# 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 June 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** | **94-3136179** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (IRS employer identification number) |
| **351 East Evelyn Avenue Mountain View, California** | **94041** |
| (Address of principal executive office) | (Zip Code) |

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

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

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

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 x No o

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 x | Accelerated filer o |
| Non-accelerated filer o (Do not check if a smaller reporting company) | Smaller reporting company o |

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

At July 29, 2013, 100,853,007 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)**

| | June 30, 2013 (Unaudited) | December 31, 2012 Note 1 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 124,713 | $ 58,605 |
| Available-for-sale securities | 233,542 | 155,981 |
| Accounts receivable, net | 5,085 | 2,778 |
| Inventories | 34,217 | 25,353 |
| Prepaid expenses and other assets | 18,338 | 19,159 |
| Total current assets | 415,895 | 261,876 |
| Property and equipment, net | 3,329 | 1,951 |
| Non-current assets | 7,788 | 287 |
| Total assets | $ 427,012 | $ 264,114 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 16,777 | $ 25,375 |
| Accrued and other liabilities | 16,047 | 14,680 |
| Deferred revenue | 2,846 | 1,150 |
| Total current liabilities | 35,670 | 41,205 |
| Long term debt | 206,220 | — |
| Total liabilities | 241,890 | 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; 100,853 and 100,659 shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively | 101 | 101 |
| Additional paid-in capital | 780,281 | 708,921 |
| Accumulated other comprehensive (loss) income | (26) | 33 |
| Accumulated deficit | (595,234) | (486,146) |
| Total stockholders' equity | 185,122 | 222,909 |
| Total liabilities and stockholders' equity | $ 427,012 | $ 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2013 | 2012 | 2013 | 2012 |
| Revenue: | | | | |
| Net product revenue | $ 5,534 | $ — | $ 9,646 | $ — |
| Operating expenses: | | | | |
| Cost of goods sold | 572 | — | 962 | — |
| Inventory impairment and commitment fee | 4,448 | — | 10,225 | — |
| Research and development | 9,232 | 8,873 | 16,278 | 15,007 |
| Selling, general and administrative | 42,727 | 15,444 | 87,423 | 28,082 |
| Total operating expenses | 56,979 | 24,317 | 114,888 | 43,089 |
| Loss from operations | (51,445) | (24,317) | (105,242) | (43,089) |
| Interest and other income (expense): | | | | |
| Interest and other income (expense), net | (71) | 56 | (36) | 74 |
| Interest expense | (4,112) | (2) | (4,112) | (3) |
| Total interest and other income (expense) | (4,183) | 54 | (4,148) | 71 |
| Loss from continuing operations before income taxes | (55,628) | (24,263) | (109,390) | (43,018) |
| Provision for income taxes | (7) | (3) | (13) | (10) |
| Loss from continuing operations | (55,635) | (24,266) | (109,403) | (43,028) |
| Income from discontinued operations, net of tax | 123 | 218 | 315 | 202 |
| Net loss | $ (55,512) | $ (24,048) | $ (109,088) | $ (42,826) |
| Basic and diluted net loss per share: | | | | |
| Continuing operations | $ (0.55) | $ (0.24) | $ (1.08) | $ (0.45) |
| Discontinued operations | 0.00 | 0.00 | 0.00 | 0.00 |
| Net loss per share | $ (0.55) | $ (0.24) | $ (1.08) | $ (0.45) |
| Shares used in per share computation: | | | | |
| Basic and diluted | 100,739 | 99,777 | 100,700 | 96,022 |

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**(In thousands)**
**(Unaudited)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2013 | 2012 | 2013 | 2012 |
| Net loss | $ (55,512) | $ (24,048) | $ (109,088) | $ (42,826) |
| Other comprehensive (loss) income: | | | | |
| Unrealized loss on securities, net of taxes | (40) | (6) | (59) | (38) |
| Comprehensive loss | $ (55,552) | $ (24,054) | $ (109,147) | $ (42,864) |

See accompanying notes to unaudited condensed consolidated financial statements.





**VIVUS, INC.**

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

| | Six Months Ended June 30, | |
|---|---|---|
| | 2013 | 2012 |
| **Cash flows from operating activities**: | | |
| Net loss from continuing operations | $ (109,403) | $ (43,028) |
| Adjustments to reconcile net loss to net cash used for operating activities from continuing operations: | | |
| Provision for cash discounts | 262 | — |

| | | |
|---|---|---|
| Depreciation | 419 | 54 |
| Amortization of debt issuance costs and discounts | 1,659 | — |
| Amortization of discount or premium on available-for-sale securities | 998 | 1,968 |
| Share-based compensation expense | 11,961 | 6,242 |
| Loss on disposal of property and equipment | 105 | — |
| Inventory impairment | 7,525 | — |
| Changes in assets and liabilities: | | |
| Accounts receivable | (2,569) | — |
| Inventories | (16,022) | (323) |
| Prepaid expenses and other assets | 821 | (6,052) |
| Accounts payable | (8,762) | 3,306 |
| Accrued and other liabilities | 1,390 | 1,286 |
| Deferred revenue | 1,696 | — |
| Net cash used for operating activities from continuing operations | (109,920) | (36,547) |
| Net cash used for operating activities from discontinued operations | (410) | (539) |
| Net cash used for operating activities | (110,330) | (37,086) |
| | | |
| **Cash flows from investing activities**: | | |
| Property and equipment purchases | (1,845) | (146) |
| Purchases of available-for-sale securities | (209,118) | (181,810) |
| Proceeds from sales and maturities of available-for-sale securities | 130,500 | 57,635 |
| Non-current assets | (228) | — |
| Net cash used for investing activities | (80,691) | (124,321) |
| | | |
| **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 | 1,083 | 10,671 |
| 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 | 257,129 | 202,793 |
| | | |
| **Net increase in cash and cash equivalents** | 66,108 | 41,386 |
| **Cash and cash equivalents**: | | |
| Beginning of period | 58,605 | 39,554 |
| End of period | $ 124,713 | $ 80,940 |

See accompanying notes to unaudited condensed consolidated financial statements.



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**VIVUS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 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 six months ended June 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 June 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 12. 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.

*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 six months ended June 30, 2013, as compared to the recent accounting pronouncements described in the Company's Form 10-K for the year ended December 31, 2012, that are of significance, or potential significance to the Company.

## 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2013 | 2012 | 2013 | 2012 |
| Research and development | $ 944 | $ 739 | $ 1,879 | $ 1,465 |
| Selling, general and administrative | 4,960 | 2,785 | 10,082 | 4,777 |
| Share-based compensation expense | $ 5,904 | $ 3,524 | $ 11,961 | $ 6,242 |

Total share-based compensation cost capitalized as part of the cost of inventory is $187,000 and $367,000 for the three and six months ended June 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 June 30, 2013 and December 31, 2012 are presented in the tables that follow.

As of June 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 | $ 124,713 | $ — | $ — | $ 124,713 |
| U.S. Treasury securities | 233,568 | 14 | (40) | 233,542 |
| Total | 358,281 | 14 | (40) | 358,255 |
| Less amounts classified as cash equivalents | (124,713) | — | — | (124,713) |
| Total available-for-sale securities | $ 233,568 | $ 14 | $ (40) | $ 233,542 |

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 | $ 155,948 | $ 33 | $ — | $ 155,981 |



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4. FAIR VALUE MEASUREMENTS

The Company defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The Company's valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect the Company's market assumptions. The Company classifies these inputs into the following hierarchy:

*Level 1 Inputs*— Quoted prices for identical instruments in active markets.

*Level 2 Inputs*— Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

*Level 3 Inputs*— Unobservable inputs and little, if any, market activity for the assets.

The Company's available-for-sale securities are measured at fair value on a recurring basis while the Company's Convertible Notes are not measured at fair value on a recurring basis. The estimated fair values were as follows:

| | Estimated Fair Value Measurements at Reporting Date Using | | | |
|---|---|---|---|---|
| Types of Instruments (in thousands) | Quoted Prices in Active Markets for Identical Assets Level 1 | Significant Other Observable Inputs Level 2 | Significant Unobservable Inputs Level 3 | Total |
| *Cash and cash equivalents and available-for-sale securities at June 30, 2013:* | | | | |
| Cash and money market funds | $ 124,713 | $ — | $ — | $ 124,713 |
| U.S. Treasury securities | 233,542 | — | — | 233,542 |
| Total | 358,255 | — | — | 358,255 |
| Less amounts classified as cash equivalents | (124,713) | — | — | (124,713) |
| Total available-for-sale securities | $ 233,542 | $ — | $ — | $ 233,542 |
| *Cash and cash equivalents and available-for-sale securities at December 31, 2012:* | | | | |
| Cash and money market funds | $ 58,605 | $ — | $ — | $ 58,605 |
| U.S. Treasury securities | 155,981 | — | — | 155,981 |
| Total | 214,586 | — | — | 214,586 |
| Less amounts classified as cash equivalents | (58,605) | — | — | (58,605) |
| Total available-for-sale securities | $ 155,981 | $ — | $ — | $ 155,981 |

As of June 30, 2013, the Company's available-for-sale securities have original contractual maturity up to 18 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.



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5. INVENTORIES

Inventories consist of (in thousands):

| | Balance as of | |
|---|---|---|
| | June 30, 2013 | December 31, 2012 |
| Raw materials | $ 19,890 | $ 5,139 |
| Work in process | 1,015 | 2,635 |
| Finished goods | 13,099 | 17,506 |
| Deferred costs | 213 | 73 |
| Total | $ 34,217 | $ 25,353 |

As of June 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 three and six months ended June 30, 2013, the Company recognized a total charge of $4.4 million and $10.2 million, respectively, for inventories on hand in excess of demand, plus a purchase commitment fee.

6. PREPAID EXPENSES AND OTHER ASSETS

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

| | Balance as of | |
|---|---|---|
| | June 30, 2013 | December 31, 2012 |
| Prepaid insurance | $ 3,220 | $ 6,979 |
| Prepaid sales and marketing expenses | 6,139 | 5,735 |
| Prepaid medical affairs expenses | 3,965 | 1,782 |
| Manufacturing capacity commitment fees | 1,131 | 2,300 |
| Other prepaid expenses and assets | 3,883 | 2,363 |
| Total | $ 18,338 | $ 19,159 |

The amounts included in prepaid expenses and other assets consist primarily of prepaid insurance, and 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, and manufacturing capacity commitment fees. 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.

7. NON-CURRENT ASSETS

Non-current assets consist of (in thousands):

| | Balance as of | |
|---|---|---|
| | June 30, 2013 | December 31, 2012 |
| Debt issuance costs | $ 6,464 | $ — |
| Other non-current assets | 1,324 | 287 |
| Total | $ 7,788 | $ 287 |

The amounts included in non-current assets consist of debt issuance costs relating to the Convertible Notes and the Senior Secured Notes Due 2018, 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.



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8. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities consist of (in thousands):

| | Balance as of | |
|---|---|---|
| | June 30, 2013 | December 31, 2012 |
| Accrued employee compensation and benefits | $ 5,655 | $ 3,859 |
| Accrued manufacturing costs | 470 | 4,135 |
| Accrued sales and marketing expenses | 2,641 | 2,908 |
| Accrued interest on debt (see Note 9) | 2,446 | — |
| Accrued research and clinical expenses | 1,804 | 1,372 |
| Other accrued liabilities | 2,853 | 1,503 |
| Liabilities of discontinued operations | 178 | 903 |
| Total | $ 16,047 | $ 14,680 |

The amounts included in accrued and other liabilities consist of obligations for past services, primarily related to 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 employee compensation and benefits, accrued interest on debt, and accrued research and clinical expenses.

9. 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. 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 $2.5 million was recognized during the three and six month periods ended June 30, 2013, which includes $1.5 million of amortization of the debt discount. The remaining expected life of the Convertible Notes at June 30, 2013 is 5.4 years. As of June 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 our 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 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 is 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 $1.5 million during the three and six month periods ended June 30, 2013.

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:

| | June 30, 2013 |
|---|---|
| **Convertible Senior Notes due 2020:** | |
| Fair value of the liability component | $ 154,738 |
| Accumulated accretion of discount | 1,482 |
| Net carrying value | $ 156,220 |
| **Senior Secured Notes due 2018:** | |
| Carrying value | $ 50,000 |
| **Total Notes:** | |
| Fair value of the liability component | $ 204,738 |
| Accumulated accretion of discount | 1,482 |
| Net carrying amount | $ 206,220 |

10. 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 9, 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 six months ended June 30, 2013 and June 30, 2012, all potential common equivalent shares were excluded for these periods as they were anti-dilutive. For the three months ended June 30, 2013 and June 30, 2012, 6,122,000 and 4,291,000 options outstanding, respectively, were not included in the computation of diluted net loss per share because the effect would be anti-dilutive. For the six months ended June 30, 2013 and June 30, 2012, 5,789,000 and 4,039,000 options outstanding, respectively, were not included in the computation of diluted net loss per share because the effect would be anti-dilutive.

11. 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 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.



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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.

*Proxy Related Lawsuit*

On July 16, 2013, First Manhattan Co., or 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 First Manhattan has advised the Company are approximately $3.5 million.

12. SUBSEQUENT EVENTS

*Commercial Supply Agreement*

On July 31, 2013, the Company entered into a commercial supply agreement, or the Commercial Supply Agreement, with Sanofi Chimie, a wholly owned subsidiary of Sanofi. Under the terms of the Commercial Supply Agreement, Sanofi Chimie will 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 and Latin America. Each year, the Company must purchase a minimum quantity of API from Sanofi Chimie.

The Supply Agreement has an initial five year term commencing on January 1, 2014 and will auto-renew for additional two year periods unless either party makes a timely election not to renew. Either party may terminate the Supply Agreement for the other party's uncured material breach or bankruptcy or in the event of a persistent force majeure event.

*License and Commercialization Agreement*

On July 5, 2013, the Company entered into a license and commercialization agreement, or the License Agreement, and a commercial supply agreement, or the Supply Agreement, with the Menarini Group through its subsidiary Berlin-Chemie AG, or Menarini.

Under the terms of the License Agreement, Menarini received an exclusive license to commercialize and promote the Company's drug SPEDRA™ (avanafil) for the treatment of erectile dysfunction in over 40 European countries, plus Australia and New Zealand. Additionally, the Company has agreed to transfer to Menarini ownership of the European Union marketing authorization for SPEDRA for the treatment of erectile dysfunction, which was granted by the European Commission in June 2013. Each party agreed not to develop, commercialize, or in-license any other product that operates as a phosphodiesterase type-5 inhibitor for the treatment of erectile dysfunction for a limited time period, subject to certain exceptions.

Per the terms of the License Agreement, the Company will receive upfront payments and various approval and sales milestones, plus royalties on SPEDRA sales. Within the first year, the Company expects to receive approximately €39 million including upfront payments totaling €16 million. Menarini will also reimburse the Company for payments made to cover various





obligations to Mitsubishi Tanabe Pharma Corporation, or MTPC, during the term of the License Agreement. The License Agreement will terminate on a country-by-country basis in the relevant territories upon the latest to occur of the following: the expiration of the last-to-expire valid Company patent covering SPEDRA; the expiration of data protection covering SPEDRA; or ten (10) years after the SPEDRA product launch. In addition, Menarini may terminate the License Agreement if certain additional regulatory obligations are imposed on SPEDRA, including if Menarini challenges the Company's patents covering SPEDRA or if Menarini commits certain legal violations. Either party may terminate the License Agreement for the other party's uncured material breach or bankruptcy.

Under the terms of the Supply Agreement, the Company will supply Menarini with STENDRA drug product until December 31, 2018 at the latest. Menarini also has the right to manufacture STENDRA independently, provided that it continues to satisfy certain minimum purchase obligations to the Company. Following the expiration of the Supply Agreement, Menarini will be responsible for its own supply of 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.

*Settlement Agreement*

On July 18, 2013, the Company entered into a Settlement Agreement with First Manhattan terminating the pending proxy contest with respect to the election of the Company's board of directors, or the Board, at the Company's 2013 annual meeting of stockholders, or the Annual Meeting.

Pursuant to the Settlement Agreement, the Company, among other things, reconstituted the Board with the following individuals: Michael James Astrue, J. Martin Carroll, Samuel F. Colin, M.D., Alexander J. Denner, Ph.D., Johannes J.P. Kastelein, Mark B. Logan, David York Norton, Jorge Plutzky, M.D., Herman Rosenman and Robert N. Wilson. In connection therewith, Charles J. Casamento, Ernest Mario, Ph.D., Linda M. Dairiki Shortliffe, M.D., Peter Y. Tam, and Leland F. Wilson resigned as directors of the Company.

Also in connection with the Settlement Agreement, Leland Wilson resigned as Chief Executive Officer of the Company. On July 22, 2013, the reconstituted Board appointed Anthony P. Zook to serve as Chief Executive Officer. On July 25, 2013, Mr. Zook was also appointed to the Board as the eleventh member of the reconstituted Board.

In connection with the Settlement Agreement, the Board has authorized the reimbursement of approximately $3.5 million to First Manhattan of expenses incurred by First Manhattan in connection with its proxy solicitation.

*New Chief Executive Officer*

On July 25, 2013, the Company's Compensation Committee granted Mr. Zook a stock option to purchase 1,000,000 shares of the Company's common stock, of which one-third of the shares subject to the option shall vest on the first anniversary of the date of grant, and 1/36th of the total number of shares subject to the option shall vest each month thereafter, subject to Mr. Zook's continued services to the Company on such dates. The stock option has an exercise price of $13.70 per share and a seven year term from the date of grant.



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

This Management's Discussion and Analysis of Financial 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 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, for the Marketing Authorization Application, or MAA, for Qsymia; (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; (14) our ability to ensure that the entire supply chain for Qsymia efficiently and consistently delivers Qsymia to our customers; (15) our ability to successfully complete our STENDRA™ partnering discussions on acceptable terms and on a timely basis; (16) risks and uncertainties related to the launch and commercialization of SPEDRA in the EU, plus Australia and New Zealand, by Menarini Group through its subsidiary Berlin-Chemie AG, or Menarini; (17) the timing of the qualification and subsequent approval by regulatory authorities of Sanofi Chimie as a qualified supplier of STENDRA/SPEDRA™ and Sanofi Chimie's ability to undertake worldwide manufacturing of the avanafil active pharmaceutical ingredient, or API; (18) whether the FDA and/or EMA will approve the amendments we intend to submit to include the recently announced study results showing avanafil (STENDRA/SPEDRA) is effective for sexual activity within 15 minutes in men with ED; (19) the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand; (20) our history of losses and variable quarterly results; (21) substantial competition; (22) risks related to the failure to protect our intellectual property and litigation in which we may become involved; (23) uncertainties of government or third-party payor reimbursement; (24) our reliance on sole source suppliers; (25) our reliance on third parties and our collaborative partners; (26) our failure to continue to develop innovative investigational drug candidates and drugs; (27) risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; (28) our ability to demonstrate through clinical testing the safety and effectiveness of our investigational drug candidates; (29) the timing of initiation and completion of clinical trials and submissions to foreign authorities; (30) the results of post-marketing studies are not favorable; (31) compliance with post-marketing regulatory standards is not maintained; (32) the volatility and liquidity of the financial markets; (33) our liquidity and capital resources; (34) our expected future revenues, operations and expenditures (35) potential change in our business strategy to enhance long term stockholder value; and (36) 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 six months ended June 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 pharmaceutical 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 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, the number of retail pharmacies through which Qsymia is available is approaching 10,000 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 second half of 2013. In addition, Qsymia continues to be available through a certified home delivery pharmacy network for patients who prefer to receive Qsymia by mail.



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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 late 2013.

In October 2012, we received the formal opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use, or CHMP, recommending against approval of the Marketing Authorization Application, or MAA, for Qsiva (the approved tradename 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. We are currently exploring options to seek centralized approval of Qsiva in the EU. 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, was approved by the FDA on April 27, 2012, for the treatment of erectile dysfunction, or ED, in the United States. 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 tradename 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. Avanafil is an oral PDE5 inhibitor that we have licensed from MTPC. We are currently in discussions with potential collaboration partners to market and sell STENDRA in the United States.

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**

*Commercial Supply Agreement*

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 and Latin America. We had entered into a technology transfer agreement earlier in the year with Sanofi Chimie and have been actively working on the transfer of the avanafil API manufacturing process since that time. Pending the completion of the transfer, we intend to submit an amendment to the NDA for avanafil to the FDA and to the MAA for avanafil to the EMA to include Sanofi Chimie as a qualified supplier of the avanafil API. The qualification and subsequent review for approval by regulatory authorities is expected to be completed no later than June 30, 2015. MTPC will continue to supply avanafil tablets until Sanofi Chimie is approved as a manufacturer by the regulatory authorities.

*Settlement Agreement*

On July 18, 2013, we entered into a Settlement Agreement with First Manhattan terminating the pending proxy contest with respect to the election of our board of directors, or the Board, at our 2013 annual meeting of stockholders, or the Annual Meeting.

Pursuant to the Settlement Agreement, we, among other things, reconstituted the Board with the following individuals: Michael James Astrue, J. Martin Carroll, Samuel F. Colin, M.D., Alexander J. Denner, Ph.D., Johannes J.P. Kastelein, Mark B. Logan, David York Norton, Jorge Plutzky, M.D., Herman Rosenman and Robert N. Wilson. In connection therewith, Charles J. Casamento, Ernest Mario, Ph.D., Linda M. Dairiki Shortliffe, M.D., Peter Y. Tam and Leland F. Wilson resigned as directors of the Company. Also in connection with the Settlement Agreement, Leland Wilson resigned as Chief Executive Officer.

On July 22, 2013, the reconstituted Board appointed Anthony P. Zook to serve as Chief Executive Officer. On July 25, 2013, Mr. Zook was also appointed to the Board as the eleventh member of the reconstituted Board.

Mr. Zook and our Board are engaging in a review of the Company's business strategy to enhance long-term stockholder value. This review process may lead to a reevaluation of, or changes to, our current plans.



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*License and Commercialization Agreement and Supply Agreement*

As aforementioned, on July 5, 2013, we entered into a License and Commercialization Agreement and a Supply Agreement with Menarini to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, plus Australia and New Zealand. Under the agreement, we will receive an upfront payment and various approval and sales milestones plus royalties on SPEDRA sales. Within the first year, we expect to receive approximately €39 million, including upfront payments totaling €16 million. Under the agreement, Menarini will also reimburse us for payments made to cover various obligations to MTPC during the term of the agreement. We are eligible to receive up to €79 million in milestones and other payments over the life of the agreement in addition to royalties. The agreement will continue on a country-by-country basis in 40 European countries, plus Australia and New Zealand, until the latest of: expiration of the last-to-expire valid VIVUS patent covering SPEDRA; data protection covering SPEDRA; or ten (10) years after the SPEDRA product launch. VIVUS and Menarini also entered into a supply agreement whereby VIVUS will supply Menarini with commercial product.

*Avanafil Study Results*

On June 19, 2013, we announced study results showing avanafil is effective for sexual activity within 15 minutes in men with ED. 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. We intend to submit the data from this successful placebo-controlled study to regulatory authorities to support a request to the FDA and EMA to amend the STENDRA and SPEDRA labels, respectively, to include a 15-minute efficacy claim. We also intend to submit the results to peer review journals and medical societal meetings for presentations.

*Convertible Note Offering*

On May 21, 2013, we 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 us 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.

**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;
- establishing medical obesity treatment as a widely accepted, chronic category supported by treatment guidelines; and
- entering into and supporting a collaboration agreement for the commercialization of STENDRA for the treatment of ED in the U.S.



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**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, 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.

*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 $358.3 million at June 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 9 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 six months ended June 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 quarter ended June 30, 2013, we reported a net loss of $55.5 million, or $0.55 net loss per share, as compared to a net loss of $24.0 million, or $0.24 net loss per share during the same period in 2012. The increased net loss in the quarter ended June 30, 2013, as compared to the quarter ended June 30, 2012, is primarily attributable to increased selling, general and administrative expenses related to commercialization activities for Qsymia. Included in the net loss for the quarter ended June 30, 2013 were $2.8 million related to the proxy contest in connection with our Annual Meeting that was settled on July 18, 2013 and a total charge of $4.4 million in inventories on hand in excess of demand, plus a purchase commitment fee due to the manufacturer of Qsymia.

We may have continued losses in future periods, depending on our success in commercializing Qsymia and STENDRA, the timing of our research and development expenditures, and our continued investment in the clinical development of our current research and investigational drug candidates, to bring those potential drugs to market.

***Continuing operations***

*Net product revenue*

Net product revenue was $5.5 million and $9.6 million for the three and six months ended June 30, 2013, respectively. As Qsymia was not approved until July 2012, we had no net product revenue from continuing operations for the three and six months ended June 30, 2012. In September 2012, we began distributing Qsymia to the certified home delivery pharmacies in our network. During the three and six months ended June 30, 2013, we recognized revenue for Qsymia based upon prescription sell-through by our certified home delivery pharmacy services networks to patients as we did not have sufficient historical information to reliably estimate returns.

At June 30, 2013, we have deferred revenue of $2.8 million, which represents Qsymia product shipped to our certified home delivery pharmacy services networks, wholesalers and certified retail pharmacies in preparation for the retail launch of Qsymia, but not yet shipped to patients through prescriptions, net of prompt payment discounts.

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, the number of retail pharmacies through which Qsymia is available is approaching 10,000 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 second half of 2013. In addition, Qsymia continues to be available through a certified home delivery pharmacy network for patients who prefer to receive Qsymia by mail.

We expect Qsymia product revenue and prescriptions shipped to patients to increase in the second half of 2013 as we continue the commercialization of Qsymia and the expansion into certified retail pharmacies.

*Cost of goods sold*

Cost of goods sold was $572,000 and $962,000 for the three and six months ended June 30, 2013, respectively, and 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 three and six months ended June 30, 2013, we recognized a total charge of $4.4 million and $10.2 million, respectively, for inventories on hand in excess of demand, plus a purchase commitment fee. 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 June 30, 2013 | 2012 | 2013 vs. 2012 Increase/ (Decrease) | Six Months Ended June 30, 2013 | 2012 | 2013 vs. 2012 Increase/ (Decrease) |
|---|---|---|---|---|---|---|
| | (In thousands, except percentages) | | | | | |
| Qsymia for obesity | $ 2,605 | $ 2,791 | (7)% | $ 3,210 | $ 5,493 | (42)% |
| STENDRA for ED | 3,289 | 3,192 | 3% | 6,227 | 3,831 | 63% |
| Other projects | 109 | 428 | (75)% | 295 | 834 | (65)% |
| Share-based compensation | 944 | 739 | 28% | 1,879 | 1,465 | 28% |
| Overhead costs* | 2,285 | 1,723 | 33% | 4,667 | 3,384 | 38% |
| Total research and development expenses | $ 9,232 | $ 8,873 | 4% | $ 16,278 | $ 15,007 | 8% |

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

The increase in research and development expenses for both the three and six months ended June 30, 2013, as compared to the same periods in 2012, is primarily due to start-up and enrollment costs associated with the post-approval studies for STENDRA, including a corresponding increase in headcount to support these projects.

We anticipate that our research and development expenses for the remainder of 2013 will increase as compared to 2012 as we continue the planning phase of a post-approval cardiovascular outcomes study for Qsymia, known as AQCLAIM. We estimate the study will cost between $150 and $250 million and the study could take as long as five to six years to complete. We are currently reviewing the proposed design of the study to determine the most cost efficient study design that meets the objective of the study, as required by the FDA. There are likely to be additional research and development expenses for other post-approval studies related to STENDRA and Qsymia, and for our investigational drug candidates under development. 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 June 30, 2013 | 2012 | 2013 vs. 2012 Increase | Six Months Ended June 30, 2013 | 2012 | 2013 vs. 2012 Increase |
|---|---|---|---|---|---|---|
| | (In thousands, except percentages) | | | | | |
| Selling and marketing | $ 21,232 | $ 6,066 | 250% | $ 49,845 | $ 11,715 | 325% |
| General and administrative | 21,495 | 9,378 | 129% | 37,578 | 16,367 | 130% |
| Total selling, general and administrative expenses | $ 42,727 | $ 15,444 | 177% | $ 87,423 | $ 28,082 | 211% |

The increase in selling, general and administrative expenses for the three months ended June 30, 2013 is primarily due to increased selling and marketing spending for Qsymia commercialization activities of $15.2 million, including expenses related to the contract sales organization, marketing programs and additional headcount, as compared to the quarter ended June 30, 2012. General administrative spending increased by $12.1 million for the three months ended June 30, 2013 due to increased medical affairs-related expenses of $3.2 million primarily related to Continuing Medical Education, or CME, grants, REMS program and additional headcount; incremental increases in other corporate expenses totaling $6.7 million, primarily proxy contest expense of $2.8 million, product liability insurance, and professional fees; and increased share-based compensation expense (a non-cash expense) of $2.2 million, as compared to the quarter ended June 30, 2012.



