

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For The Quarterly Period Ended September 30, 2016

OR

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

For the transition period from to

Commission File Number 001-33389

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

351 East Evelyn Avenue  
Mountain View, California

(Address of principal executive office)

94-3136179

(IRS employer  
identification number)

94041

(Zip Code)

(650) 934-5200

(Registrant's telephone number, including area code)

N/A

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

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

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

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

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

At October 31, 2016, 104,843,301 shares of common stock, par value \$.001 per share, were outstanding.

## VIVUS, INC.

## Quarterly Report on Form 10-Q

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**PART I: FINANCIAL INFORMATION**
**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**
**VIVUS, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(In thousands, except par value)

	September 30, 2016	December 31, 2015
	Unaudited	Note 1
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 154,137	\$ 95,395
Available-for-sale securities	129,449	146,168
Accounts receivable, net	10,295	8,997
Inventories	11,259	13,602
Prepaid expenses and other current assets	5,552	9,430
Total current assets	310,692	273,592
Property and equipment, net	715	994
Non-current assets	1,744	2,616
Total assets	<u>\$ 313,151</u>	<u>\$ 277,202</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 6,440	\$ 7,060
Accrued and other liabilities	9,944	15,891
Deferred revenue	89,128	22,142
Current portion of long-term debt	9,015	14,356
Total current liabilities	114,527	59,449
Long-term debt, net of current portion	229,876	217,034
Deferred revenue, net of current portion	6,845	6,508
Non-current accrued and other liabilities	16	1,296
Total liabilities	351,264	284,287
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock; \$1.00 par value; 5,000 shares authorized; no shares issued and outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock; \$.001 par value; 200,000 shares authorized; 104,819 and 104,055 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	105	104
Additional paid-in capital	831,192	829,428
Accumulated other comprehensive income (loss)	207	(261)
Accumulated deficit	(869,617)	(836,356)
Total stockholders' deficit	(38,113)	(7,085)
Total liabilities and stockholders' deficit	<u>\$ 313,151</u>	<u>\$ 277,202</u>

See accompanying notes to unaudited condensed consolidated financial statements.

## VIVUS, INC.

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

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

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

(In thousands)  
(Unaudited)

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

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)  
(Unaudited)

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

See accompanying notes to unaudited condensed consolidated financial statements.

## VIVUS, INC.

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2016

## 1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2016, are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. Management has evaluated all events and transactions that occurred after September 30, 2016, through the date these unaudited condensed consolidated financial statements were filed. There were no events or transactions during this period that require recognition or disclosure in these unaudited condensed consolidated financial statements. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP.

The unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015 as filed on March 9, 2016 with the Securities and Exchange Commission, or SEC, and as amended by the Form 10-K/A filed on April 22, 2016 with the SEC. The unaudited condensed consolidated financial statements include the accounts of VIVUS, Inc. and its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

When reference is made to the "Company" or "VIVUS" in these footnotes, it refers to the Delaware corporation, or VIVUS, Inc., and its California predecessor, as well as all of its consolidated subsidiaries.

## Implementation of ASU 2015-03

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

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

### Use of Estimates

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

### Significant Accounting Policies

Other than the implementation of ASU 2015-03 discussed above, there have been no changes to the Company's significant accounting policies since the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

### Recent Accounting Pronouncements

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

In March 2016, the FASB issued Accounting Standards Update 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which is designed to simplify several aspects of accounting for share-based payment award transactions, including income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and forfeiture rate calculations. For public companies, the standard is effective for annual and interim periods beginning on or after December 15, 2016. Early adoption is permitted. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

## 2. SHARE-BASED COMPENSATION

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Cost of goods sold	\$ 40	\$ 34	\$ 115	\$ 86
Selling, general and administrative	413	207	1,299	2,550
Research and development	188	(49)	326	332
Non-recurring charges	—	64	—	64
Total share-based compensation expense	\$ 641	\$ 256	\$ 1,740	\$ 3,032

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

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

The fair value and the amortized cost of cash, cash equivalents, and available-for-sale securities by major security type at September 30, 2016 and December 31, 2015, are presented in the tables that follow (in thousands).

	As of September 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>Cash and cash equivalents and available-for-sale securities</b>				
Cash and money market funds	\$ 154,137	\$ —	\$ —	\$ 154,137
U.S. Treasury securities	28,223	13	(1)	28,235
Corporate debt securities	101,018	236	(40)	101,214
Total	283,378	249	(41)	283,586
Less amounts classified as cash and cash equivalents	(154,137)	—	—	(154,137)
Total available-for-sale securities	\$ 129,241	\$ 249	\$ (41)	\$ 129,449

	As of December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>Cash and cash equivalents and available-for-sale securities</b>				
Cash and money market funds	\$ 95,395	\$ —	\$ —	\$ 95,395
U.S. Treasury securities	84,734	—	(107)	84,627
Corporate debt securities	61,696	20	(175)	61,541
Total	241,825	20	(282)	241,563
Less amounts classified as cash and cash equivalents	(95,395)	—	—	(95,395)
Total available-for-sale securities	\$ 146,430	\$ 20	\$ (282)	\$ 146,168

As of September 30, 2016, the Company's available-for-sale securities had original contractual maturities up to 57 months. However, in response to changes in the availability of and the yield on alternative investments as well as liquidity requirements, the Company may sell these securities prior to their stated maturities. As these securities are readily marketable and are viewed by the Company as available to support current operations, securities with maturities beyond 12 months are classified as current assets. Due to their short-term maturities, the Company believes that the fair value of its bank deposits, accounts payable and accrued expenses approximate their carrying value.

#### Fair Value Measurements

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

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.



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

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

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

#### 4. ACCOUNTS RECEIVABLE

Accounts receivable consist of the following (in thousands):

	Balance as of	
	September 30, 2016	December 31, 2015
Qsymia	\$ 9,216	\$ 8,508
STENDRA/SPEDRA	1,245	652
	10,461	9,160
Qsymia allowance for cash discounts	(166)	(163)
Net	\$ 10,295	\$ 8,997

#### 5. INVENTORIES

Inventories consist of the following (in thousands):

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

Raw materials inventories consist primarily of the active pharmaceutical ingredients, or API, for Qsymia and STENDRA/SPEDRA. Deferred costs inventories consist primarily of Qsymia and represent Qsymia product shipped to the Company's wholesalers and certified retail pharmacies, but not yet dispensed to patients through prescriptions, net of prompt payment discounts, and for which recognition of revenue has been deferred.

Inventories are stated at the lower of cost or market. Cost is determined using the first in, first out method for all inventories, which are valued using a weighted-average cost method calculated for each production batch. The Company periodically evaluates the carrying value of inventory on hand for potential excess amounts over demand using the same lower of cost or market approach as that used to value the inventory. In the second quarter of 2015, the Company recorded inventory impairment charges of \$29.5 million primarily for Qsymia API inventory in excess of expected demand.

## 6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

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

The amounts included in prepaid expenses and other current assets consist primarily of prepayments for future services, a receivable from a supplier and interest income receivable. These costs have been deferred as prepaid expenses and other current assets on the consolidated balance sheets and will be either (i) charged to expense accordingly when the related prepaid services are rendered to the Company, or (ii) converted to cash when the receivable is collected by the Company.

## 7. NON-CURRENT ASSETS

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

## 8. ACCRUED AND OTHER LIABILITIES

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

	Balance as of	
	September 30, 2016	December 31, 2015
Accrued employee compensation and benefits	\$ 2,576	\$ 3,621
Accrued non-recurring charges (see Note 10)	12	503
Accrued interest on debt (see Note 13)	1,917	1,293
Accrued manufacturing costs	686	5,408
Other accrued liabilities	4,753	5,066
Total	\$ 9,944	\$ 15,891

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

## 9. NON-CURRENT ACCRUED AND OTHER LIABILITIES

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

# 10. INVENTORY IMPAIRMENT AND OTHER NON-RECURRING CHARGES

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

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

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

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

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

2016 (remaining three months)	\$ 7
2017	5
	<u>\$ 12</u>

# 11. DEFERRED REVENUE

Deferred revenue consists of the following (in thousands):

	September 30, 2016	December 31, 2015
Qsymia deferred revenue - current	\$ 17,566	\$ 19,275
STENDRA deferred revenue - current	71,562	2,867
Deferred revenue - current	<u>\$ 89,128</u>	<u>\$ 22,142</u>
STENDRA deferred revenue - non-current	\$ 6,845	\$ 6,508

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

prescriptions, net of prompt payment discounts. SPEDRA deferred revenue primarily relates to a prepayment of \$70 million in licensing fees from Metuchen Pharmaceuticals LLC, or Metuchen, (see Note 12) and a prepayment for future royalties on sales of SPEDRA.

## 12. LICENSE, COMMERCIALIZATION AND SUPPLY AGREEMENTS

During 2013, the Company entered into separate license and commercialization agreements and separate commercial supply agreements with each of the Menarini Group, through its subsidiary Berlin Chemie AG, or Menarini, Auxilium Pharmaceuticals, Inc, or Auxilium, and Sanofi and its affiliate, or Sanofi, to commercialize and promote avanafil (STENDRA or SPEDRA) in their respective territories. Menarini's territory is comprised of over 40 European countries, including the European Union, or EU, plus Australia and New Zealand. Sanofi's territory is comprised of Africa, the Middle East, Turkey and Eurasia. Auxilium's territory was comprised of the United States and Canada and their respective territories. In January 2015, Auxilium was acquired by Endo. Auxilium terminated the supply agreement effective June 30, 2016, and the license agreement effective September 30, 2016.

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

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

## 13. LONG-TERM DEBT AND COMMITMENTS

### *Convertible Senior Notes Due 2020*

In May 2013, the Company closed an offering of \$220.0 million in 4.5% Convertible Senior Notes due May 2020, or the Convertible Notes. The Convertible Notes are governed by an indenture, dated May 2013 between the Company and Deutsche Bank National Trust Company, as trustee. In May 2013, the Company closed on an additional \$30.0 million of Convertible Notes upon exercise of an option by the initial purchasers of the Convertible Notes at a conversion rate of approximately \$14.86 per share. Total net proceeds from the Convertible Notes were approximately \$241.8 million. The Convertible Notes are convertible at the option of the holders under certain conditions at any time prior to the close of business on the business day immediately preceding November 1, 2019. On or after November 1, 2019, holders may convert all or any portion of their Convertible Notes at any time at their

option at the conversion rate then in effect, regardless of these conditions. Subject to certain limitations, the Company will settle conversions of the Convertible Notes by paying or delivering, as the case may be, cash, shares of its common stock or a combination of cash and shares of our common stock, at the Company's election. Interest payments are made quarterly.

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

#### *Senior Secured Notes Due 2018*

In March 2013, the Company entered into the Purchase and Sale Agreement between the Company and BioPharma Secured Investments III Holdings Cayman LP, or Biopharma, a Cayman Islands exempted limited partnership, providing for the purchase of a debt like instrument, or the Senior Secured Notes. Under the agreement, the Company received \$50 million, less \$500,000 in funding and facility payments, at the initial closing in April 2013. The scheduled quarterly payments on the Senior Secured Notes are subject to the net sales of (i) Qsymia and (ii) any other obesity agent developed or marketed by us or our affiliates or licensees. The scheduled quarterly payments, other than the payment(s) scheduled to be made in the second quarter of 2018, are capped at the lower of the scheduled payment amounts or 25% of the net sales of (i) and (ii) above. Accordingly, if 25% of the net sales is less than the scheduled quarterly payment, then 25% of the net sales is due for that quarter, with the exception of the payment(s) scheduled to be made in the second quarter of 2018, when any unpaid scheduled quarterly payments plus any accrued and unpaid make whole premiums must be paid. Any quarterly payment less than the scheduled quarterly payment amount will be subject to a make whole premium equal to the applicable scheduled quarterly payment of the preceding quarter less the actual payment made to BioPharma for the preceding quarter multiplied by 1.03. The Company may elect to pay full scheduled quarterly payments if it chooses.

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

Debt is as follows (in thousands):

	September 30, 2016
Principal amount of Convertible Senior Notes due 2020	\$ 250,000
Principal amount of Senior Secured Notes due 2018	34,643
	284,643
Less: Debt issuance costs	(2,501)
Less: Discount on convertible senior notes	(43,251)
	238,891
Less: Current portion	(9,015)
Long-term debt, net of current portion	\$ 229,876
Future estimated payments on the Senior Secured Notes as of September 30, 2016 are as follows:	
2016 (remaining three months)	\$ 8,875
2017	23,750
2018	38,376
Total	71,001
Less: Interest portion	(36,358)
Senior Secured Notes	\$ 34,643

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

#### 14. NET INCOME (LOSS) PER SHARE

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

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

## 15. INCOME TAXES

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

The Company periodically evaluates the realizability of its net deferred tax assets based on all available evidence, both positive and negative. The realization of net deferred tax assets is dependent on the Company's ability to generate sufficient future taxable income during periods prior to the expiration of tax attributes to fully utilize these assets. The Company weighed both positive and negative evidence and determined that there is a continued need for a full valuation allowance on its deferred tax assets in the United States as of September 30, 2016. Should the Company determine that it would be able to realize its remaining deferred tax assets in the foreseeable future, an adjustment to its remaining deferred tax assets would cause a material increase to income in the period such determination is made.

