MTPC and VIVUS pursuant to Section 11.6(a) of the MTPC Agreement to ensure the accuracy of all amounts paid by VIVUS to MTPC for manufacture of Product. To the extent that this final reconciliation results in any payments by or refunds to VIVUS in respect of Product manufactured by MTPC and ultimately sold to Purchaser hereunder, the Manufacturing Cost and Price for such Product shall be appropriately re-calculated hereunder, and appropriate payments to VIVUS shall be made (or appropriate credits to Purchaser shall be issued, as the case may be).

Purchaser acknowledges that the Manufacturing Cost specified above may need to be modified in order to maintain consistency between this Agreement and the MTPC Agreement if the price charged by MTPC to VIVUS for Product changes, it being understood that (a) such price will not *** prior to ***; (b) after such date such price can only *** if MTPC’s Manufacturing Cost for the Product *** percent (***) of the Fixed Manufacturing Cost above, provided that MTPC provides reasonable and customary evidence of such *** and that MTPC and VIVUS have negotiated the price *** in good faith; and (c) any such change that would result in *** will require ***.

Additionally, for the avoidance of doubt, the Manufacturing Cost specified above only applies to Product manufactured by MTPC and will need to be modified in order to maintain consistency between this Agreement and the agreement under which the New Third Party Manufacturer manufactures and supplies Product; provided, however, that the Manufacturing Cost for a New Third Party Manufacturer shall in no event be greater than ***.

As used in this Exhibit B, the following initially capitalized term(s), whether used in the singular or plural form, shall have the meanings set forth below:

“**MTPC’s Manufacturing Cost**” means MANUFACTURING COST (as defined in the MTPC Agreement).

“**MTPC Agreement Net Sales**” means NET SALES (as defined in the MTPC Agreement).

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EXHIBIT C
Minimum Purchase Obligations

Calendar Year	Minimum Purchase Obligation
***	*** ⁽¹⁾
***	***
***	***
***	***

(1) ***

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EXHIBIT D
Current Inventory

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Schedule 2.5(b)
Order of Current Inventory

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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: November 7, 2013

By: /s/ SETH H. Z. FISCHER

Seth H. Z. Fischer

Chief Executive Officer

CERTIFICATION

I, Svai Sanford, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VIVUS, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2013

By: /s/ SVAI SANFORD

Svai Sanford

Chief Financial Officer

**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 September 30, 2013 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: November 7, 2013

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

I, Svai Sanford, Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended September 30, 2013 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: November 7, 2013

By: /s/ SVAI SANFORD
Svai Sanford