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The increase in selling, general and administrative expenses for the six months ended June 30, 2013 is again primarily due to increased selling and marketing spending for Qsymia commercialization activities of $38.1 million, including expenses related to the contract sales organization, marketing programs and additional headcount, as compared to the six months ended June 30, 2012. General administrative spending increased by $21.2 million for the six months ended June 30, 2013 due to increased medical affairs-related expenses of $5.4 million primarily related to CME grants, REMS program and additional headcount; incremental increases in other corporate expenses totaling $10.5 million, including proxy contest expense of $3.5 million, product liability insurance, and professional fees; and increased share-based compensation expense (a non-cash expense) of $5.3 million, as compared to the six

months ended June 30, 2012. Regarding the proxy contest, we expect to incur additional charges for the activity occurring in July 2013, including approximately $3.5 million incurred by First Manhattan Co. as part of the settlement agreement.

*Interest expense*

Interest expense was $4.1 million in both the three and six months ended June 30, 2013, primarily due to interest expense and amortization of issuance costs and discounts from our Convertible Notes and Senior Secured Notes (as defined below) and the amortization of the debt discount on the Convertible Notes.

***Income from discontinued operations***

Income from discontinued operations of $123,000 and $315,000 in the three and six months ended June 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 months and six ended June 30, 2012 was $218,000 and $202,000, respectively.

LIQUIDITY AND CAPITAL RESOURCES

**Continuing Operations**

*Cash.* Cash, cash equivalents and available-for-sale securities (cash) totaled $358.3 million at June 30, 2013, as compared to $214.6 million at December 31, 2012. The increase of $143.7 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.

Since inception, we have financed operations primarily from the issuance of equity, debt and debt-like securities. Through June 30, 2013, we have raised approximately $720.0 million from financing activities, received $150 million from the sale of Evamist, and had an accumulated deficit of $595.2 million at June 30, 2013.

At June 30, 2013, we had $124.7 million in cash and cash equivalents and $233.5 million in available-for-sale securities. We invest our excess cash balances in money market and marketable securities, primarily U.S. Treasury securities and debt securities of U.S. government agencies, in accordance with our investment policy. At June 30, 2013, all of our cash equivalents and available-for-sale securities were invested in either U.S. government securities or money market funds that invest only in U.S. Treasury securities. 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 $241.9 million at June 30, 2013, which is $200.7 million higher than at December 31, 2012, primarily due to the issuances of our Convertible Notes and Senior Secured Notes.

*Operating Activities.* Our operating activities used $110.3 million and $37.1 million in cash during the six months ended June 30, 2013 and 2012, respectively. During the six months ended June 30, 2013, our net operating loss from continuing operations of $109.4 million was offset by $12.0 million in non-cash share-based compensation expense due to increased headcount 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 $16.0 million increase in inventories, primarily for Qsymia, and a decrease in accounts payable of $8.8 million during the first half of 2013 due to the timing of vendor payments.



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During the six months ended June 30, 2012, our net operating loss from continuing operations of $43.0 million was offset by $6.2 million in non-cash share-based compensation expense and a $3.3 million increase in accounts payable. These positive cash flows to our net operating loss were in turn offset by a $6.1 million increase in prepaid expenses and other assets.

*Investing Activities.* Our investing activities used $80.7 million and $124.3 million in cash during the six months ended June 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 cash of $257.1 million and $202.8 million during the six months ended June 30, 2013 and 2012, respectively. In the first six months of 2013, 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 six 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 and STENDRA 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.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs at least for the next twelve months. However, we anticipate that we may require additional funding to 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 current and future investigational drug candidates, finance the costs involved in filing and prosecuting patent applications and enforcing or defending our patent claims, if any, to fund operating expenses, 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 June 30, 2013.



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***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 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 are 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.



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

| | Convertible Notes | Senior Secured Notes | Total |
|---|---|---|---|
| 2013 | $ 5,625 | $ — | $ 5,625 |
| 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 | $ 328,750 | $ 73,700 | $ 402,450 |

## 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 June 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 June 30, 2013 by approximately $1.2 million. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

## 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.



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# 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.

*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 First Manhattan has advised the Company are approximately $3.5 million.



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**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. The implementation of these changes, including our recent appointment of a new Chief Executive Officer and new members of the Board and the potential for additional changes to our management, organizational structure and strategic business plan, may cause speculation and uncertainty regarding our future business strategy and direction. These changes may cause or result in:

- disruption of our business or distraction of our employees and management;
- difficulty in recruiting, hiring, motivating and retaining talented and skilled personnel;
- stock price volatility; and
- difficulty in negotiating, maintaining or consummating business or strategic relationships or transactions.

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

***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.



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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.

***We depend on Menarini to market and sell SPEDRA™ (avanafil) in over 40 European countries, plus Australia and New Zealand.***

On July 5, 2013, we entered into a License and Commercialization Agreement and a 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 Menarini to successfully commercialize SPEDRA in these territories, and there are no assurances that Menarini will be successful in doing so. In general, we cannot control the amount and timing of resources that Menarini devotes to the commercialization of SPEDRA. If Menarini fails to successfully commercialize SPEDRA, our business may be negatively affected. For example, if Menarini does not successfully commercialize SPEDRA, we may receive limited or no revenues under our License and Commercialization Agreement with Menarini. Additionally, because we lack the resources and experience to commercialize SPEDRA ourselves in these territories, we would need to seek a replacement licensee to undertake this commercialization. We may be unable to find another licensee in a timely manner, which could delay or impair our ability to commercialize SPEDRA in these territories.

Under our license agreement with MTPC, we are obligated to ensure that Menarini, as a sublicensee, complies with its terms and conditions. MTPC has the right to terminate our license rights to avanafil in the event of any uncured material breach of the license agreement. Consequently, failure by Menarini 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.

***We intend to market and sell STENDRA™ (avanafil) in the U.S. under a collaboration arrangement with a third party. This arrangement, together with our license with Menarini, might subject us to a number of risks.***

We intend to enter into collaborative arrangements or a strategic alliance with one or more pharmaceutical partners or others to commercialize STENDRA in the U.S. We may be unable to enter into agreements with third parties for STENDRA in the U.S. on favorable terms or at all, which could delay or impair our ability to commercialize STENDRA in the U.S.

Additionally, our dependence on collaborative arrangements or strategic alliances in the U.S. and other territories, including our license with 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;

- 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.



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***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 tradename for Qsymia in the EU) was not approved 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, together with 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;
- 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.



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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 half 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 three and six months ended June 30, 2013, we recognized total charges of $4.4 million and $10.2 million, respectively, for inventories on hand in excess of demand, plus a purchase commitment fee. The inventory impairment charges were based on our analysis of current Qsymia inventory on hand and remaining shelf life, in relation to our projected demand for the product. The current FDA-approved commercial product shelf life for Qsymia is 24 months and for STENDRA is 36 months. We have submitted a request to the FDA to extend the shelf life of Qsymia to 36 months, and we have submitted a similar application 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. 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 extensions of the shelf lives for Qsymia and 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.

***Our failure to manage and maintain our distribution network for Qsymia could compromise the commercialization of this product.***

We rely on Cardinal Health PTS, LLC, 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. We also have entered into agreements with select certified pharmacies, including CVS Pharmacy, Express Scripts, Walgreens, Wal-Mart Pharmacy and Kaiser Permanente, to distribute Qsymia to eligible patients through their certified home delivery networks and have entered into agreements with Walgreens, Costco and Duane Reade to establish a certified retail pharmacy distribution network. Patients and physicians have experienced delays in processing prescriptions in the home delivery network. In addition to providing services to support the distribution and use of Qsymia, each of the pharmacies has agreed to comply with the REMS program certified pharmacy requirements and will provide us with the necessary patient and prescribing physician data. We have contracted with third-party data warehouses to collect this patient and prescribing physician data from the certified pharmacy home delivery network and the certified retail pharmacy network 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.

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, and we rely on these pharmacies to implement a number of safety procedures and report certain information to the third-party data warehouse. Failure to maintain our contracts with Cardinal Health, with the select certified home delivery pharmacies, wholesalers and certified retail pharmacies, or with the third-party data warehouse, or the inability or failure of any of them to adequately perform under the contracts, 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.



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***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 the U.S.

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 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 and Latin America. 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 relationship with 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. Failure 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 MPTC 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.



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***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;
- 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.



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***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 study will cost between $150 and $250 million and the study could take as long as five to six years to complete. We are currently reviewing the proposed design of the study to determine the most cost efficient study design that meets the objective of the study, as required by the FDA. Enrollment in AQCLAIM is expected to begin in the fourth quarter of 2013. There can be no assurance that the FDA will not request or require us to provide additional information or undertake additional prospective studies or retrospective observational studies.

In addition, 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 current and 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 and formulation (extended-release vs. immediate-release) would differ. As a result, Qsymia may be subject to substitution by prescribing physicians 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



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Qsymia, these patents may be ineffective or impractical to prevent physicians from prescribing 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. has announced it plans to launch Trokendi XR, an extended-release pediatric formulation of the generic drug topiramate that is indicated for pediatric epilepsy. Topiramate is not approved for obesity treatment, and phentermine is only approved for short-term treatment of obesity. However, because the price of Qsymia is significantly higher than the prices of the individual components as marketed by other companies, physicians may have a greater incentive to write prescriptions for the individual components outside of their approved indication, instead of for our combination drug, and this may limit how we price or market Qsymia. Similar concerns could also limit the reimbursement amounts private health insurers or government agencies in the U.S. are prepared to pay for Qsymia, which could also limit market and patient acceptance of our drug and could negatively impact our revenues.

In many regions and countries where we may plan to market Qsymia, the pricing of reimbursed prescription drugs is controlled by the government or regulatory agencies. The government or regulatory agencies in these countries could determine that the pricing for Qsymia should be based on prices for its APIs when sold separately, rather than allowing us to market Qsymia at a premium as a new drug.

***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, diabetes and sexual health and medical device companies for the treatment of sleep apnea. Many of these companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. Some of the drugs 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 to be 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 (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. 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.

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 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.



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Our third-party manufacturers and collaborative partners, may encounter delays and problems in manufacturing our investigational drug candidates or approved drugs for a variety of reasons, including accidents during operation, failure of equipment, delays in receiving materials, natural or other disasters, political or governmental changes, or other factors inherent in operating complex manufacturing facilities. Supply chain management is difficult. Commercially available starting materials, reagents, excipients, and other materials may become scarce, more expensive to procure, or not meet quality standards, and we may not be able to obtain favorable terms in agreements with subcontractors. Our third-party manufacturers, may not be able to operate manufacturing facilities in a cost-effective manner or in a time frame that is consistent with our expected future manufacturing needs. If our third-party manufacturers, cease or interrupt production or if our third-party manufacturers and other service providers fail to supply materials, products or services to us for any reason, such interruption could delay progress on our programs, or interrupt the commercial supply, with the potential for additional costs and lost revenues. If this were to occur, we may also need to seek alternative means to fulfill our manufacturing needs.

For example, Catalent Pharma Solutions, LLC, or Catalent, supplied the product for the Phase 3 program for Qsymia and is our sole source of clinical and commercial supplies for Qsymia. Catalent has been successful in validating the commercial manufacturing process for Qsymia 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 Supply Agreement with Menarini, and our ability to enter into a collaboration agreement for the commercialization of STENDRA in the U.S.

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 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 and Latin America. 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 relationship with 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 agreement with Menarini and our ability to enter into a collaboration agreement for the commercialization of STENDRA in the U.S.

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

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



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***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;

- 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 will require 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.



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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 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 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 Supply Agreement with Menarini, and our ability to enter into additional collaboration agreements for the commercialization of STENDRA in the U.S. and other territories outside of the U.S. and EU. 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 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 and Latin America 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 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 agreement with Menarini, and our ability to enter into a collaboration agreement for the commercialization of STENDRA in the U.S.

***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.



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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 investigational drug candidates or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our 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.



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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.

***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 has hindered our Qsymia sales efforts, the nature and extent of which is not yet known. 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.



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**Risks Relating to our Intellectual Property**

***Obtaining intellectual property rights is a complex process, and we may be unable to adequately protect our proprietary technologies.***

We hold various patents and patent applications in the U.S. and abroad targeting obesity and morbidities related to obesity, including sleep apnea and diabetes, and sexual health, among other indications. The procedures for obtaining a patent in the U.S. and in most foreign countries are complex. These procedures require an analysis of the scientific technology related to the invention and many sophisticated legal issues. Consequently, the process for having our pending patent applications issue as patents will be difficult, complex and time consuming. We do not know when, or if, we will obtain additional patents for our technologies, or if the scope of the patents obtained will be sufficient to protect our investigational drug candidates or products, or be considered sufficient by parties reviewing our patent positions pursuant to a potential licensing or financing transaction.

In addition, 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 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.



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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.

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.



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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.

**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 the next twelve months. Should product sales be significantly less than internal expectations, we would need to raise additional capital to support operating activities beyond the next twelve months. However, we anticipate that we will be required to obtain additional financing to fund our commercialization efforts, additional clinical studies for approved products and the development of our research and development pipeline in future periods. Our future capital requirements will depend upon numerous factors, including:

- our ability to expand the use of Qsymia through targeted patient and physician education;
- our ability to find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience on a timely basis;
- our ability to 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 certified home delivery pharmacy network and 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 to successfully commercialize STENDRA in the U.S 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 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 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 June 30, 2013, we had $124.7 million in cash and cash equivalents and $233.5 million in available-for-sale securities. While at June 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 June 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.



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***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. 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. 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.

***We have an accumulated deficit of $595.2 million as of June 30, 2013, and we may continue to incur substantial operating losses for the future.***

We have generated a cumulative net loss of $595.2 million for the period from our inception through June 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 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.



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**Risks Relating to an Investment in our Common Stock**

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

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

- our ability to meet the expectations of investors related to the commercialization of Qsymia and STENDRA;
- our ability to find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience;
- our ability to 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 STENDRA and Qsymia;
- the substantial cost to expand into certified retail pharmacy locations and the cost required to maintain the certified home delivery pharmacy network and REMS program for Qsymia;
- results within the clinical trial programs for Qsymia and STENDRA or other results or decisions affecting the development of our investigational drug candidates;
- announcements of technological innovations or new products by us or our competitors;
- approval of or announcements of other anti-obesity compounds in development;
- publication of generic drug combination weight loss data by outside individuals or companies;
- actual or anticipated fluctuations in our financial results;
- our ability to obtain needed financing;
- sales by insiders or major stockholders;
- economic conditions in the U.S. and abroad;
- the volatility and liquidity of the financial markets;
- comments by or changes in assessments of us or financial estimates by security analysts;
- negative reports by the media or industry analysts on various aspects of our products, our performance and our future operations;
- adverse regulatory actions or decisions;
- any loss of key management;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- discussions about us or our stock price by the financial and scientific press and in online investor communities;
- investment activities employed by short sellers of our common stock;
- developments or disputes concerning patents or other proprietary rights;
- reports of prescription data by us or from independent third parties for our products;
- licensing, product, patent or securities litigation; and
- public concern as to the safety and efficacy of our drugs or future investigational drug candidates developed by us.

These factors and fluctuations, as well as political and other market conditions, may adversely affect the market price of our common stock. Securities related class action litigation is often brought against a company and senior officers following periods of volatility in the market price of its securities. We have been a defendant in shareholder lawsuits—a securities class action against the Company and several senior officers has been dismissed with prejudice but plaintiff has filed an appeal—and we could be the target of similar litigation in the future, particularly if we release news about the Company and its performance that proves to be disappointing to investors. Securities related litigation, whether with or without merit, could result in substantial costs and divert management's attention and financial resources, which could harm our business and financial condition, as well as 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 a License and Commercialization Agreement with Menarini, to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, plus Australia and New Zealand, we have not entered into a marketing, sales or promotional arrangement with a pharmaceutical partner to commercialize STENDRA in the U.S. 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 of Directors without prior stockholder approval, commonly referred to as "blank check" preferred stock, with rights senior to those of common stock;
- prohibit stockholder actions by written consent;
- specify procedures for director nominations by stockholders and submission of other proposals for consideration at stockholder meetings; and
- eliminate cumulative voting in the election of directors.

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





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

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 |
|---|---|
| 2.2(1)† | Asset Purchase Agreement dated October 1, 2010 between the Registrant, MEDA AB and Vivus Real Estate, LLC. |
| 3.1(2) | Amended and Restated Certificate of Incorporation of the Registrant. |
| 3.2(3) | Amended and Restated Bylaws of the Registrant. |
| 3.3(4) | Amendment No. 1 to the Amended and Restated Bylaws of the Registrant. |
| 3.4(5) | Amendment No. 2 to the Amended and Restated Bylaws of the Registrant. |
| 3.5(6) | Amendment No. 3 to the Amended and Restated Bylaws of the Registrant. |
| 3.6(7) | Amendment No. 4 to the Amended and Restated Bylaws of the Registrant. |
| 3.7(8) | Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Registrant. |
| 4.1(9) | Specimen Common Stock Certificate of the Registrant. |
| 4.2(10) | Preferred Stock Rights Agreement dated as of March 27, 2007 between the Registrant and Computershare Investor Services, LLC. |
| 4.3(11) | Indenture dated as of May 21, 2013 by and between the Registrant and Deutsche Bank Trust Company Americas, as trustee. |
| 4.4(12) | Form of 4.50% Convertible Senior Note due May 1, 2020. |
| 10.1(13) | Capped Call Confirmation dated May 15, 2013 by and between the Registrant and Deutsche Bank AG, London Branch. |
| 10.2(14)* | Form of Amended and Restated Change of Control and Severance Agreement. |



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| 10.4†† | Commercial Supply Agreement dated as of July 5, 2013 between the Registrant and Berlin-Chemie AG. |
| 10.5(15) | Agreement dated July 18, 2013 by and between the Registrant and First Manhattan Co. |
| 10.6(16)* | Letter Agreement dated July 18, 2013 by and among the Registrant, First Manhattan Co. and Peter Y. Tam. |
| 10.7(17) | Fourth Amendment to the Agreement dated as of December 28, 2000 between the Registrant and Mitsubishi Tanabe Pharma Corporation (formerly Tanabe Seiyaku Co., Ltd.), effective as of July 1, 2013. |
| 10.8†† | Commercial Supply Agreement dated July 31, 2013 by and between the Registrant and Sanofi Chimie. |
| 31.1 | Certification of Chief Executive Officer dated August 8, 2013 pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended. |
| 31.2 | Certification of Chief Financial Officer dated August 8, 2013 pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended. |
| 32 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101 | The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, formatted in Extensible Business Reporting Language (XBRL), include: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) related notes (furnished herewith). |

† Confidential treatment granted.

†† Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request

in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

* Indicates management contract or compensatory plan or arrangement.

(1) Incorporated by reference to Exhibit 2.2 filed with the Registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2012 filed with the Commission on June 12, 2013.

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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: August 8, 2013

VIVUS, Inc.

/s/ TIMOTHY E. MORRIS
Timothy E. Morris
Sr. Vice President Finance and Global Corporate Development, Chief Financial Officer

/s/ ANTHONY P. ZOOK
Anthony P. Zook
Chief Executive Officer

VIVUS, INC.

INDEX TO EXHIBITS

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# LICENSE AND COMMERCIALIZATION AGREEMENT

**by and between**

**VIVUS, INC.**

**and**

**BERLIN-CHEMIE AG**

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## LICENSE AND COMMERCIALIZATION AGREEMENT

**THIS LICENSE AND COMMERCIALIZATION AGREEMENT** (the **"Agreement"**) is executed on the 5th of July, 2013 (the "**Execution Date**") by and between **VIVUS, INC.**, a Delaware corporation with its principal place of business at 351 E. Evelyn Avenue, Mountain View, CA 94041, United States (**"VIVUS"**), and **BERLIN-CHEMIE AG**, a German public limited company having a place of business at Glienicker Weg 125 — 127, 12489 Berlin, Germany (**"Menarini"**). VIVUS and Menarini are sometimes referred to herein individually as a **"Party"** and collectively as the **"Parties"**.

## RECITALS

VIVUS owns or has a license to certain patent rights and other intellectual property rights relating to a medicinal product known as avanafil.

VIVUS has received regulatory approval for avanafil in the United States for the treatment of male erectile dysfunction (under the trade name Stendra®) and has submitted an application to the EMA (as defined below) requesting that the European Commission grant marketing authorization for avanafil in the European Union for the same indication (under the trade name Spedra®).

VIVUS desires to grant to Menarini, and Menarini desires to receive, a license for the use and commercialization of avanafil in certain territories as defined herein.

VIVUS has invested significant amounts of time, effort, and financial resources in the research and development of avanafil, and the grant of marketing authorization for avanafil in the European Union will become possible only as a result of these efforts and investment by VIVUS, all of which is understood and acknowledged by Menarini.

**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 **"Accounting Standards"** has the meaning set forth in the definition of "Net Sales" in this Article 1.

1.2 "**Acquisition**" has the meaning set forth in Section 2.7(b).

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1.3 "**Action Date**" means, with respect to a legal action in connection with a 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 substantively limited or compromised with respect to the remedies available against the alleged Third Party infringer.

1.4 **"Affiliate"** means, with respect to a particular Party, any person, firm, trust, corporation, company, partnership, or other entity or combination thereof that directly or indirectly controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under 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.

1.5 **"Alliance Managers"** has the meaning set forth in Section 3.7.

1.6 **"Applicable Law"** means any and all laws, statutes, ordinances, regulations, permits, orders, decrees, judgments, directives, or rules of any kind whatsoever that are promulgated by a European Union, national, federal, state, or other institution or 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 Menarini Territory, all as amended from time to time.

1.7 **"Bankrupt Party"** has the meaning set forth in Section 12.7.

1.8 **"Business Day"** means each day of the week excluding Saturday, Sunday or a day on which banking institutions in New York or in Germany are closed.

1.9 **"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.

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

1.11 **"Commercialization and Medical Affairs Plan"** has the meaning set forth in Section 4.5(a).

1.12 ***

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1.13 "**Competing Product**" means any product that operates as phosphodiesterase type-5 inhibitor.

1.14 "**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-pyrimidinecarboxyamide.

1.15 **"Confidential Information"** means, with respect to a Party, all proprietary Information of such Party that is disclosed to or accessed by the other Party under this Agreement.

1.16 **"Control"** means, with respect to any material, Information, or intellectual property right, that a Party owns or has a license or right to such material, Information, or intellectual property right and has the ability 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 then-existing agreement or other arrangement with any Third Party.

1.17 **"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 a Product is presented and is a topic of discussion. When used as a verb, "**Detail**" shall mean to engage in a Detail.

1.18 **"Development"** means all activities that relate to obtaining, maintaining or expanding Regulatory Approval of 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 and other post-Regulatory Approval clinical trials of Product. **"Develop"** and "**Developed**" have correlative meanings.

1.19 "**EFPIA Code**" means the code on the promotion of prescription-only medicines to, and interactions with healthcare professionals adopted by the European Federation of Pharmaceutical Industries and Associations, as amended from time to time and related national codes or equivalent industry codes as applicable in any of the countries of the Menarini Territory.

1.20 "**EMA**" means that European Medicines Agency or its successor.

1.21 "**European Commission**" means the European Union institution responsible for grant of marketing authorization to medicinal products for which authorization is sought through the centralized marketing authorization procedure.

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1.22 **"Existing Confidentiality Agreement"** means the Confidentiality Agreement entered into by the Parties, dated November 30, 2011.

1.23 "**Existing MAA**" means the MAA that was filed by VIVUS with the EMA prior to the Execution Date and that, as of the Execution Date, is pending approval of the European Commission.

1.24 **"FD&C Act"** means the United States Federal Food, Drug and Cosmetic Act.

1.25 **"Federal Arbitration Act"** has the meaning set forth in Section 13.2.

1.26 "**Field**" means the treatment of male erectile dysfunction in humans.

1.27 **"IND"** means an Investigational New Drug Application, as defined in the FD&C Act, or a similar application filed with an applicable Regulatory Authority outside of the United States such as a clinical trial application (CTA) or a clinical trial exemption (CTX).

1.28 **"Indemnified Claim"** has the meaning set forth in Section 10.3.

1.29 **"Indemnified Party"** has the meaning set forth in Section 10.3.

1.30 **"Indemnifying Party"** has the meaning set forth in Section 10.3.

1.31 **"Independent Manufacturing"** has the meaning set forth in Section 6.2(a).

1.32 **"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.

1.33 **"JAMS Rules"** has the meaning set forth in Section 13.2.

1.34 **"Joint Invention"** has the meaning set forth in Section 8.1.

1.35 **"Joint Patent"** has the meaning set forth in Section 8.3(b).

1.36 **"JSC"** means the Joint Steering Committee formed by the Parties as described in Section 3.1.

1.37 **"Losses"** means (a) all damages (including compensatory damages, monetary damages, statutory damages, punitive and exemplary damages and any pre-judgment and post-judgment interest), judgments, or settlements payable to Third Parties; and (b) all legal expenses (including attorneys' fees and disbursements, expert and witness fees, fees and costs associated with any investigations, court costs and appeal bonds).

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1.38 "**Major Countries**" means Germany, France, Spain, Italy, and the United Kingdom.

1.39 "**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.

1.40 **"Marketing Authorization Application"** or **"MAA"** means an application to the appropriate Regulatory Authority for approval to market the Product in any particular jurisdiction in the Menarini Territory, including without limitation such an application submitted to the EMA and approved by the European Commission.

1.41 **"Menarini Indemnitees"** has the meaning set forth in Section 10.1.

1.42 **"Menarini Know-How"** means all Information (excluding any patents and patent applications) (a) that is Controlled by Menarini or any Affiliate as of the Effective Date or during the Term and (b) is reasonably necessary or useful for the research, development, manufacture, use, importation or sale of Products. For clarity, the Menarini Know-How does not include the VIVUS Know-How licensed to Menarini hereunder.

1.43 **"Menarini Patents"** means all patents and patent applications (a) that are Controlled by Menarini or any Affiliate as of the Effective Date or during the Term and (b) that disclose or claim a Product or the manufacture, use, or sale of a Product. For clarity, the Menarini Patents do not include the VIVUS Patents licensed to Menarini hereunder.

1.44 **"Menarini Technology"** means the Menarini Patents and Menarini Know-How.

1.45 **"Menarini Territory"** means the following countries: Albania, Andorra, Australia, Austria, Belgium, Bosnia Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lichtenstein, Lithuania, Luxembourg, Kosovo, Malta, Montenegro, the Netherlands, New Zealand, Norway, Poland, Portugal, Republic of Macedonia, Republic of Serbia, Romania, San Marino Republic, Slovakia, Slovenia, Spain, Sweden, Switzerland, the United Kingdom, and Vatican City.

1.46 **"Menarini Trademarks"** has the meaning set forth in Section 8.6(c).

1.47 "**MTPC**" means Mitsubishi Tanabe Pharma Corporation.

1.48 "**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.

1.49 **"Net Sales"** means the amount invoiced or otherwise billed by Menarini or its Affiliate or sublicensee ("**Selling Party**") for sales or other commercial disposition of a Product

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to a Third Party purchaser ("**Gross Sales**"), less the following (collectively, "**Net Sales Deductions**"):

(a) discounts actually given on Product, including cash, trade and quantity discounts, price reduction or incentive programs, retroactive price adjustments with respect to sales of such Product, and charge-back payments (but excluding any discounts associated with vouchers distributed as Sample Distributions);

(b) credits or allowances actually allowed or given upon rejections or returns of Product, including for recalls or damaged goods;

(c) rebates, reimbursements, or similar allowances actually granted to managed health care organizations or to federal, state and local governments in the Menarini Territory with respect to Products;

(d) freight, postage, shipping and insurance charges actually allowed or paid for delivery of Product (but only to the extent such amounts are included when calculating Gross Sales above);

(e) taxes, duties or other governmental charges imposed on the sale of Product and actually paid by the Selling Party (but only to the extent such amounts are included when calculating Gross Sales above), as adjusted for rebates and refunds, but specifically excluding taxes based on net income of the Selling Party;

provided that all of the foregoing deductions shall be calculated in accordance with then-current International Financial Reporting Standards for revenue recognition purposes, consistently applied during the applicable calculation period throughout the Selling Party's organization ("**Accounting Standards**").

A sale of a Product is deemed to occur upon transfer of risk-of-loss with respect to the Product.

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.

1.50 **"Net Sales Deductions"** has the meaning set forth in the definition of "Net Sales" in this Article 1.

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

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1.52 **"Product"** means the drug product containing Compound that is the subject of the Existing MAA, in the form, formulation, and dosage strength as defined in the Existing MAA as of the Effective Date, along with any modifications to the current processing techniques, formulation or uses of such drug product in the Field (including but not limited to, line extensions, new administration modalities, new dosages, etc.).

1.53 **"Product Infringement"** has the meaning set forth in Section 8.4(a).

1.54 **"Product Launch"** means the first placing on the market of Product by Menarini 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 Menarini Territory, excluding any transfer of Product for research, test marketing, clinical trial purposes, compassionate use, or named patient arrangements, or for warehousing or staging in advance of release of the Product for commercial sale.