As of September 30, 2016, the Company's only unrecognized tax benefit is related to California research and development activities in the amount of \$66,000. We do not expect to have any other significant changes to unrecognized tax benefits through the end of the fiscal year. Because of our history of tax losses, certain tax years remain open to tax audit. The Company's policy is to recognize interest and penalties related to uncertain tax positions (if any) as a component of the income tax provision.

## 16. LEGAL MATTERS

### *Shareholder Lawsuit*

On March 27, 2014, Mary Jane and Thomas Jasin, who purport to be purchasers of VIVUS common stock, filed an Amended Complaint in Santa Clara County Superior Court alleging securities fraud against the Company and three of its former officers and directors. In that complaint, captioned *Jasin v. VIVUS, Inc.*, Case No. 114-cv-261427, plaintiffs asserted claims under California's securities and consumer protection securities statutes. Plaintiffs alleged generally that defendants misrepresented the prospects for the Company's success, including with respect to the launch of Qsymia, while purportedly selling VIVUS stock for personal profit. Plaintiffs alleged losses of "at least" \$2.8 million, and sought damages and other relief. On June 5, 2014, the Company and the other defendants filed a demurrer to the Amended Complaint seeking its dismissal. With the demurrer pending, on July 18, 2014, the same plaintiffs filed a complaint in the United States District Court for the Northern District of California, captioned *Jasin v. VIVUS, Inc.*, Case No. 5:14-cv-03263. The Jasins' federal complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, based on facts substantially similar to those alleged in their state court action. On September 15, 2014, pursuant to an agreement between the parties, plaintiffs moved to voluntarily dismiss, with prejudice, the state court action. In the federal action, defendants filed a motion to dismiss on November 12, 2014. On December 3, 2014, plaintiffs filed a First Amended Complaint in the federal action. On January 21, 2015, defendants filed a motion to dismiss the First Amended Complaint. The court ruled on that motion on June 18, 2015, dismissing the seven California claims with prejudice and dismissing the two federal claims with leave to amend. Plaintiffs filed a Second Amended Complaint on August 17, 2015. Defendants moved to dismiss that complaint on October 2, 2015. On September 10, 2015, plaintiffs moved for entry of judgment on their state claims. Briefing on both defendants' motion to dismiss and plaintiffs' motion for entry of judgment was completed on December 15, 2015. On April 19, 2016, the court issued a ruling granting defendants' motion to dismiss without leave to amend and denying as moot plaintiffs' motion for entry of judgment. On May 18, 2016, the plaintiffs filed a notice of appeal, and on September 23, 2016, plaintiffs filed their opening appellate brief. Defendants' response is due on November 23, 2016. The Company maintains directors' and officers' liability insurance that it believes affords coverage for much of the anticipated cost of the remaining *Jasin* action, subject to the use of the Company's financial resources to pay for its self-insured retention and the policies' terms and conditions.

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

## Qsymia ANDA Litigation

On May 7, 2014, the Company received a Paragraph IV certification notice from Actavis Laboratories FL indicating that it filed an abbreviated new drug application, or ANDA, with the U.S. Food and Drug Administration, or FDA, requesting approval to market a generic version of Qsymia and contending that the patents listed for Qsymia in the FDA Orange Book at the time the notice was received (U.S. Patents 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, and 8,580,299 (collectively “patents-in-suit”)) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Qsymia as described in their ANDA. On June 12, 2014, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as Actavis. The lawsuit (Case No. 14-3786 (SRC)(CLW)) was filed on the basis that Actavis’ submission of their ANDA to obtain approval to manufacture, use, sell or offer for sale generic versions of Qsymia prior to the expiration of the patents-in-suit constitutes infringement of one or more claims of those patents.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Actavis, FDA approval of Actavis’ ANDA will be stayed until the earlier of (i) up to 30 months from the Company’s May 7, 2014 receipt of Actavis’ Paragraph IV certification notice (i.e. November 7, 2016) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

On January 21, 2015, the Company received a second Paragraph IV certification notice from Actavis contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 8,895,057 and 8,895,058) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, or offer for sale of a generic form of Qsymia. On March 4, 2015, the Company filed a second lawsuit in the U.S. District Court for the District of New Jersey against Actavis (Case No. 15-1636 (SRC)(CLW)) in response to the second Paragraph IV certification notice on the basis that Actavis’ submission of their ANDA constitutes infringement of one or more claims of the patents-in-suit.

On July 7, 2015, the Company received a third Paragraph IV certification notice from Actavis contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 9,011,905 and 9,011,906) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, or offer for sale of a generic form of Qsymia. On August 17, 2015, the Company filed a third lawsuit in the U.S. District Court for the District of New Jersey against Actavis (Case No. 15-6256 (SRC)(CLW)) in response to the third Paragraph IV certification notice on the basis that Actavis’ submission of their ANDA constitutes infringement of one or more claims of the patents-in-suit. The three lawsuits against Actavis have been consolidated into a single suit (Case No. 14-3786 (SRC)(CLW)). On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit. The Court adopted the Company’s proposed constructions for all but one of the disputed claim terms and adopted a compromise construction that was acceptable to the Company for the final claim term. Expert discovery is ongoing and no trial date has been scheduled.

On March 5, 2015, the Company received a Paragraph IV certification notice from Teva Pharmaceuticals USA, Inc. indicating that it filed an ANDA with the FDA, requesting approval to market a generic version of Qsymia and contending that eight patents listed for Qsymia in the Orange Book at the time of the notice (U.S. Patents 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, 8,580,299, 8,895,057 and 8,895,058) (collectively “patents-in-suit”) are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of a generic form of Qsymia as described in their ANDA. On April 15, 2015, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Teva Pharmaceutical USA, Inc. and Teva Pharmaceutical Industries, Ltd., collectively referred to as Teva. The lawsuit (Case No. 15-2693 (SRC)(CLW)) was filed on the basis that Teva’s submission of their ANDA to obtain approval to manufacture, use, sell, or offer for sale generic versions of Qsymia prior to the expiration of the patents-in-suit constitutes infringement of one or more claims of those patents.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Teva, FDA approval of Teva’s ANDA will be stayed until the earlier of (i) up to 30 months from our March 5, 2015 receipt of Teva’s Paragraph IV certification notice (i.e. September 5, 2017) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.



On August 5, 2015, the Company received a second Paragraph IV certification notice from Teva contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 9,011,905 and 9,011,906) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, or offer for sale of a generic form of Qsymia. On September 18, 2015, the Company filed a second lawsuit in the U.S. District Court for the District of New Jersey against Teva (Case No. 15-6957(SRC)(CLW)) in response to the second Paragraph IV certification notice on the basis that Teva's submission of their ANDA constitutes infringement of one or more claims of the patents-in-suit. The two lawsuits against Teva have been consolidated into a single suit (Case No. 15-2693 (SRC)(CLW)).

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

#### STENDRA ANDA Litigation

On June 20, 2016, the Company received a Paragraph IV certification notice from Hetero USA, Inc. indicating that it filed an ANDA with the FDA, requesting approval to market a generic version of STENDRA and contending that patents listed for STENDRA in the Orange Book at the time of the notice (U.S. Patents 6,656,935, and 7,501,409) (collectively "patents-in-suit") are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of a generic form of STENDRA as described in their ANDA. On July 27, 2016, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Hetero USA, Inc. and Hetero Labs Limited, collectively referred to as Hetero. The lawsuit (Case No. 16-4560 (KSH)(CLW)) was filed on the basis that Hetero's submission of their ANDA to obtain approval to manufacture, use, sell, or offer for sale generic versions of STENDRA prior to the expiration of the patents-in-suit constitutes infringement of one or more claims of those patents.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Hetero, FDA approval of Hetero's ANDA will be stayed until the earlier of (i) up to 30 months from the expiration of STENDRA's New Chemical Entity, or NCE, exclusivity period (i.e. October 27, 2019) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

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

The Company is not aware of any other asserted or unasserted claims against it where it believes that an unfavorable resolution would have an adverse material impact on the operations or financial position of the Company.

#### 17. SEGMENT INFORMATION

The Company operates in one reportable segment—the development and commercialization of novel therapeutic products. The Company has identified its Chief Executive Officer as the Chief Operating Decision Maker, or CODM, who manages the Company's operations on a consolidated basis for purposes of allocating resources. When evaluating financial performance, the CODM reviews individual customer and product information, while other financial information is reviewed on a consolidated basis. Therefore, results of operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Disclosures about revenues by product and by geographic area are presented below.

##### *Geographic Information*

Outside the United States, or ROW, the Company sells avanafil (STENDRA/SPEDRA) through a commercialization licensee principally in the EU. The geographic classification of product sales was based on the

location of the customer. The geographic classification of supply, license and milestone revenue was based on the domicile of the entity from which the revenue was earned.

Net product revenue by geographic region was as follows (in thousands):

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

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

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

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations and other parts of this Quarterly Report on Form 10-Q contain "forward looking" statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as "may," "believe," "expect," "forecast," "intend," "anticipate," "predict," "should," "planned," "likely," "opportunity," "estimated," and "potential," the negative use of these words or other similar words. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to:

- the timing of initiation and completion of the post-approval clinical studies required as part of the approval of Qsymia by the U.S. Food and Drug Administration, or FDA;
- the response from the FDA to the data that we will submit relating to post-approval clinical studies;
- the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy requirements;
- our ability to continue to certify and add to the Qsymia retail pharmacy network and sell Qsymia through this network;
- whether the Qsymia retail pharmacy network will simplify and reduce the prescribing burden for physicians, improve access and reduce waiting times for patients seeking to initiate therapy with Qsymia;
- that we may be required to provide further analysis of previously submitted clinical trial data;
- our ability to work with leading cardiovascular outcome trial experts in planning substantial revisions to the original design and execution of the clinical post-marketing cardiovascular outcomes trial, or CVOT, with the goal of reducing trial costs and obtaining FDA agreement that the revised CVOT would fulfill the requirement of demonstrating the long-term cardiovascular safety of Qsymia;
- our ongoing dialog with the European Medicines Agency, or EMA, relating to our CVOT, and the resubmission of an application for the grant of a marketing authorization to the EMA, the timing of such resubmission, if any, the results of the CVOT, assessment by the EMA of the application for marketing authorization, and their agreement with the data from the CVOT;
- our ability to successfully seek approval for Qsymia in other territories outside the U.S. and EU;
- whether healthcare providers, payors and public policy makers will recognize the significance of the American Medical Association officially recognizing obesity as a disease, or the new American Association of Clinical Endocrinologists guidelines;
- our ability to successfully commercialize Qsymia including risks and uncertainties related to expansion to retail distribution, the broadening of payor reimbursement, the expansion of Qsymia's primary care presence, and the outcomes of our discussions with pharmaceutical companies and our strategic and franchise-specific pathways for Qsymia;
- our ability to focus our promotional efforts on health-care providers and on patient education that, along with increased access to Qsymia and ongoing improvements in reimbursement, will result in the accelerated adoption of Qsymia;
- our ability to minimize expenses that are not essential to expanding the use of STENDRA and Qsymia or are related to product development;
- our ability to ensure that the entire supply chain for Qsymia efficiently and consistently delivers Qsymia to our customers;
- risks and uncertainties related to the timing, strategy, tactics and success of the launches and commercialization of STENDRA® (avanafil) or SPEDRA™ (avanafil) by our sublicensees in the

U.S., Canada, South America, India, the EU, Australia, New Zealand, Africa, the Middle East, Turkey, and the Commonwealth of Independent States, including Russia;

- our ability to successfully complete on acceptable terms, and on a timely basis, avanafil partnering discussions for territories under our license with Mitsubishi Tanabe Pharma Corporation in which we do not have a commercial collaboration, including Mexico and Central America;
- Sanofi Chimie's ability to undertake manufacturing of the avanafil active pharmaceutical ingredient and Sanofi Winthrop Industrie's ability to undertake manufacturing of the tablets for avanafil;
- the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand;
- our ability to accurately forecast Qsymia demand;
- our ability to commercialize Qsymia efficiently;
- the number of Qsymia prescriptions dispensed through the mail order system and through certified retail pharmacies;
- the impact of promotional programs for Qsymia on our net product revenue and net income (loss) in future periods;
- our history of losses and variable quarterly results;
- substantial competition;
- risks related to our ability to protect our intellectual property and litigation in which we are involved or may become involved;
- uncertainties of government or third-party payor reimbursement;
- our reliance on sole-source suppliers, third parties and our collaborative partners;
- our ability to continue to identify, acquire and develop innovative investigational drug candidates and drugs;
- risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations;
- our ability to demonstrate through clinical testing the quality, safety, and efficacy of our investigational drug candidates;
- the timing of initiation and completion of clinical trials and submissions to foreign authorities;
- the results of post-marketing studies are not favorable;
- compliance with post-marketing regulatory standards, post-marketing obligations or pharmacovigilance rules is not maintained;
- the volatility and liquidity of the financial markets;
- our liquidity and capital resources;
- our expected future revenues, operations and expenditures;
- potential change in our business strategy to enhance long-term stockholder value;
- the impact, if any, of changes to our Board of Directors or management team; and
- other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, or the SEC, including those set forth in this filing as "Item 1A. Risk Factors."

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

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the three and nine months ended September 30, 2016 are not necessarily indicative of the results that may be expected for the full fiscal year or any future period.