1.55 "**Promotion**" means those product-related activities, including (i) scientific and medical advertising, detailing, and distributing samples of a prescription-only medicinal product to healthcare professionals; and (ii) advertising of over-the-counter medicinal products to consumers; normally undertaken by a pharmaceutical company that are aimed at legally marketing and promoting, and encouraging the appropriate use of, a particular pharmaceutical product. "**Promote**" and "**Promotional**" have correlative meanings. For the avoidance of doubt, "**Promotion**" does not include any interactions with patients or members of the general public in the Menarini Territory in relation to prescription-only medicinal products. The Parties shall not undertake any activities that could constitute promotion of prescription-only medicinal products to patients or members of the general public in the Menarini Territory.

1.56 "**Promotional Materials**" means all Product-related scientific 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 of over-the-counter medicinal products (to the extent applicable), Internet postings and broadcast advertisements, in each case created by Menarini or on its behalf, and used or intended for use in connection with any Promotion of the Product in the Menarini Territory under this Agreement.

1.57 **"Prosecuting Party"** has the meaning set forth in Section 8.3(b).

1.58 **"PV Agreement"** has the meaning set forth in Section 5.5.

1.59 **"Regulatory Approval"** means all approvals necessary for the manufacture, marketing, importation and sale of a 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.

1.60 **"Regulatory Authority"** means, in a particular country or regulatory jurisdiction, any applicable governmental authority involved in granting Regulatory Approval and/or, to the

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extent required in such country or regulatory jurisdiction, Pricing Approval, including the European Commission in the case of the European Union and/or its member countries.

1.61 **"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, manufacture, market, sell or otherwise Commercialize a Product in a particular country or regulatory jurisdiction, along with any documents of Regulatory Approval issued by a Regulatory Authority in a particular country or regulatory jurisdiction. Regulatory Materials include INDs and MAAs.

1.62 "**Required Notice Date**" has the meaning set forth in Section 2.7(b).

1.63 "**Royalty Term**" means the period commencing on the Effective Date and continuing, on a country-by-country basis in the Menarini Territory, until the latest of: (i) expiration of the last to expire valid VIVUS Patent covering the Product; (ii) data protection covering the Product; or (iii) ten (10) years after Product Launch.

1.64 "**Sales Force**" means Menarini's sales personnel Detailing Product in the Menarini Territory including employees of, and contract sales organizations engaged by, Menarini who are qualified to do so pursuant to the terms and conditions of this Agreement.

1.65 **"Sales Quarter"** means the three-month period commencing with the first full calendar month after Product Launch and each consecutive three (3)-month period thereafter.

1.66 **"Sales Year"** means the twelve (12) month period commencing with the first full calendar month after Product Launch, and each subsequent twelve (12) month period. The first Sales Year is referred to herein as "Sales Year 1," the second Sales Year is referred to herein as "Sales Year 2," and so on.

1.67 **"Sample Distribution"** means the distribution to a physician's office of (a) a voucher for free Product or (b) free Product packaged as a complimentary trial for use by patients in the Menarini Territory and in accordance with Applicable Law.

1.68 **"SEC"** means the United States Securities and Exchange Commission or any successor.

1.69 "**Selling Party**" has the meaning set forth in the definition of "Net Sales" in this Article 1.

1.70 **"Sole Inventions"** has the meaning set forth in Section 8.1.

1.71 **"Supply Chain Transfer"** has the meaning set forth in Section 6.2(a).

1.72 **"Term"** has the meaning set forth in Section 12.1.

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1.73 **"Third Party"** means any legal person, entity or organization other than VIVUS, Menarini or an Affiliate of either Party.

1.74 "**Time of Onset Claim**" means a claim or other similar description in the Summary of Product Characteristics ("**SmPC**") and Patient Information Leaflet ("**PIL**") for the Product referencing an onset of action in approximately ***, but no more than ***, of drug ingestion.

1.75 "**Time of Onset Study**" means the clinical trial being conducted by VIVUS in the United States as of the Execution Date that is designed to support a Time of Onset Claim.

1.76 "**Urology Field**" means the treatment of benign prostatic hyperplasia or any other urological disease or condition in humans.

1.77 "**VIVUS-Acquired Competing Product**" means a Competing Product (other than the Product) to which VIVUS gains Control after the Execution Date as a result of VIVUS's acquisition of a Third Party.

1.78 **"VIVUS Indemnitees"** has the meaning set forth in Section 10.2.

1.79 **"VIVUS Know-How"** means all Information (excluding any patents and patent applications) that (a) is Controlled as of the Effective Date or during the Term by VIVUS or its Affiliates and (b) relates to the Product or the use or sale of a Product in the Field.

1.80 **"VIVUS Patents"** means (a) the Patents that are listed in Exhibit A; and (b) any reissues, renewals, re-examinations, or extensions of the foregoing.

1.81 **"VIVUS Technology"** means the VIVUS Patents and VIVUS Know-How.

1.82 **"VIVUS Territory"** means the entire world other than the Menarini Territory.

1.83 **"VIVUS Trademarks"** means the mark "SPEDRA", together with any registrations or applications for registration therefor, in the Menarini Territory, including the Trademarks listed in Exhibit B, all designs and styles used by VIVUS in the depiction of the foregoing Trademark in the Menarini Territory, and any copyrights therein, and all goodwill appurtenant to any of the foregoing, in each case Controlled by VIVUS as of the Effective Date or during the Term, and in each case to the extent in the Menarini Territory.

## ARTICLE 2
## LICENSES

2.1 **Effectiveness of Agreement; Condition Precedent**. This Section 2.1, Section 2.9, and Articles 10, 11, 13, and 14 shall be effective as of the Execution Date. The remainder of this Agreement shall be effective as of the date that VIVUS provides Menarini with *** (such date, the "**Effective Date**"); provided, however, that Menarini may waive this condition by

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providing written notice of such waiver to VIVUS. The Parties shall use *** to satisfy the foregoing condition precedent and work together in good faith to perform the activities required to satisfy such condition precedent. In the event that the Effective Date has not occurred by ***, either Party shall have the right to terminate this Agreement in its entirety, in which case neither Party shall have any further rights or obligations hereunder, unless the Parties otherwise agree in writing.

2.2 **Licenses to Menarini**.

(a) **License under VIVUS Technology**. Subject to the terms and conditions of this Agreement, VIVUS hereby grants to Menarini an exclusive (even as to VIVUS), royalty-bearing, sublicensable (subject to Section 2.6(a)) 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 Menarini Territory; (ii) to conduct certain Development activities on Product in the Field in the Menarini Territory pursuant to Article 4; and (iii) to make and have made Product in the Manufacturing Territory, where such Product is for use or sale in the Menarini Territory (subject to Section 2.2(b)).

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

(i) Until the completion of the Supply Chain Transfer, Menarini'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, except that, as set forth in Section 6.2, Menarini shall have the right to make and have make Product for the purpose of Independent Manufacturing, if and to the extent it elects to do so.

(ii) In the event of a Supply Chain Transfer pursuant to Section 6.2, Menarini'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 Menarini, from time to time, until the completion of the Supply Chain Transfer pursuant to Section 6.2).

(iii) VIVUS shall not grant any rights to Third Party manufacturers of Product that are inconsistent with Menarini's right to engage in Independent Manufacturing.

(iv) 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 outside the Menarini Territory, including the right to license Third Parties to do the same.

(c) **License under VIVUS Licensed Trademarks**. Subject to the terms and conditions of this Agreement including the terms set forth in Section 8.6, VIVUS hereby grants to Menarini an exclusive (even as to VIVUS), sublicensable (subject to Section 2.6(a)) license to

use the VIVUS Trademarks solely in connection with the Commercialization of Products in the Field in the Menarini Territory. Such license shall become perpetual and irrevocable, on a country-by-country basis, at the end of the Royalty Term for such country, subject to Menarini's compliance with any payment obligations in Section 7.6.

2.3 **Licenses to VIVUS**. Subject to the terms and conditions of this Agreement, Menarini hereby grants to VIVUS a non-exclusive, royalty-free, sublicensable (subject to Section 2.6(b)) license under the Menarini Technology solely to the extent necessary to (a) conduct those responsibilities assigned to VIVUS under this Agreement, (b) to conduct research, Development and manufacturing activities in the Menarini Territory solely in support of the Regulatory Approval of Products in the VIVUS Territory, (c) use, distribute, import, Promote, market, sell, offer for sale, and otherwise Commercialize Products in the VIVUS Territory; and (d) make and have made Products anywhere in the world for sale in the VIVUS Territory.

2.4 **VIVUS Retained Rights.** Notwithstanding the rights granted to Menarini in Section 2.1, VIVUS retains under the VIVUS Technology (a) the right to conduct those responsibilities assigned to VIVUS under this Agreement and (b) the exclusive right to conduct research, Development, and manufacturing activities in the Menarini Territory in support of the Regulatory Approval, Pricing Approval, or Commercialization of Products in the VIVUS Territory. VIVUS retains all rights to the VIVUS Technology outside the Field; *provided*, *however*, that VIVUS hereby covenants that neither it nor its Affiliates will, directly or indirectly (including via a license to a Third Party), Develop, or Promote Products in the Urology Field in the Menarini Territory.

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 Menarini.** Menarini acknowledges that the licenses granted to Menarini in Section 2.2 include 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 licenses granted by VIVUS to Menarini in Section 2.2 may be further sublicensed by Menarini subject to the following requirements: (i) in the case of sublicensees to Affiliates of Menarini, Menarini shall ***; and (ii) in the case of sublicenses to Third Parties, Menarini shall only grant such sublicenses with the prior written consent of VIVUS, which consent shall not be unreasonably denied or delayed. At Menarini's request, VIVUS shall use *** to obtain any consents or approvals from MTPC that are required for Menarini to grant a sublicense to a Third Party, it being understood that, so long as VIVUS uses such ***, VIVUS shall not be responsible for any denials or delays resulting from MTPC's action or inaction. Any agreement granting a sublicense under the licenses granted by VIVUS to Menarini in Section 2.2 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.

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(b) **Sublicensing by VIVUS**. The licenses granted by Menarini to VIVUS in Section 2.3(a) may be sublicensed by VIVUS to VIVUS's Affiliates or to any of VIVUS's subcontractors existing on the Effective Date or VIVUS's future subcontractors approved by Menarini, such approval not unreasonably withheld. The licenses granted by Menarini to VIVUS 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 licenses granted by Menarini to VIVUS in Section 2.2 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.

2.7 **Mutual Exclusivity.**

(a) Except for its activities with respect to Product under this Agreement, for a period of *** following the Effective Date, each Party hereby covenants that neither it nor any of its Affiliates that are involved in the Commercialization of the Product will, directly or indirectly, develop, commercialize, or in-license any Competing Product in the Menarini Territory in the Field. For clarity, for purposes of the preceding sentence, any Menarini Affiliate that receives a sublicense, in whole or in part, under any of the licenses granted to Menarini in Section 2.1 shall be deemed to be involved in the Commercialization of the Product.

(b) Notwithstanding Section 2.7(a), if VIVUS or any of its Affiliates, acquires, is acquired by, or merges with, an entity that owns or has a license or other right to, a Competing Product that does not contain Compound or any salt, free acid, free base, solvate, hydrate, anhydride, ester, or chelate thereof (such transaction, an "**Acquisition**"), then VIVUS and/or its Affiliates (or the surviving or acquiring entity, as applicable) shall not be prohibited from developing or commercializing such Competing Product during the *** following the Effective Date, provided that VIVUS or its Affiliate (or the surviving or acquiring entity, as applicable) (i) notifies Menarini of such Competing Product in writing no later than the Required Notice Date (as defined below) and (ii) does not use any Confidential Information of Menarini in connection with the development or commercialization of such Competing Product. For the avoidance of doubt, Section 2.7(a) only restricts conduct during the *** following the Effective Date, and the exception provided in this Section 2.7(b) is not necessary after this period.

(c) Notwithstanding Section 2.7(a), if Menarini or any of its Affiliates engages in an Acquisition, then Menarini and/or its Affiliates (or the surviving or acquiring entity, as applicable) shall not be prohibited from developing or commercializing the applicable Competing Product during the *** following the Effective Date, provided that Menarini or its Affiliate (or the surviving or acquiring entity, as applicable) (x) notify VIVUS of such Competing Product in writing no later than the Required Notice Date (as defined below); (y) does not use any Confidential Information of VIVUS in

connection with the development or commercialization of such Competing Product; and (z) performs one of the following acts, selected at its own discretion (and specify which of the following it will perform in the notice provided pursuant to subsection (x), which decision shall be final and binding):

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(i) divest itself of such Competing Product on a country-by-country basis and notify VIVUS in writing of such divestiture; *provided* that such divestiture is completed within *** after the Required Notice Date; or

(ii) immediately terminate this Agreement on a country-by-country basis (in which case the notice delivered pursuant to subsection (x) above shall be deemed to be a notice of termination); or

(iii) include, on a country-by-country basis in the Menarini Territory, in Net Sales, all sales of such Competing Product in the Field by Menarini, its Affiliates, or licensees during the Restricted Period, for purposes of calculating payments due to VIVUS under Section 7.5 and Section 7.6.

For the avoidance of doubt, Section 2.7(a) only restricts conduct during the *** following the Effective Date, and the exception provided in this Section 2.7(c) is not necessary after this period.

(d) As used herein, "**Required Notice Date**" means ***.

2.8 **Right of First Negotiation**. In the event that, during the Term, VIVUS elects to, whether itself or with or through any of its Affiliates or any Third Party, license, sell, offer for sale, or otherwise Commercialize (a) any Product that has *** for use outside of the Field (other than in the Urology Field, which is prohibited pursuant to Section 2.4) in the Menarini Territory or (b) any VIVUS-Acquired Competing Product that has *** for use in the Field ( (a) and (b), collectively, the "**ROFN Rights**"), VIVUS shall provide written notice (a "**VIVUS ROFN Notice**") to Menarini that VIVUS desires to exercise such ROFN Rights. Upon Menarini's written request (the "**Menarini ROFN Notice**") within *** after Menarini's receipt of the VIVUS ROFN Notice, and for a period of *** after VIVUS receives the Menarini ROFN Notice (or such longer period as the Parties may mutually agree), the Parties shall, in good faith, exclusively negotiate the terms of a definitive agreement pursuant to which VIVUS would grant a license to Menarini to exercise such ROFN Rights on commercially reasonable terms and conditions. In the event that the Parties fail to execute a definitive agreement relating to such ROFN Rights within such period or in the event that Menarini does not provide the Menarini ROFN Notice within the time period required above, VIVUS may exercise such ROFN Rights, whether itself or with or through any of its Affiliates or any Third Party.

2.9 *****.** VIVUS shall use *** to obtain ***.

## ARTICLE 3
## GOVERNANCE

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

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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 meeting of the JSC on reasonable 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 Menarini shall have the right to make the decisions and take the actions previously reserved to the JSC, and shall keep VIVUS 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) Encourage, plan, implement, and oversee the Commercialization of Product in the Field in the Menarini Territory, and the manufacturing of Product in support of such activities;

(b) Review the Commercialization and Medical Affairs Plan and any proposed amendments or updates thereto;

(c) Monitor the Commercialization of Product in the Field in the Menarini Territory against the Commercialization and Medical Affairs Plan;

(d) Monitor Menarini's performance of the Menarini Medical Affairs Activities against the Commercialization and Medical Affairs Plan;

(e) 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

(f) 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, interpret, or terminate 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, the JSC shall submit the respective positions of the Parties with respect to such matter for discussion in good faith by the Alliance Managers. If such Alliance Managers are not able to mutually agree upon the resolution to such matter within *** after the JSC's submission to them, then the Alliance Managers shall submit the respective positions of the Parties with respect to such matter to the respective chief executive officers of VIVUS and Menarini 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) to the extent such matter relates to a Development, regulatory, or manufacturing issue, the chief executive officer of VIVUS shall have the right to decide such matter, always with the aim of preserving the commercial viability of the Product in the Menarini Territory, and 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 *** in the Menarini Territory; or (iii) is contrary to the express terms of this Agreement or any other written agreement between the Parties; and (b) to the extent such matter relates to a Commercialization issue (other than a manufacturing or regulatory issue), the chief executive officer of Menarini shall have the right to decide such matter, always with the aim of preserving the commercial viability of the Product in the Menarini Territory, and except that in no event can the chief executive officer of Menarini 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 (ii) is contrary to the express 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 would be one of the *** representatives on the JSC for each Party.

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## ARTICLE 4
## DEVELOPMENT AND COMMERCIALIZATION

4.1 **Marketing Authorization**. VIVUS shall use *** to obtain marketing authorization for the Product by the European Commission on the basis of the Existing MAA (such marketing authorization, the "**Product Marketing Authorization**"). In any event, as part of VIVUS's efforts to obtain the Product Marketing Authorization, VIVUS shall be responsible, at its sole cost and expense, for ensuring that the Product Marketing Authorization, when granted by the European Commission, accurately sets forth any and all post-approval commitments that have been presented in the opinion adopted by the EMA Committee for Medicinal Products for Human Use (the "**Post-Marketing Requirements**"). Other than the Product Marketing Authorization, Menarini shall be responsible for obtaining any and all other Regulatory Approvals and Pricing Approvals for the Product that are necessary for marketing and sale of the Product in the individual countries of the Menarini Territory ("**Other Approvals**"). For the avoidance of doubt, the Other Approvals shall not include any Regulatory Approvals granted by the European Commission. The Parties acknowledge and agree that, as of the Execution Date, it is anticipated that, with respect to the European Union, the Other Approvals shall not include any formal regulatory approvals, but shall include only Pricing Approvals and certain local permits, notifications, and other similar ministerial regulatory activities. Each Party shall keep the other Party reasonably informed of, and use

reasonable efforts to consult with the other Party with respect to, any discussions between such Party and applicable Regulatory Authorities relating to post-Regulatory Approval studies of Product that may be required in connection with the Regulatory Approvals for which such Party is responsible hereunder.

4.2 **Transfer of Marketing Authorization**.

(a) **Transfer**. Following the Execution Date, VIVUS shall promptly share with Menarini copies of (i) all documentation (including the electronic Common Technical Document sequences) submitted to EMA in connection with the Existing MAA, to the extent such documentation would be reasonably necessary for Menarini to exercise its rights and carry out its obligations under this Agreement and (ii) the Product information texts sent to the European Commission. Concomitantly, VIVUS, in cooperation with Menarini, shall initiate activities for the filing of the request to transfer such Product Marketing Authorization to Menarini or its Affiliates as well any other variations agreed to be submitted before the transfer of the Product Marketing Authorization according to the terms set forth in this Section 4.2. Within *** following the grant of the Product Marketing Authorization by the European Commission, VIVUS shall file a request for transfer of the Product Marketing Authorization to Menarini with the EMA. VIVUS shall be responsible for submission to EMA of the application for transfer and for providing responses and additional documentation in response to any related questions posed by EMA concerning the transfer. Menarini shall assist and cooperate with VIVUS in connection with such transfer. Menarini 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, from and against any and all liabilities, losses, claims, suits, damages, costs and expenses (including but not limited to Losses) arising in connection with the filing of the application for the transfer of the Product Marketing Authorization with the EMA or otherwise relating to or resulting from such transfer. Menarini shall be responsible for out of pocket costs and expenses incurred by

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VIVUS or its Affiliates in connection with the application to the EMA for transfer of the Product Marketing Authorization and the related approval or refusal by the European Commission to transfer of such Product Marketing Authorization. Such payments shall be based on documentarily evidenced invoices submitted by VIVUS to Menarini from time to time. Menarini shall comply with all requirements imposed by this Section 4.2(a) independently of the outcome of the application procedure related to the transfer of the Product Marketing Authorization. For clarity, only the Product Marketing Authorization will be transferred to Menarini, and no patents, patent applications, or other intellectual property of VIVUS shall be transferred.

(b) **Post-Transfer Responsibilities**. Following transfer of the Product Marketing Authorization to Menarini, Menarini shall comply with all requirements imposed on Menarini as the holder of the Product Marketing Authorization by the Applicable Law. Menarini shall be fully responsible for maintaining the on-going validity of the Product Marketing Authorization and shall not take any steps that would reasonably be expected to undermine this validity; provided, however, that the Parties acknowledge that VIVUS will continue to have certain financial and operational responsibilities with respect to Development of the Product following transfer of the Product Marketing Authorization, as described in Section 4.3. VIVUS shall have the right to propose and agree with Menarini (and vice-versa) on post-transfer activities that are required to maintain the validity of the Product Marketing Authorization and to allow Menarini to comply with its obligation to maintain the Product Marketing Authorization. VIVUS will cooperate with Menarini in the submission of the post-transfer notifications. Failure by Menarini to comply with the obligations imposed by Applicable Law in relation to the Product or any actions and omissions by Menarini that would reasonably be expected to undermine the validity of the Product Marketing Authorization shall be deemed to be a material breach of this Agreement, giving rise to VIVUS's right to terminate this Agreement pursuant to Section 12.2(a).

(c) **Restriction on Further Transfer**. Menarini shall in no circumstances transfer, or permit any Affiliates to transfer, the Product Marketing Authorization to any Third Party. Any attempt by Menarini or its Affiliates to transfer the Product Marketing Authorization to a Third Party shall be deemed to be a material breach of this Agreement, giving rise to VIVUS's right to terminate this Agreement pursuant to Section 12.2(a).

(d) **VIVUS Retained Rights**. Notwithstanding the transfer of the Product Marketing Authorization for the Product by VIVUS to Menarini as provided in Section 4.2 above, VIVUS shall, in all circumstances, retain the following rights after such transfer: (i) VIVUS shall, in accordance with Section 2.2(a) of this Agreement, exercise control over the selection of the manufacturer of the Product in Menarini Territory unless and until the supply chain for the Menarini Territory is transferred to Menarini pursuant to Section 6.2; (ii) VIVUS shall remain the owner of all data filed with Regulatory Authorities in connection with the Existing MAA and the Label Expansion Filing and shall retain the right, with prior notice to Menarini, to grant access to this data to Third Parties who are collaborating with or otherwise assisting VIVUS in connection with the Development, Commercialization, or manufacturing of

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the Product and/or the development, commercialization, or manufacturing of any other VIVUS product; and (iii) VIVUS shall, in accordance with Section 5.1(d), retain final decision-making right with respect to the content of any communications with Regulatory Authorities in the Menarini Territory in connection with (A) any Post-Marketing Requirements or any post-Regulatory Approval studies in relation to the Product and (B) qualification of Product manufacturers.

4.3 **Development Obligations**.

(a) **QT Study**. VIVUS shall be responsible for conducting, at its sole cost and expense, a study evaluating any QTc prolongation by Product (the "**QT Study**") in accordance with any relevant details set forth the Post-Marketing Requirements and the guidance provided by the EMA.

(b) **Post-Approval Studies**. Where requirements to conduct post-Regulatory Approval studies are imposed by a Regulatory Authority in the Menarini Territory (including the Post-Marketing Requirements, but excluding the QT Study), whether imposed on VIVUS as the initial holder of the Product Marketing Authorization or on Menarini as the subsequent holder of the Product Marketing Authorization, Menarini shall be responsible for conducting such post-Regulatory Approval studies of Product. VIVUS shall pay for *** percent (***%) of the costs of conducting any such post-Regulatory Approval studies. Notwithstanding the foregoing, if and when VIVUS's actual aggregate payments under the preceding sentence exceed *** Euros (€***), VIVUS shall have the right to forego any further ***, in which case Menarini shall be solely responsible for any further costs of conducting such post-Regulatory Approval studies, subject to its termination right described in the following sentence. For clarity, if the EMA or the European Commission requires any post-Regulatory Approval studies under the Existing MAA that were not included in the opinion adopted by the EMA's Committee for Medicinal Products for Human Use and the Product Marketing Authorization or if the QT Study results into any change of the SmPC of Product which would reasonably have a negative impact on the Commercialization of the Product in the Territory, Menarini shall have the right to terminate this Agreement at its sole discretion pursuant to Section 12.2(c).

(c) **Use of Data**. VIVUS shall have the right, without any additional payment, to use any clinical or non-clinical data developed by or on behalf of Menarini or its Affiliates relating to the Product solely (i) to support the Regulatory Approval of Products in the Menarini Territory, (ii) to support the Regulatory Approval of Products in the VIVUS Territory, and (iii) for Promotional, marketing, and medical education purposes in support of the Commercialization of Product in the VIVUS Territory. The rights set forth in subsections (ii) and (iii) may be sublicensed by VIVUS to any Third Party collaborator or licensee in the VIVUS Territory (or a portion of the VIVUS Territory) who also holds Development or Commercialization rights to the Product.

(d) **Time of Onset Study**. VIVUS shall continue to perform the Time of Onset Study, at VIVUS's sole cost and expense. At its sole cost and discretion, VIVUS may

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prepare and file with the EMA 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 Menarini Territory (the "**Label Expansion Filing**"). Menarini shall provide VIVUS with all reasonable assistance necessary for such preparation and filing. If the Product Marketing Authorization has been transferred to Menarini pursuant to Section 4.2, such assistance shall include, without limitation, filing the Label Expansion Filing on VIVUS's behalf. Data or results from the Time of Onset Study shall be owned by VIVUS and, provided that Menarini makes any Label Expansion Filing-related milestone payment under Section 7.2 that comes due, shall be licensed to Menarini hereunder as VIVUS Know-How pursuant to Section 2.2.

(e) **Other Development**. As between the Parties, except for the responsibilities assigned to Menarini pursuant to Sections 4.1, 4.2(b), 4.3(b), and 4.9, VIVUS shall have the sole right to conduct any further Development work (including clinical trials) on the Product, at its sole discretion but with the aim of preserving the Product profile and the commercial viability of the Product in the Menarini Territory. VIVUS shall be responsible for all of its costs in connection with any further Development activities that it conducts, unless otherwise mutually agreed by the Parties.

4.4 **Commercialization — General.** Subject to the terms of this Agreement, Menarini shall have responsibility and decision-making authority for Commercialization activities for the Menarini Territory to be carried out in accordance with the Commercialization and Medical Affairs Plan. Menarini shall be responsible for all costs and expenses associated with such Commercialization activities. The Commercialization activities shall comply with Applicable Law and shall not undermine the validity of any Regulatory Approvals granted for the Products.

4.5 **Commercialization and Medical Affairs Plan**.

(a) Commercialization of the Product under this Agreement shall be governed by a written Commercialization and Medical Affairs Plan that describes the anticipated minimum requirements pertaining to the Commercialization activities to be performed with respect to Product in the Menarini Territory by Menarini or on its behalf by permitted Third Parties, as well as projected timelines and line-item quarterly budgets for such activities (the **"Commercialization and Medical Affairs Plan"**). Each Commercialization and Medical Affairs Plan shall address, in reasonable detail, at least the minimum requirements pertaining to call plans for Detailing of Product, Sales Force training, Sample Distribution strategies and quantities, Product positioning and scientific communication strategy, DTC advertising of over-the-counter medicinal products, and non-DTC advertising of over-the-counter and prescription-only medicinal products intended solely for physicians. Additional content requirements for the Commercialization and Medical Affairs Plan are set forth in Section 4.9. In compliance with the Applicable Law and particularly with Article 98(1) of Directive 2001/83/EC on the Community code relating to medicinal products for human use, Menarini shall be responsible for the establishment and functioning of the scientific service in charge of information concerning the Products.

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(b) Attached hereto as Exhibit C is a Commercialization and Medical Affairs Plan covering activities to be conducted in preparation of Product Launch and during Sales Year 1. No later than *** after the date on which the European Commission grants the Product Marketing Authorization, Menarini shall prepare an updated version of the Commercialization and Medical Affairs Plan for review and approval by the JSC. In accordance with

Section 4.5(a) of this Agreement, this Commercialization and Medical Affairs Plan will include a description of the actions to be taken by Menarini to fulfill the scientific information obligations to which the Existing MAA and any other Regulatory Approvals give rise.

(c) Menarini shall thereafter update the Commercialization and Medical Affairs Plan on an annual basis as follows: Menarini shall provide the JSC with a draft update to the Commercialization and Medical Affairs Plan no later than *** of each year. In preparing the updated version of the Commercialization and Medical Affairs Plan, Menarini shall analyze the effectiveness of the elements of the prior year Commercialization and Medical Affairs Plan and an updated sales forecast to develop a future year Commercialization and Medical Affairs Plan. The JSC shall either approve the proposed Commercialization and Medical Affairs Plan or request specific changes to it. Menarini shall then modify the proposal based on the JSC's direction and re-submit the Commercialization and Medical Affairs Plan for JSC review and approval. Menarini may, at its election, update the Commercialization and Medical Affairs Plan between annual updates by following this same procedure.

(d) Each Party shall use *** in performing its obligations under this Section 4.5 concerning (as applicable) the preparation, review, and approval of the Commercialization and Medical Affairs Plan.