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our audited consolidated financial statements and related notes thereto included as

part of our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC on March 9, 2016 and as amended by the Form 10-K/A filed with the SEC on April 22, 2016, and other disclosures (including the disclosures under “Part II. Item 1A. Risk Factors”) included in this Quarterly Report on Form 10-Q. Our unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles and are presented in U.S. dollars.

## OVERVIEW

VIVUS is a biopharmaceutical company with two therapies approved by the FDA: Qsymia® (phentermine and topiramate extended release) for chronic weight management and STENDRA® (avanafil) for erectile dysfunction, or ED. STENDRA is also approved by the European Commission, or EC, under the trade name, SPEDRA, for the treatment of ED in the EU.

### *Qsymia*

Qsymia was approved by the FDA in July 2012, as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index, or BMI, of 30 or greater, or obese patients, or 27 or greater, or overweight patients, in the presence of at least one weight related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol, or dyslipidemia. Qsymia incorporates a proprietary formulation combining low doses of active ingredients from two previously approved drugs, phentermine and topiramate. Although the exact mechanism of action is unknown, Qsymia is believed to suppress appetite and increase satiety, or the feeling of being full, the two main mechanisms that impact eating behavior.

We commercialize Qsymia in the U.S. primarily through a sales force of approximately 50 sales territories, supported by an internal commercial team, who promote Qsymia to physicians. Our efforts to expand the appropriate use of Qsymia include scientific publications, participation and presentations at medical conferences, and development and implementation of patient-directed support programs. Most recently, we have rolled out unique marketing programs to encourage targeted prescribers to gain more experience with Qsymia with their obese patient population. We continue to invest in digital media in order to amplify our messaging to information-seeking consumers. The digital messaging encourages those consumers most likely to take action to speak with their physicians about obesity treatment options. We believe our enhanced web-based strategies deliver clear and compelling communications to potential patients. In 2016, we are optimizing the use of our field sales force and our digital campaign, continuing to work with third-party institutions and advancing our efforts to fulfill, in a cost-effective manner, the remaining Qsymia regulatory post-marketing requirements. In June 2016, we announced an upgraded patient savings plan to further drive Qsymia brand preference at the point of prescription and encourage long-term use of the brand.

We defined and identified the healthcare provider, or HCP, audience of anti-obesity prescribers as numbering approximately 8,000 to 10,000. Of these, we believe the most highly productive writers are adequately covered by the VIVUS sales force. We are focused on maintaining a commercial presence with important Qsymia prescribers, and we have capacity to cover new potential prescribers, who are those physicians that begin prescribing branded obesity products. We are constantly monitoring prescribing activity in the market, and we have seen new prescriptions being written by HCPs on whom we have not previously dedicated field sales resources. The current alignment addresses this new prescriber group, and we believe we have been successful in initiating and maintaining dialog with these HCPs.

In October 2012, we received a negative opinion from the European Medicines Agency, or EMA, Committee for Medicinal Products for Human Use, or CHMP, recommending refusal of the marketing authorization for the medicinal product Qsiva™, the intended trade name for Qsymia in the EU, due to concerns over the potential cardiovascular and central nervous system effects associated with long-term use, potential for interfering with the development of a fetus and use by patients for whom Qsiva would not have been indicated. We requested that this opinion be re-examined by the CHMP. After re-examination of the CHMP opinion, in February 2013, the CHMP adopted a final opinion that reaffirmed the Committee's earlier negative opinion to refuse the marketing authorization for Qsiva in the EU. In May 2013, the EC issued a decision refusing the grant of marketing authorization for Qsiva in the EU.

In September 2013, we submitted a request to the EMA for Scientific Advice, a procedure similar to the U.S. Special Protocol Assessment process, regarding use of a pre-specified interim analysis from the CVOT, known as AQCLAIM, to assess the long-term treatment effect of Qsymia on the incidence of major adverse cardiovascular events in overweight and obese subjects with confirmed cardiovascular disease. Our request was to allow this interim analysis to support the resubmission of an application for a marketing authorization for Qsiva for treatment of obesity in accordance with the EU centralized marketing authorization procedure. We received feedback in 2014 from the EMA and the various competent authorities of the EU Member States associated with review of the AQCLAIM CVOT protocol, and we received feedback from the FDA in late 2014 regarding the amended protocol. As a part of addressing the FDA comments from a May 2015 meeting to discuss alternatives to completion of a CVOT, we are now working with cardiovascular and epidemiology experts in exploring alternate solutions to demonstrate the long-term cardiovascular safety of Qsymia. After reviewing a summary of Phase 3 data relevant to cardiovascular, or CV, risk and post-marketing safety data, the cardiology experts noted that they believe there was an absence of an overt CV risk signal and indicated that they did not believe a randomized placebo controlled CVOT would provide additional information regarding the CV risk of Qsymia. The epidemiology experts maintained that a well-conducted retrospective observational study could provide data to further inform on potential CV risk. We are working with the expert group to develop a protocol for the retrospective observational study. Although we and the consulted experts believe there is no overt signal for CV risk to justify the AQCLAIM CVOT, VIVUS is committed to working with the FDA to reach a resolution. As for the EU, even if the FDA were to accept a retrospective observational study in lieu of a CVOT, there would be no assurance that the EMA would accept the same.

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

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

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

#### **STENDRA**

STENDRA is an oral phosphodiesterase type 5, or PDE5, inhibitor that we have licensed from Mitsubishi Tanabe Pharma Corporation, or MTPC. STENDRA was approved by the FDA in April 2012 for the treatment of ED in the United States. In June 2013, the EC adopted a decision granting marketing authorization for SPEDRA, the approved trade name for avanafil in the EU, for the treatment of ED in the EU. In July 2013, we entered into an agreement with the Menarini Group, through its subsidiary Berlin Chemie AG, or Menarini, under which Menarini received an exclusive license to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, including the EU, as well as Australia and New Zealand. Menarini commenced its commercialization launch of the product in the EU in early 2014. As of the date of this filing, SPEDRA is commercially available in 25 countries within the territory granted to Menarini pursuant to the license and commercialization agreement.

In October 2013, we entered into an agreement with Auxilium Pharmaceuticals, Inc., or Auxilium, under which Auxilium received an exclusive license to commercialize and promote STENDRA in the United States and Canada. On the same date, we also entered into a supply agreement with Auxilium, whereby we would supply Auxilium with STENDRA for commercialization. Auxilium began commercializing STENDRA in the U.S. market in December 2013. In January 2015, Auxilium was acquired by Endo International, plc, or Endo. Auxilium terminated the supply agreement effective June 30, 2016 and the license agreement effective September 30, 2016.

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

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

In December 2013, we entered into an agreement with Sanofi under which Sanofi received an exclusive license to commercialize and promote avanafil for therapeutic use in humans in Africa, the Middle East, Turkey, and the Commonwealth of Independent States, or CIS, including Russia. Sanofi will be responsible for obtaining regulatory approval in its territories. Sanofi intends to market avanafil under the trade name SPEDRA or STENDRA. Effective as of December 11, 2013, we also entered into a supply agreement, or the Sanofi Supply Agreement, with Sanofi Winthrop Industrie, a wholly owned subsidiary of Sanofi.

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

On June 20, 2016, we received a Paragraph IV certification notice from Hetero USA, Inc. indicating that it filed an ANDA with the FDA, requesting approval to market a generic version of STENDRA and contending that patents listed for STENDRA in the Orange Book at the time of the notice (U.S. Patents 6,656,935, and 7,501,409), collectively "patents-in-suit", are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of a generic form of STENDRA as described in their ANDA. On July 27, 2016, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Hetero USA, Inc. and Hetero Labs Limited, collectively referred to as Hetero. The lawsuit was filed on the basis that Hetero's submission of their ANDA to obtain approval to manufacture, use, sell, or offer for sale generic versions of STENDRA prior to the expiration of the patents-in-suit constitutes infringement of one or more claims of those patents.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Hetero, FDA approval of Hetero's ANDA will be stayed until the earlier of (i) up to 30 months from the expiration of STENDRA's New Chemical Entity, or NCE, exclusivity period (i.e. October 27, 2019) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. The Company intends to vigorously enforce its intellectual property rights relating to Qsymia and STENDRA, but the Company cannot predict the outcome of these matters.

#### ***Business Strategy Review***

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

#### ***NOL Rights Plan***

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

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

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

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

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

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

Our significant accounting policies are more fully described in Note 1 to our audited consolidated financial statements and in "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates" contained in our Annual Report on Form 10-K, or our Annual Report, as filed with the SEC on March 9, 2016. There have been no significant changes in our critical accounting policies during the three and nine months ended September 30, 2016, as compared to those disclosed in our Annual Report.

## RESULTS OF OPERATIONS

### Revenues

(in thousands, except for percentages)	Three Months Ended September 30,		% Change Increase/ (Decrease) 2016 vs 2015	Nine Months Ended September 30,		% Change Increase/ (Decrease) 2016 vs 2015
	2016	2015		2016	2015	
Revenue:						
Net product revenue	\$ 12,294	\$ 14,011	(12)%	\$ 37,455	\$ 40,652	(8)%
License and milestone revenue	—	—	—	—	11,574	(100)%
Supply revenue	—	10,056	(100)%	1,526	26,651	(94)%
Royalty revenue	1,059	869	22 %	3,472	1,210	187 %
Total revenue	\$ 13,353	\$ 24,936	(46)%	\$ 42,453	\$ 80,087	(47)%

### Net product revenue

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



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

We recognize Qsymia net product revenue when units are dispensed to patients through prescriptions as we have a limited history of selling Qsymia and do not have sufficient information to reliably estimate expected returns of Qsymia at the time of shipment. As of September 30, 2016, we had deferred revenue related to gross sales of Qsymia of \$17.6 million, which represents Qsymia product shipped to wholesalers and certified retail pharmacies, but not yet dispensed to patients through prescriptions, net of prompt-payment discounts.

#### *License and milestone revenue*

For the nine months ended September 30, 2015, under the terms of the license and commercialization agreement with Menarini, we recognized \$11.6 million in license and milestone revenue related to the time-to-onset claim, which was approved by the EC in January 2015. There was no license and milestone revenue for the three and nine months ended September 30, 2016 or for the three months ended September 30, 2015. In September 2016, we received \$70 million from Metuchen under the license agreement. This amount was recorded as deferred revenue on the consolidated balance sheet at September 30, 2016 and will be recognized as license revenue as we complete our obligations under the license agreement.

#### *Supply revenue*

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

#### *Royalty revenue*

For the three and nine months ended September 30, 2016, we recognized \$1.1 million and \$3.5 million, respectively, in net royalty revenue on net sales reported by our commercialization partners, compared to \$0.9 million and \$1.2 million, respectively, in royalty revenue in the three and nine months ended September 30, 2015. We record royalty revenue related to STENDRA based on reports provided by our partners. One of our partners, Auxilium, was acquired by Endo in January 2015. In April 2015, we were informed by Endo that Endo had revised its accounting estimate for its return reserve for STENDRA sold in 2014. Under the terms of the license and commercialization agreement, adjustments to the return reserve can be deducted from the reported net revenue. As a result, in the first quarter of 2015, we recorded an adjustment of \$1.2 million to reduce our royalty revenue. On September 30, 2016, Auxilium returned the U.S. and Canadian commercial rights for STENDRA to us. Also, on September 30, 2016, we entered into a license agreement and a supply agreement with Metuchen Pharmaceuticals LLC, providing them with, among other rights, commercial rights to sell STENDRA/SPEDRA in the U.S., Canada, South America, and India. The license agreement with Metuchen does not include future royalties on the sales of STENDRA/SPEDRA in their territories.

#### *Cost of goods sold*

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

Cost of goods sold for Qsymia dispensed to patients includes the inventory costs of APIs, third-party contract manufacturing and packaging and distribution costs, royalties, cargo insurance, freight, shipping, handling

and storage costs, and overhead costs of the employees involved with production. Cost of goods sold for STENDRA or SPEDRA shipped to our commercialization partners includes the inventory costs of purchased tablets, freight, shipping and handling costs. The cost of goods sold associated with deferred revenue on Qsymia and STENDRA or SPEDRA product shipments is recorded as deferred costs, which are included in inventories in the condensed consolidated balance sheets, until such time as the deferred revenue is recognized.

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

*Selling, general and administrative expense*

	Three Months Ended September 30,		% Change Increase/(Decrease) 2016 vs 2015	Nine Months Ended September 30,		% Change Increase/(Decrease) 2016 vs 2015
	2016	2015		2016	2015	
	(In thousands, except percentages)			(In thousands, except percentages)		
Selling and marketing	\$ 4,377	\$ 11,045	(60)%	\$ 17,976	\$ 44,349	(59)%
General and administrative	6,063	6,084	(0)%	21,278	21,381	(0)%
Total selling, general and administrative expenses	\$ 10,440	\$ 17,129	(39)%	\$ 39,254	\$ 65,730	(40)%

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

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

*Research and development expense*

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

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

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

We anticipate additional research and development expenses for post-approval studies related to Qsymia. Our research and development expenses may fluctuate from period to period due to the timing and scope of our development activities and the results of clinical and pre-clinical studies.