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

4.6 **Diligent Commercialization by Menarini.** Menarini, itself or through its Affiliates or permitted sublicensees, shall use *** to Commercialize the Product in the Field in the Menarini Territory. Without limiting the generality of the foregoing, Menarini shall satisfy the following requirement:

(a) **Product Launch**. Subject to Section 4.6(b), Menarini shall (i) commence a Product Launch in each Major Country in the Menarini Territory no later than *** after grant of the Product Marketing Authorization by the European Commission; (ii) commence a Product Launch in each other country in the Menarini Territory (except ***) no later than *** after grant of the Product Marketing Authorization by the European Commission; and (iii) commence a Product Launch in *** no later than ***.

(b) **Conditions**.

(i) Menarini's obligations with respect to Product Launch in Section 4.6(a) shall not apply to the extent that such Product Launch is delayed or otherwise

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compromised by VIVUS's failure to supply (or have supplied), in accordance with Commercial Supply Agreement, bulk tablets of Product ordered by Menarini thereunder.

(ii) In the event that, for reasons outside the reasonable control of Menarini, the transfer the Product Marketing Authorization to Menarini has not occurred by the deadline for Product Launch set forth in Section 4.6(a) (a "**Transfer Delay**"), the deadline for Menarini to comply with Section 4.6(a) shall be automatically extended, for all countries in the Menarini Territory (other than ***), until *** after such transfer is complete; provided that such extension is expressly conditioned on Menarini paying the applicable Product Launch milestone(s) in Section 7.2 no later than *** after grant of the Product Marketing Authorization by the European Commission (i.e., notwithstanding the failure of Product Launch to occur by such date), but only if VIVUS has complied with its obligations pursuant to Section 4.2(a); and provided, further, that Menarini shall use *** to comply with Section 4.6(a) within *** after the transfer is complete rather than using *** granted above.

(iii) The deadline for Menarini to comply with Section 4.6(a) shall be automatically extended, on a country-by-country basis, in proportion to any delay in Product Launch that is caused by the action or inaction of a Regulatory Authority and that is outside the reasonable control of Menarini (excluding any such delay resulting from a Transfer Delay, which shall be addressed as provided in Section 4.6(b)(ii)); provided, however, that in the case of a delay in a Major Country, any such extension shall in no event be greater than *** and, in addition, such extension is expressly conditioned on Menarini paying the applicable Product Launch milestone(s) in Section 7.2 no later than *** after grant of the Product Marketing Authorization by the European Commission (i.e., notwithstanding the failure of Product Launch to occur by such date); and (ii) in the case of a delay in any other country in the Menarini Territory, any such extension shall in no event be greater than *** and, in addition, is expressly conditioned on Menarini using *** to complete Product Launch in such country as soon as reasonably practicable.

4.7 **Sales Force**.

(a) **General**. Menarini shall at all times during the Term maintain a Sales Force containing a reasonable number of sales representatives in order to meet Menarini's obligations under Section 4.6. The Sales Force may consist of employees of Menarini or a contract sales force (or a combination thereof); provided that Menarini shall remain responsible for the management, supervision, and performance of such contract sales force.

(b) **Qualifications.** Menarini 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 Menarini Territory.

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

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4.8 **Promotional Materials**.

(a) Menarini shall be responsible, at its expense, for preparing and producing the Promotional Materials, which will be reviewed and approved by the VIVUS within and not later than *** from the receipt of the Promotional materials from Menarini. In case of no reply by VIVUS within the aforesaid timeframe, the Promotional Material in question shall be considered accepted and approved by VIVUS. VIVUS shall not refuse approval of Promotional Material unreasonably; however, to the extent that VIVUS disagrees with Promotional messages or tactics proposed by Menarini for Product in the Menarini Territory, it may raise such issues with Menarini for discussion and resolution.

(b) Menarini shall not use or distribute in connection with Promotion of the Product in the Menarini Territory any promotional materials other than the Promotional Materials in the form(s) prepared and approved in accordance with this Section 4.8. Menarini shall be solely responsible for timely submitting, as applicable, any Promotional Materials to Regulatory Authorities in the Menarini Territory (including any applicable governmental authorities in individual countries in the Menarini Territory). Menarini shall use and distribute the Promotional Materials in accordance with the Commercialization and Medical Affairs Plan and the terms of this Agreement, and Menarini shall not use or distribute out-dated Promotional Materials.

(c) Menarini 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, Menarini shall be permitted to use the VIVUS Trademarks in accordance with the license granted in Section 2.2(c).

4.9 **Medical Affairs Activities.** The Commercialization and Medical Affairs Plan shall describe the anticipated medical affairs activities to be performed with respect to Product in the Menarini Territory by Menarini or on its behalf by permitted Third Parties (the "**Menarini Medical Affairs Activities**"), as well as projected timelines and line-item quarterly budgets for such activities. Each Commercialization and Medical Affairs Plan shall address, in reasonable detail, 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 Menarini Territory). For clarity, the foregoing content requirements are in addition to those described in Section 4.5(a). Menarini, itself or through its Affiliates or permitted sublicensees, shall carry out the Menarini Medical Affairs Activities in accordance with the Commercialization and Medical Affairs Plan, using ***. Should Menarini, in its reasonable opinion, believe that the Medical Affairs Plan or the Menarini Medical Affairs Activities need to be adjusted or modified, it shall send the proposed adjustment or modification to VIVUS' review and approval and VIVUS shall reply to Menarini within and not later than *** from the receipt of Menarini's request. In case of no reply by VIVUS within the aforesaid timeframe, the adjustment or modification in question shall be considered accepted and approved by VIVUS. VIVUS shall not refuse approval of any of the foregoing unreasonably.

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4.10 **Compliance.**

(a) In performing its duties hereunder, Menarini shall and shall cause its Sales Force to: (i) Commercialize the Product in conformity with its approved labeling; and (ii) comply with all Applicable Laws, including all laws and regulations and other guidelines concerning the sale, promotion, and advertising of prescription drug products that are applicable to the Menarini Territory, and the EFPIA Code and related national codes, in each case to the extent applicable to the Menarini's activities hereunder and as may be amended or supplemented from time to time.

(b) Menarini shall Commercialize the Product in a professional, ethical and competent manner. Without limiting the generality of the foregoing, Menarini shall ensure that each of its employees and Sales Force representatives does not make any representation, statement, warranty or guaranty with respect to the Product that is inconsistent with its current labeling or with the JSC-approved Promotional Materials, that is deceptive or misleading, or that disparages the Product or the good name, goodwill or reputation of VIVUS or its Affiliates.

(c) Menarini shall ensure that all interactions with healthcare professionals licensed to practice in any country in the Menarini Territory comply with the Applicable Law, including but not limited to the prohibition of inducements and the requirement of conclusion of written agreements with the healthcare professionals, and the notification, approval and public disclosure of these agreements.

4.11 **Re-Sale Price.** Menarini shall be free to determine the price(s) at which it sells Products in the Menarini Territory, subject to any Pricing Approvals or other requirements imposed by Applicable Laws.

4.12 **Commercialization Reports.** Menarini shall keep the JSC reasonably informed regarding the material progress and results of its Commercialization activities and those of its Affiliates, sublicensees and Third Party contractors, including providing the following:

(a) On a monthly basis during the Term, an email report of gross sales and Net Sales of the Products in the Menarini Territory, on a country-by-country basis, during said period and on a calendar year-to-date basis.

(b) Within *** after the end of each calendar quarter during the Term, a written report summarizing Menarini's material Commercialization activities pursuant to this Agreement for such quarter and on a calendar year-to-date basis, including: (i) the number of Details made; (ii) the total number of Sample Distributions delivered and/or redeemed, and (iii) Information in Menarini's possession regarding any advertising relating to the Product.

Any report submitted to VIVUS by Menarini under this Agreement shall be in a reasonable format, as determined by Menarini in good faith. Each such report shall be considered Menarini's Confidential Information.

4.13 **Menarini Records and Audits.** Menarini shall keep complete and accurate records of (a) the number of Details delivered by sales representatives under Menarini's control, (b) the total number of Sample Distributions distributed and/or redeemed, and (c) Information regarding any advertising relating to the Product. All such records shall be retained for at least *** following the Sales Year in which they are generated, or longer if required by Applicable Laws. At VIVUS's request, such records and Menarini's Detail and Sample Distribution activity reporting system shall be available for review at a Menarini facility in the Menarini Territory 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 mutually agreed upon by the Parties 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 reports furnished by Menarini pursuant to this Section. The expense of such auditor shall be borne solely by VIVUS unless such audit reveals a numerical reporting error of *** percent (***%) or more during the applicable audit period, in which case Menarini shall bear the full cost of such audit. Such auditor shall not disclose Menarini's confidential information to VIVUS, except to the extent such disclosure is necessary to verify the accuracy of the reports furnished by Menarini.

4.14 **Cross-Territory Sales**. Menarini shall Commercialize the Products only in the Menarini Territory. Menarini shall not directly or indirectly solicit, advertise, sell, distribute, ship, consign, or otherwise transfer the Products outside the Menarini Territory, unless Menarini knows that the Products in question are to be re-imported in the European Union by the purchaser. To the extent permitted by Applicable Law, Menarini shall use *** to ensure that Products sold in the Menarini Territory are not used outside the Menarini Territory. Menarini shall use *** to ensure that its sublicensees, distributors, and wholesalers comply with all of the foregoing obligations.

## ARTICLE 5
## REGULATORY

5.1 **Regulatory Materials and Regulatory Approvals**.

(a) **Product Marketing Authorization**. Except as provided in the remainder of this Section 5.1(a), VIVUS shall be the legal and beneficial owner of the Existing MAA and any Regulatory Approvals in the Menarini Territory that are not Other Approvals (including the Product Marketing Authorization and any other Regulatory Approval granted by the European Commission). All Regulatory Materials for Products in the Menarini Territory that are related to the Existing MAA (as well as all other Regulatory Materials for Products in the Menarini Territory that are not related to Other Approvals) shall be filed by, and in the name of, VIVUS. VIVUS alone shall be responsible for all communications and other dealings with the EMA, the European Commission, or other multi-jurisdictional Regulatory Authorities in the Menarini Territory relating to the Product, the Existing MAA, or the Product Marketing Authorization. Notwithstanding the foregoing, upon transfer of the Product Marketing Authorization to Menarini in accordance with Section 4.2, (i) Menarini shall be the legal and beneficial owner of



the Product Marketing Authorization and any other Regulatory Approval granted by the European Commission, (ii) Menarini shall be solely responsible for all communications and other dealings with the EMA, the European Commission, or other multi-jurisdictional Regulatory Authorities in the Menarini Territory relating to the Product or the Product Marketing Authorization, subject to Section 5.1(d) of this Agreement.

(b) **Other Approvals**. Menarini shall be the legal and beneficial owner of all Other Approvals. Regulatory Materials relating to the Other Approvals shall be filed by, and in the name of, Menarini.

(c) **Costs**. Each Party shall bear its own costs in connection with its performance of regulatory activities hereunder. Notwithstanding the foregoing, Menarini shall be responsible for any fees payable to the EMA, European Commission, or any other Regulatory Authority in the Menarini Territory with respect to the Product.

(d) **Notifications; Communications with Regulatory Authorities.** During the Term, each Party shall keep the other Party 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 Menarini Territory, pursuant to procedures to be developed by the JSC. Prior to transfer of the Product Marketing Authorization to Menarini in accordance with Section 4.2, VIVUS shall retain 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 any commitments to a Regulatory Authority in the Menarini Territory that would reasonably be expected to materially increase the costs incurred by Menarini in Commercializing the Product in the Menarini Territory or to have a material impact on Menarini's Commercialization of the Product in the Menarini Territory shall require Menarini's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. Following transfer of the Product Marketing Authorization to Menarini in accordance with Section 4.2, Menarini 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 Menarini 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 and (ii) Menarini shall consult with VIVUS regarding any communications or other dealings with Regulatory Authorities in the Menarini Territory in connection with (A) any Post-Marketing Requirements or post-Regulatory Approval studies in relation to the Product or (B) qualification of Product

manufacturers, and VIVUS shall retain final decision-making right with respect to the content of any related communications with Regulatory Authorities in the Menarini Territory. To such end, Menarini agrees to comply with and implement VIVUS's decisions with respect to such communications or other dealings.

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5.2 **Other Regulatory Obligations**.

(a) Menarini shall comply with all pharmacovigilance obligations imposed by the Applicable Law in relation to the Product. Menarini shall keep VIVUS informed, in a timely manner consistent with Applicable Laws governing adverse event reporting obligations and the pharmacovigilance reporting requirements to Regulatory Authorities in the Menarini Territory, of any Information that Menarini receives (directly or indirectly) that (i) raises any material concerns regarding the safety or efficacy of the Product; (ii) 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; 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. Menarini shall provide VIVUS with drafts of all pharmacovigilance reports to the Regulatory Authorities and shall not submit such reports before VIVUS has reviewed and been provided a reasonably opportunity to comment on such reports and discuss such reports with Menarini. Failure by Menarini to comply with the provisions of this Section shall be deemed to be a material breach of this Agreement, giving rise to VIVUS's right to terminate this Agreement pursuant to Section 12.2(a).

(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 Menarini Territory. Without limiting the foregoing, if a Party receives an inquiry from a Regulatory Authority relating to the Product and such Party is responsible for communications with such Regulatory Authority (as described in Section 5.1 and Section 5.2(c)), the other Party shall provide to such responsible Party upon request, within *** (or sooner if reasonably required for the responsible Party to meet a deadline set by the relevant Regulatory Authority or by Applicable Law), such information and documentation in its possession as may be necessary or helpful to prepare a response to such inquiry.

(c) Prior to the transfer of the Product Marketing Authorization to Menarini, Menarini shall not communicate with any Regulatory Authority regarding any Product unless explicitly requested or permitted in writing to do so by VIVUS. Following the transfer of the Product Marketing Authorization to Menarini, Menarini's communications with Regulatory Authorities regarding the Product shall comply with Section 5.1(d), Section 5.2(a), and Section 5.2(b).

5.3 **Audit Right**. VIVUS shall have the right at its own expense, upon reasonable notice to Menarini and during regular business hours, to inspect and audit the systems, processes, and standard operating procedures being used by Menarini in connection with the Commercialization of Product in the Territory (including procedures for collecting and reporting adverse events) to assure compliance by Menarini with (a) Applicable Law and (b) the terms and provisions of this Agreement and the PV Agreement. Such audits will be limited to *** per calendar year (provided, however, that more frequent audits shall be permitted if in response to a specific problem or deficiency). Menarini shall within *** remedy or cause the remedy of any deficiencies which may be noted in any such audit or, if any such deficiencies cannot reasonably be remedied within such *** period, present to VIVUS a written plan to remedy such deficiencies as soon as possible; and the failure by Menarini to remedy or cause the remedy of

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any such deficiencies within such *** period or to present such a plan within such *** period and then use its *** to remedy or cause the remedy of such deficiencies in accordance with such written plan, as the case may be, shall be deemed a material breach of this Agreement. Menarini acknowledges that the provisions of this Article 5 granting VIVUS certain audit rights shall in no way relieve Menarini of any of its obligations under this Agreement, nor shall such provisions require VIVUS to conduct any such audits.

5.4 **Rights of Reference**. VIVUS hereby grants to Menarini 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 Other Approvals and, after transfer of the Product Marketing Authorization to Menarini, the Product Marketing Authorization, in each case subject to Section 4.3(d). Menarini hereby grants to VIVUS an exclusive right of reference to all Regulatory Materials, Regulatory Approvals, and Pricing Approvals owned or Controlled by Menarini solely for the purpose of obtaining or maintaining Regulatory Approval for Product in the Menarini Territory or the VIVUS Territory during the Term.

5.5 **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 in the Menarini Territory of non-compliance with Applicable Laws in connection with the Product.

(b) **Inspection or Audit.** If a Regulatory Authority desires to conduct an inspection or audit of Menarini's facility or a facility under contract with Menarini with regard to the Product in the Menarini Territory, Menarini shall cooperate and cause the contract facility to cooperate with such Regulatory Authority during such inspection or audit. Menarini shall notify VIVUS immediately by telephone and facsimile (with a follow-up by mail) upon, but not later than *** after learning that an audit or inspection by a Regulatory Authority is scheduled to take place, or, if there is no prior notice by any Regulatory Authority, that an audit or inspection has commenced. Menarini shall make all efforts to coordinate any scheduling of an audit or inspection by a Regulatory Authority to permit VIVUS and its representatives to attend such an audit or inspection. Menarini shall permit VIVUS and its representatives to

review and comment in advance on any written communication from Menarini to any Regulatory Authority in connection with such an audit or inspection. Menarini shall promptly provide VIVUS with copies of all communications between Menarini and any Regulatory Authority related to such an audit or inspection and shall promptly propose to VIVUS actions to correct any deficiencies found by the Regulatory Authority during the audit or inspection. Menarini shall segregate, and not disclose, any Confidential Information of VIVUS 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 Menarini, rather than VIVUS, receives the inspection or audit observations of such Regulatory Authority, Menarini shall provide a copy of such observations to VIVUS within *** following receipt. Menarini shall prepare the response to any such observations, but the submission of the response to the applicable Regulatory Authority shall be

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subject to VIVUS's final approval of response, which approval shall not be unreasonably withheld. Upon written approval by VIVUS, Menarini shall implement at its own cost the actions to correct any material deficiencies found by the Regulatory Authority during the audit or inspection in accordance with VIVUS' instructions, the requirements of the Regulatory Authority and the Applicable Law ("**Corrective Actions**"). If Menarini fails to implement the Corrective Actions in any material respect, this shall be deemed to be a material breach of this Agreement, giving rise to VIVUS's right to terminate this Agreement pursuant to Section 12.2(a). In the case of any audit or inspection of Menarini's facility or a facility under contract with Menarini where such audit or inspection is not related to the Product, Menarini shall promptly notify VIVUS of any findings of such an audit or inspection that may have an effect on Menarini's ability to assume its obligation and responsibilities imposed by this Agreement.

(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, VIVUS's SOP shall control unless and until VIVUS transfers ownership of the Product Marketing Authorization to Menarini, and Menarini's SOP shall control thereafter. If either Party becomes aware of information relating to any 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 Menarini decides to initiate a recall, field correction, or withdrawal of Product in the Menarini Territory, Menarini shall have the right and responsibility, at its expense, 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 5.5(c), if applicable); provided, however, Menarini shall consider in good faith the views of VIVUS as to whether a recall, field correction, or withdrawal is necessary or appropriate. If (i) a Regulatory Authority or other Applicable Law requires a recall, field correction, or withdrawal of Product in the Menarini Territory, and (ii) Menarini fails to initiate such recall, field correction, or withdrawal within the deadline imposed by the Regulatory Authority, VIVUS shall have the right, at its expense, 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 5.5(c), if applicable); provided, however, VIVUS shall consider in good faith the views of Menarini 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 five (5) years.

5.6 **PV Agreement**. Not later than *** after the Effective Date, the Parties shall use *** to enter into a separate pharmacovigilance agreement (the "**PV Agreement**") containing the

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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. Menarini acknowledges that its obligations under the PV Agreement shall include collecting and monitoring adverse events in the Menarini Territory and providing VIVUS with information on such adverse events in a format and on a timeline specified in the PV Agreement, which format shall be consistent with regulatory obligations under Applicable Law (including any obligations imposed on VIVUS or Menarini, as the case may be, as the holder of the Product Marketing Authorization). Any failure to comply with the PV Agreement by Menarini in any material respect shall be deemed to be a material breach of this Agreement, giving rise to VIVUS's right to terminate this Agreement pursuant to Section 12.2(a).

## 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 D, under which VIVUS has agreed to supply, for the time period set forth therein, itself or through *** Third Party manufacturers, bulk tablets of Product to Menarini, its Affiliates, and/or its sublicensees for Commercialization in the Field in the Menarini Territory. The Parties have also entered into a quality agreement governing the agreed-upon specifications and other technical aspects of supply of Products for Commercialization in the Field in the Menarini 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 Menarini on the Effective Date.

6.2 **Manufacturing Transition.**

(a) At any time during the Term, Menarini may elect (by written notice to VIVUS) either of the following: (a) to accept an assignment of VIVUS's agreements with the manufacture(s) then part of the supply chain for Product for use in the Field in the Menarini Territory (such option, "**Supply Chain Transfer**") or (b) to manufacture, itself or through *** Third Party manufacturers, Compound and/or bulk tablets of Product for use by Menarini, its Affiliates, and/or its sublicensees in the Field in the Menarini Territory (such option, "**Independent Manufacturing**"). Notwithstanding Menarini's election to initiate Independent Manufacturing, the Commercial Supply Agreement shall continue in full force and effect, and Menarini may trigger the Supply Chain Transfer at a later date. Similarly, if Menarini triggers the Supply Chain Transfer, Menarini shall retain the right to initiate Independent Manufacturing at a later date, but Menarini's right to manufacture Product shall be subject to the limitation set forth in Section 2.2(b)(ii).

(b) As promptly as practicable after the Effective Date, in preparation for the possibility of Supply Chain Transfer and/or Independent Manufacturing, the Parties shall

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discuss and agree on a written plan for these scenarios (the "**Manufacturing Transfer Plan**"), including without limitation procedures for ensuring that Menarini's management of the supply chain following Supply Chain Transfer or initiation of Independent Manufacturing does not materially compromise the supply to VIVUS or its licensees of Product for use and/or sale in the VIVUS Territory. Following agreement on such Manufacturing Transfer Plan, the Parties shall each use *** to carry out their respective obligations thereunder in a timely fashion; provided, however, the Supply Chain Transfer or initiation of Independent Manufacturing shall only occur if and when Menarini makes the applicable election pursuant to Section 6.2(a). Following the Supply Chain Transfer, Menarini shall pay the Third Party manufacturer of Product directly for supply of Product.

(c) Menarini's right to conduct Independent Manufacturing is expressly conditioned on (i) grant of a related manufacturing authorization by the applicable Regulatory Authority; (ii) grant of a related variation to the existing Regulatory Approvals for the Products by the applicable Regulatory Authority; and (iii) Menarini's continued compliance with any requirements imposed by Applicable Law or the applicable Regulatory Authority. For clarity, the variation and manufacturing authorization referenced in subsections (i) and (ii) shall name Menarini and/or its Third Party manufacturer(s), as the case may be. At any time following transfer of the Product Marketing Authorization to Menarini, Menarini may elect (by written notice to VIVUS) to proceed with any such variation and/or manufacturing authorizations that are necessary for Independent Manufacturing; provided, however, that Menarini's right to conduct Independent Manufacturing shall not commence until Menarini formally makes the election to conduct Independent Manufacturing pursuant to Section 6.2(a).

(d) If Menarini elects to conduct Independent Manufacturing, itself or through *** Third Party manufacturers, VIVUS shall cause its then-existing manufacturer(s) to transfer the technology of production to Menarini or the Third Party designated by Menarini, exclusive of any proprietary or confidential manufacturing technology of such manufacturer that can be used independently of the manufacture of Product. Menarini shall be responsible for paying all out of pocket costs and expenses incurred by VIVUS or its Affiliates in connection with the variation to the Regulatory Approvals required for the appointment of Menarini or its designee(s) as new manufacturers for the Products, any other authorizations from a Regulatory Authority required for such appointment, or the aforesaid technology transfer, based on invoices submitted by VIVUS from time to time. Menarini 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, from and against any and all liabilities, losses, claims, suits, damages, costs and expenses (including but not limited to Losses) arising in connection with the filing or seeking of such variations to the Regulatory Approvals or other manufacturing authorizations, or any personal injury or death resulting from the activities of Menarini or its designee(s) as new manufacturers.

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## ARTICLE 7
## FINANCIALS

7.1 **License Fee**. No later than *** after the Effective Date, Menarini shall pay to VIVUS a one-time, non-refundable, non-creditable license fee of *** Euros (€***) by wire transfer of immediately available funds into an account designated by VIVUS.

7.2 **Regulatory Milestone Payment**. Menarini shall, subject to Section 4.6(b) and 7.11, make each of the payments indicated below to VIVUS within *** after the achievement of the corresponding milestone event.

| Milestone Event | Payment |
|---|---|
| Approval of MAA by European Commission | € *** |
| Approval by European Commission (or other Regulatory Authority in the Menarini Territory) of a Time of Onset Claim for Product in the Menarini Territory, whether as part of the initial approval of an MAA, through approval of a Label Expansion Filing, or otherwise * | € *** |
| Product Launch in Italy | € *** |
| Product Launch in Spain | € *** |
| Product Launch in Germany | € *** |
| Product Launch in France | € *** |
| Product Launch in the United Kingdom | € *** |

* For the avoidance of doubt, this second milestone would be in addition to the first milestone, since the first milestone applies regardless of whether the Label Expansion Filing is filed or approved. If the Time of Onset Claim is not permitted as a result of the initial approval of an MAA by the European Commission, VIVUS shall work with Menarini to include the Time of Onset Claim in the SmPC upon the successful completion of the Time of Onset Study. VIVUS shall have *** from approval of an MAA by the European Commission to modify the SmPC; provided, however, that such deadline shall automatically be extended to *** after approval of an MAA by the European Commission if modification of the SmPC is delayed as a result of the action or inaction of Menarini.

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 €***. Each such payment shall be made by wire transfer of immediately available funds into an account designated by VIVUS. Each such payment is nonrefundable and noncreditable against any other payments due hereunder.



7.3 **Royalty Pre-Payment Milestones**. No later than *** after approval of the MAA by EMA, Menarini shall pay to VIVUS a one-time payment of €*** as a pre-payment on royalties to be owed under Section 7.5. Each such payment shall be made by wire transfer of immediately available funds into an account designated by VIVUS. Each such payment is nonrefundable and, except as provided in Section 7.5, noncreditable against any other payments due hereunder.

7.4 **Sales Milestone Payments.** Menarini shall make each of the sales milestone payments indicated below to VIVUS when aggregate Net Sales of Product in any calendar year in the Menarini Territory reach the specified values.

| Aggregate Net Sales in a Calendar Year | | Payment | |
|---|---|---|---|
| € | *** | € | *** |
| € | *** | € | *** |
| € | *** | € | *** |

Each sales milestone payment in this Section 7.4 shall be paid only once. The maximum total amount of payment to VIVUS pursuant to this Section 7.4 shall be €***. Menarini shall notify and pay to VIVUS the amounts set forth in this Section 7.4 together with the delivery of the quarterly report pursuant to Section 7.8 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, Menarini shall owe each of the corresponding payments. Each such payment shall be made in Euros by wire transfer of immediately available funds into an account designated by VIVUS. Each such payment is nonrefundable and noncreditable against any other payments due hereunder.

7.5 **Royalty to VIVUS.**

(a) During the Royalty Term, on a calendar quarter basis, Menarini shall pay to VIVUS a royalty equal to *** percent (***%) of Net Sales of Products in the Menarini Territory; provided, however, that until the Royalty Pre-Payment has been fully credited pursuant to Section 7.5(b), such royalty percentage shall be *** percent (***%).

(b) Menarini may credit the Royalty Pre-Payment against royalties owed under Section 7.5(a) (but not any payments owed under Section 7.6). The Royalty Pre-Payment shall be creditable against *** Euros of royalty owed under Section 7.5(a).

7.6 **Additional Royalty**. In addition to the royalties owed to VIVUS pursuant to Section 7.5, Menarini shall be responsible for paying to VIVUS the royalties and other payments outlined in Exhibit E. 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, Menarini's payment obligations under this



Section 7.6 and Exhibit E that are based on net sales shall be determined using the definition of "MTPC Agreement Net Sales" contained in Exhibit E.

7.7 **Reports; Payments.** Within *** after the end of each calendar month, Menarini shall provide VIVUS with a statement of (a) the amount of gross sales of Product by country in local currency during the applicable calendar month, (b) an itemized calculation of Net Sales showing Net Sales Deductions by country in local currency during such calendar month. Within *** after the end of each calendar quarter, Menarini shall provide a statement of the details in (a) and (b) above and the calculation of the amount of royalty payment due on such sales for such calendar quarter pursuant to Section 7.5, any sales milestone payment due pursuant to Section 7.4, and any payment due pursuant to Section 7.6. Together with such quarterly statement, Menarini shall provide VIVUS with any such payments due. Notwithstanding the foregoing, with respect to the sales milestone payment owed by Menarini pursuant to Section 7.6 and Exhibit E, Menarini shall pay such sales milestone payment no later than *** after receipt of an invoice from VIVUS specifying such sales milestone payment. All amounts payable to VIVUS under this Section 7.7 shall be paid in United States dollars ("**USD**") by wire transfer of immediately available funds into an account designated by VIVUS (other than the sales milestone payments, which will be paid in Euros). These amounts payable to

VIVUS in USD will be calculated starting from the amounts in local currencies (on a country by country and currency by currency basis) and converting these amounts to USD at the average quarterly cross-exchange rates, local currency into USD, as published by the European Central Bank, and the details of the calculation of the local currency amounts and the conversion to USD will be provided to VIVUS along with the quarterly statement described above.