*Inventory impairment and other non-recurring charges*

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

*Interest expense and other expense, net*

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

*Provision for (benefit from) income taxes*

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

We periodically evaluate the realizability of our net deferred tax assets based on all available evidence, both positive and negative. The realization of net deferred tax assets is dependent on our ability to generate sufficient future taxable income during periods prior to the expiration of tax attributes to fully utilize these assets. We weighed both positive and negative evidence and determined that there is a continued need for a full valuation allowance on our deferred tax assets in the U.S. as of September 30, 2016.

**LIQUIDITY AND CAPITAL RESOURCES**

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

We invest our excess cash balances in money market, U.S. government securities and highly-rated corporate debt securities, in accordance with our investment policy. At September 30, 2016, all of our cash equivalents and available-for-sale securities were invested in U.S. government securities, highly-rated corporate debt securities or money market funds. Our investment policy has the primary investment objective of preservation of principal; however, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy. If those securities are downgraded or impaired, we would experience realized or unrealized losses in the value of our portfolio, which would have an adverse effect on our results of operations, liquidity and financial condition. From time to time, the Company may also invest its cash to retire or purchase its outstanding debt in open market purchases, privately negotiated transactions or otherwise.

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

**Accounts Receivable.** We extend credit to our customers for product sales, resulting in accounts receivable. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written off against the allowance for doubtful accounts. Allowances for doubtful accounts are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. We offer cash discounts to our customers, generally 2% of the sales price as an incentive for prompt payment.

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

#### Summary Cash Flows

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

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

For the nine months ended September 30, 2015, the use of cash resulted from our net loss of \$80.9 million, which was partially offset by non-cash charges of \$29.5 million for inventory impairment, \$12.8 million in debt issuance cost and discount amortization, and \$3.0 million in non-cash share-based compensation expense. Additional cash used in operating activities resulted from changes in assets and liabilities during the quarter, including an increase of \$4.1 million in inventory spending, due to increased inventory production in supporting customer demands for STENDRA, and decreases of \$3.6 million in prepaid and other assets, due to the timing and nature of payments, and increases in accounts payable of \$2.9 million, due to the timing of activities and vendor payments, and decreases of \$2.6 million in accrued and other liabilities, due to timing.

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

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

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

candidates may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of an investigational drug candidate. It is also important to note that if an investigational drug candidate is identified, the further development of that candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, lack of efficacy or safety or change in market demand.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs at least for the next twelve months. However, we anticipate that we may require additional funding to conduct post-approval clinical studies for Qsymia, conduct non-clinical and clinical research and development work to support regulatory submissions and applications for our future investigational drug candidates, finance the costs involved in filing and prosecuting patent applications and enforcing or defending our patent claims, to fund operating expenses, establish additional or new manufacturing and marketing capabilities, and manufacture quantities of our drugs and investigational drug candidates and to make payments under our existing license and supply agreements for STENDRA.

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

#### ***Off-Balance Sheet Arrangements***

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

#### ***Commitments and Contingencies***

We indemnify our officers and directors for certain events or occurrences pursuant to indemnification agreements, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, stockholder suits and tax matters and as such, we are unable to estimate the potential exposure related to these indemnification agreements. We have not recognized any liabilities relating to these agreements as of September 30, 2016.

#### ***Contractual Obligations***

During the nine months ended September 30, 2016, there were no material changes to our contractual obligations described under Management's Discussion and Analysis of Financial Condition and Results of Operations contained in Part II, Item 7 of our Annual Report on Form 10-K for our fiscal year ended December 31, 2015, filed with the SEC on March 9, 2016, other than the fulfillment of existing obligations in the ordinary course of business.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

#### **Market and Interest Rate Risk**

In the normal course of business, our financial position is subject to a variety of risks, including market risk associated with interest rate movements and foreign currency exchange risk. Our cash, cash equivalents and available-for-sale securities as of September 30, 2016, consisted primarily of money market funds, U.S. Treasury securities and corporate debt securities. Our cash is invested in accordance with an investment policy approved by our Board of Directors that specifies the categories (money market funds, U.S. Treasury securities and debt securities of U.S. government agencies, corporate bonds, asset-backed securities, and other securities), allocations,

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

Our market risk associated with interest rate movements is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable debt securities. The primary objective of our investment activities is to preserve principal. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment may decline. A hypothetical 100 basis point increase in interest rates would reduce the fair value of our available-for-sale securities at September 30, 2016, by approximately \$1.5 million. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

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

#### **ITEM 4. CONTROLS AND PROCEDURES**

(a.) Evaluation of disclosure controls and procedures. We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the timelines specified in the rules and forms of the SEC and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), our management carried out an evaluation, under the supervision and with the participation of our principal executive officer and our principal financial officer, of the effectiveness of the design and operation of VIVUS's disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective.

(b.) Changes in internal controls. There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II: OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS***Shareholder Lawsuit*

On March 27, 2014, Mary Jane and Thomas Jasin, who purport to be purchasers of VIVUS common stock, filed an Amended Complaint in Santa Clara County Superior Court alleging securities fraud against the Company and three of its former officers and directors. In that complaint, captioned *Jasin v. VIVUS, Inc.*, Case No. 114-cv-261427, plaintiffs asserted claims under California's securities and consumer protection securities statutes. Plaintiffs alleged generally that defendants misrepresented the prospects for the Company's success, including with respect to the launch of Qsymia, while purportedly selling VIVUS stock for personal profit. Plaintiffs alleged losses of "at least" \$2.8 million, and sought damages and other relief. On June 5, 2014, the Company and the other defendants filed a demurrer to the Amended Complaint seeking its dismissal. With the demurrer pending, on July 18, 2014, the same plaintiffs filed a complaint in the United States District Court for the Northern District of California, captioned *Jasin v. VIVUS, Inc.*, Case No. 5:14-cv-03263. The Jasins' federal complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, based on facts substantially similar to those alleged in their state court action. On September 15, 2014, pursuant to an agreement between the parties, plaintiffs moved to voluntarily dismiss, with prejudice, the state court action. In the federal action, defendants filed a motion to dismiss on November 12, 2014. On December 3, 2014, plaintiffs filed a First Amended Complaint in the federal action. On January 21, 2015, defendants filed a motion to dismiss the First Amended Complaint. The court ruled on that motion on June 18, 2015, dismissing the seven California claims with prejudice and dismissing the two federal claims with leave to amend. Plaintiffs filed a Second Amended Complaint on August 17, 2015. Defendants moved to dismiss that complaint on October 2, 2015. On September 10, 2015, plaintiffs moved for entry of judgment on their state claims. Briefing on both defendants' motion to dismiss and plaintiffs' motion for entry of judgment was completed on December 15, 2015. On April 19, 2016, the court issued a ruling granting defendants' motion to dismiss without leave to amend and denying as moot plaintiffs' motion for entry of judgment. On May 18, 2016, the plaintiffs filed a notice of appeal, and on September 23, 2016, plaintiffs filed their opening appellate brief. Defendants' response is due on November 23, 2016. The Company maintains directors' and officers' liability insurance that it believes affords coverage for much of the anticipated cost of the remaining *Jasin* action, subject to the use of our financial resources to pay for our self-insured retention and the policies' terms and conditions.

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

*Qsymia ANDA Litigation*

On May 7, 2014, the Company received a Paragraph IV certification notice from Actavis Laboratories FL indicating that it filed an abbreviated new drug application, or ANDA, with the U.S. Food and Drug Administration, or FDA, requesting approval to market a generic version of Qsymia and contending that the patents listed for Qsymia in the FDA Orange Book at the time the notice was received (U.S. Patents 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, and 8,580,299 (collectively "patents-in-suit")) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of Qsymia as described in their ANDA. On June 12, 2014, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as Actavis. The lawsuit (Case No. 14-3786 (SRC)(CLW)) was filed on the basis that Actavis' submission of their ANDA to obtain approval to manufacture, use, sell or offer for sale generic versions of Qsymia prior to the expiration of the patents-in-suit constitutes infringement of one or more claims of those patents.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Actavis, FDA approval of Actavis' ANDA will be stayed until the earlier of (i) up to 30 months from the Company's May 7, 2014 receipt of Actavis' Paragraph IV certification notice (i.e. November 7, 2016) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

On January 21, 2015, the Company received a second Paragraph IV certification notice from Actavis contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 8,895,057 and 8,895,058)

are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, or offer for sale of a generic form of Qsymia. On March 4, 2015, the Company filed a second lawsuit in the U.S. District Court for the District of New Jersey against Actavis (Case No. 15-1636 (SRC)(CLW)) in response to the second Paragraph IV certification notice on the basis that Actavis' submission of their ANDA constitutes infringement of one or more claims of the patents-in-suit.

On July 7, 2015, the Company received a third Paragraph IV certification notice from Actavis contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 9,011,905 and 9,011,906) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, or offer for sale of a generic form of Qsymia. On August 17, 2015, the Company filed a third lawsuit in the U.S. District Court for the District of New Jersey against Actavis (Case No. 15-6256 (SRC)(CLW)) in response to the third Paragraph IV certification notice on the basis that Actavis' submission of their ANDA constitutes infringement of one or more claims of the patents-in-suit. The three lawsuits against Actavis have been consolidated into a single suit (Case No. 14-3786 (SRC)(CLW)). On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit. The Court adopted the Company's proposed constructions for all but one of the disputed claim terms and adopted a compromise construction that was acceptable to the Company for the final claim term. Expert discovery is ongoing and no trial date has been scheduled.

On March 5, 2015, the Company received a Paragraph IV certification notice from Teva Pharmaceuticals USA, Inc. indicating that it filed an ANDA with the FDA, requesting approval to market a generic version of Qsymia and contending that eight patents listed for Qsymia in the Orange Book at the time of the notice (U.S. Patents 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, 8,580,299, 8,895,057 and 8,895,058) (collectively "patents-in-suit") are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of a generic form of Qsymia as described in their ANDA. On April 15, 2015, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Teva Pharmaceutical USA, Inc. and Teva Pharmaceutical Industries, Ltd., collectively referred to as Teva. The lawsuit (Case No. 15-2693 (SRC)(CLW)) was filed on the basis that Teva's submission of their ANDA to obtain approval to manufacture, use, sell, or offer for sale generic versions of Qsymia prior to the expiration of the patents-in-suit constitutes infringement of one or more claims of those patents.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Teva, FDA approval of Teva's ANDA will be stayed until the earlier of (i) up to 30 months from our March 5, 2015 receipt of Teva's Paragraph IV certification notice (i.e. September 5, 2017) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

On August 5, 2015, the Company received a second Paragraph IV certification notice from Teva contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 9,011,905 and 9,011,906) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, or offer for sale of a generic form of Qsymia. On September 18, 2015, the Company filed a second lawsuit in the U.S. District Court for the District of New Jersey against Teva (Case No. 15-6957(SRC)(CLW)) in response to the second Paragraph IV certification notice on the basis that Teva's submission of their ANDA constitutes infringement of one or more claims of the patents-in-suit. The two lawsuits against Teva have been consolidated into a single suit (Case No. 15-2693 (SRC)(CLW)).

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

#### *STENDRA ANDA Litigation*

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



and 7,501,409) (collectively “patents-in-suit”) are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of a generic form of STENDRA as described in their ANDA. On July 27, 2016, the Company filed a lawsuit in the U.S. District Court for the District of New Jersey against Hetero USA, Inc. and Hetero Labs Limited, collectively referred to as Hetero. The lawsuit (Case No. 16-4560 (KSH)(CLW)) was filed on the basis that Hetero’s submission of their ANDA to obtain approval to manufacture, use, sell, or offer for sale generic versions of STENDRA prior to the expiration of the patents-in-suit constitutes infringement of one or more claims of those patents.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Hetero, FDA approval of Hetero’s ANDA will be stayed until the earlier of (i) up to 30 months from the expiration of STENDRA’s New Chemical Entity, or NCE, exclusivity period (i.e. October 27, 2019) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

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

The Company is not aware of any other asserted or unasserted claims against it where it believes that an unfavorable resolution would have an adverse material impact on the operations or financial position of the Company.

#### ITEM 1A. RISK FACTORS

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

##### Risks Relating to our Business

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

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

- expand the use of Qsymia through targeted patient and physician education;
- obtain marketing authorization by the EC for Qsiva™ in the EU through the centralized marketing authorization procedure;
- manage our alliances with MTPC, Menarini, Metuchen and Sanofi, to help ensure the commercial success of avanafil;
- manage costs;
- continue to certify and add to the Qsymia retail pharmacy network nationwide and sell Qsymia through this network;
- improve third-party payor coverage, lower out-of-pocket costs to patients with discount programs, and obtain coverage for obesity under Medicare Part D;
- create market demand for Qsymia through patient and physician education, marketing and sales activities;
- achieve market acceptance and generate product sales;
- comply with the post-marketing requirements established by the FDA, including Qsymia’s Risk Evaluation and Mitigation Strategy, or REMS, any future changes to the REMS, and any other requirements established by the FDA in the future;

- efficiently conduct the post-marketing studies required by the FDA;
- comply with other healthcare regulatory requirements;
- maintain and defend our patents, if challenged;
- ensure that the active pharmaceutical ingredients, or APIs, for Qsymia and STENDRA and the finished products are manufactured in sufficient quantities and in compliance with requirements of the FDA and similar foreign regulatory agencies and with an acceptable quality and pricing level in order to meet commercial demand;
- ensure that the entire supply chain for Qsymia and STENDRA, from APIs to finished products, efficiently and consistently delivers Qsymia and STENDRA to customers; and
- manage our internal sales force and internal commercial team in their commercialization efforts for Qsymia.