7.8 **Taxes.** If, at any time during the Term,, Menarini is legally required to withhold any Taxes from payments due hereunder, Menarini shall (a) deduct such Taxes from the payment made to VIVUS, (b) timely pay the taxes to the proper taxing authority, and (c) send proof of payment to VIVUS. 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' reasonable control. Notwithstanding the foregoing, if a deduction or withholding of Taxes hereunder arises as a result of any action by Menarini that has 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 "**Menarini Withholding Tax Action**"), including without limitation an assignment of this Agreement by Menarini or any failure on the part of Menarini to comply with Applicable Law, then (i) the payment by Menarini 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 Menarini Withholding Tax Action occurred, and (ii) the obligations in subsections (a)-(c) above shall apply with respect to such Additional Tax. 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.

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7.9 **Late Payments.** If a Party does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at the yearly rate of *** percent (***%) above the then-applicable ***, or at the maximum rate permitted by Applicable Law, whichever is the lower..

7.10 **Records; Audits.** Menarini shall maintain complete and accurate books and records in accordance with Accounting Standards 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 Menarini Territory not more than once each calendar year (during normal business hours on a mutually agreed date with reasonable advance notice) at a location in the Menarini Territory by an independent Third Party auditor selected by VIVUS and approved by Menarini (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 Menarini pursuant to this Agreement or of any payments made by Menarini to VIVUS pursuant to this Agreement. Any such auditor shall not disclose Menarini's Confidential Information to VIVUS, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Menarini or the amount of payments due by Menarini under this Agreement. Any amounts shown to be owed but unpaid shall be paid within *** from the accountant's report, plus interest (as set forth in Section 7.9) from the original due date. Any amounts shown to have been overpaid may be credited by Menarini against future payments to VIVUS hereunder. No payment to VIVUS shall be reduced by more than *** percent (***%) as a result of such credit, and Menarini may carry forward any unused credits to future calendar quarters. VIVUS shall bear the full cost of such audit unless such audit reveals a payment or reporting error of *** percent (***%) or more during the applicable audit period, in which case Menarini shall bear the full cost of such audit.

## ARTICLE 8
## INTELLECTUAL PROPERTY

8.1 **Ownership of Inventions.** Each Party shall own all inventions and Information made solely by the respective employees, agents, and independent contractors of it and its Affiliates in the course of conducting such Party's activities under this Agreement (collectively, **"Sole Inventions"**), along with any patents and patent applications 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 any exclusive licenses granted pursuant to Section 2.2 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 law, such consent is hereby deemed granted) and without a duty of accounting to the other Party.

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8.2 **Disclosure of Inventions.** Each Party shall promptly disclose to the other all Sole Inventions or Joint Inventions relating to 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.** Subject to the provisions below, VIVUS shall, or shall cause MTPC to, use *** to prosecute and maintain the VIVUS Patents in accordance with Applicable Law and customary practices in the pharmaceutical industry.

(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 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

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Third Party's manufacture, use or sale of a Product in the Field in the Menarini 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 certification or filing with a governmental authority in the Menarini Territory that asserts that infringement of a VIVUS Patent or Joint Patent will not arise from the manufacture, use or sale of a Product in the Field in the Menarini Territory by a Third Party or that asserts that any claims of a VIVUS Patent or Joint Patent covering Product in the Field in the Menarini Territory is invalid or unenforceable shall be deemed to be a Product Infringement hereunder, and each Party shall provide written notice of other Party of any such filed certification within *** of becoming aware thereof.

(b) **Enforcement**. Under the terms of the MTPC Agreement, as between VIVUS and MTPC, VIVUS has the first right to initiate, prosecute and control legal proceedings against any person or entity engaged in such Product Infringement of the VIVUS Patents in the Menarini Territory (the "**Enforcement Right**"). During the Term, in the event of any Product Infringement of the VIVUS Patents in the Menarini Territory, VIVUS shall permit Menarini to exercise, or shall exercise on Menarini's behalf (subject to Menarini's consent), the Enforcement Right, subject to the remainder of this Section 8.4. The foregoing exercise of the Enforcement Right shall be at Menarini's sole expense, and Menarini agrees to pay for all reasonable costs and expenses incurred by VIVUS or its Affiliates in connection with such exercise. To the extent the foregoing exercise of the Enforcement Right results in any Claim of a Third Party against VIVUS or its Affiliates, Menarini shall defend VIVUS against such Claim and shall indemnify VIVUS against Losses payable by VIVUS in connection therewith. If Menarini decides not to bring such legal action, or if Menarini fails to initiate such legal action by the Action Date, it shall so inform VIVUS promptly, and 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 Menarini 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 Menarini, VIVUS agrees to exercise its right under the MTPC Agreement to require MTPC to cooperate in any enforcement by or on behalf of Menarini 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 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.

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(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 Products in its territory (i.e., the Menarini Territory in the case of Menarini or the VIVUS Territory in the case of VIVUS). Notwithstanding the foregoing, in the event that (A) Menarini decides not to bring a legal action against Product Infringement in the Menarini Territory, or if Menarini 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 Menarini Territory or the VIVUS Territory, settlement of such action shall be at MTPC's sole discretion and shall not require the consent of Menarini.

(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 Menarini 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 or entity 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**. Menarini 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.

8.6 **Trademarks.**

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

(b) **VIVUS Trademarks**. Menarini's use of the VIVUS Trademarks shall be limited to the marketing, sale and distribution of the Product in the Menarini Territory. Menarini

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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. Menarini 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 Menarini Territory during the Term shall inure to VIVUS's benefit. Menarini agrees that the Products with which the VIVUS Trademarks are used shall conform to all requirements of the Regulatory Authority in the Menarini Territory. Menarini shall, as soon as practicable after receiving notice of any potential infringement of the VIVUS Trademarks in the Menarini 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.

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

8.7 **Infringement of Third Party IP.** Each Party shall promptly notify the other in writing of any allegation, claim or suit that the manufacture, use or sale of a Product infringes or misappropriates a Third Party's Patent or other intellectual property rights. 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.

## 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 Execution Date:

(a) **Corporate Existence and Power**. It is a corporation or limited partnership, as applicable, 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

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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 Execution 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 or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Execution Date.

9.2 **VIVUS Technology**. VIVUS hereby represents and warrants to Menarini as of the Execution Date that:

(a) To the knowledge of VIVUS, VIVUS is the exclusive licensee of the VIVUS Patents in the Field in the Menarini Territory;

(b) VIVUS has granted no rights to a Third Party under the VIVUS Technology with respect to the Commercialization of Products in the Field in the Menarini Territory;

(c) to the knowledge of VIVUS as of the Execution Date, the manufacture and Commercialization of the Product in the Field in the Menarini Territory does not infringe any valid and enforceable Third Party patents in the Menarini Territory; and

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

9.3 **VIVUS Trademark Representations and Warranties**. VIVUS hereby represents and warrants to Menarini as of the Execution Date that:

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

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(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 Menarini 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 Menarini 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 Menarini Territory and to license to Menarini 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 Menarini Territory.

9.4 **Compliance with Law**. Each Party shall, and shall ensure that its Affiliates and sublicensees shall, comply with all Applicable Laws in exercising their rights and fulfilling their obligations under this Agreement.

9.5 **Representations regarding Debarment and Compliance.**

(a) Each Party represents, warrants and covenants that as of the Execution Date, to the best of each Party's knowledge based on reasonable inquiry, neither it nor its Affiliates that are involved in the Commercialization of the Product nor any of their legal representatives or agents who are legally empowered to bind the Party, nor any Third Party (and its legal representatives or agents who are legally empowered to bind the Third Party), that is 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 or under any substantially equivalent Applicable Laws;

(ii) have been convicted, with sentence having value of *res judicata*, 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; Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use,

the national laws of individual EU Member States implementing the provisions of these Directives into their national law, Regulation (EC) No 726/2004 of the European



Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, or any similar Applicable Laws; (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, any state health care program, or any healthcare program in any country in the European Union or any other part of the Menarini Territory) or provision of illegal inducements to physicians or healthcare institutions to recommend, endorse, prescribe, order, supply, purchase, use or administer any drug product; (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), excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any healthcare program in any country in the European Union or any other country in the Menarini Territory, or excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any United States federal procurement or nonprocurement programs or procurement or nonprocurement programs in any country in the European Union or any other countries in the Menarini Territory.

(b) Each Party will notify the other Party promptly, but in no event later than ***, after knowledge of any exclusion, debarment, conviction, suspension or other ineligibility set forth in Section 9.5(a) 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, conviction, debarment, suspension or other ineligibility of such Party and the Parties shall immediately discuss in good faith on how to cope with such an event.

9.6 **Disclaimer**. VIVUS makes no warranties except as set forth in this Article 9 concerning the Product or VIVUS Technology and Menarini makes no warranties except as set forth in this Article 9 concerning the Menarini Technology.

9.7 **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 RIGHTS, 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.



## ARTICLE 10
## INDEMNIFICATION

10.1 **Indemnification by VIVUS.** VIVUS shall defend, indemnify, and hold harmless Menarini, 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 **"Menarini Indemnitees"**) from and against any and all Losses to the extent resulting from any Claim of a Third Party against such Menarini 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) any allegation by a Third Party that the use of the VIVUS Trademark by one or more of the Menarini Indemnitees or the Commercialization of the Product by one or more of the Menarini Indemnitees infringes such Third Party's valid patent or trademark rights in the Menarini Territory (except to the extent such allegation is based on (i) other products being used or sold in conjunction with the Product or (ii) additions or modifications to the Product that are not made by VIVUS or its Affiliates or Third Party contractors).

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

10.2 **Indemnification by Menarini.** Menarini 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 to the extent resulting from any Claim of a Third Party against such VIVUS Indemnitee based on or arising out of:

(a) any misrepresentation or breach of any of Menarini's representations, warranties, covenants or obligations under this Agreement; or

(b) the negligence or willful misconduct of, or violation of Applicable Law by, Menarini, its Affiliates, licensees, distributors or their respective officers, directors, employees, consultants or authorized agents under this Agreement; or

(c) the Commercialization of any Product, or the performance of any Menarini Medical Affairs Activities, by Menarini, its Affiliates, and sublicensees.

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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 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. 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. 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 THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY IN CONNECTION WITH (A) 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 GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OR FRAUDULENT ACTS OR OMISSIONS OF A PARTY.

10.5 **Insurance.** 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 property and product liability risks through

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insurance companies with a rating of at least an "A-VII" in the latest addition of A.M. Best or its equivalent as follows:

(a) commercial general liability, including product liability coverage with minimum per claim limits of at least $*** per occurrence and annual aggregate;

(b) property coverage having limits adequate for Product inventory to which such Party holds title.

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 this Article 10. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall endeavor to 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.

## ARTICLE 11
## CONFIDENTIALITY

11.1 **Confidentiality.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each 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 other 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 other 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

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

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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 other 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.** Each Party may disclose Confidential Information belonging to the other Party to the extent such 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, disclosure to MTPC as required pursuant to the MTPC Agreement provided that the use by MTPC of such Confidential Information shall be subject to the confidentiality and non-use obligations set forth in 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 Menarini 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 the 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 the Product; (iii) is reasonably likely to lead to a recall or market withdrawal of the 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 disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Section 11.1 and this Section 11.2 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 disclosee);

(d) disclosure to its and its Affiliates' respective directors, officers, employees, consultants, attorneys, professional advisors, lenders, insurers and sublicensees only on a need-to-know basis and solely as necessary in connection with this Agreement, provided that each disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Section 11.1 and this Section 11.2 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 disclosee); 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 disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Section 11.1 and this Section 11.2 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 disclosee).

11.3 **Publicity; Terms of Agreement.**

(a) 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 F on or after the Effective Date. 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) After release of the 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) VIVUS may publicly disclose without violation of this Agreement, such terms of this Agreement as are, on the advice of VIVUS's counsel, required by the rules and regulations of the SEC or any other applicable entity having regulatory authority over VIVUS's securities; provided that VIVUS shall advise Menarini 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 VIVUS. In the event of any such filing, VIVUS will provide Menarini, a reasonable time prior to filing, with a copy of the Agreement marked to show provisions for which VIVUS intends to seek confidential treatment and shall reasonably consider and incorporate Menarini's comments thereon to the extent consistent with the legal requirements applicable to VIVUS and that govern redaction of information from material agreements that must be publicly filed. Menarini shall provide any such comments as promptly as practicable.

## ARTICLE 12
## TERM AND TERMINATION

12.1 **Term.** This Agreement shall become effective as set forth in Section 2.1 and, unless earlier terminated pursuant to this Article 12, shall remain in effect until the expiration of the last to expire royalty obligation with respect to Products under this Agreement (the **"Term"**).



Upon the expiration of the Term, the licenses in 2.2 shall become perpetual, fully paid up, royalty free and irrevocable and Menarini shall become the ultimate owner of any Regulatory Approval. Notwithstanding anything to the contrary in this Agreement, except for Section 12.6, 12,7 and 12.8, in no event the rest of this Section 12 shall apply after the expiration of the Term.

12.2 **Termination before the expiration of the Term.**

(a) **Breach of contract.** 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 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 Menarini), Menarini's uncured failure to pay the amount set forth in Section 7.1 shall be deemed to be a material breach of this Agreement. Notwithstanding the above, VIVUS shall have the right to terminate the Agreement immediately without notice in case of the breaches by Menarini provided in Section 4.2(b), Section 4.2(c), Section 5.2(a), 5.5(b), and Section 5.6 of this Agreement.

(b) **Government Action.** VIVUS shall have the right to terminate this Agreement immediately upon written notice to Menarini if either of the following occurs, but only with respect to the affected country(-ies) in the Menarini Territory: (i) Menarini or its Affiliate involved in the Commercialization of the Product has been convicted of a violation of the Applicable Laws Menarini or its Affiliate, which conviction has value of *res judicata* and which conviction prevents or renders commercially impracticable Menarini or its Affiliates that are involved in the Commercialization of the Product (as the case may be) from marketing, promoting, selling, or distributing Product in a given country of the Menarini Territory; or (ii) Menarini or its Affiliate involved in the Commercialization of the Product is excluded from the access to the pharmaceutical market by the competent authorities in a given country in the Menarini Territory.

(c) **EMA Requirements**. Menarini shall have the right to terminate this Agreement immediately upon written notice to VIVUS if the EMA or the European Commission requires any post-Regulatory Approval studies under the Existing MAA that were not included in the opinion adopted by the EMA's Committee for Medicinal Products for Human Use and the Product Marketing Authorization or if the QT Study results into any change of the SmPC of Product which would reasonably have a negative impact on the Commercialization of the Product in the Territory; provided, however, that Menarini shall only be permitted to exercise such right during the *** following either (i) the date on which Menarini first learns of such requirement or SmPC change or (ii) the date on which Menarini receives notice from VIVUS that VIVUS is forgoing, pursuant to Section 4.3(b), the further sharing of costs of the post-Regulatory Approval studies of Product in the Menarini Territory (it being understood that subsection (ii) is not applicable to any termination based on an SmPC change). For clarity, in the



event of such a termination, none of the payments made by Menarini prior to such termination would be refundable.

(d) **Termination for Patent Challenge.** VIVUS may terminate this Agreement in its entirety upon written notice to Menarini if Menarini 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, enforceability or scope of any VIVUS Patent in the Menarini Territory. In the event Menarini 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 Menarini Territory, Menarini shall promptly terminate the applicable sublicense. If Menarini does not terminate such sublicense within *** of Menarini becoming aware of such challenge, VIVUS may terminate this Agreement in its entirety upon written notice to Menarini.

(e) **Termination Upon Bankruptcy**. To the extent permitted by Applicable Law, either Party shall have the right to terminate this Agreement immediately by providing written notice, if: (i) 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, (ii) the other Party makes a general assignment for the benefit of its creditors, (iii) the other Party is dissolved or liquidated in full or in substantial part, (iv) the other Party is the subject of voluntary or involuntary bankruptcy proceedings instituted on behalf of or against such other Party (except for involuntary bankruptcy proceedings which are dismissed within ***, or (v) the other Party takes any corporate action for the purpose of effecting any of the foregoing.

12.3 **Effect of Termination of the Agreement before the expiration of the Term.** Upon termination of this Agreement for any reason provided for in Section 12.2, 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) **Licenses; Covenant.** The licenses granted to Menarini under Section 2.2 shall terminate (and, as between the Parties, all rights in the VIVUS Technology shall revert to VIVUS), and the license granted to VIVUS in Section 2.3 shall automatically convert into an exclusive, royalty-free license, with the right to grant sublicenses through multiple tiers, under the Menarini Technology, to research, Develop, make, have made, use, distribute, import, Promote, market, sell, offer for sale, and otherwise Commercialize Product in the Menarini Territory and the VIVUS Territory.

(b) **Marks.** All rights in the VIVUS Trademarks shall return to VIVUS, and Menarini shall assign to VIVUS any Menarini Trademarks that are Controlled by Menarini and then being used to Commercialize Product in the Menarini Territory.

(c) **Regulatory Materials**. Except to the extent prohibited by Applicable Law, Menarini shall transfer and assign to VIVUS any and all Regulatory Materials, Regulatory

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Approvals, and Pricing Approvals with respect to Product that are Controlled by Menarini or its Affiliates (including the Product Marketing Authorization).

(d) **Transition Assistance**. Except in the case of termination by Menarini pursuant to Section 12.2(a), Menarini 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 Menarini Territory, including without limitation, upon request of VIVUS, using reasonable efforts to (A) transfer any agreements or arrangements with distributors that apply solely to the sale or supply of Product in the Menarini Territory, and (B) amend any agreement or arrangements with distributors that apply to some extent to the sale or supply of Products in the Menarini Territory to transfer to VIVUS the rights solely with respect to Product in the Menarini Territory.

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

12.4 **Certain Pre-Termination Liabilities**. Following termination of this Agreement for any reason provided for in Section 12.2, Menarini 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 that any such deductions are charged to or otherwise borne by VIVUS, Menarini shall reimburse VIVUS promptly (but in any event no later than ***) following Menarini's receipt of an invoice therefor.

12.5 **Sales Volume**. Menarini shall use *** to ensure that the average monthly sales volume of the Product leading up to the effective date of termination does not substantially exceed the average monthly sales volume of the Product for the *** period prior to date of the notice of termination, and in any event Menarini 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 Menarini 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

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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 for the period of time specified: Sections 2.3 (as amended by Section 12.3(a)), 4.13, 5.4 (second sentence only and solely until assignment in Section 12.3(c) is complete), 7.10, 8.1, 12.3, 12.4, 12.6, 12.7, 12.8, 12.9; Articles 10, 11, 13, and 14; and any necessary definitions in Article 1

12.9 **Liquidated Damages.** If, within *** after termination of this Agreement for any reason provided for in Section 12.2, Menarini has failed or has been unable to transfer to VIVUS the Product Marketing Authorization and any other Regulatory Approval(s) for the Product in the Menarini Territory, Menarini shall pay to VIVUS the amount of €*** as liquidated damages (and not as a penalty). Menarini acknowledges that the actual damages likely to result from Menarini's failure to transfer such Regulatory Approval(s) are difficult to estimate as of the Execution Date and would be difficult for VIVUS to prove. For the sake of convenience, the Parties have agreed to require the payment of foregoing liquidated damages as compensation to VIVUS for Menarini's failure to transfer such Regulatory Approval(s), and the Parties do not intend for this provision to serve as punishment for any such failure by Menarini. In the event that VIVUS is awarded economic damages pursuant to an action against Menarini for failure to transfer to VIVUS the Product Marketing Authorization and any other Regulatory Approval(s) for the Product in the Menarini Territory, VIVUS agrees that any payments made by Menarini hereunder shall be creditable against such damages award (unless such the applicable court, arbitration panel, or other tribunal already took such payments into account when calculating such damages award).

## 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 dispute, controversy or difference arising from the JSC pursuant to Article 3 shall be resolved in accordance with Section 3.5.

(b) **Arising Between the Parties.** Other than any dispute, controversy or difference which may arise from the JSC, 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(b), 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 San Francisco, California, 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 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.** Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of the VIVUS Patents, VIVUS Trademarks, or



Menarini Trademarks 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 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 Execution 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 other electronic transmission, or one Business Day after being sent by a reputable overnight delivery service.

If to VIVUS:

With a copy to:

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If to Menarini:

With a copy to:

For details see **Exhibit G** in attachment.

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 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.

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, except that a Party may

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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. Notwithstanding any assignment of this Agreement, the assigning Party shall remain liable for performance of its obligations hereunder, unless the non-assigning Party agrees otherwise in writing. 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 Menarini Technology shall exclude any intellectual property held or developed by a permitted successor of Menarini prior to the transaction in which it became a successor of such Party. 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.

14.6 **Records Retention**. Each of VIVUS and Menarini 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 Menarini 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 California, 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 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 Menarini under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at Menarini's sole and exclusive option, either by Menarini directly or by any Affiliate of Menarini that Menarini



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 **Compliance with Applicable Law.** Each Party shall comply with all Applicable Laws in the course of performing its obligations or exercising its rights pursuant to this Agreement. Either Party, in performing this Agreement, represents and warrants that it shall fully and absolutely comply with the provisions of any Applicable Law intended to prevent corruption and/or bribery (e.g., national laws adopted and implemented pursuant to the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, including but not necessarily limited to the United States Foreign Corrupt Practices Act of 1977, as amended, and the German Act on Combating Bribery of Foreign Public Officials In International Business Transactions of 1998 and related legislation) as are in force from time to time (hereinafter referred to as the "**Anti-Bribery Laws**"), commits itself to adopt all necessary measures to prevent violation of the Anti-Bribery Laws. Without limiting the foregoing, either Party agrees that it will not, in the conduct of its performance under this Agreement, offer, pay, give, or promise to pay or give, directly or indirectly, any payment or gift of any money or thing of value to (i) any government official (which term shall, for purposes of this Section 14.11, include without limitation health care providers in state-run hospitals and health care systems and decision-makers in state-owned or -controlled enterprises) to influence any acts or decisions of such official or to induce such official to use his influence with any government to effect or influence the decision of such government in order to assist the Party in its performance of its obligations under this Agreement or to benefit either of the Parties; (ii) any political party or candidate for public office for such purpose; or (iii) any person if either Party knows or has reason to know that such money or thing of value will be offered, promised, paid, or given, directly or indirectly, to any official, political party, or candidate for such purpose. A defaulting Party shall hold harmless and indemnify the other Party from any and all claim, expense, fine, sanction, prejudice, obligations, consequences or adverse implications that may arise resulting from the conduct of the defaulting Party violating the Anti-Bribery Laws.



14.12 **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.

14.13 **No Waiver**. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

14.14 **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 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.

14.15 **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.

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

| **VIVUS INTERNATIONAL, L.P.** | | | **BERLIN-CHEMIE AG** | | |
|---|---|---|---|---|---|
| By: | /s/ Peter Y. Tam | /s/ Timothy E. Morris | By: | /s/ Dr R. Uppenkamp | /s/ Dr A. Sebastio |
| Name: | Peter Y. Tam | Timothy E. Morris | Name: | Dr R. Uppenkamp | Dr A. Sebastio |
| Title: | President | CFO | Title: | CEO | CFO |

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**EXHIBITS**

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| **Exhibit A** | VIVUS Patents |
| **Exhibit B** | VIVUS Trademarks |
| **Exhibit C** | Commercialization and Medical Affairs Plan |
| **Exhibit D** | Supply Agreement |
| **Exhibit E** | Additional Financial Terms |
| **Exhibit F** | Press Release |
| **Exhibit G** | References |

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**EXHIBIT A**
**VIVUS PATENTS**

*******

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**EXHIBIT B**
**VIVUS TRADEMARKS**

| Country in Menarini Territory | Application Number/Registration Number | Filing date | Status |
|---|---|---|---|
| *** | *** | *** | *** |

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**EXHIBIT C**
**COMMERCIALIZATION AND MEDICAL AFFAIRS PLAN**

[To be completed after signing]

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**EXHIBIT D**
**SUPPLY AGREEMENT**

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**EXHIBIT E**
**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$*** | ***% of MTPC Agreement Net Sales related to the Menarini Territory |
| Portion in excess of US$*** | ***% of MTPC Agreement Net Sales related to the Menarini Territory |

Additional Milestone Payments:

- US$*** upon obtainment of the first regulatory approval of Product in any of the United Kingdom, Germany, France, Italy, or Spain.
- A pro-rata share of US $*** sales milestone, due when for the first time the total MTPC Agreement Net Sales during any calendar year of Product sold by VIVUS, its Affiliates, and sublicensees exceed US$***. ***

Trademark Royalty Payments:

In consideration for the trademark license granted in Section 2.2(b) and the use of the trademarks associated with the Product and the VIVUS Technology, Menarini shall (a) during *** following the expiration of the MTPC Royalty Period in a particular country in the Menarini Territory, pay to VIVUS a royalty equal to *** percent (***%) of MTPC Agreement Net Sales of Products in such country; and (b) during *** following the end of the Royalty Term in such country, pay to VIVUS a royalty equal to *** percent (***%) of 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.

As used in this Exhibit E, the following initially capitalized terms, whether used in the singular or plural form, shall have the meanings set forth below:

"**Bulk Drug Substance**" means any Licensed Compound in bulk form which, if appropriately formulated and finished, would constitute Final Product.

"**CMO**" shall mean any entity (other than MTPC or VIVUS or their respective affiliates) to replace MTPC as the sole supplier of the Bulk Drug Substance that manufacturers Bulk Drug Substance, including an assignee or sublicensee under the MTPC Agreement (other than MTPC or VIVUS or their respective affiliates).

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"**Final Product**" means any product which has been manufactured into a final dosage form, packaged and labeled for any therapeutic use in humans, and which contains the Licensed Compound as an active ingredient.

"**Licensed Compound**" means all the compounds which are selective phosphodiesterase type-5 inhibitors, which compounds are contained within a claim of any unexpired VIVUS Patent no matter when filed or in a claim of a pending application for a VIVUS Patent no matter when filed which is being prosecuted in good faith by or on behalf of MTPC or its Affiliate, including the Compound.

"**MTPC Agreement Net Sales**" means, with respect to a Final Product, the amount invoiced by VIVUS, its affiliates and their sublicensees (each, a "**Seller**") for sales of such Product to a Customer (as defined below), less estimates which will be adjusted to actual on a periodic basis of:

(a) Sales returns (to the extent that customary practice is to allow the Customer to return Seller a Final Product expired or will expire unsold, or in the event of a Final Product recall, rejections or damaged Final Product);

(b) Discounts (including prompt pay cash discounts, patient cash discounts, price reductions and incentive programs, rebates, trade and quantity discounts, purchase volume discounts, patient co-pay assistance, price reduction programs, retroactive price adjustments, sales coupons, etc.) to managed care organizations, or to federal, state and local governments, or to the Customer;

(c) Wholesaler fees, inventory management agreement fees and specialty pharmacy fees, which are commercially reasonable and customary fees paid by Seller to the Customer;

(d) Chargebacks incurred or paid by Seller to government entities (Seller's programs with government entities whereby pricing on a Final Product by Seller to the participating entities is extended below wholesaler list price);

(e) Managed health care rebates and other contract discounts (including rebates, administrative fees, reimbursements and discounts to managed health care and pharmacy benefit organizations which manage prescription drug programs and prescription drug plans covering the Medicare Part D drug benefit or similar government programs in addition to their commercial plans, as well as other contract counterparties such as hospitals and group purchasing organizations);

(f) Medicaid or similar government rebates (local, state and federal government-managed Medicaid or similar programs as well as certain other qualifying Federal, state and local government programs (or their respective agencies, purchasers and reimbursers) whereby discounts and rebates are provided by Seller to participating federal, state and local government entities);

(g) Taxes, duties and other governmental charges levied on, absorbed or otherwise imposed on sale of a Final Product, including value-added taxes, or other governmental charges otherwise measured by the billing amount, when separately included on a billing by Seller to the Customer, as adjusted for rebates and refunds, but specifically excluding taxes based on net income of Seller;

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(h) Freight, postage, shipping and insurance charges actually allowed or paid for delivery of Final Product, to the extent billed as a separate line item by Seller to the Customer; and

(i) Customs duties, surcharges and other governmental charges incurred in connection with the exportation or importation of Final Product, to the extent billed as a separate line item by Seller to the Customer.

It is understood and agreed that (x) sales or transfers of Final Products between VIVUS, its affiliates and their sublicensees shall not constitute "MTPC Agreement Net Sales" unless such party is an end-user of such product and (y) "**Customer**" shall mean any entity (other than MTPC or VIVUS or their respective affiliates or their sublicensees) that is invoiced by Seller in a commercial arms-length transaction for the sale of Final Product in VIVUS's Licensed Territory.

"**MTPC Royalty Period**" means a period commencing on the first day of the calendar quarter following the calendar quarter in which the MTPC Supply Period expired and expiring, on a country-by-country and Product-by-Product basis, upon the later of (a) ten (10) years after Product Launch of such Product and (b) expiration of the last to expire patents within the VIVUS Patents covering such Product in such country.

"**MTPC Supply Period**" means a period commencing on August 1, 2012, and expiring upon the earlier of (i) the last day of the calendar quarter ]in which VIVUS notifies MTPC in writing that CMO (as hereinafter defined) assumes all of the manufacturing of the Bulk Drug Substance required by VIVUS for commercial use in its territory or (ii) the 30th day of June, 2015.