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

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

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

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

Since 2013, there have been significant changes in our management. For example, several members of management have departed the Company, including our President in September 2013, our Chief Financial Officer in December 2013, our Vice President, U.S. Operations and General Manager in May 2014, our Chief Financial Officer and Chief Accounting Officer in September 2015 and our Vice President, Clinical Development in December 2015. In addition, we commenced corporate restructuring plans in November 2013 and July 2015 that resulted in significant reductions in our workforce. These changes, and the potential for additional changes to our management, organizational structure and strategic business plan, may cause speculation and uncertainty regarding our future business strategy and direction. These changes may cause or result in:

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

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

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

In July 2013, we entered into a license and commercialization agreement with Menarini under which Menarini received an exclusive license to commercialize and promote SPEDRA for the treatment of ED in over 40 countries, including the EU, plus Australia and New Zealand. In October 2013, we entered into a license and commercialization agreement with Auxilium under which Auxilium received an exclusive license to commercialize and promote STENDRA for the treatment of erectile dysfunction, or ED, in the United States and Canada. In January 2015, Auxilium was acquired by Endo International, plc. Auxilium terminated the supply agreement effective June 30, 2016 and the license agreement effective September 30, 2016. On September 30, 2016, we entered into a license agreement and a supply agreement with Metuchen Pharmaceuticals LLC, or Metuchen, whereby Metuchen received an exclusive license to develop, commercialize and promote STENDRA in the U.S., Canada, South America, and India, effective October 1, 2016. In December 2013, we entered into a license and commercialization agreement with Sanofi under which Sanofi received an exclusive license to commercialize and promote avanafil for therapeutic use in humans in Africa, the Middle East, Turkey, and CIS, including Russia. Sanofi will be responsible for obtaining regulatory approval in its territories. Sanofi intends to market avanafil under the trade name SPEDRA or STENDRA.

We are relying on our collaboration partners to successfully commercialize STENDRA or SPEDRA in their respective territories, inclusive of obtaining any necessary approvals. There can be no assurances that these collaboration partners will be successful in doing so. In general, we cannot control the amount and timing of resources that our collaboration partners devote to the commercialization of our drugs. If any of our collaboration partners fails to successfully commercialize our drug products, our business may be negatively affected. For example, if our collaboration partners do not successfully commercialize STENDRA or SPEDRA, we may receive limited or no revenues under our agreements with them.

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

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

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

- We may not be able to control the commercialization of our drug products in the relevant territories, including amount, timing and quality of resources that our collaborators may devote to our drug products;
- our collaborators may experience financial, regulatory or operational difficulties, which may impair their ability to commercialize our drug products;
- our collaborators may be required under the laws of the relevant territory to disclose our confidential information or may fail to protect our confidential information;
- as a requirement of the collaborative arrangement, we may be required to relinquish important rights with respect to our drug products, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to satisfactorily complete its commercialization or other obligations under any collaborative arrangement;
- legal disputes or disagreements may occur with one or more of our collaborators;

- a collaborator could independently move forward with a competing investigational drug candidate developed either independently or in collaboration with others, including with one of our competitors; and
- a collaborator could terminate the collaborative arrangement, which could negatively impact the continued commercialization of our drug products. For example, in December 2015, Auxilium notified us of its intention to return the U.S. and Canadian commercial rights for STENDRA, and such commercial rights returned to us on September 30, 2016.

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

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

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

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

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

In order to market products in many foreign jurisdictions, we must obtain separate regulatory approvals. Approval by the FDA in the U.S. does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. For example, while our drug STENDRA has been approved in both the U.S. and the EU, our drug Qsymia has been approved in the U.S. but Qsiva (the intended trade name for Qsymia in the EU) was denied a marketing authorization by the EC due to concerns over the potential cardiovascular and central nervous system effects associated with long-term use, teratogenic potential and use by patients for whom Qsiva would not have been indicated. We intend to seek approval, either directly or through our collaboration partners, for Qsymia and STENDRA in other territories outside the U.S. and the EU. However, we have had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional testing. Foreign regulatory approvals may not be obtained, by us or our collaboration partners responsible for obtaining approval, on a timely basis, or at all, for any of our products. The failure to receive regulatory approvals in a foreign country would prevent us from marketing and commercializing our products in that country, which could have a material adverse effect on our business, financial condition and results of operations.

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

We, through Sanofi, Menarini and potential future collaborators in certain territories, intend to manufacture, market, and distribute STENDRA or SPEDRA outside the U.S. We expect that we will be subject to additional risks related to conducting business internationally, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing U.S. and foreign drug import and export rules;
- reduced protection for intellectual property rights in some foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incidental to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- production shortages resulting from events affecting raw material supply or manufacturing capabilities abroad;
- potential liability resulting from development work conducted by these distributors; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

***We have significant inventories on hand and, for the years ended December 31, 2015, 2014 and 2013, we recorded inventory impairment and commitment fees totaling \$29.5 million, \$2.2 million and \$10.2 million, respectively, primarily to write off excess inventory related to Qsymia.***

We maintain significant inventories and evaluate these inventories on a periodic basis for potential excess and obsolescence. During the years ended December 31, 2015, 2014 and 2013, we recognized total charges of \$29.5 million, \$2.2 million and \$10.2 million, respectively, primarily for Qsymia inventories on hand in excess of projected demand. The inventory impairment charges were based on our analysis of current Qsymia inventory on hand and remaining shelf life, in relation to our projected demand for the product. The current FDA-approved commercial product shelf life for Qsymia is 36 months. STENDRA is approved in the U.S. and SPEDRA is approved in the EU for 48 months of commercial product shelf life.

Our write-down for excess and obsolete inventory is subjective and requires forecasting of the future market demand for our products. Forecasting demand for Qsymia, a drug in the obesity market in which there had been no new FDA-approved medications in over a decade prior to 2012, and for which reimbursement from third-party payors had previously been non-existent, has been difficult. Forecasting demand for STENDRA or SPEDRA, a drug that is new to a crowded and competitive market and has limited sales history, is also difficult. We will continue to evaluate our inventories on a periodic basis. The value of our inventories could be impacted if actual sales differ significantly from our estimates of future demand or if any significant unanticipated changes in future product demand or market conditions occur. Any of these events, or a combination thereof, could result in additional inventory write-downs in future periods, which could be material.

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

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

Pursuant to the REMS program applicable to Qsymia, our distribution network is through a small number of certified home delivery pharmacies and wholesalers and through a broader network of certified retail pharmacies. We have contracted through a third-party vendor to certify the retail pharmacies and collect required data to support the Qsymia REMS program. In addition to providing services to support the distribution and use of Qsymia, each of the certified pharmacies has agreed to comply with the REMS program requirements and, through our third-party data collection vendor, will provide us with the necessary patient and prescribing healthcare provider, or HCP, data. In addition, we have contracted with third-party data warehouses to store this patient and HCP data and report it to us. We rely on this third-party data in order to recognize revenue and comply with the REMS requirements for Qsymia, such as data analysis. This distribution and data collection network requires significant coordination with our sales and marketing, finance, regulatory and medical affairs teams, in light of the REMS requirements applicable to Qsymia.

We rely on the certified pharmacies to implement a number of safety procedures and report certain information to our third-party REMS data collection vendor. Failure to maintain our contracts with Cardinal Health, our third-party REMS data collection vendor, or with the third-party data warehouses, or the inability or failure of any of them to adequately perform under our contracts with them, could negatively impact the distribution of Qsymia, or adversely affect our ability to comply with the REMS applicable to Qsymia. Failure to comply with a requirement of an approved REMS can result in, among other things, civil penalties, imposition of additional burdensome REMS requirements, suspension or revocation of regulatory approval and criminal prosecution. Failure to coordinate financial systems could also negatively impact our ability to accurately report and forecast product revenue. If we are unable to effectively manage the distribution and data collection process, sales of Qsymia could be severely compromised and our business, financial condition and results of operations would be harmed.

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

We currently do not have supply agreements for topiramate or phentermine, which are the APIs used in Qsymia. We cannot guarantee that we will be successful in entering into supply agreements on reasonable terms or at all or that we will be able to obtain or maintain the necessary regulatory approvals for potential future suppliers in a timely manner or at all.

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

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

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

In July 2013, we entered into a Commercial Supply Agreement with Sanofi Chimie to manufacture and supply the API for avanafil on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. In November 2013, we entered into a Manufacturing and Supply Agreement with Sanofi Winthrop Industrie to manufacture and supply the avanafil tablets on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. We have obtained approval from the FDA and the European Medicines Agency, or EMA, of Sanofi Chimie as a qualified supplier of avanafil API and of Sanofi Winthrop Industrie as a qualified supplier of the avanafil tablets. We have entered into supply agreements with Menarini and Metuchen under which we are obligated to supply them with avanafil tablets. If we are unable to maintain a reliable supply of avanafil API or tablets from Sanofi Chimie and/or Sanofi Winthrop Industrie, we may be unable to satisfy our obligations under these supply agreements in a timely manner or at all, and we may, as a result, be in breach of one or both of these agreements.

***We have in-licensed all or a portion of the rights to Qsymia and STENDRA from third parties. If we default on any of our material obligations under those licenses, we could lose rights to these drugs.***

We have in-licensed and otherwise contracted for rights to Qsymia and STENDRA, and we may enter into similar licenses in the future. Under the relevant agreements, we are subject to commercialization, development, supply, sublicensing, royalty, insurance and other obligations. If we fail to comply with any of these requirements, or otherwise breach these license agreements, the licensor may have the right to terminate the license in whole or to terminate the exclusive nature of the license. Loss of any of these licenses or the exclusive rights provided therein could harm our financial condition and operating results.

In particular, we license the rights to avanafil from MTPC, and we have certain obligations to MTPC in connection with that license. We license the rights to Qsymia from Dr. Najarian. We believe we are in compliance with the material terms of our license agreements with MTPC and Dr. Najarian. However, there can be no assurance that this compliance will continue or that the licensors will not have a differing interpretation of the material terms of the agreements. If the license agreements were terminated early or if the terms of the licenses were contested for any reason, it would have a material adverse impact on our ability to commercialize products subject to these agreements, our ability to raise funds to finance our operations, our stock price and our overall financial condition. The monetary and disruption costs of any disputes involving our agreements could be significant despite rulings in our favor.

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

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

- our ability to expand the use of Qsymia through targeted patient and physician education;
- our ability to find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience;
- our ability to obtain marketing authorization by the EC for Qsiva in the EU through the centralized procedure;
- our ability to successfully expand the certified retail pharmacy distribution channel in the United States for Qsymia;
- contraindications for Qsymia and STENDRA;
- competition and timing of market introduction of competitive drugs;
- quality, safety and efficacy in the approved setting;

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

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

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

As part of the approval of Qsymia, we are required to conduct several post-marketing studies and trials, including a clinical trial to assess the long-term treatment effect of Qsymia on the incidence of major adverse cardiovascular events in overweight and obese subjects with confirmed cardiovascular disease, or AQCLAIM, studies to assess the safety and efficacy of Qsymia for weight management in obese pediatric and adolescent subjects, studies to assess drug utilization and pregnancy exposure and a study to assess renal function. We estimate the AQCLAIM trial as currently designed will cost between \$180 million and \$220 million and the trial could take as long as five to six years to complete. In September 2013, we submitted a request to the EMA for Scientific Advice, a procedure similar to the U.S. Special Protocol Assessment process, regarding use of a pre-specified interim analysis from the CVOT, known as AQCLAIM, to assess the long-term treatment effect of Qsymia on the incidence of major adverse cardiovascular events in overweight and obese subjects with confirmed cardiovascular disease. Our request was to allow this interim analysis to support the resubmission of an application for a marketing authorization for Qsiva for treatment of obesity in accordance with the EU centralized marketing authorization procedure. We received feedback in 2014 from the EMA and the various competent authorities of the EU Member States associated with review of the AQCLAIM CVOT protocol, and we received feedback from the FDA in late 2014 regarding the amended protocol. As a part of addressing the FDA comments from a May 2015 meeting to discuss alternatives to completion of a CVOT, we are now working with cardiovascular and epidemiology experts in exploring alternate solutions to demonstrate the long-term cardiovascular safety of Qsymia. After reviewing a summary of Phase 3 data relevant to CV risk and post-marketing safety data, the cardiology experts noted that they believe there was an absence of an overt CV risk signal and indicated that they did not see a justification for a



randomized placebo controlled CVOT trial. The epidemiology experts maintained that a well-conducted retrospective observational study could provide data to further inform on potential CV risk. We are working with the expert group to develop a protocol for the retrospective observational study. Although we and the consulted experts believe there is no overt signal for CV risk to justify the AQLAIM CVOT, VIVUS is committed to working with the FDA to reach a resolution. As for the EU, even if the FDA were to accept a retrospective observational study in lieu of a CVOT, there would be no assurance that the EMA would accept the same. There can be no assurance that we will be successful in developing a further revised protocol or that any such revised protocol will reduce the costs of the study or obtain FDA or EMA agreement that it will fulfill the requirement of demonstrating the long-term cardiovascular safety of Qsymia. Furthermore, there can be no assurance that the FDA or EMA will not request or require us to provide additional information or undertake additional preclinical studies and clinical trials or retrospective observational studies.