"**VIVUS's Licensed Territory**" means all the countries in the world excluding Japan, Democratic People's Republic of Korea (North Korea), Republic of Korea (South Korea), People's Republic of China (PRC including Hong Kong and Macao), Republic of China (Taiwan), Singapore, Indonesia, Malaysia, Thailand, Vietnam and the Philippines.

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**EXHIBIT F**
**PRESS RELEASE**

**VIVUS, Inc.**
Timothy E. Morris
Chief Financial Officer
morris@vivus.com
650-934-5200

**Menarini GROUP**
Valeria Speroni Cardi
Head of Press office
pressoffice@menarini.com

**Investor Relations: The Trout Group**
Brian Korb
bkorb@troutgroup.com
646-378-2923

**VIVUS ANNOUNCES AVANAFIL PARTNERSHIP WITH MENARINI**
***Menarini to Launch and Market SPEDRA in 40 Countries in Europe and Abroad***

***VIVUS to Receive Upfront Payment Plus Milestones and Royalties Over the Term of the Agreement***

**MOUNTAIN VIEW, Calif., July 9, 2013 —** VIVUS, Inc. (NASDAQ: VVUS) today announced that it has entered into a License and Commercialization Agreement and a Supply Agreement with Menarini and its wholly-owned subsidiary BERLIN-CHEMIE AG/MENARINI, to commercialize and promote SPEDRA™ (avanafil) in over 40 European countries plus Australia and New Zealand. SPEDRA is a new phosphodiesterase-5 inhibitor (PDE5-i) approved under the trade name STENDRA™ by the U.S. FDA in April 2012 and by the European Commission (EC) in June 2013 for the treatment of erectile dysfunction (ED).

The Menarini Group is the leading Italian pharmaceutical company in the world with over 125 years of history. Menarini, a private company headquartered in Florence, Italy, has a 2012 turnover of more than €3.2 billion ($4.2 billion) and has over 16,000 employees worldwide. In the EU, Menarini expects to field a sales force of 1,350 representatives to promote SPEDRA.

"Menarini will be an excellent partner for SPEDRA," stated **Timothy E. Morris**, **senior vice president, global corporate development and finance and CFO of VIVUS, Inc.** "Menarini has tremendous know how and marketing capabilities throughout Europe and has already established a presence in men's health with the acquisition last year of Priligy® (Dapoxetine) for treatment of premature ejaculation (PE). The licensing process was competitive and Menarini was chosen for their extensive presence in their territories and their history of successful drug launches across Europe. We look forward to a long and productive collaboration with Menarini."

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VIVUS will receive an upfront payment and various approval and sales milestones plus royalties on SPEDRA sales. Within the first year, VIVUS is expected to receive approximately €39 million (or approximately $51 million at current exchange rates) including upfront payments totaling €16 million (or approximately $21 million at current exchange rates). Menarini will also reimburse VIVUS for payment made to cover various obligations to Mitsubishi-Tanabe Pharma Company (MTPC) during the term of the agreement. VIVUS is eligible to receive up to €79 million (or approximately $102 million at current exchange rates) in milestones and other payments over the life of the agreement in addition to royalties. The agreement will continue on a country-by-country basis in the Menarini Territory, until the latest of: expiration of the last-to-expire valid VIVUS patent covering SPEDRA; data protection covering SPEDRA; or ten (10) years after the SPEDRA product launch. VIVUS and Menarini also entered into a supply agreement whereby VIVUS will supply Menarini with commercial product.

"SPEDRA is an important addition into our commercial portfolio. The rapid onset of action and unique profile make SPEDRA an important treatment option for men with ED," stated **Alberto Giovanni Aleotti, vice chairman of Menarini Group**. "We are eagerly preparing for the launch of SPEDRA, which we expect to occur in the major EU countries early next year".

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

Priligy® (Dapoxetine) is the first oral medication approved for "on-demand" treatment of PE.

ED is considered a disease of vascular origins in many patients and affects approximately 52 percent of men between the ages of 40 and 70. Prevalence increases with age and can be caused by a variety of factors, including medications (anti-hypertensives, histamine receptor antagonists); lifestyle (tobacco, alcohol use, drug use); diseases (diabetes, vascular conditions, metabolic syndrome, obesity), and spinal cord injuries. Left untreated, ED can negatively impact relationships and self-esteem, causing feelings of embarrassment and guilt. However, about half of men being treated with currently available PDE5 inhibitors are dissatisfied with treatment. The market opportunity for ED medical treatments continues to grow, with worldwide sales exceeding $5.5 billion in 2012.

**About Avanafil**

SPEDRA™, the trade name for avanafil in the EU, has just been approved by the EMA for the treatment of erectile dysfunction in the EU.

STENDRA is approved by the FDA for the treatment of erectile dysfunction in the U.S. VIVUS, through collaboration arrangements with third parties, intends to market and sell STENDRA in the U.S. and under the trade name SPEDRA in the EU and other territories outside the U.S. 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 currently in discussions with potential partners to commercialize STENDRA in the

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U.S. and other territories throughout the world.

Currently, it is recommended that STENDRA should be taken approximately 30 minutes before sexual activity. STENDRA should not be taken more than once per day. For more information about STENDRA, please visit www.Stendra.com.

**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 the company, 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 the launch and commercialization of SPEDRA in the EU, Australia and New Zealand. 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 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.

**About the MENARINI GROUP**

Menarini is an international pharmaceutical company with over 16,000 employees worldwide and a presence in more than 100 countries in Europe, Asia, Latin America, Africa and the Middle East, and has a 2012 turnover of more than €3.2 billion ($4.2 billion). Research and internationalization represent the main areas of strategic development for its future. The Group has 14 manufacturing sites located in Italy and abroad where over 545 million packages/year are produced and distributed throughout the five continents; thus, allowing Menarini to contribute to the health of patients all over the world with its high quality standards.

*Menarini Group- Valeria Speroni Cardi, Head of Menarini Group Press office - pressoffice@menarini.com*

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**EXHIBIT G**
**REFERENCES**

**SEE ARTICLE 14.3**

| | |
|---|---|
| If to VIVUS: | VIVUS, Inc.<br>351 E. Evelyn Avenue<br>Mountain View, CA 94041<br>Attention: General Counsel<br>Fax: (650) 934-5320 |
| With a copy to: | Hogan Lovells US LLP<br>525 University Avenue<br>3rd Floor<br>Palo Alto, CA 94301<br>Attention: Shane Albright, Partner<br>Fax: (650) 463-4199 |
| If to Menarini: | Berlin-Chemie AG,<br>Glienicker Weg 125-127<br>12489 Berlin, Germany<br>Attention: CFO<br>Fax: +49 3067073443 |

With a copy to:

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# COMMERCIAL SUPPLY AGREEMENT

**THIS COMMERCIAL SUPPLY AGREEMENT** (this "**Agreement**") is entered into and effective as of July 5th, 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 BERLIN-CHEMIE AG, a German public limited company having a place of business at Glienicker Weg 125 — 127, 12489 Berlin, Germany ("**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 July 6th, 2013 (the "**License Agreement**") pursuant to which VIVUS granted to Purchaser a license in the Menarini Territory for the commercialization of the therapeutic drug 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.

"**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 (b) comparable laws or regulations applicable to the manufacture, processing, packing, testing, shipping, and holding of drug active ingredients in the European Union, as they may be updated from time to time, including applicable guidelines promulgated under the International Conference on Harmonization.

"**European Union**" means any and all member countries of the European Union, as updated from time to time.

"**Forecast**" shall have 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**" shall have the meaning set forth in the recitals above.

"**MAA**" means an application for Regulatory Approval filed with the EMA.

"**Manufacturing Cost**" means VIVUS's out-of-pocket costs in obtaining, transporting, and storing raw materials for manufacturing Product and in having the Product manufactured, tested, and

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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.

"**Minimum Purchase Obligation**" means the quantities of Product described in Exhibit C; provided, however, that if Purchaser exercises its right to conduct Independent Manufacturing (as defined in the License Agreement), Minimum Purchase Obligation shall thereafter mean, for each calendar year during the Term, the greater of (a) *** (***%) percent of Purchaser's requirements of Product during such calendar year and (b) the quantities of Product described in Exhibit C.

"**New Third Party Manufacturer**" shall have 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 (***%); 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 Spedra™, as described in the MAA for such product filed with the EMA (as such MAA may be modified in the future in accordance with this Agreement and/or the License Agreement). Product will be ordered and supplied at three different dosage strengths: 50 mg, 100 mg, and 200 mg.

"**Product Shortage**" means a circumstance that is 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 the most recent Forecast.

"**Purchase Order**" shall have the meaning set forth in Section 2.3.

"**Purchaser Territory**" means the "Menarini Territory" as defined in the License Agreement.

"**Quality Agreement**" shall have the meaning set forth in Section 5.4.

"**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.

"**Term**" shall have 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, and Purchaser shall purchase the Product from VIVUS, pursuant

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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 has a minimum remaining shelf life of at least ***; provided, however, that the shelf life for the initial shipments of Product shall be as set forth in Section 2.5. 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 identify, qualify, and contract with another Third Party manufacturer having suitable capabilities (the "New Third Party Manufacturer").

(b) *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 (subject to Purchaser's right to conduct Independent Manufacturing (as defined in the License Agreement). Notwithstanding the foregoing, for so long as MTPC is the sole supplier of Product to VIVUS, Purchaser shall be permitted to obtain Product from a Third Party manufacturer to the extent that Purchase Orders submitted by Purchaser exceed MTPC's capacity. VIVUS shall be free to supply Product to any Third Party worldwide, subject to the exclusive rights granted to Purchaser 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.** 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 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. Because bulk Compound is only manufactured in whole batches of ***, all Purchase Orders must specify a quantity of Product equivalent to an integral multiple of *** of Compound. 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. To the extent there is any conflict or inconsistency between this Agreement and any Purchase Order, this Agreement shall govern.

**2.4 Minimum Purchase Requirements**. Each 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) ***.

**2.5 Initial Order**. Purchaser and VIVUS shall agree on one or more initial orders of Product to be filled from quantities of Product then on hand or in process. Product supplied to fill such initial order(s) shall be subject to the requirements set forth in this Agreement that apply to supplied Product generally, except there will be no requirements with respect to the minimum remaining shelf life of such Product. Purchaser shall have an opportunity to review information detailing the remaining shelf life for Product on hand prior to agreeing on the initial order(s).

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**2.6 Delivery and Shipping Terms.**

(a) For Product shipped from a location ***, this Section 2.6(a) shall apply.Product shall be shipped EXW (Incoterms 2010) directly to the packaging facility. 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 be responsible for obtaining any necessary export and/or import licenses, or other similar official

authorizations, and for carrying out all customs formalities for the exportation and importation of the Product. VIVUS shall issue (or shall have its manufacturer issue) a certificate of analysis ("COA") for shipment of Product sent to Purchaser.

(b) For Product shipped from a location ***, this Section 2.6(b) shall apply. Product shall be shipped CIP (Incoterms 2010) ***. Title to the Product and risk of loss shall pass to Purchaser at the time of delivery of the Product. All costs of insurance, shipping, freight, custom duties, and other charges associated with the shipment of the Product to Purchaser's designated destination (including without limitation VIVUS's fully burdened cost of obtaining any necessary export licenses, or other similar official authorizations, and for carrying out all customs formalities for the exportation of the Product) shall be charged to Purchaser. VIVUS shall issue (or shall have its manufacturer issue) a certificate of analysis ("COA") for shipment of Product sent to Purchaser.

**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. Any labels, product inserts, and other packaging for the Product shall be consistent with then-current Regulatory Approval(s) for the Product in the Purchaser Territory and with Applicable Law. VIVUS's name will not appear on the label or anywhere else on the commercial packaging of the Product unless: (i) required by any Applicable Laws; or (ii) VIVUS consents in writing to the use of its name.

**2.8 Product Shortage.** If VIVUS becomes aware of any circumstances that may cause VIVUS to be unable to deliver the forecasted or ordered quantities of Product, VIVUS shall provide Purchaser with prompt written notice of such inability. In the event of a Product Shortage, without prejudice to any other remedy Menarini may have under this Agreement, 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.

**2.9 Adjustments Related to New Third Party Manufacturer.** Purchaser acknowledges that the terms under which the New Third Party Manufacturer will manufacture and supply Product to VIVUS may differ from the terms under which MTPC manufactures and supplies Product to VIVUS and that as a result certain terms of this Agreement may 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. VIVUS shall use *** to minimize the need for any such modifications, but Purchaser agrees to work with VIVUS in good faith to implement any such modifications that may be necessary. The Parties agree that, in principle, the terms under which the New Third Party Manufacturer will manufacture and supply Product to VIVUS will, in the aggregate, be no less favorable to VIVUS (and therefore to Purchaser as well) than ***.

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**2.10 Delay in Delivery.** In case of delay in the delivery of the Product attributable to ***, in addition to any other remedy Menarini may have for such delay hereunder, VIVUS agrees to credit to Menarini against the Price for the Product affected by the delay, as liquidated damages (and not as penalty), after a grace period of ***, ***% (*** percent) of such Price per each day of delay, up to a maximum of *** percent (***%).

**2.11 New Forecast and Orders Method**. The Parties expressly agree that Section 2.2, 2.3 and 2.4 shall apply only for so long as MTPC is the sole supplier of Product to VIVUS. Afterwards, VIVUS shall use *** to agree with a new possible Third Party manufacturer forecasts and orders rules in line with the provisions set forth in Exhibit E.

**3. PRICE; PAYMENT**

**3.1 Prices for Product**. 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 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 the invoice which invoice shall be issued at the delivery date. If Menarini is legally required to withhold any Taxes from payments due hereunder, Menarini shall (a) deduct such Taxes from the payment made to VIVUS, (b) timely pay the taxes to the proper taxing authority, and (c) send proof of payment to VIVUS. 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' reasonable control. Notwithstanding the foregoing, if a deduction or withholding of Taxes hereunder arises as a result of any action by Purchaser that has 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 "**Purchaser Withholding Tax Action**"), including without limitation an assignment of this Agreement by Purchaser or any failure on the part of Purchaser to comply with Applicable Law, then (i) the payment by Purchaser 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 Purchaser Withholding Tax Action occurred, and (ii) the obligations in subsections (a)-(c) above shall apply with respect to such Additional Tax. 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.

**4. REPRESENTATIONS AND WARRANTIES**

4.1 **Mutual Representations**. 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 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 so as to be able to sell and market the Product in a particular territory.

**4.2 Product Warranties of VIVUS.**

(a) VIVUS warrants that at the time of shipment, the Product shall: (i) comply with the Specifications, and (ii) be manufactured in compliance with cGMP.

(b) The foregoing warranty shall not apply to damaged Product to the extent such damage is directly caused in whole or in part by Purchaser's breach of this Agreement or use, handling, or storage that is not in accordance with VIVUS's instructions or that constitutes improper treatment.

(c) 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(a).

**4.3 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 4, 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 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 Product as it deems necessary in compliance with Applicable Law. 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 use to implement such corrective

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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.** VIVUS shall notify Purchaser promptly after the discovery that any lot of Product shipped to Purchaser, which had previously been approved in accordance with procedures set forth herein, fails to comply with its applicable Specifications. VIVUS will make, at its expense, such further internal investigation of any failure to meet the Specifications VIVUS deems appropriate under the circumstances and otherwise consistent with its obligations hereunder.

**5.3 Changes to Specifications.**

(a) *Changes Requested by Purchaser*. VIVUS shall consider in good faith any reasonable requests by Purchaser to change the manufacturing process, Specifications, or any testing method with respect to the Product; provided, however that VIVUS shall in no event be obligated to implement any such change unless VIVUS, in its sole discretion, agrees to do so.

(b) *Changes Requested by VIVUS*. VIVUS shall have the right, in its sole discretion, to change to any procedures, Specifications, methods (including testing methods) or standard operating procedures relating to the manufacture or supply of the Product. Notwithstanding the foregoing, VIVUS shall not implement any such change that is (i) inconsistent with the then-current MAA for the Product or (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.

**5.4 Quality Agreement**. Concurrent with the execution of this Agreement, the Parties have entered into a quality agreement governing the agreed-upon specifications and other technical aspects of supply of Products to Purchaser hereunder, in the form attached hereto as Exhibit D (the "**Quality Agreement**") In the event of any inconsistency between this Agreement and the Quality Agreement, this Agreement shall control.

## 6. ACCEPTANCE AND REJECTION PROCEDURES

**6.1 Inspection.** Purchaser shall have *** after receipt of a shipment of Product to proceed with a visual inspection of the Product to verify if there is any apparent damage to or defect in the Product or any non-compliance with the Specifications which is discoverable by a visual inspection, or if there any errors in the quantities of Product shipped (the "**Inspection Period**"). Purchaser shall notify VIVUS of any such non-compliance prior to the end of the Inspection Period, describing in 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 be reasonably be expected to have been found by diligent and adequate visual inspection during the Inspection Period and Purchaser notifies VIVUS of such non-compliance, describing the Latent Defect in detail, within *** of Purchaser's knowledge of the Latent Defect and within *** from the date of receipt of such Product, such non-compliance shall be deemed to be a "**Latent Defect**" hereunder, provided however that such deadline shall apply only for so long as MTPC is the sole supplier of Product to VIVUS. Afterwards, VIVUS shall use *** to agree with a new possible Third Party manufacturer a new deadline as long ***. 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

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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' 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 (taking into account, without limitation, the time necessary for VIVUS to receive a response from MTPC and/or any other relevant Third Party manufacturer with respect to such 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 they are 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 Specifications. 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.

## 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 Purchaser Territory, and other regulatory matters relating to the Product in the Purchaser Territory are set forth in the License Agreement.

## 8. RECORD-KEEPING; INSPECTION; AUDIT

**8.1 Recordkeeping.** VIVUS will keep records of the manufacture and testing of the Product, and retain samples of Product sold hereunder 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 Product necessary to comply with the legal/regulatory requirements applicable to Purchaser.

**8.2 Audits.** 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 inspection and audit of the facilities being used by VIVUS or a VIVUS Affiliate for the production of Product by an independent Third Party auditor to assure compliance by VIVUS with cGMPs. At Purchaser's reasonable request, VIVUS agrees to use *** 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 sharing the results of such audit with Purchaser. Purchaser acknowledges that VIVUS's audit right in the MTPC Agreement is limited to periodic audits to ensure that cGMP continue to be followed.

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**8.3 Procedure.** The inspection and audit provided for under Section 8.2 shall not be carried out by Purchaser more than once per calendar year. Each inspection and audit shall be conducted in a manner so as to minimize disruption of the business operations of VIVUS. 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 shall enter into a written confidentiality agreement with VIVUS containing provisions regarding the disclosure of information obtained during the inspection and 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.

**8.4 Results.** If an inspection or audit reveals a failure to comply with cGMP in any material respects, 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 proposed deficiencies and, to the extent there is agreement on the proposed deficiencies, VIVUS shall use reasonable efforts to remedy such deficiencies, or implement a plan to remedy such deficiencies, as soon as reasonably practical following receipt of the notification thereof.

## 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).

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**9.5 Effects of Termination.** Upon expiration or termination of this Agreement, 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 bulk 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.

**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 shall survive termination or expiration of this Agreement for any reason: 1 (any relevant definitions), 3 (solely in relation to Product sold prior to expiration or termination of this Agreement or in relation to Product or other materials sold pursuant to Section 9.5), 4.4, 4.3, 8.1, 9.5, 9.6, 10, 11, 12, 13, 14, 15, 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 "**Menarini Indemnified Parties**") harmless against any and all Third Party claims, suits or proceedings, and all associated expenses, recoveries and damages, including court costs and reasonable attorneys' fees and expenses, arising out of, based on, or caused by (i) the breach by VIVUS of any representation or warranty or covenant contained in this Agreement; or (ii) Product supplied by VIVUS to Menarini hereunder that fails to meet the warranties set forth in Section 4.2 (in such case indemnification by VIVUS shall include costs of Product recall), except in each case to the extent that such claims, suits, proceedings, expenses, recoveries or damages arise from the breach by Menarini of any representation or warranty or covenant contained in this Agreement or any negligence or willful misconduct by a Menarini 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 Third Party claims, suits, proceedings, and all associated expenses, recoveries, and damages including court costs and reasonable attorneys' fees and expenses, arising out of, based on, or caused by (i) the storage, sale, shipment, promotion or distribution of the Product by Purchaser, 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 claims, suits, proceedings, expenses, recoveries or damages arise 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; provided that, the Indemnifying Party shall not have the right to assume any Indemnified Claim if (x) the

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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. 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. 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.**

(a) 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 GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR FRAUDULENT ACTS OR OMISSIONS OF A PARTY OR (D) DIRECT DAMAGES. IN NO EVENT SHALL VIVUS' AGGREGATE LIABILITY ARISING OUT OF OR RELATING TO THIS AGREEMENT UNDER ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT, STATUTORY OR OTHERWISE) EXCEED THE GREATER OF €*** EUROS OR THE SUM OF AMOUNTS ACTUALLY RECEIVED BY VIVUS UNDER THIS AGREEMENT ANDOR THE LICENSE AGREEMENT (EXCLUDING ***); 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 WILLFUL MISCONDUCT OR FRAUDULENT ACTS OR OMISSIONS.

(b) *Allocation of Risks*. The limitation of liability set forth in this Article 11 reflects a deliberate and bargained for allocation of risks between Purchaser and VIVUS and is intended to be independent of any exclusive remedies available under this Agreement, including any failure of such remedies to achieve their essential purpose.

(c) *Essential Part of the Bargain*. The Parties acknowledge that the limitations of liability set forth in this Article 11 are an essential element of this Agreement between the Parties and that the Parties would not have entered into this Agreement without such limitations of liability.

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(d) *Duty to Mitigate*. Each Party shall use reasonable efforts to mitigate any damages incurred by such Party hereunder.

**12. INSURANCE.**

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 product liability hereunder and which are consistent with normal business practices of prudent companies similarly situated. Upon 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 notice to the other Party with information demonstrating the adequacy of such program.

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 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.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each 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 other 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 other 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

(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 other 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

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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.

**13.2 Authorized Disclosures.** Each Party may disclose Confidential Information belonging to the other Party to the extent such Party determines such disclosure is reasonably necessary in the following situations:

(a) prosecuting or defending litigation relating to this Agreement subject to using *** to obtain confidential treatment of such disclosure;

(b) in the case of VIVUS as the receiving Party, 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 Menarini 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 the 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 the Product; (iii) is reasonably likely to lead to a recall or market withdrawal of the 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 (as such terms are defined in the License Agreement) in such licensee's, sublicensee's, or collaborator's territory; provided that each disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Section 13.1 and this Section 13.2prior 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 disclosee);

(d) disclosure to its and its Affiliates' respective directors, officers, employees, consultants, attorneys, professional advisors, 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 disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Section 13.1 and this Section 13.2 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 disclosee); and

(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, and 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 disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Section 13.1 and this Section 13.2 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 disclosee).

**13.3 Proprietary Rights**. This Agreement shall not affect the ownership of any intellectual property owned by or licensed to either Party ("**Intellectual Property**") or any rights granted in the License Agreement with respect to such Intellectual Property.

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**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 San Francisco, California, 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. 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

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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, 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

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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.

**15.2 Use of Names.** Except as otherwise required by law or by the terms of this 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 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.

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**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:

With a copy to:

If to Purchaser:

With a copy to:

For details see **Exhibit F** in attachment.

**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

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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, 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. Notwithstanding any assignment of this Agreement, the assigning Party shall remain liable for performance of its obligations hereunder, unless the non-assigning Party agrees otherwise in writing. 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.

**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 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 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.

**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.

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**IN WITNESS WHEREOF,** the Parties have caused this Agreement to be duly executed as of the date first above written.

**BERLIN-CHEMIE AG**

By: /s/ Dr R. Uppenkamp /s/ Dr A. Sebastio

Name: Dr R. Uppenkamp Dr A. Sebastio

| | | |
|---|---|---|
| Title: | CEO | CFO |
| Date: | 27th June 2013 | |

**VIVUS, Inc.**

| | | |
|---|---|---|
| By: | /s/ Peter Y. Tam | /s/ Timothy E. Morris |
| Name: | Peter Y. Tam | Timothy E. Morris |
| Title: | President | CFO |
| Date: | July 5, 2013 | |

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## EXHIBIT A

**Specifications**

*******

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## 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:

| Dosage forms | Fixed Manufacturing Cost (per tablet) | |
|---|---|---|
| 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 Menarini Territory according to the following (the "Net Sales Manufacturing Cost"):

| Annual Total MTPC Agreement Net Sales in the Menarini Territory | Net Sales Manufacturing Cost (per tablet) |
|---|---|
| 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 Menarini 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 Menarini, 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:

"Manufacturing Cost Adjustment" = ***.

No later than *** after the end of each ***, VIVUS shall notify Menarini whether there is a Manufacturing Cost Adjustment with respect to such *** and if there is such a Manufacturing Cost Adjustment, shall invoice Menarini for Product sold during such *** at a new Price calculated based on the Manufacturing Cost Adjustment, net of payments already made by Menarini 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 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 Menarini 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 Menarini shall be issued, as the case may be).

Menarini 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 *** and (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.

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**" shall mean the manufacturing cost of the Product that is manufactured by or on behalf of MTPC, and which includes the following:

(a) Materials Cost, which means the price paid for raw material components and finished goods which are purchased from outside vendors as well as any freight and duty where applicable;

(b) Direct Labor Costs, which means the employment costs attributable to manufacturing the Product including, without limitation, salary and employee benefits within the relevant manufacturing operating unit;

(c) Overhead Costs, which means the cost of specific activities attributable to manufacturing the Product that are provided by support functions and are performed at a frequency which is in correlation with the production. Overhead Costs includes, expenses associated with quality assurance testing, batch review, equipment maintenance costs, manufacturing utilities, waste removal, management and administrative expenses, general facilities costs, environmental engineering, property taxes and insurance.

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(d) Equipment Depreciation, which means the amortization of the costs of specific manufacturing facility, machinery or equipment dedicated either solely or partly (on a pro rata basis) to the production, calculated in accordance with the applicable generally accepted accounting practices.

It is understood and agreed that the definition of MTPC's Manufacturing Cost shall be consistently applied during the term of the MTPC Agreement.

"**MTPC Agreement Net Sales**" means, with respect to a Product, the amount invoiced by VIVUS, its affiliates and their sublicensees (each, a "**Seller**") for sales of such Product to a Customer (as defined below), less estimates which will be adjusted to actual on a periodic basis of:

(a) Sales returns (to the extent that customary practice is to allow the Customer to return Seller a Product expired or will expire unsold, or in the event of a Product recall, rejections or damaged Product);

(b) Discounts (including prompt pay cash discounts, patient cash discounts, price reductions and incentive programs, rebates, trade and quantity discounts, purchase volume discounts, patient co-pay assistance, price reduction programs, retroactive price adjustments, sales coupons, etc.) to managed care organizations, or to federal, state and local governments, or to the Customer;

(c) Wholesaler fees, inventory management agreement fees and specialty pharmacy fees, which are commercially reasonable and customary fees paid by Seller to the Customer;

(d) Chargebacks incurred or paid by Seller to government entities (Seller's programs with government entities whereby pricing on a Product by Seller to the participating entities is extended below wholesaler list price);

(e) Managed health care rebates and other contract discounts (including rebates, administrative fees, reimbursements and discounts to managed health care and pharmacy benefit organizations which manage prescription drug programs and prescription drug plans covering the Medicare Part D drug

benefit or similar government programs in addition to their commercial plans, as well as other contract counterparties such as hospitals and group purchasing organizations);

(f) Medicaid or similar government rebates (local, state and federal government-managed Medicaid or similar programs as well as certain other qualifying Federal, state and local government programs (or their respective agencies, purchasers and reimbursers) whereby discounts and rebates are provided by Seller to participating federal, state and local government entities);

(g) Taxes, duties and other governmental charges levied on, absorbed or otherwise imposed on sale of a Product, including value-added taxes, or other governmental charges otherwise measured by the billing amount, when separately included on a billing by Seller to the Customer, as adjusted for rebates and refunds, but specifically excluding taxes based on net income of Seller;

(h) Freight, postage, shipping and insurance charges actually allowed or paid for delivery of Product, to the extent billed as a separate line item by Seller to the Customer; and

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(i) Customs duties, surcharges and other governmental charges incurred in connection with the exportation or importation of Product, to the extent billed as a separate line item by Seller to the Customer.

It is understood and agreed that (x) sales or transfers of Products between VIVUS, its affiliates and their sublicensees shall not constitute "MTPC Agreement Net Sales" unless such party is an end-user of such product and (y) "**Customer**" shall mean any entity (other than MTPC or VIVUS or their respective affiliates or their sublicensees) that is invoiced by Seller in a commercial arms-length transaction for the sale of Product in VIVUS's Licensed Territory.