In addition to these studies, the FDA may also require us to perform other lengthy post-approval studies or trials, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results, financial condition and stock price. Failure to comply with the applicable regulatory requirements, including the completion of post-marketing studies and trials, can result in, among other things, civil monetary penalties, suspensions of regulatory approvals, operating restrictions and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition, results of operations and stock price. We have not complied with all the regulatory timelines for the required post-marketing trials and studies, and this may be considered a violation of the statute if the FDA does not find good cause.

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

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

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

Although Qsymia is a once-a-day, proprietary extended-release formulation, both of the approved APIs (phentermine and topiramate) that are combined to produce Qsymia are commercially available as drug products at prices that together are lower than the price at which we sell Qsymia. In addition, the distribution and sale of these drug products is not limited under a REMS program, as is the case with Qsymia. Further, the individual drugs contained in the Qsymia formulation are available in retail pharmacies. We cannot be sure that physicians will view Qsymia as sufficiently superior to a treatment regimen of Qsymia's individual APIs to justify the significantly higher cost for Qsymia, and they may prescribe the individual generic drugs already approved and marketed by other companies instead of our combination drug. Although our U.S. and European patents contain composition, product formulation and method-of-use claims that we believe protect Qsymia, these patents may be ineffective or impractical to prevent physicians from prescribing, or pharmacists from dispensing, the individual generic constituents marketed by other companies instead of our combination drug. Phentermine and topiramate are currently available in generic form, although the doses used in Qsymia are currently not available. In the third quarter of 2013, Supernus Pharmaceuticals, Inc. launched Trokendi XR™ and in the second quarter of 2014, Upsher-Smith Laboratories, Inc. launched Qudexy™. Both products provide an extended-release formulation of the generic drug topiramate that is indicated for certain types of seizures and migraines. Topiramate is not approved for obesity treatment, and phentermine is only approved for short-term treatment of obesity. However, because the price

of Qsymia is significantly higher than the prices of the individual components as marketed by other companies, physicians may have a greater incentive to write prescriptions for the individual components outside of their approved indication, instead of for our combination drug, and this may limit how we price or market Qsymia. Similar concerns could also limit the reimbursement amounts private health insurers or government agencies in the U.S. are prepared to pay for Qsymia, which could also limit market and patient acceptance of our drug and could negatively impact our revenues.

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

Once an applicant receives authorization to market a medicinal product in an EU Member State, through any application route, the applicant is required to engage in pricing discussions and negotiations with a separate pricing authority in that country. The legislators, policymakers and healthcare insurance funds in the EU Member States continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to healthcare cost containment and other austerity measures in the EU. Certain of these changes could impose limitations on the prices pharmaceutical companies are able to charge for their products. The amounts of reimbursement available from governmental agencies or third-party payors for these products may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products. Furthermore, an increasing number of EU Member States and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in the price of medicinal products in some countries could contribute to similar downward trends elsewhere. In addition, the ongoing budgetary difficulties faced by a number of EU Member States, including Greece and Spain, have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal products, which could negatively impact our revenues and profitability. Moreover, in order to obtain reimbursement of our medicinal products in some countries, including some EU Member States, we may be required to conduct clinical trials that compare the cost-effectiveness of our products to other available therapies. There can be no assurance that our medicinal products will obtain favorable reimbursement status in any country.

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

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

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

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

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

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

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

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

Competition in the pharmaceutical and medical products industries is intense and is characterized by costly and extensive research efforts and rapid technological progress. We are aware of several pharmaceutical companies also actively engaged in the development of therapies for the treatment of obesity and erectile dysfunction. Many of these companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. Some of the drugs that may compete with Qsymia may not have a REMS requirement and the accompanying complexities such a requirement presents. Our competitors may develop technologies and products that are more effective than those we are currently marketing or researching and developing. Such developments could render Qsymia and STENDRA less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience.

Qsymia for the treatment of chronic weight management competes with several approved anti-obesity drugs including, Belviq® (lorcaserin), Arena Pharmaceutical's approved anti-obesity compound marketed by Eisai Inc., Eisai Co., Ltd.'s U.S. subsidiary; Xenical® (orlistat), marketed by Roche; alli®, the over-the-counter version of orlistat, marketed by GlaxoSmithKline; Suprenza™, an orally disintegrating tablet (phentermine hydrochloride), marketed by Akrimax Pharmaceuticals, LCL; Contrave® (naltrexone/bupropion), Orexigen Therapeutics, Inc.'s anti-obesity compound; and Saxenda® (liraglutide), an anti-obesity compound marketed by Novo Nordisk A/S. Agents that have been approved for type 2 diabetes that have demonstrated weight loss in clinical studies may also compete with Qsymia. These include Farxiga™ (dapagliflozin) from AstraZeneca and Bristol-Myers Squibb, an SGLT2 inhibitor, approved January 8, 2014; Jardiance® (empagliflozin) from Boehringer Ingelheim, an SGLT2 inhibitor, approved August 1, 2014; Victoza® (liraglutide) from Novo Nordisk A/S, a GLP-1 receptor agonist approved January 25, 2010; Invokana® (canagliflozin) from Johnson & Johnson's Janssen Pharmaceuticals, an SGLT2 inhibitor, approved March 29, 2013 and Glyxambi® (empagliflozin/linagliptin) from Boehringer Ingelheim and Eli Lilly, an SGLT2 inhibitor and DPP-4 inhibitor combination product, approved January 30, 2015. Also, on January 14, 2015, FDA approved the Maestro Rechargeable System for certain obese adults, the first weight loss treatment device that targets the nerve pathway between the brain and the stomach that controls feelings of hunger and fullness. The Maestro Rechargeable System is approved to treat patients aged 18 and older who have not been able to lose weight with a weight loss program, and who have a body mass index of 35 to 45 with at least one other obesity-related condition, such as type 2 diabetes.

There are also several other investigational drug candidates in Phase 2 clinical trials for the treatment of obesity. There are also a number of generic pharmaceutical drugs that are prescribed for obesity, predominantly

phentermine. Phentermine is sold at much lower prices than we charge for Qsymia. The availability of branded prescription drugs, generic drugs and over-the-counter drugs could limit the demand for, and the price we are able to charge for, Qsymia.

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

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

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

We anticipate that generic PDE5 inhibitors will enter the market in the U.S. in late 2017. Generic PDE5 inhibitors would likely be sold at lower prices and may reduce the demand for STENDRA, especially at the prices we would be required to charge for STENDRA to cover our manufacturing and other costs. In addition, PDE5 inhibitors are in various stages of development by other companies. Warner-Chilcott plc, which was acquired by Actavis, Inc. and changed its name to Actavis plc, has licensed the U.S. rights to udenafil, a PDE5 inhibitor, from Dong-A Pharmaceutical, now known as Mezzion Pharma Co. Ltd. Actavis, Inc. acquired Allergan, changed its name to Allergan, plc and has announced that it is being acquired by Pfizer. Other treatments for ED exist, such as needle injection therapies, vacuum constriction devices and penile implants, and the manufacturers of these products will most likely continue to develop or improve these therapies.

Qsymia and STENDRA may also face challenges and competition from newly developed generic products. Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, newly approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act stimulates competition by providing incentives to generic pharmaceutical manufacturers to introduce non-infringing forms of patented pharmaceutical products and to challenge patents on branded pharmaceutical products. If we are unsuccessful at challenging an Abbreviated New Drug Application, or ANDA, filed pursuant to the Hatch-Waxman Act, a generic version of Qsymia or STENDRA may be launched, which would harm our business. Generic manufacturers pursuing ANDA approval are not required to conduct costly and time-consuming clinical trials to establish the safety and efficacy of their products; rather, they are permitted to rely on the FDA's finding that the innovator's product is safe and effective. Additionally, generic drug companies generally do not expend significant sums on sales and marketing activities, instead relying on physicians or payors to substitute the generic form of a drug for the branded form. Thus, generic manufacturers can sell their products at prices much lower than those charged by the innovative pharmaceutical or biotechnology companies who have incurred substantial expenses associated with the research and development of the drug product and who must spend significant sums marketing a new drug.

The FDCA provides that an ANDA and an innovator drug with a REMS with Elements to Assure Safe use, like Qsymia, must use a single shared REMS system to assure safe use unless FDA waives this requirement and permits the ANDA holder to implement a separate but comparable REMS. We cannot predict the outcome or impact on our business of any future action that we may take with regard to sharing our REMS program or if the FDA grants a waiver allowing the generic competitor to market a generic drug with a separate but compatible REMS.

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

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

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

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

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

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

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

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

The process of proposing, negotiating and implementing a license or acquisition of an investigational drug candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of investigational drug candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail

to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional investigational drug candidates on terms that we find acceptable, or at all.

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

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

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

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

Our success is highly dependent upon the skills of a limited number of key management personnel. To reach our business objectives, we will need to retain and hire qualified personnel in the areas of manufacturing, commercial operations, research and development, regulatory and legal affairs, business development, clinical trial design, execution and analysis, and pre-clinical testing. There can be no assurance that we will be able to retain or hire such personnel, as we must compete with other companies, academic institutions, government entities and other agencies. The loss of any of our key personnel or the failure to attract or retain necessary new employees could have an adverse effect on our research programs, investigational drug candidate development, approved drug commercialization efforts and business operations.

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

We do not have the ability to manufacture the materials we use in our pre-clinical and clinical trials and commercial operations. Rather, we rely on various third parties to manufacture these materials and there may be long lead times to obtain materials. There can be no assurance that we will be able to identify, contract with, qualify and obtain prior regulatory approval for additional sources of clinical materials. If interruptions in this supply occur for any reason, including a decision by the third parties to discontinue manufacturing, technical difficulties, labor disputes, natural or other disasters, or a failure of the third parties to follow regulations, we may not be able to obtain regulatory approvals for our investigational drug candidates and may not be able to successfully commercialize these investigational drug candidates or our approved drugs.

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

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

In the case of avanafil, we currently rely on Sanofi to supply the API and tablets for STENDRA and SPEDRA. Sanofi is responsible for all aspects of manufacture, including obtaining the starting materials for the production of API. If Sanofi is unable to manufacture the API or tablets in sufficient quantities to meet projected demand, future sales could be adversely affected, which in turn could have a detrimental impact on our financial results, our license, commercialization, and supply agreements with our collaboration partners, and our ability to enter into a collaboration agreement for the commercialization in other territories.

In July 2013, we entered into a Commercial Supply Agreement with Sanofi Chimie to manufacture and supply the API for avanafil on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. On November 18, 2013, we entered into a Manufacturing and Supply Agreement with Sanofi Winthrop Industrie to manufacture and supply the avanafil tablets on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. Sanofi received FDA and EMA approval in 2015 and began manufacturing API and tablets for avanafil in 2015.

Any failure of current or future manufacturing sites, including those of Sanofi Chimie and Sanofi Winthrop Industrie, to receive or maintain approval from FDA or foreign authorities, obtain and maintain ongoing FDA or foreign regulatory compliance, or manufacture avanafil API or tablets in expected quantities could have a detrimental impact on our ability to commercialize STENDRA under our agreements with Menarini, Metuchen and Sanofi and our ability to enter into a collaboration agreement for the commercialization of STENDRA in our other territories not covered by our agreements with Menarini, Metuchen and Sanofi.

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

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

The collection and use of personal health data and other personal data in the EU is governed by the provisions of the Data Protection Directive as implemented into national laws by the EU Member States. This Directive imposes restrictions on the processing (e.g., collection, use, disclosure) of personal data, including a number of requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals prior to processing their personal data, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict restrictions on the transfer of personal data out of the EU to the United States. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the EU Member States may result in fines and other administrative penalties. On December 15, 2015, a proposal for an EU Data Protection Regulation, intended to replace the current EU Data Protection Directive, was agreed to by the European Parliament, the Council of the European Union and the European Commission. The EU Data Protection Regulation, which will be officially adopted in early 2016, will introduce new data protection requirements in the EU and substantial fines for violations of the data protection rules. The EU Data Protection Regulation, which will be applicable two years after the date of its publication in the Official Journal for the European Union, will increase our responsibility and liability in relation to EU personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules. This may be onerous and increase our cost of doing business.

***If we fail to comply with applicable healthcare and privacy and data security laws and regulations, we could face substantial penalties, liability and adverse publicity and our business, operations and financial condition could be adversely affected.***

Our arrangements with third-party payors and customers expose us to broadly applicable federal and state healthcare laws and regulations pertaining to fraud and abuse. In addition, our operations expose us to privacy and data security laws and regulations. The restrictions under applicable federal and state healthcare laws and regulations, and privacy and data security laws and regulations, that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Law, which prohibits, among other things, knowingly or willingly offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare items or service for which payment may be made, in whole or in part, by federal healthcare programs such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Further, the Affordable Care Act, among other things, clarified that liability may be established under the federal Anti-Kickback Law without proving actual knowledge of the federal Anti-Kickback statute or specific intent to violate it. In addition, the Affordable Care Act amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Law constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Law protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exemption or safe harbor may be subject to scrutiny. We seek to comply with the exemptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability;
- the federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing, or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product;



providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government healthcare programs. In addition, in recent years the government has pursued civil False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved, and thus non-reimbursable, uses. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs;

- numerous U.S. federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and protection of personal information. Other countries also have, or are developing, laws governing the collection, use, disclosure and protection of personal information. In addition, most healthcare providers who prescribe our products and from whom we obtain patient health information are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA. We are not a HIPAA-covered entity and we do not operate as a business associate to any covered entities. Therefore, the HIPAA privacy and security requirements do not apply to us (other than potentially with respect to providing certain employee benefits). However, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting and/or conspiring to commit a violation of HIPAA. We are unable to predict whether our actions could be subject to prosecution in the event of an impermissible disclosure of health information to us. The legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing amount of focus on privacy and data security issues with the potential to affect our business. These privacy and data security laws and regulations could increase our cost of doing business, and failure to comply with these laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business;
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the payor. Some state laws also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to certain health care providers in the states. Other states prohibit providing meals to prescribers or other marketing-related activities. In addition, California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes of conduct. Foreign governments often have similar regulations, which we also will be subject to in those countries where we market and sell products;
- the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain pharmaceutical manufacturers to engage in extensive tracking of payments and other transfers of value to physicians and teaching hospitals, and to submit such data to CMS, which will then make all of this data publicly available on the CMS website. Pharmaceutical manufacturers with products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program were required to have started tracking reportable payments on August 1, 2013, and must submit a report to CMS on or before the 90th day of each calendar year disclosing reportable payments made in the previous calendar year. Failure to comply with the reporting obligations may result in civil monetary penalties; and
- the federal Foreign Corrupt Practices Act of 1977 and other similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the SEC. A determination that our operations or activities are not, or were not, in compliance with United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of

business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

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

In the EU, the advertising and promotion of our products will also be subject to EU Member States' laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices, as well as other EU Member State legislation governing statutory health insurance, bribery and anti-corruption. Failure to comply with these rules can result in enforcement action by the EU Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

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

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

Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including but not limited to trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business.

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

The FDA, and third-country authorities, including the competent authorities of the EU Member States, have the authority to impose significant restrictions, including REMS requirements, on approved products through regulations on advertising, promotional and distribution activities. After approval, if products are marketed in contradiction with FDA laws and regulations, the FDA may issue warning letters that require specific remedial measures to be taken, as well as an immediate cessation of the impermissible conduct, resulting in adverse publicity. The FDA may also require that all future promotional materials receive prior agency review and approval before use. Certain states have also adopted regulations and reporting requirements surrounding the promotion of pharmaceuticals. Qsymia and STENDRA are subject to these regulations. Failure to comply with state requirements may affect our ability to promote or sell pharmaceutical drugs in certain states. This, in turn, could have a material adverse impact on our financial results and financial condition and could subject us to significant liability, including civil and administrative remedies as well as criminal sanctions.

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

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

Even if we maintain FDA approval, or receive a marketing authorization from the EC, and other regulatory approvals, if we or others identify adverse side effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval or EU marketing authorization may be varied, suspended or withdrawn and reformulation of our products, additional clinical trials, changes in labeling and additional marketing applications may be required, any of which could harm our business and cause our stock price to decline.

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

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

We obtain the necessary raw materials and components for the manufacture of Qsymia and STENDRA as well as certain services, such as analytical testing packaging and labeling, from third parties. In particular, we rely on Catalent to supply Qsymia capsules and Packaging Coordinators, Inc., or PCI, for Qsymia packaging services. We rely on Sanofi Chimie and Sanofi Winthrop to supply avanafil API and tablets. We and these suppliers and service providers are required to follow cGMP requirements and are subject to routine and unannounced inspections by the FDA and by state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Upon inspection of these facilities, the FDA or foreign regulatory agencies may find the manufacturing process or facilities are not in compliance with cGMP requirements and other regulations. Because manufacturing processes are highly complex and are subject to a lengthy regulatory approval process, alternative qualified supply may not be available on a timely basis or at all.

Difficulties, problems or delays in our suppliers and service providers' manufacturing and supply of raw materials, components and services could delay our clinical trials, increase our costs, damage our reputation and cause us to lose revenue or market share if we are unable to timely meet market demands.

***If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

We participate in the Medicaid Drug Rebate program, established by the Omnibus Budget Reconciliation Act of 1990 and amended by the Veterans Health Care Act of 1992 as well as subsequent legislation. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug.

The Affordable Care Act made significant changes to the Medicaid Drug Rebate program. Effective in March 2010, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. With regard to the amount of the rebates owed, the Affordable Care Act increased the minimum Medicaid rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products and from 11% to 13% for non-innovator products; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, the Affordable Care Act and subsequent legislation changed the definition of average manufacturer price. Finally, the Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of \$3.0 billion in 2015, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law.

In February 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. These regulations become effective on April 1, 2016. We are evaluating the impact of these regulations on our business and operations. Moreover, in the future, Congress could enact legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time consuming, and could have a material adverse effect on our results of operations.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing discount program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as

hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Affordable Care Act and CMS's issuance of final regulations implementing those changes also could affect our 340B ceiling price calculations and negatively impact our results of operations.

The Affordable Care Act expanded the 340B program to include additional entity types: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act. The Affordable Care Act also obligates the Secretary of the U.S. Department of Health and Human Services, or HHS, to create regulations and processes to improve the integrity of the 340B program and to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The Health Resources and Services Administration, or HRSA, the agency that administers the 340B program, recently issued a proposed regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, as well as proposed omnibus guidance that addresses many aspects of the 340B program. HRSA is currently expected to issue additional proposed regulations in 2016. When such regulations and guidance are finalized, they could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current average manufacturer prices and best prices for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed 12 quarters from the quarter in which the data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B drug discount program.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false average manufacturer price or best price information to the government, we may be liable for civil monetary penalties in the amount of \$100,000 per item of false information. Our failure to submit monthly/quarterly average manufacturer price and best price data on a timely basis could result in a civil monetary penalty of \$10,000 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs.

In September 2010, CMS and the Office of the Inspector General indicated that they intend to pursue more aggressively companies that fail to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

If we misstate Non-FAMPs or FCPs, we must restate these figures. Additionally, pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject us to penalties of \$100,000 for each item of false information. If we overcharge the government in connection with our FSS contract or the Tricare Retail Pharmacy Program, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-

consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

***Changes in reimbursement procedures by government and other third-party payors, including changes in healthcare law and implementing regulations, may limit our ability to market and sell our approved drugs, or any future drugs, if approved, may limit our product revenues and delay profitability, and may impact our business in ways that we cannot currently predict. These changes could have a material adverse effect on our business and financial condition.***

In the U.S. and abroad, sales of pharmaceutical drugs are dependent, in part, on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. Some third-party payor benefit packages restrict reimbursement, charge co-pays to patients, or do not provide coverage for specific drugs or drug classes.

In addition, certain healthcare providers are moving towards a managed care system in which such providers contract to provide comprehensive healthcare services, including prescription drugs, for a fixed cost per person. We are unable to predict the reimbursement policies employed by third-party healthcare payors.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and Actual Acquisition Cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS, the federal agency that administers Medicare and the Medicaid Drug Rebate program, surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost, or NADAC, files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products.

The healthcare industry in the U.S. and abroad is undergoing fundamental changes that are the result of political, economic and regulatory influences. The levels of revenue and profitability of pharmaceutical companies may be affected by the continuing efforts of governmental and third-party payors to contain or reduce healthcare costs through various means. Reforms that have been and may be considered include mandated basic healthcare benefits, controls on healthcare spending through limitations on the increase in private health insurance premiums and the types of drugs eligible for reimbursement and Medicare and Medicaid spending, the creation of large insurance purchasing groups, and fundamental changes to the healthcare delivery system. These proposals include measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide. Further, federal budgetary concerns could result in the implementation of significant federal spending cuts, including cuts in Medicare and other health related spending in the near-term. For example, recent legislative enactments have resulted in Medicare payments being subject to a two percent reduction, referred to as sequestration, until 2025. These changes could impact our ability to maximize revenues in the federal marketplace.

In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to in this report as the Affordable Care Act. The Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers, and could have a material adverse effect on our future business, cash flows, financial condition and results of operations, including by operation of the following provisions:

- Effective in March 2010, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. This expanded eligibility affects rebate liability for that utilization.
- With regard to the amount of the rebates owed, the Affordable Care Act increased the minimum Medicaid rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products and from 11% to 13% for non-innovator products; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price.

- Effective in January 2011, pharmaceutical companies must provide a 50% discount on branded prescription drugs dispensed to beneficiaries within the Medicare Part D coverage gap or “donut hole,” which is a coverage gap that currently exists in the Medicare Part D prescription drug program. We currently do not have coverage under Medicare Part D for our drugs, but this could change in the future.
- Effective in January 2011, the Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of \$3.0 billion in 2016, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law.
- Some states have elected to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales, business and financial condition. We expect any Medicaid expansion to impact the number of adults in Medicaid more than children because many states have already set their eligibility criteria for children at or above the level designated in the Affordable Care Act. An increase in the proportion of patients who receive our drugs and who are covered by Medicaid could adversely affect our net sales.

In February 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate Program under the Affordable Care Act. These regulations become effective on April 1, 2016. We are evaluating the impact of these regulations on our business and operations. At this time, we cannot predict the full impact of the Affordable Care Act, or the timing and impact of any future rules or regulations promulgated to implement the Affordable Care Act.

The Affordable Care Act also expanded the Public Health Service’s 340B drug pricing discount program. The 340B pricing program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs. The Affordable Care Act expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act. The Affordable Care Act also obligates the Secretary of the Department of Health and Human Services to create regulations and processes to improve the integrity of the 340B program and to ensure the agreement that manufacturers must sign to participate in the 340B program obligates a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The Health Resources and Services Administration, or HRSA, the agency that administers the 340B program, recently issued a proposed regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, as well as proposed omnibus guidance that addresses many aspects of the 340B program. HRSA is currently expected to issue additional proposed regulations in 2016. When such regulations and guidance are finalized, they could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

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

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

has enacted healthcare reform and may enact further reform, which could adversely affect the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business.

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

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

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

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

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

Despite the implementation of security measures, our internal computer systems and those of our contract sales organization, or CSO, CROs, safety monitoring company and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, accidents, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or



security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our investigational drug candidate development programs and drug manufacturing operations. For example, the loss of clinical trial data from completed or ongoing clinical trials for our investigational drug candidates could result in delays in our regulatory approval efforts with the FDA, the EC, or the competent authorities of the EU Member States, and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our investigational drug candidates, or commercialization of our approved drugs, could be delayed. If we are unable to restore our information systems in the event of a systems failure, our communications, daily operations and the ability to develop our investigational drug candidates and approved drug commercialization efforts would be severely affected.

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

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

**Risks Relating to our Intellectual Property**

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

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

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

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

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

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

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

***We have received notices of ANDA filings for Qsymia and STENDRA submitted by generic drug companies. These ANDA filings assert that generic forms of Qsymia and STENDRA would not infringe on our issued patents. As a result of these filings, we have commenced litigation to defend our patent rights, which is expected to be costly and time-consuming and, depending on the outcome of the litigation, we may face competition from lower cost generic or follow-on products in the near term.***

Qsymia and STENDRA are approved under the provisions of the Federal Food, Drug and Cosmetic Act, or FDCA, which renders it susceptible to potential competition from generic manufacturers via the Hatch-Waxman Act and ANDA process. The ANDA procedure includes provisions allowing generic manufacturers to challenge the innovator's patent protection by submitting "Paragraph IV" certifications to the FDA in which the generic manufacturer claims that the innovator's patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the generic product. A patent owner who receives a Paragraph IV certification may choose to sue the generic applicant for patent infringement.