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## EXHIBIT C

**Minimum Purchase Obligations**

| Calendar Year | Minimum Purchase Obligation |
|---|---|
| *** | *** |

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## EXHIBIT D

**Quality Agreement**

[To be completed after signing]

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## EXHIBIT E

On a *** basis of each ***, Menarini shall provide VIVUS with a rolling *** forecast, no later than the *** of the *** preceding the *** of such forecast, of Product requirements. Such forecast shall represent Menarini's reasonable estimates of the quantity of Product required in the Territory during the *** period covered by the forecast. At the time each forecast is delivered to VIVUS, the quantity of Product specified for first *** of the forecast shall be binding and the first *** period deemed the period of firm order. Menarini shall be required to purchase *** percent (***%) of all quantities specified in the firm order

period. The quantity of Product specified for the remaining *** shall be considered non-binding. Delivery of Product shall be within *** from receipt of order by VIVUS. No orders shall be unreasonably refused by VIVUS.

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**EXHIBIT F**

**References**

**See Article 16.4**

| | |
|---|---|
| If to VIVUS: | VIVUS, Inc.<br>351 E. Evelyn Avenue<br>Mountain View, CA 94041<br>Attention: General Counsel<br>Fax: (650) 934-5320 |
| With a copy to: | Hogan Lovells US LLP<br>525 University Avenue<br>3rd Floor<br>Palo Alto, CA 94301<br>Attention: Shane Albright, Partner<br>Fax: (650) 463-4199 |
| If to Menarini: | Berlin-Chemie AG,<br>Glienicker Weg 125-127<br>12489 Berlin, Germany<br>Attention: CFO<br>Fax: +49 3067073443 |
| With a copy to: | |

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# COMMERCIAL SUPPLY AGREEMENT

**BETWEEN THE UNDERSIGNED:**

**SANOFI CHIMIE**, a company organised and existing under the laws of France, having its registered office at 9 rue du Président Allende, 94256 Gentilly, France, and a principal place of business at 20 avenue Raymond Aron, 92165 Antony Cedex, France, represented by Hervé LEBRUN, Chairman and Chief Executive Officer,

acting for itself and on behalf of its Affiliates as hereinafter defined,

Hereinafter collectively referred to as "**SANOFI CHIMIE**",

ON THE ONE PART

**AND**

**VIVUS, Inc.** a company incorporated in the State of Delaware and having its registered office at 351 E. Evelyn Avenue, Mountain View, CA 94041, represented by Leland F. Wilson, Chief Executive Officer

Hereinafter referred to as "**VIVUS**",

ON THE OTHER PART

VIVUS and SANOFI CHIMIE are hereinafter individually referred to as a "Party" or collectively as the "Parties".

**WITNESSETH:**

**WHEREAS**, SANOFI CHIMIE is within the SANOFI group, a company specialized in the development, manufacture and supply of active pharmaceutical ingredients, intermediates and pharmaceutical specialties.

**WHEREAS**, VIVUS is a biopharmaceutical company that has been pursuing the development and regulatory approval of a drug product known by the international nonproprietary name avanafil.

**WHEREAS**, pursuant to the Technology Transfer and Development Services Agreement executed by the Parties on March 25, 2013 ("TTA"), the Parties now wish to set the terms and conditions for the supply by SANOFI CHIMIE of VIVUS commercial needs of avanafil API.

**NOW, THEREFORE**, in consideration of the mutual promises set forth herein, VIVUS and SANOFI CHIMIE, intending to be legally bound, hereby agree as follows:



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## ARTICLE 1 — DEFINITIONS

The following terms as used in this agreement shall have the meanings set forth in this *Article 1*:

**1.1** **"Affiliate(s)"** shall mean any corporation or business entity which is controlled by, controls, or is under common control of a Party. For this purpose, the meaning of the word "control" shall include, without limitation, direct or indirect ownership of more than fifty percent (50%) of the voting shares of interest of such corporation or business entity.

For SANOFI CHIMIE, the term Affiliate shall include any company, which, directly or indirectly, is controlled or is under common control with SANOFI — a French corporation registered in the Company and Trade Register of Paris under N° 395 030 844, having its registered office at 54, rue La Boétie, 75008 Paris, France.

**1.2** **"Agreement"** shall mean the present agreement and all exhibits attached hereto.

**1.3** **"API"** shall mean the PDE5 inhibitor avanafil active ingredient to be Manufactured by SANOFI CHIMIE using the Process and/or any Severable Improvements, according to the Specifications attached in Exhibit 3 and the Quality Agreement.

**1.4** **"Background Technology"** shall mean a Party's intellectual property used to perform the Services including any patented technology, know-how, trade secrets, and proprietary information (including Confidential Information) that was in the Party's possession prior its disclosure or, is later generated or, acquired independently by a Party outside the scope of the Services.

**1.5** **"Business Day"** means each day of the week excluding Saturday, Sunday or a day on which banking institutions in New York, New York or Paris, France, are closed.

**1.6** **"Calendar Quarter"** shall mean any consecutive 3-month period ending March 31, June 30, September 30 or December 31.

**1.7** **"Calendar Year"** shall mean a twelve (12) month period commencing January 1.

**1.5** **"cGMP"** shall mean (a) current good manufacturing practices for the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, packing, testing, shipping, and holding of drug active ingredients, as promulgated by the FDA (including 21 C.F.R. Parts 210 and 211), including all amendments and supplements thereto during the term of this Agreement and (b) comparable laws or regulations applicable to the manufacture, processing, packing, testing, shipping, and holding of drug active ingredients in the European Union, as they may be updated from time to time, including applicable guidelines promulgated under the International Conference on Harmonization.

**1.6** **"Commercialization Partner"** means any third party to which VIVUS has agreed to transfer all or any of its rights to commercialize VIVUS' Product in all or any portion of the VIVUS Territory.

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**1.7** **"Commercially Reasonable Efforts"** means with respect to the efforts to be expended by any Party with respect to any action, objective or obligation, those reasonable, diligent, good faith efforts to accomplish such action, objective, or obligation as a person engaged in the relevant business activity for its own account would normally use to accomplish a similar action, objective, or obligation under similar circumstances.

**1.8** **"Confidential Information"** shall mean, as the case may be, any and all VIVUS's Confidential Information, any and all SANOFI CHIMIE's Confidential Information, as applicable. The present Agreement shall be considered as Confidential Information of each Party.

**1.9** **"VIVUS's Confidential Information"** shall mean the proprietary and/or confidential information relating to VIVUS's and/or its Affiliates' Background Technology (including the API and the Process), including proprietary and/or confidential information received by or on behalf of VIVUS from MTPC or another third party), as well as know-how, operational methods, formulae, specifications, analytical methods, quality standards, operating procedures, financial information, forecasts, costs, pricing information and any details of commercial, technical, pharmaceutical, scientific and industrial nature provided to SANOFI CHIMIE by or on behalf of VIVUS, whether in written, oral, electronic or any other form. VIVUS's Confidential Information shall include the Results.

**1.10** **"SANOFI CHIMIE's Confidential Information"** shall mean the proprietary and/or confidential information of SANOFI CHIMIE and/or its Affiliates related to SANOFI CHIMIE's and/or its Affiliates Background Technology as well as any details of commercial or industrial nature of SANOFI CHIMIE's and/or its Affiliates' business, whether in written, oral, electronic or any other form.

**1.11** **"Documentation"** shall mean all written reports and any supporting documentation and data generated in the performance of the Services, including but not limited to final report, batch records, laboratory notebooks, original data and slides.

**1.12** **"Exclusive Territory"** shall mean all countries in the VIVUS Territory, excluding the Semi-Exclusive Territory.

**1.13** **"License Agreement"** shall mean ***.

**1.14** **"Manufacture/Manufacturing/Manufactured"** means, for the purpose of this Agreement, all or any part of the operations which include:

- Procurement of the Starting Materials in respect of the cGMP and the specifications of the Starting Materials
- Storage of the Starting Materials and the API
- Production of technical, validation and commercial batches
- Control of API and their release for regulatory purpose, according to the Quality Agreement
- Delivery of API

**1.15** **"Manufacturing Site"** means SANOFI CHIMIE's chemical site located 45, chemin de Météline — BP15 — 04201 Sisteron Cedex, France.

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**1.16** **"MTPC"** means Mitsubishi Tanabe Pharma Corporation, formerly known as Tanabe Seiyaku Co., Ltd.

**1.17** **"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 successively amended by Amendment N°1 dated January 9, 2004 and Amendment N°2 dated August 1, 2012, and as it may be further amended from time to time.

**1.18** **"Process"** shall mean all methods and know how used for the Manufacturing of the API, including but not limited to (i) the VIVUS proprietary or licensed methods, provided to SANOFI CHIMIE by VIVUS, (ii) any *** modification made to the Process necessary for the adaptation to SANOFI CHIMIE's industrial equipment and facilities and (iii) any improvements to the foregoing other than Severable Improvements, as defined in *Article 10.3* hereafter, made by SANOFI CHIMIE.

**1.19** **"Quality Agreement"** has the meaning set forth in *Article 6.4*.

**1.20** **"Results"** shall mean the API and the Documentation conceived and/or generated under or in connection with the performance of the Services. Any results outside the scope and purpose of the Services or results that are not related to the API as such or are not limited to a process for manufacturing the API, which SANOFI CHIMIE merely generates while performing the Services, shall not constitute a Result. Notwithstanding the foregoing, Results shall include, without limitation, any and all Documentation that is incorporated into the Process, the DMF or the ASMF for the API, or any other regulatory filing filed by or on behalf of VIVUS.

**1.21** **"SANOFI Territory"** means ***.

**1.22** **Semi-Exclusive Territory"** shall mean the following countries: Albania, Andorra, Argentina, Australia, Austria, Belgium, Bosnia Herzegovina, Brazil, Bulgaria, Chile, Colombia, Costa Rica, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Dominican Republic, Ecuador, El Salvador, Estonia, Finland, France, Germany, Greece, Guatemala, Honduras, Hungary, Iceland, India, Ireland, Italy, Jamaica, Latvia, Lichtenstein, Lithuania, Luxembourg, Kosovo, Malta, Mexico, Montenegro, the Netherlands, New Zealand, Nicaragua, Norway, Panama, Paraguay, Peru, Poland, Portugal, Republic of Macedonia, Republic of Serbia, Romania, San Marino Republic, Slovakia, Slovenia, Spain, Sweden, Switzerland, Trinidad & Tobago, the United Kingdom, Uruguay, Vatican City, and Venezuela.

**1.23** **"Services"** shall mean the Manufacturing program described in the Quality Agreement, as well as the supply of the API to be performed by SANOFI CHIMIE according to the terms and conditions of this Agreement.

**1.24** **"Starting Material"** shall mean regulatory starting materials ESTE, PROL and AMIN used for the Manufacture the API as described in the Quality Agreement.

**1.25** **"VIVUS's Product"** shall mean any composition containing the avanafil active ingredient whether or not manufactured by SANOFI CHIMIE, alone or in combination with one or more active ingredient(s), in all dosage strengths whether packaged and labeled or in bulk form, commercialized by VIVUS or its Commercialization Partners.

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**1.26 "VIVUS Territory"** means all countries in the world in which VIVUS has a right under the MTPC Agreement to sell avanafil, other than ***.

**ARTICLE 2 - SCOPE OF THIS AGREEMENT**

This Agreement sets forth the terms and conditions whereby VIVUS undertakes to purchase from SANOFI CHIMIE, and SANOFI CHIMIE undertakes to Manufacture, sell and deliver the API to VIVUS.

**ARTICLE 3 - PERFORMANCE OF THE SERVICES**

3.1 SANOFI CHIMIE shall perform the Services in accordance with the terms of the Agreement, and in particular with (i) the Quality Agreement, (ii) all applicable principles and guidelines of cGMP, and (iii) other legal provisions, regulations or decisions of competent authorities which are applicable.

3.2 SANOFI CHIMIE warrants that the Services shall be performed :

(i) in a manner commensurate with professional standards, by implementing all necessary means, and in accordance with applicable laws, rules and regulations;
(ii) using equipment, proprietary or leased to SANOFI CHIMIE.

3.3 VIVUS or its Affiliates shall provide SANOFI CHIMIE, when available, with all relevant information relating to the API and the Process. Such information shall only be used by SANOFI CHIMIE solely for the purpose of performing the Services and shall in particular not be provided to any third parties.

3.4 SANOFI CHIMIE shall maintain complete and accurate records of the Services conducted under this Agreement and in particular of all Results, data and developments made pursuant to its efforts under the Agreement.

**ARTICLE 4 - COLLABORATION BETWEEN THE PARTIES**

4.1 SANOFI CHIMIE and VIVUS shall each designate an individual contact person to be responsible for coordination of the performance of the Services under the Agreement (hereinafter the "Business Manager(s)"). The Business Manager shall cooperate and consult with each other through teleconferences or meetings, on a reasonable basis and frequency in relation to the Services to be carried out under this Agreement and all matters arising thereof.

The Parties shall establish a joint manufacturing committee (the "Joint Manufacturing Committee"), which shall oversee the manufacturing of the API. VIVUS and SANOFI CHIMIE shall each appoint *** representatives with the required expertise and seniority enabling them to make operational decisions on behalf of VIVUS and SANOFI CHIMIE. From time to time, VIVUS and SANOFI CHIMIE each may substitute any of its representatives to the Joint Manufacturing Committee on prior written notice to the other Party. Each Party may invite a reasonable number of additional employees and/or advisors to attend part or all of the meetings of the Joint Manufacturing Committee.

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The Joint Manufacturing Committee shall notably, but not limited to, (i) review the progress of the Services according to key milestones and Documentation; (ii) serve as the initial forum to resolve any issue between the Parties relating to this Agreement; (iii) serve as the forum to discuss and decide on any significant modification of Services.

The Joint Manufacturing Committee shall meet as needed upon request of either Party, by teleconference or video conference, and according to a planning agreed upon by the Parties every Calendar Year.

VIVUS shall be responsible for drafting the minutes of each JMC meeting and them to SANOFI CHIMIE for approval within *** Business Days of the date of the JMC meeting. In the event that SANOFI CHIMIE does not reply within *** Business Days of receipt of any JMC minutes, such minutes shall be deemed to be accepted by SANOFI CHIMIE.

4.2 SANOFI CHIMIE shall determine at its sole discretion the composition of the team performing the Services, and undertakes to ensure that the members of the team are appropriately qualified and with the appropriate knowledge required for the proper performance of the Services. SANOFI CHIMIE may also use personnel of its Affiliates.

SANOFI CHIMIE's team performing the Services remains under SANOFI CHIMIE's sole control, management and responsibility.

4.3 Each Party shall promptly notify the other Party in writing of any changes concerning pending processes, methods, specifications or any quality related changes of which it becomes aware during the Services and which could affect the performance of the Services and/or the Results and both Parties shall endeavour to agree upon any studies or additional work resulting therefrom.

**ARTICLE 5 — MANUFACTURING AND SUPPLY OF API**

5.1 SANOFI CHIMIE shall be responsible for the procurement of the Starting Materials needed for the Manufacture of the API; provided that SANOFI CHIMIE shall not enter into any exclusive agreement that would preclude other manufacturers that are authorized by MTPC or VIVUS and/or its Affiliates and Commercialization Partners from obtaining the Starting Materials.

5.2 The API shall be Manufactured in SANOFI CHIMIE Manufacturing Site.

In case SANOFI CHIMIE decides in its sole discretion to transfer the Manufacture of the API to another facility, SANOFI CHIMIE will notify VIVUS with a sufficient period of notice to be compliant with the regulatory matters related to such facility change, and SANOFI CHIMIE shall bear its own costs generated by such a transfer in addition to VIVUS's reasonable and necessary costs in assisting with the regulatory filing as a result of such facility change. Any transfer of Manufacture of the API to a facility not controlled by SANOFI CHIMIE or its AFFLIATE shall require the prior written consent of VIVUS which cannot be withheld unreasonably or delayed.

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5.3 *Minimum purchase commitment*

5.3.1 For the duration of this Agreement, subject to the terms and conditions of this Agreement, SANOFI CHIMIE undertakes to supply, and VIVUS undertakes to purchase and be delivered:

(i) exclusively from SANOFI CHIMIE its total needs of API for the manufacture of VIVUS' Product to be commercialized in the Exclusive Territory; and

(ii) each Calendar Year, ***% of VIVUS's global annual demand of API needed for the manufacture of VIVUS' Product to be commercialized in the Semi-Exclusive Territory
(for purposes of this Section 5.3.1(ii), the purchase of ***% of VIVUS's global annual demand during a particular Calendar Year shall be calculated based on *** for API for the manufacture of VIVUS' Product to be commercialized in the Semi-Exclusive Territory, in each case submitted as of *** and requesting delivery of API no later than ***); and

(iii) minimum yearly quantities of API through the term of the Agreement, *** as follows:

- ***;

*** collectively referred to herein as the "Minimum Yearly Quantities".

The Parties recognize that for the ***, VIVUS shall use its best Commercially Reasonable Efforts to meet its obligations *** considering the *** of *** already ***, but in no event shall VIVUS *** in *** and *** in ***.

5.3.2 VIVUS undertakes to purchase the Minimum Yearly Quantities, which shall not be subject to any reduction or variation whatsoever. Remedies for failure to comply with such undertaking are described in Section 5.3.3.

Promptly after *** of each Calendar Year during the term of this Agreement, VIVUS shall provide to SANOFI CHIMIE a report indicating (a) the quantities of API ordered by VIVUS from SANOFI CHIMIE during such Calendar Year and delivered to VIVUS during *** or having a requested delivery date before *** (the "Ordered Yearly Quantity"), including a separate report of quantities of such API ordered for the manufacture of VIVUS' Product to be commercialized in the Semi-Exclusive Territory (the "Semi-Exclusive Ordered Yearly Quantity"), and (b) the quantities of API ordered by VIVUS from a third-party supplier during such Calendar Year and delivered to VIVUS during *** or having a requested delivery date before *** for the manufacture of VIVUS' Product to be commercialized in the Semi-Exclusive Territory (the "Semi-Exclusive Third-Party Yearly Quantity"). If SANOFI CHIMIE failed to supply any portion of VIVUS's firm orders during such Calendar Year, the quantity of Product that SANOFI CHIMIE failed to supply shall, for purposes of determining whether VIVUS satisfied its obligations and/or calculating any payments under this Section 5.3, be deemed to have been ordered and delivered to VIVUS.

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In the specific case where the validation program would not enable SANOFI CHIMIE to deliver the ***, then such *** shall be delivered *** but will be deemed delivered *** for purposes of determining whether VIVUS satisfied its obligations under this Section 5.3.

VIVUS shall keep complete and accurate records of the aggregate quantities of API bought from SANOFI CHIMIE or from any other supplier for the commercialization of VIVUS' Product in the VIVUS Territory. All such records shall be retained for at least *** years following the Calendar Year in which they are generated. At SANOFI CHIMIE's request, such records shall be available for review not more than once each Calendar Year (during normal business hours on a mutually agreed date with reasonable advance notice) by an independent auditor mutually agreed upon by the Parties and subject to confidentiality and non-use obligations no less stringent than those set forth in *Article 13* for the sole purpose of verifying the respect of VIVUS commitment pursuant to *Article 5.1* and *Article 5.3.1*. The expense of such auditor shall be borne by SANOFI CHIMIE unless the audit report reveals a breach of such commitments by VIVUS, in which case, VIVUS shall reimburse SANOFI CHIMIE the expense of such independent auditor. Such auditor shall not disclose VIVUS's Confidential Information to SANOFI CHIMIE, except to the extent such disclosure is necessary to verify the accuracy of the reports furnished by VIVUS.

5.3.3 In the event that the quantities of API purchased by VIVUS are below the Minimum Yearly Quantity applicable for a given Calendar Year (a "Minimum Yearly Quantity Shortfall"), not caused by a force majeure occurrence and determined based on the reports specified in *Article 5.3.2*, then VIVUS shall either (i) promptly (but in any event no later than ***) submit to SANOFI CHIMIE a purchase order for the amount of the Minimum Yearly Quantity Shortfall, requesting delivery of the Shortfall Quantity on or before ***, or (ii) pay a penalty corresponding to the amount of the Minimum Yearly Quantity Shortfall

5.3.4 This Section 5.3 describes VIVUS's sole obligations, and SANOFI CHIMIE's sole remedies, for VIVUS's failure to comply with its obligations under *Article 5.3.1*.

5.4 *Forecast*

In order to enable SANOFI CHIMIE to establish its production schedule and to regularly supply VIVUS with API, VIVUS shall provide SANOFI CHIMIE at the beginning of every Calendar Quarter throughout the term of this Agreement with a *** months rolling forecast, broken down in ***, of its estimated requirements of API.

The first *** of each rolling forecast (***) shall be considered a firm commitment to purchase from SANOFI CHIMIE and a firm commitment to supply to VIVUS the volume of API detailed therein, with the remaining months (***) of the forecast constituting VIVUS's non-binding forecasts, being understood that:

(i) the volume forecasted in *** shall not vary by more than plus or minus *** percent (±***%) from the volume specified in *** of the immediately preceding rolling forecast; and

(ii) the volume forecasted in *** shall not vary by more than plus or minus *** (±***%) from the volume specified in *** of the immediately preceding rolling forecast.

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5.5 VIVUS shall order quantities of API in accordance with *Article 5.4* and no less than *** before the delivery date specified by VIVUS. Each order shall detail the quantity, the delivery date, payment terms, the incoterm and the shipping details.
The minimum order quantity shall be *** and each order quantity shall be a multiple of ***.

Within *** of receipt of VIVUS's orders by SANOFI CHIMIE, SANOFI CHIMIE will acknowledge receipt of each order and confirm that it will deliver the order on the delivery date requested by VIVUS or if necessary will propose any other reasonable delivery date to VIVUS.
Such confirmation shall not be denied by SANOFI CHIMIE unless (i) the purchase order is inconsistent with the most recent forecast or, (ii) there exists any other failure or omission by VIVUS under this Agreement preventing SANOFI CHIMIE from performing the Services.

5.6 If SANOFI CHIMIE is unable to supply confirmed orders to VIVUS with respect to the quantity or the delivery date, SANOFI CHIMIE shall inform VIVUS immediately and the parties shall agree on appropriate delivery time and/or other appropriate measures. Notwithstanding Section 5.1, VIVUS shall be permitted to obtain from another source the quantities of API that SANOFI CHIMIE is unable to supply. For clarity, this Section 5.6 shall not be deemed to limit SANOFI CHIMIE's supply obligations hereunder or VIVUS's remedies for any failure to supply.

## ARTICLE 6 - QUALITY — CONTROL

6.1 The API delivered by SANOFI CHIMIE hereunder shall meet the specifications (hereinafter referred to as the "SPECIFICATIONS"), as specified the Quality Agreement. Each delivery of API by SANOFI CHIMIE shall be accompanied by a certificate of analysis issued by SANOFI CHIMIE showing the conformity of the delivered batch of API with the SPECIFICATIONS. Such certificate of analysis shall conform with and be signed in accordance with cGMP and the other applicable regulatory requirements.

6.2 VIVUS (or its designee, such as the manufacturer of bulk tablets) shall promptly, upon arrival on its site, carefully inspect each shipment of API for transport damages, losses and shortfalls. Apparent defects like for instance damaged containers or missing packages of API have to be notified to the carrier promptly upon arrival of the shipment and the freight documents at VIVUS or its designee and, where possible, countersigned by the carrier's representative. Failure of VIVUS to notify such visually detectable defects to the carrier promptly upon arrival of the concerned shipment and freight documents shall exclude any liability of SANOFI CHIMIE for such defects.

Upon delivery of the API, VIVUS (or its designee, such as the manufacturer of bulk tablets) shall inspect and test such API against the SPECIFICATIONS and according to the relevant analytical methods set forth in the Quality Agreement. If the API delivered does not conform to the SPECIFICATIONS, VIVUS or its designee shall so notify SANOFI CHIMIE in writing within *** calendar days from the date of delivery to VIVUS. If no written notice of such non-conformity is sent to SANOFI CHIMIE by VIVUS within

said *** calendar day period after delivery, it shall be conclusively presumed that such API was inspected and tested by VIVUS and conformed to the SPECIFICATIONS.

Notwithstanding the foregoing, VIVUS reserves the right, for a period of ***, to reject any API shipment, in whole or in part, in the event that at the time of receipt by VIVUS or its designee, latent defects existed in the API which could not reasonably have been discovered by VIVUS by careful inspection according to the pharmaceutical industry standards and through the testing of the API according to the Quality Agreement, provided that VIVUS reports such latent defect to SANOFI CHIMIE within *** of its discovery.

6.3 Any dispute between the Parties regarding the conformity or non-conformity of the API to the SPECIFICATIONS shall be submitted to an independent expert, to be agreed upon by the Parties.

Should the Parties fail to agree on the designation of the independent expert within *** after a notice of rejection by VIVUS the dispute shall be governed by *Article 20* herein.

6.4 No later than *** after the signature of the Agreement, the Parties shall enter into a quality agreement governing certain operational and quality-related aspects of the supply of API to VIVUS hereunder (the "Quality Agreement") In the event of any inconsistency between this Agreement and the Quality Agreement, this Agreement shall control.

**ARTICLE 7 — ENVIRONMENT, HEALTH AND SAFETY**

7.1 *Health, Safety and Working Conditions*

7.1.1 SANOFI CHIMIE undertakes to comply with all and any legislative, regulatory or conventional requirements relating to health, safety and working conditions, which SANOFI CHIMIE is required to satisfy with by reason of its activity with respect to the subject matter of the Agreement.

To the extent not previously provided by VIVUS under the TTA, VIVUS shall provide SANOFI CHIMIE with all and any available information necessary for the performance of the Services, concerning:

- the particular hazards (i) of the substances or preparations, including the API and (ii) of the manufacturing procedures, to be used and/or to be implemented for the purpose of the performance of the Services.
- the measures to be taken against these hazards, including those related to handling, use and, should the case arise, storage of such substances or preparations;
- the rules for packaging and labeling the API and other substances, if relevant;
- the action(s) to take in case of accident.

The information disclosed by VIVUS to SANOFI CHIMIE within the context of this Agreement shall be found on the existing scientific and technical knowledge to which VIVUS may have had reasonable access at the effective date of the Agreement, and shall reflect VIVUS's best professional analysis and judgment, recognizing that



VIVUS has newly and only recently acquired the right to manufacture VIVUS' Product without a direct experience manufacturing the API. Nevertheless, this information is furnished upon the condition that SANOFI CHIMIE shall make its own determination of the suitability of the Process for the particular purpose of the performance of the Services.

7.1.2 Each Party shall as soon as possible bring to the knowledge of the other Party:

- All known new facts concerning the hazardous properties of the API or other substances or dangerous preparations which are the subject of the Agreement, which result from the improvement of scientific or technical understanding, or result from the observation of the effects of these products on the health and safety of workers or the environment; and
- The possible modification of physicochemical or toxicological properties of the API or of these same substances or preparations, by reason notably of a change in the nature or concentration of the impurities which they contain.

7.1.3 The Parties will meet as often as necessary to examine together the conditions, and possibly the difficulties in the implementation of:

- the legislative, regulatory or conventional dispositions relating to health, safety and working conditions to which the terms of the Agreement shall be subjected;

- the procedure for reciprocal exchange of information stipulated in *Article 7.1.2*.

Furthermore, each Party will have the right to request from the other the holding of an ad hoc technical meeting in order to resolve all questions that particularly relate to health or to industrial safety, or to deal with an emergency situation, whatever the cause. The date and duration of this ad hoc technical meeting will be agreed jointly.

7.2 *Protection of the environment*

7.2.1 SANOFI CHIMIE acknowledges expressly that, in order to have been duly authorized by the competent administrative authority or to have been so declared to it, all the premises necessary for the execution of the Agreement are compliant with the legislative or regulatory requirements to which they are subjected with regard to the protection of the environment.

Consequently, SANOFI CHIMIE undertakes to maintain such compliance during the term of the Agreement and to be in a position to justify such compliance at all times to VIVUS.

7.2.2 SANOFI CHIMIE will strictly comply with all applicable legislative or regulatory provisions relating to the disposal of waste, the term "disposal" describing the operations of collection, transport, storage, sorting and treatment so as to prevent all harm to the environment.

In particular, SANOFI CHIMIE undertakes that the waste which results from the performance of the Services will be treated only in installations duly authorized or accepted to this effect by the competent administrative authority. The respect of such obligation shall be evidenced by SANOFI CHIMIE upon request of VIVUS.

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## ARTICLE 8 - PRICES AND PAYMENT

8.1 The price payable to SANOFI CHIMIE by VIVUS for the performance of Services shall be as follows:

- ***

Such price is for delivery of the API *** in Europe at the site of tablet manufacture, or *** outside Europe at the site of tablet manufacture (Incoterms® 2010).

8.2 Title to the API, including the assignment of all intellectual property rights with regard to the Results as set forth *in Article 10* hereunder, shall pass to VIVUS upon ***. Notwithstanding the retention of title, transfer of the risks on the API shall occur upon ***. For clarity, to the extent that SANOFI CHIMIE or its AFFILIATE manufactures avanafil tablets using the API, the risk of loss to the API during the manufacturing of such tablets will be addressed in the a separate tablet manufacturing agreement.

8.3 During the term of this Agreement, SANOFI CHIMIE shall invoice VIVUS upon shipment on the basis of the applicable price at the following address:

**VIVUS, Inc.**
1172 Castro Street
Mountain View, CA 94040
Attention: Accounts Payable

With an electronic copy to: accountspayable@vivus.com

VIVUS shall make all payments for all deliveries in euros, by bank transfer to a bank account to be designated by SANOFI CHIMIE within forty-five (45) calendar days of the invoice date.

8.4 As from *** for the first time, and thereafter on a *** basis, the purchase price defined above shall be reviewed according to the latest available *** as shown by way of example in Exhibit 2 hereto, issued in *** of each year by ***.

In addition, should any increase in the price of any raw materials necessary for the manufacture of the API result in an increase of more than *** percent of the cost of goods of API in one Calendar Year and should such increase not be compensated by the application of the variation of the *** pursuant to the above paragraph, then the Parties shall increase the price accordingly by applying the portion of the increase between *** percent and the effective total increase of the considered raw materials in addition to the application of the variation of the *** for the considered period. At VIVUS's request, SANOFI CHIMIE shall provide written documentation evidencing any price increase in raw materials for which SANOFI CHIMIE seeks an adjustment of the price hereunder.

8.5 VIVUS and SANOFI CHIMIE, through specifically designated personnel of each Party, shall collaborate on a regular basis during the term of the Agreement to identify, track and review specific cost-saving improvement opportunities relating to the

manufacturing process of the API hereunder and shall agree on funding for required technical or other resources to develop such improvements. Clearly identified and mutually agreed savings resulting from such improvements and their implementation costs shall be shared equally by the Parties and shall be so reflected in the purchase price.

**ARTICLE 9 - TERM AND TERMINATION**

9.1 *Term*

This Agreement shall become effective as of January 1st, 2014 and unless otherwise terminated as provided herein, shall remain in full force and effect for a period of five (5) years.
Thereafter, it shall be automatically renewed for successive period of two (2) years, unless SANOFI CHIMIE provides notice of desire not to renew *** in advance of end of the current term or VIVUS provides *** notice.

9.2 *Termination*

9.2.1 Either Party may terminate the Agreement without prejudice to any claim for damages, if the other Party commits a material breach and fails to remedy such material breach within *** calendar days of receipt of a registered letter with return receipt requested, specifying the breach. The termination will become effective on the date of first presentation of a second registered letter with return receipt requested, notifying the decision of termination.

9.2.2 Either Party may immediately terminate the Agreement, by registered letter with return receipt requested in the following events:

a) the other Party is declared insolvent or bankrupt by a court of competent jurisdiction, or a voluntary petition in bankruptcy is filed in any court of competent jurisdiction, or the other Party makes or executes any assignment for the benefit of creditor, in accordance with the applicable laws;

b) a force majeure event occurs and persists over *** calendar days, according to the provisions of *Article 18* hereof.

9.3 Effects of expiry or early termination of the Agreement

9.3.1 Upon early termination of the Agreement by VIVUS in accordance with *Article 9.2.1*, VIVUS shall be under no further obligation, in particular no consideration shall be paid for the Services which are not performed in accordance with this Agreement, but to pay for the Services correctly performed until the effective date of termination.

Upon such termination, SANOFI CHIMIE shall:

a) supply VIVUS with all Documentation concerning the Services performed as well as the Results obtained through the effective date of termination;

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b) return to VIVUS (i) all data and documents in any form comprising or containing any VIVUS's Confidential Information contemplated by the Agreement (except for one (1) copy thereof that may be retained in secure legal archives for evidentiary purposes only); and

c) at VIVUS's request, supply to VIVUS and invoice accordingly, at cost and without mark-up, any and all quantities of Starting Materials and the API manufactured up to the effective date of termination.

9.3.2 Upon early termination of the Agreement by VIVUS for causes stated in *Article 9.2.2* or by SANOFI CHIMIE for causes stated in *Article 9.2.2(b)*, VIVUS shall be under no further obligation but to pay SANOFI CHIMIE the amount set forth in the relevant invoice in consideration of the Services actually performed or irrevocably committed and any related expenses up to the effective date of termination.

Upon such termination, SANOFI CHIMIE shall:

a) supply VIVUS with all Documentation concerning the Services performed as well as the Results obtained through the effective date of termination;

b) return to VIVUS (i) all data and documents in any form comprising or containing any VIVUS's Confidential Information contemplated by the Agreement (except for one copy thereof that may be retained in secure legal archives for evidentiary purposes only); (ii) any and all quantities of API manufactured up to the effective date of termination.

c) deliver to VIVUS, and invoice VIVUS accordingly for, all the pending orders of API placed by VIVUS.

9.3.3 Upon early termination of the Agreement by SANOFI CHIMIE either due to a breach by VIVUS in accordance with *Article 9.2.1* or for causes stated at *Article 9.2.2(a)*, VIVUS shall be obligated to pay the full amount set forth in the relevant invoice(s), in consideration of the Services actually performed or irrevocably committed by SANOFI CHIMIE up to the effective date of termination.

Upon such termination, SANOFI CHIMIE shall:

a) supply VIVUS with all Documentation concerning the Services performed and paid as well as the Results obtained through the effective date of termination;

b) return to VIVUS all data and documents in any form comprising or containing any VIVUS's Confidential Information contemplated by the Agreement (except for one (1) copy thereof that may be retained in secure legal archives for evidentiary purposes only); and

c) (i) deliver to VIVUS, and invoice VIVUS accordingly for, all the pending orders of API placed by VIVUS, and (ii) invoice VIVUS for the remaining quantity of API on hand up to the corresponding Yearly Minimum Quantity according to *Article 5.3*.

9.4 Termination of this Agreement shall have the following effects on the licenses and rights granted under *Article 10* hereafter:

a) All licenses granted by VIVUS under *Article 10.6* shall terminate immediately;

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b) The license granted by SANOFI CHIMIE in *Article 10.5* shall continue provided VIVUS pays the corresponding royalties, except in case VIVUS terminated the Agreement due to a breach by SANOFI CHIMIE, in which case the license shall be royalty-free.

9.5 Notwithstanding the expiry or early termination of the Agreement for any cause whatsoever, the provisions of *Articles 9, 10, 12, 13, 14, 15, 17 and 20* hereof shall remain in effect.

**ARTICLE 10 - INTELLECTUAL PROPERTY**

10.1 SANOFI CHIMIE expressly agrees that all VIVUS's Confidential Information is and shall remain the sole property of VIVUS and/or its Affiliates, and nothing herein contained shall be deemed to convey to SANOFI CHIMIE any right, including a property right, relating to any VIVUS's Confidential Information, nor to grant SANOFI CHIMIE any right, patents, patent applications, know-how, patterns or trademarks relating to the API, the Process and/or VIVUS's know-how, in any country, during the term of this Agreement or at any time thereafter except as expressly set forth herein for the purpose of the performance of the Services.

10.2 VIVUS expressly agrees that all SANOFI CHIMIE's Confidential Information is and shall remain the sole property of SANOFI CHIMIE and/or its Affiliates, and nothing herein contained shall be deemed to transfer to VIVUS any right, including property rights, under any SANOFI CHIMIE's Confidential Information, nor to grant VIVUS any right, patents, patent applications, know-how, patterns or trademarks relating to SANOFI CHIMIE's and/or its Affiliates' equipment or know-how together with related developments whichever they could be, in any country, during the term of this Agreement or at any time thereafter, except as otherwise provided for herein.

10.3 Notwithstanding *Article 13* hereunder, the Parties hereto acknowledge and agree that the Results and the Process, except the improvements to the Process that are generated in whole or in part by SANOFI CHIMIE or its Affiliates and that *** ("Severable Improvements") (which, pursuant to *Article 10.5* below, remain the sole property of SANOFI CHIMIE), shall be and remain at all times, both during and after the expiry or termination date of this Agreement, the exclusive property of VIVUS, which will file in its sole name, any and all patents and/or any and all intellectual property rights.
SANOFI CHIMIE hereby assigns all right, title and interest to any Result and/or Process (excluding Severable Improvements) to VIVUS and agrees to execute all documents and to take all actions necessary or advisable to assign and transfer such Results and/or Process to VIVUS and upon VIVUS's request to assist VIVUS, at VIVUS's costs and expenses, in obtaining patent protection or other forms of protection for such Results and/or Process.

10.4 Any patent that may be filed on the Results or Process (excluding Severable Improvements) shall be the exclusive property of VIVUS. They shall be filed in the name and at the cost of VIVUS. If required, SANOFI CHIMIE will provide VIVUS with all necessary assistance, even after termination of the Agreement, in order to enable it to apply for, obtain, and maintain in force such patents, without any payment other than the reimbursement of the reasonable costs and expenses incurred by SANOFI CHIMIE for the time devoted to such assistance, subject to prior written approval of VIVUS on such expenses.

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10.5 VIVUS agrees that any SANOFI CHIMIE's and/or its Affiliates' Background Technology used by SANOFI CHIMIE during the term of this Agreement, as well as any Severable Improvements, shall be and remain the sole and exclusive property of SANOFI CHIMIE and/its Affiliates. To the sole extent that the Manufacture of the API by or on behalf of VIVUS requires the use of SANOFI CHIMIE's and/or its Affiliates' Background Technology and/or any Severable Improvements, SANOFI CHIMIE hereby grants to VIVUS an irrevocable (except in case of material breach by VIVUS and subject to VIVUS's termination right below), sub-licensable, non-exclusive and worldwide license to use such SANOFI CHIMIE's and/or its Affiliates' Background Technology and/or such Severable Improvements. Such license shall be ***, except upon expiration or termination of this Agreement, VIVUS shall thereafter pay to SANOFI CHIMIE a royalty as set forth in *Article 10.5* of the TTA. VIVUS may terminate such license at any time upon written notice to SANOFI CHIMIE, in which case such royalty obligation shall terminate as well.

In the case of a sublicense under the foregoing license, VIVUS shall ensure the proper compliance by its sublicensee with any and all obligation and restriction in relation to the use of any sublicensed Background Technology and/or Severable Improvements for the Manufacture of the API, and VIVUS agrees to terminate the sublicense if such sublicensee violates this restriction and does not cease the unauthorized use after reasonable written notice to the sublicensee of such violation.

In the event VIVUS becomes aware of any suspected infringement of any sublicensed Background Technology and/or Severable Improvements, VIVUS shall promptly notify SANOFI CHIMIE and provide it with all details of such infringement of which it is aware.
VIVUS shall assist and cooperate with SANOFI CHIMIE as the latter may reasonably request from time to time, including by providing access to relevant documents and other evidence and making its employees available at reasonable business hours; provided that VIVUS shall not be required to disclose legally privileged information unless and until procedures reasonably acceptable to VIVUS are in place to protect such privilege.

10.6 VIVUS hereby grants to SANOFI CHIMIE and/or its Affiliates a royalty-free, non-exclusive license to use, subject to the terms of this Agreement, and for the sole purpose of performing SANOFI CHIMIE's obligations hereunder, any and all VIVUS's and/or its Affiliates' Background Technology, VIVUS's Confidential Information, the Process and the Results that are owned by or licensed to VIVUS or any of its Affiliates and that are necessary for the performance of the Services and the Manufacture of the API during the term of this Agreement.

**ARTICLE 11 — ETHIC - ANTI-BRIBERY**

Each Party will conduct itself and undertake the arrangements contemplated by this Agreement in a manner which is consistent with good business ethics and all applicable anti-bribery legislation (national and foreign), including but not limited to the OECD Convention dated 17th December 1997 on combating bribery of public officials in international business

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and the United States Foreign Corrupt Practices Act, as amended. Failure of a Party to comply with the provisions of this Article will be deemed a material breach of a material provision of this Agreement by the other Party.

**ARTICLE 12 — WARRANTY / LIABILITY / INDEMNITY / INSURANCE**

12.1 Warranties

12.1.1 VIVUS warrants to SANOFI CHIMIE that to its knowledge the Process and the API are free from infringement of any patent or other right of third parties. In the case of a third party claim arising out of breach of warranty, Indemnity provisions at *Article 12.3* shall apply.

12.1.2 SANOFI CHIMIE warrants and represents that it will perform the Services in a competent and professional manner in accordance with (i) quality standards required by ICH Q7 guidelines and cGMP, (ii) the terms and conditions set forth in this Agreement and/or in any amendment and (iii) with any and all applicable laws, rules and regulations.

12.1.3 SANOFI CHIMIE shall not be responsible for any answers to questions of any health authority which needs further scientific investigations as, for example, determination and quantification of genotoxic impurities. SANOFI CHIMIE may assist VIVUS upon VIVUS's request, at VIVUS's costs and expenses.

12.2 *Liability*

12.2.1 SANOFI CHIMIE will be solely responsible for the performance of the Services and liable for direct, losses of property, injuries to any person, arising out or resulting from any use of the SANOFI CHIMIE's Background Technology, and/or Severable Improvements, handling of the samples of the API and/or implementation of the Process within SANOFI CHIMIE's facilities and by SANOFI CHIMIE's employees.

12.2.2 Subject to provisions of *Article 12.2.5*, in no event shall either Party be liable to the other for lost profits, punitive or other indirect, special, exemplary, incidental or consequential damages of any kind arising out of, or in connection with this Agreement.

12.2.3 Liability for non-conforming API

The liability of SANOFI CHIMIE for any delivery of API not compliant with the SPECIFICATIONS and the related Quality Agreement (hereinafter the "Non-Conforming API") shall be limited toward VIVUS to, at VIVUS' election, the replacement of the Non-Conforming API as soon as technically possible, at no additional cost for VIVUS, or the reimbursement of the Non-Conforming API .

12.2.4 Subject to the provisions of *Article 12.2.5*, SANOFI CHIMIE's aggregate liability to VIVUS for any loss or damage suffered by VIVUS as a result of a breach of SANOFI CHIMIE shall, for the duration of this Agreement, be limited to, on a cumulative basis, the total amount invoiced by

SANOFI CHIMIE to VIVUS hereunder during ***; provided, however, that for the first *** months of this Agreement SANOFI CHIMIE's aggregate liability shall not exceed ***.

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12.2.5 Notwithstanding the foregoing, nothing in this Agreement except *Article 12.2.2* shall exclude or limit the liability of each Party in the case of (a) personal injury or death, (b) a Party's breach of its confidentiality obligations, (c) an intellectual property right infringement claim brought by a third party that is a breach of a Party's representation or warranty set forth above at *Article 12.1*, (d) a Party's gross negligence or willful misconduct and (e) a third party's claim for which a Party is obligated to indemnify the other Party under this Agreement (as provided for under *Article 12.3* below). Furthermore, *Article 12.2.2* shall not exclude or limit the liability of each Party in the case of (i) a Party's breach of its confidentiality obligations or (ii) a third party's claim for which a Party is obligated to indemnify the other Party under this Agreement (as provided for under *Article 12.3* below).

12.3 Indemnity

12.3.1 SANOFI CHIMIE shall be liable for and agrees to indemnify and hold harmless VIVUS (including its Affiliates), its directors, officers, and employees against any and all liability, damages, demands, claims, actions, proceedings, suits, judgments, costs, losses, and expenses (hereinafter referred to as "Claims") that may be brought by a third party against or suffered by VIVUS as a direct result of any breach by SANOFI CHIMIE of its obligations or warranties hereunder, except to the extent that such Claims are due to the negligence, gross negligence, fault or intentional misconduct of VIVUS.

12.3.2 VIVUS shall be liable for and agrees to indemnify and hold harmless SANOFI CHIMIE (including its Affiliated Companies), its directors, officers, and employees against any and all liability, damages, demands, claims, actions, proceedings, suits, judgments, costs, losses, and expenses (hereinafter referred to as "Claims") that may be brought by a third party against or suffered by SANOFI CHIMIE as a direct result of any breach by VIVUS of its obligations or warranties hereunder, except to the extent that such Claims are due to the negligence, gross negligence, fault or intentional misconduct of SANOFI CHIMIE.

12.3.3 If either Party expects to seek indemnification under this Agreement with respect to a Claim, made, or filed, the Party seeking indemnification shall:

i) promptly give notice to the other Party of any such Claim against it, such Claim forming the basis of indemnification under this Agreement, and

ii) fully cooperate with the other Party in the investigation and defence of all such Claim.

12.3.4 The indemnifying Party shall have the option to assume the other Party's defence in any such Claim with counsel reasonably satisfactory to the other Party. No settlement or compromise shall be binding on a Party hereto without such Party's prior written consent, which will not be unreasonably withheld. The Party seeking indemnification shall have the right of appearance of counsel of its own selection, at its own cost and expense.

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12.4 Insurance

Each Party represents that it has and shall maintain during the term of this Agreement, a reasonable level of insurance, which may include an appropriate program of self-insurance, and in particular product liability insurance, with policy limits reasonably appropriate for its business. Each Party agrees to provide upon request copies of the certificate of insurance as written evidence to the other of such coverage.

## ARTICLE 13 — CONFIDENTIALITY

13.1 Each Party acknowledges and agrees that while performing this Agreement, it will be exposed to or be given Confidential Information of the other Party.

13.2 Each Party undertakes to maintain the Confidential Information of the other Party in strict secrecy and to avoid any disclosure and/or use for another purpose than performing the Agreement, in any manner whatsoever and in any form, with the same care it has or should have regarding its own Confidential Information.

Each Party undertakes to make the Confidential Information of the other Party available only to its and/or its Affiliates' employees who have a direct need to have access in order to perform this Agreement, and to take all steps necessary to ensure that these employees shall not disclose and/or use such Confidential Information of the other Party in a manner which is not authorized under this Agreement.

13.3 The foregoing undertaking of confidentiality and non-use shall remain in full force and effect for the term of this Agreement and for *** years thereafter, even if this Agreement is declared null and void for any reason, unless the Confidential Information:

a) was known to the public, or generally available to the public, at the date of disclosure,

b) becomes known to the public, or generally available to the public, after the date of signature of this Agreement, through no act or omission of the receiving Party or of its employees in breach of this Agreement;

c) is obtained lawfully from a third party without any secrecy obligation, provided that such Confidential Information has not been acquired directly or indirectly, by the third party from the disclosing Party under a secrecy obligation,

d) is subsequently independently discovered or developed by or on behalf of the receiving Party, without reliance on Confidential Information disclosed by the disclosing Party under this Agreement, as evidenced by written records,

e) is required to be disclosed as a result of applicable laws or regulations or final order of a court, provided that the receiving Party promptly notifies the disclosing Party, that reasonable measures shall be taken by the receiving Party to assure confidential treatment of such information and that the receiving Party will restrict the disclosure to the piece of Confidential Information legally required.

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For the purpose of the Agreement, no Confidential Information shall be deemed to be in the public domain or knowledge merely because such Confidential Information is embraced by more general information in the public domain or knowledge.

13.4 **Authorized Disclosure.** Each Party may disclose Confidential Information belonging to the other Party to the extent such 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, disclosure to Mitsubishi Tanabe Pharma Corporation as required pursuant to VIVUS' license agreement with Mitsubishi Tanabe Pharma Corporation;

(c) in the case of VIVUS as the receiving Party, disclosure to its licensees, sublicensees, and collaborators with respect to the Product, but solely to the extent that such Confidential Information (i) raises any material concerns regarding the safety 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 of any Product in such licensee's, sublicensee's, or collaborator's territory; *provided* that each such disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Sections 13.2 and 13.3 prior to any such disclosure;

(d) disclosure to its and its Affiliates' respective directors, officers, employees, consultants, attorneys, professional advisors, lenders, insurers, service providers and licensees only on a need-to-know basis and solely as necessary in connection with this Agreement, provided that each disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Sections 13.2 and 13.3 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 disclosee); and

(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 disclosee must be bound by obligations of confidentiality and non-use no less stringent than those set forth in Sections 13.2 and 13.3 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 disclosee).

13.5 Upon expiry or prior termination of this Agreement, unless the Parties should decide otherwise, each Party shall return to other Party any and all Confidential Information of the latter.

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## ARTICLE 14 - PUBLICATIONS — COMMUNICATIONS

Neither Party shall (a) make any publication or communication which discloses the terms and conditions of the Agreement or any amendment (other than terms and conditions that are or become publicly available through no breach of this Agreement), without the prior written approval of the other Party or (b) use the name of the other Party or any of its Affiliates as a commercial reference, without its prior written consent. Notwithstanding the foregoing, (A) VIVUS may disclose such information to actual or potential partners or licensees or to Mitsubishi Tanabe Pharma Corporation (or to directors, officers, employees, consultants, attorneys, professional advisors, lenders, insurers, or service providers on a need-to-know basis), without obtaining the consent of SANOFI CHIMIE provided said third parties shall be subject to the same or greater level of confidentiality as set forth in

*Article 13*; (B) VIVUS may, in its sole discretion and in the ordinary course of business, make publications or communications relating to its research, development, regulatory, and commercialization efforts, provided that it complies with subsection (b) and *Article 13* above; and (C) nothing in this *Article 14* shall prevent a Party from making any disclosure that is required as a result of applicable laws or regulations or final order of a court, provided that such Party promptly notifies the other Party, that reasonable measures shall be taken by such Party to assure confidential treatment of such information and such Party will restrict the disclosure to the piece of Confidential Information legally required.

For sake of clarity, this provision does not prevent VIVUS from disclosing the terms and conditions of the Agreement to a third party as long as such disclosure is strictly needed for the sole purpose of an acquisition due diligence and that VIVUS treats said information with the same care it has or should have regarding its own Confidential Information.

**ARTICLE 15 - ASSIGNMENT / SUBCONTRACT**

Neither Party may subcontract, assign, extend or transfer any of its rights and obligations under this Agreement, without the express and prior written consent of the other Party, such consent not to be unreasonably withheld. Notwithstanding the foregoing, SANOFI CHIMIE may transfer or assign its rights and obligations under this Agreement to its Affiliates, and that VIVUS may transfer or assign its rights and obligations under this Agreement, in whole or in part, to its Affiliates and/or its Commercialization Partners.

No assignment nor transfer of this Agreement or of any rights hereunder shall relieve the assigning Party of any of its obligations and liability hereunder, unless the assignee undertakes in writing to, and can reasonably, assume such obligations and liabilities.

This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their respective successors and assigns.

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**ARTICLE 16 - AUDIT**

16.1 VIVUS, or any third party appointed by VIVUS, will be allowed, upon reasonable notice, to carry out, once per ***, *** technical or quality assurance audit in the premises where the Services are performed by SANOFI CHIMIE as specified in the Quality Agreement.

16.2 SANOFI CHIMIE undertakes to cooperate with VIVUS for such audit that VIVUS, or any third party appointed by VIVUS, shall carry out during the term of this Agreement.

16.3 In case the audit is performed by a third party appointed by VIVUS, then such audit shall be processed under a separate secrecy agreement signed before the date of the audit.

**ARTICLE 17 - NOTICES**

Any notice required or permitted to be given under this Agreement shall be deemed to have been sufficiently given if mailed by registered mail, postage prepaid, or sent by fax or electronic mail, addressed to the Party to be notified, at its address stated in this Agreement or at such other address as may hereafter be provided in an Amendment (or in any other document exchanged between the Parties) and shall be deemed to have been served *** Business Days after mailing in the case of mail, and *** Business Days after dispatch in the case of fax or electronic mail.

**ARTICLE 18 - FORCE MAJEURE**

18.1 If either of the Parties is impeded in fulfilling its obligations in accordance with this Agreement due to an event or a cause beyond its control, such as, an unforeseen labor conflict, fire, earthquakes, floods, war, mobilization or unforeseen military call-up of a large magnitude, requisition, confiscation, commandeering, public decrees, riots, insurrections, general shortage of transport, goods or energy, delays in deliveries from suppliers caused by any circumstances referred to in this Article, this impediment will be considered as a “force majeure” event and the Party shall be exempted from liability for delays due to such reasons; provided, however, that it notifies the other Party thereof without undue delay after such an event has occurred.

18.2 The Party suffering from the occurrence of such force majeure shall (i) promptly inform the other Party and send to the other Party all appropriate justification evidencing the occurrence of such event and (ii) shall make all reasonable efforts to mitigate the consequences of such force majeure and to remedy the situation as quickly as possible.

18.3 If after *** consecutive days from the date of receipt of the notice of the force majeure occurrence, such event persists, either Party may terminate the Agreement by registered mail with return receipt requested and termination shall become effective forthwith.

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**ARTICLE 19 - GENERAL PROVISIONS**

19.1 Entire agreement

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. 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.

Notwithstanding the foregoing, any prior Confidentiality Agreement between the Parties remains in full force and effect.

19.2 Headings

Headings are inserted for convenience and shall not affect the meaning or interpretation of this Agreement.

19.3 Independent contractor

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

19.4 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.

19.5 No waiver

Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

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19.6 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 SANOFI CHIMIE under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at SANOFI CHIMIE's sole and exclusive option, either by SANOFI CHIMIE directly or by any Affiliate of SANOFI CHIMIE that SANOFI CHIMIE 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.

19.7 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.

## ARTICLE 20 - GOVERNING LAW / DISPUTES

20.1 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, United States of America, 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.

20.2 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

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and without resort to litigation. To accomplish this objective, the Parties agree to meet and discuss in good faith 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. Such 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 *** days following the request for discussions, either Party may then invoke the provisions of *Article 20.3*.

20.3 Arbitration

20.3.1 *Claims*. Subject to *Article 20.4* below, any claim, dispute, or controversy of whatever nature arising out of or relating to this Agreement that is not resolved under *Article 20.2* within the required *** day period, including, without limitation, any claim concerning the interpretation, effect, termination, validity, performance and/or breach of this Agreement shall be resolved by final and binding arbitration administered by ***. The arbitration and all associated discovery proceedings and communications shall be conducted in English, and the arbitration shall be held in New York, New York, USA.

20.3.2 *English Language*. All proceedings shall be held in English and a transcribed record prepared in English. Documents submitted in the arbitration (the originals of which are not in English) shall be submitted together with a reasonably complete and accurate English translation.

20.3.3 *Selection of Arbitrators*. The Parties shall each choose one arbitrator within *** days of receipt of notice of the intent to arbitrate and the said two arbitrators shall select by mutual agreement a third arbitrator within *** days after they have been selected as arbitrators. If no arbitrator is appointed within the times herein provided or any extension of time that is mutually agreed on, the *** shall make such appointment (i.e. shall appoint *** arbitrators) within *** days of such failure.

20.3.4 *Arbitrators' Award*. The arbitrators' award shall include a written statement describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The arbitrators shall, in rendering their decision, apply the substantive laws of the State of New York, without giving effect to its conflicts of laws principles. The arbitrators' authority to award special, incidental, consequential or punitive damages shall be subject to the limitation set forth in *Article 12.2*. The award rendered by the arbitrators shall be final, binding and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction.

20.3.5 *Costs***.** Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; *provided, however,* the arbitrators shall be authorized to determine whether a Party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, *etc.*), and/or the fees and costs of the *** and the arbitrators.

20.4 Court Actions**.** Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the

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context of a *bona fide* emergency or prospective irreparable harm, including but not limited to a breach or threatened breach of any confidentiality provision herein, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of patents or other intellectual property rights, and no such claim shall be subject to arbitration pursuant to *Article 20.3*.

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**IN WITNESS WHEREOF**, the Parties hereto have caused this Agreement to be duly executed on the dates indicated herein below.

Made in two (2) original copies.

| **SANOFI CHIMIE** | | **VIVUS INC.** | |
|---|---|---|---|
| By: | /s/ Hervé Lebrun | By: | /s/ Leland F. Wilson |
| Name: | Hervé LEBRUN | Name: | Leland F. WILSON |
| Title: | Chairman and Chief Executive Officer | Title: | Chief Executive Officer |
| Date: | 24th July 2013 | Date: | July 17, 2013 |

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***EXHIBIT 1 — QUALITY AGREEMENT***

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***EXHIBIT 2 — PRICING ADJUSTMENT REFERENCE***

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***EXHIBIT 3 — SANOFI'S TERRITORY***

*******

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**Exhibit 31.1**

CERTIFICATION

I, Anthony P. Zook, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 8, 2013

By: /s/ ANTHONY P. ZOOK
Anthony P. Zook
Chief Executive Officer

**Exhibit 31.2**

CERTIFICATION

I, Timothy E. Morris, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 8, 2013

By: /s/ TIMOTHY E. MORRIS
Timothy E. Morris
Sr. Vice President Finance and Global Corporate Development, Chief Financial Officer

**Exhibit 32**

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

I, Anthony P. Zook, Chief Executive Officer of VIVUS, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended June 30, 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: August 8, 2013

By: /s/ ANTHONY P. ZOOK
Anthony P. Zook

I, Timothy E. Morris, Sr. Vice President Finance and Global Corporate Development, 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 June 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: August 8, 2013

By: /s/ TIMOTHY E. MORRIS
Timothy E. Morris