We have received a Paragraph IV certification notice from Actavis Laboratories FL, Inc., or Actavis, contending that our patents listed in the Orange Book for Qsymia (U.S. Patents 7,056,890, 7,553,818, 7,659,256, 7,674,776, 8,580,298, and 8,580,299) are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of a generic form of Qsymia. In response to this notice, we have filed suit to defend our patent rights. We have received a second Paragraph IV certification notice from Actavis contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 8,895,057 and 8,895,058) are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of a generic form of Qsymia. In response to this second notice, we have filed a second lawsuit against Actavis. We have received a third Paragraph IV certification notice from Actavis contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 9,011,905 and 9,011,906) are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of a generic form of Qsymia. In response to this third notice, we have filed a third lawsuit against Actavis. The lawsuits have been consolidated into a single suit. On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit. Expert discovery is ongoing and no trial date has been scheduled.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Actavis, FDA approval of Actavis' ANDA will be stayed until the earlier of (i) up to 30 months from our May 7, 2014

receipt of Actavis' Paragraph IV certification notice (i.e. November 7, 2016) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

We have received a Paragraph IV certification notice from Teva Pharmaceutical USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, Teva) contending that eight of our patents listed in the Orange Book for Qsymia (U.S. Patents 7,056,890, 7,533,818, 7,659,256, 7,674,776, 8,580,298, 8,580,299, 8,895,057, and 8,895,058) are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of a generic form of Qsymia. In response to this notice, we have filed suit against Teva to defend our patent rights. We have received a second Paragraph IV certification notice from Teva contending that two additional patents listed in the Orange Book for Qsymia (U.S. Patents 9,011,905 and 9,011,906) are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of a generic form of Qsymia. In response to this second notice, we have filed a second lawsuit against Teva. The lawsuits have been consolidated into a single suit. On July 20, 2016, the U.S. District Court for the District of New Jersey issued a claim construction (Markman) ruling governing the suit. On September 27, 2016, Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc., collectively referred to as DRL, were substituted for Teva as defendants in the lawsuit. Fact discovery is ongoing and no trial date has been scheduled.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Teva, FDA approval of Teva's ANDA will be stayed until the earlier of (i) up to 30 months from our March 5, 2015 receipt of Teva's Paragraph IV certification notice (i.e. September 5, 2017) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

We have received a Paragraph IV certification notice from Hetero USA Inc., or Hetero, contending that our patents listed in the Orange Book for STENDRA (U.S. Patents 6,656,935 and 7,501,409) are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of a generic form of STENDRA. In response to this notice, we have filed suit to defend our patent rights.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Hetero, FDA approval of Hetero's ANDA will be stayed until the earlier of (i) up to 30 months from the expiration of STENDRA's New Chemical Entity, or NCE, exclusivity period (i.e. October 27, 2019) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

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

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

Our commercial success also depends, in part, upon our ability to develop future investigational drug candidates, market and sell approved drugs and conduct our other research, development and commercialization activities without infringing or misappropriating the patents and other proprietary rights of others. There are many patents and patent applications owned by others that could be relevant to our business. For example, there are numerous U.S. and foreign issued patents and pending patent applications owned by others that are related to the therapeutic areas in which we have approved drugs or future investigational drug candidates as well as the therapeutic targets to which these drugs and candidates are directed. There are also numerous issued patents and patent applications covering chemical compounds or synthetic processes that may be necessary or useful to use in our research, development, manufacturing or commercialization activities. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our approved drugs, future investigational drug candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our approved drugs, investigational drug candidates or technologies may infringe. Further, it is not always clear to industry participants, including us, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. We cannot assure you that others holding any of these patents or patent applications will not assert infringement claims against us for damages or seek to enjoin our activities. If we are

sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, and we may not be able to do this.

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

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

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

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

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

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

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

**Risks Relating to our Financial Position and Need for Financing**

***We may require additional capital for our future operating plans, and we may not be able to secure the requisite additional funding on acceptable terms, or at all, which would force us to delay, reduce or eliminate commercialization or development efforts.***

We expect that our existing capital resources combined with future anticipated cash flows will be sufficient to support our operating activities at least through the next twelve months. However, we anticipate that we will be required to obtain additional financing to fund our commercialization efforts, additional clinical studies for approved products and the development of our research and development pipeline in future periods. Our future capital requirements will depend upon numerous factors, including:

- our ability to expand the use of Qsymia through targeted patient and physician education;
- our ability to find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience on a timely basis;
- our ability to obtain marketing authorization by the EC for Qsiva in the EU through the centralized marketing authorization procedure;
- our ability to manage costs;
- the substantial cost to expand into certified retail pharmacy locations and the cost required to maintain the REMS program for Qsymia;
- the cost, timing and outcome of the post-approval clinical studies the FDA has required us to perform as part of the approval for Qsymia;
- our ability, along with our collaboration partners, to successfully commercialize STENDRA in the U.S., Canada, South America, India, the EU, Australia, New Zealand, Africa, the Middle East, Turkey, and the CIS, including Russia;
- our ability to successfully commercialize STENDRA through a third party in other territories in which we do not currently have a commercial collaboration;
- the progress and costs of our research and development programs;
- the scope, timing, costs and results of pre-clinical, clinical and retrospective observational studies and trials;
- the cost of access to electronic records and databases that allow for retrospective observational studies;
- patient recruitment and enrollment in future clinical trials;
- the costs involved in seeking regulatory approvals for future drug candidates;
- the costs involved in filing and pursuing patent applications, defending and enforcing patent claims;
- the establishment of collaborations, sublicenses and strategic alliances and the related costs, including milestone payments;
- the cost of manufacturing and commercialization activities and arrangements;
- the level of resources devoted to our future sales and marketing capabilities;
- the cost, timing and outcome of litigation, if any;
- the impact of healthcare reform, if any, imposed by the federal government; and
- the activities of competitors.

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

To obtain additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of equity or debt securities, corporate alliances, joint ventures and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all. We are continually evaluating our existing portfolio and we may choose to divest, sell or spin-off one or more of our drugs and/or investigational drug candidates at any time. We cannot assure you that our drugs will generate revenues sufficient to enable us to earn a profit. If we are unable to obtain additional capital, management may be required to explore alternatives to reduce cash used by operating activities, including the termination of research and development efforts that may appear to be promising to us, the sale of certain assets and the reduction in overall operating activities. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts.

***Raising additional funds by issuing securities will cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.***

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. We have financed our operations, and we expect to continue to finance our operations, primarily by issuing equity and debt securities. Moreover, any issuances by us of equity securities may be at or below the prevailing market price of our common stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our common stock to decline. To raise additional capital, we may choose to issue additional securities at any time and at any price.

As of September 30, 2016, we have \$250.0 million in 4.5% Convertible Senior Notes due May 1, 2020, which we refer to as the Convertible Notes. The Convertible Notes are convertible into approximately 16,826,000 shares of our common stock under certain circumstances prior to maturity at a conversion rate of 67.3038 shares per \$1,000 principal amount of Convertible Notes, which represents a conversion price of approximately \$14.858 per share, subject to adjustment under certain conditions. On October 8, 2015, IEH Biopharma LLC, a subsidiary of Icahn Enterprises L.P., announced that it had received tenders for \$170,165,000 of the aggregate principal amount of our Convertible Notes in its previously announced cash tender offer for any and all of the outstanding Convertible Notes. The Convertible Notes are convertible at the option of the holders under certain conditions at any time prior to the close of business on the business day immediately preceding November 1, 2019. Investors in our common stock will be diluted to the extent the Convertible Notes are converted into shares of our common stock, rather than being settled in cash.

We may also raise additional capital through the incurrence of debt, and the holders of any debt we may issue would have rights superior to our stockholders' rights in the event we are not successful and are forced to seek the protection of bankruptcy laws.

In addition, debt financing typically contains covenants that restrict operating activities. For example, on March 25, 2013, we entered into the Purchase and Sale Agreement with BioPharma Secured Investments III Holdings Cayman LP, or BioPharma, which provides for the purchase of a debt-like instrument. Under the BioPharma Agreement, we may not (i) incur indebtedness greater than a specified amount, (ii) pay a dividend or other cash distribution on our capital stock, unless we have cash and cash equivalents in excess of a specified amount, (iii) amend or restate our certificate of incorporation or bylaws unless such amendments or restatements do not affect BioPharma's interests under the BioPharma Agreement, (iv) encumber the collateral, or (v) abandon certain patent rights, in each case without the consent of BioPharma. Any future debt financing we enter into may involve similar or more onerous covenants that restrict our operations.

If we raise additional capital through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our drugs or future investigational drug candidates, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the commercialization of one or more of our approved drugs or the development of one or more of our future investigational drug candidates.

***The investment of our cash balance and our available-for-sale securities are subject to risks that may cause losses and affect the liquidity of these investments.***

At September 30, 2016, we had \$283.6 million in cash, cash equivalents and available-for-sale securities. While at September 30, 2016, our excess cash balances were invested in money market, U.S. Treasury securities and corporate debt securities, our investment policy as approved by our Board of Directors, also provides for investments in debt securities of U.S. government agencies, corporate debt securities and asset-backed securities. Our investment policy has the primary investment objectives of preservation of principal. However, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy. These factors could impact the liquidity or valuation of our available-for-sale securities, all of which were invested in U.S. Treasury securities or corporate debt securities as of September 30, 2016. If those securities are downgraded or impaired we would experience losses in the value of our portfolio which would have an adverse effect on our results of operations, liquidity and financial condition. An investment in money market mutual funds is not insured or guaranteed by the Federal Deposit Insurance Corporation or any other government agency. Although money market mutual funds seek to preserve the value of the investment at \$1 per share, it is possible to lose money by investing in money market mutual funds.

***Our involvement in securities-related class action and shareholder litigation could divert our resources and management's attention and harm our business.***

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

For example, on March 27, 2014, Mary Jane and Thomas Jasin, who purport to be purchasers of VIVUS common stock, filed an Amended Complaint in Santa Clara County Superior Court alleging securities fraud against the Company and three of its former officers and directors. In that complaint, captioned *Jasin v. VIVUS, Inc.*, Case No. 114-cv-261427, plaintiffs asserted claims under California's securities and consumer protection securities statutes. Plaintiffs alleged generally that defendants misrepresented the prospects for the Company's success, including with respect to the launch of Qsymia, while purportedly selling VIVUS stock for personal profit. Plaintiffs alleged losses of "at least" \$2.8 million, and sought damages and other relief. On June 5, 2014, the Company and the other defendants filed a demurrer to the Amended Complaint seeking its dismissal. With the demurrer pending, on July 18, 2014, the same plaintiffs filed a complaint in the United States District Court for the Northern District of California, captioned *Jasin v. VIVUS, Inc.*, Case No. 5:14-cv-03263. The Jasins' federal complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, based on facts substantially similar to those alleged in their state court action. On September 15, 2014, pursuant to an agreement between the parties, plaintiffs moved to voluntarily dismiss, with prejudice, the state court action. In the federal action, defendants filed a motion to dismiss on November 12, 2014. On December 3, 2014, plaintiffs filed a First Amended Complaint in the federal action. On January 21, 2015, defendants filed a motion to dismiss the First Amended Complaint. The court ruled on that motion on June 18, 2015, dismissing the seven California claims with prejudice and dismissing the two federal claims with leave to amend. Plaintiffs filed a Second Amended Complaint on August 17, 2015. Defendants moved to dismiss the complaint on October 2, 2015. On September 10, 2015, plaintiffs moved for entry of judgment on their state claims. Briefing on both defendants' motion to dismiss and plaintiffs' motion for entry of judgment was completed on December 15, 2015. On April 19, 2016, the court issued a ruling granting defendants' motion to dismiss without leave to amend and denying as moot plaintiffs' motion for entry of judgment. On May 18, 2016, the plaintiffs filed a notice of appeal, and on September 23, 2016, plaintiffs filed their opening appellate brief. Defendants' response is due on November 23, 2016. The Company and the defendant former officers and directors

cannot predict the outcome of the lawsuit, but believe that the lawsuit is without merit and intend to continue vigorously to defend against the claims.

The Company maintains directors' and officers' liability insurance that it believes affords coverage for much of the anticipated cost of the remaining *Jasin* action, subject to the use of our financial resources to pay for our self-insured retention and the policies' terms and conditions.

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

We have generated a cumulative net loss of \$869.6 million for the period from our inception through September 30, 2016, and we anticipate losses in future years due to continued investment in our research and development programs. There can be no assurance that we will be able to achieve or maintain profitability or that we will be successful in the future.

***Our ability to utilize our net operating loss carryforwards and other tax attributes to offset future taxable income may be limited.***

As of December 31, 2015, we had approximately \$675.6 million and \$301.5 million of net operating loss, or NOL, carryforwards with which to offset our future taxable income for federal and state income tax reporting purposes, respectively. Utilization of our net operating loss and tax credit carryforwards, or tax attributes, may be subject to substantial annual limitations provided by the Internal Revenue Code and similar state provisions to the extent certain ownership changes are deemed to occur. Such an annual limitation could result in the expiration of the tax attributes before utilization. The tax attributes reflected above have not been reduced by any limitations. To the extent it is determined upon completion of the analysis that such limitations do apply, we will adjust the tax attributes accordingly. We face the risk that our ability to use our tax attributes will be substantially restricted if we undergo an "ownership change" as defined in Section 382 of the U.S. Internal Revenue Code, or Section 382. An ownership change under Section 382 would occur if "5-percent shareholders," within the meaning of Section 382, collectively increased their ownership in the Company by more than 50 percentage points over a rolling three-year period. We have not completed a recent study to assess whether any change of control has occurred or whether there have been multiple changes of control since the Company's formation, due to the significant complexity and cost associated with the study. We have completed studies through December 31, 2015 and concluded no adjustments were required. If we have experienced a change of control at any time since our formation, our NOL carryforwards and tax credits may not be available, or their utilization could be subject to an annual limitation under Section 382. A full valuation allowance has been provided against our NOL carryforwards, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Accordingly, there would be no impact on the consolidated balance sheet or statement of operations.

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

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



## Risks Relating to an Investment in our Common Stock

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

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

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

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

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

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

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

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

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

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

Some provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws could delay or prevent a change in control of our Company. Some of these provisions:

- authorize the issuance of preferred stock by the Board without prior stockholder approval, commonly referred to as "blank check" preferred stock, with rights senior to those of common stock;

- prohibit stockholder actions by written consent;
- specify procedures for director nominations by stockholders and submission of other proposals for consideration at stockholder meetings; and
- eliminate cumulative voting in the election of directors.

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

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

### Issuer Purchases of Equity Securities

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

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

## ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

## ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## ITEM 5. OTHER INFORMATION

None.

**ITEM 6. EXHIBITS**

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

## SIGNATURES

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

Date: November 9, 2016

VIVUS, Inc.

/s/ SETH H. Z. FISCHER

Seth H. Z. Fischer  
Chief Executive Officer

/s/ MARK K. OKI

Mark K. Oki  
Chief Financial Officer and Chief Accounting Officer

## VIVUS, INC.

## INDEX TO EXHIBITS

EXHIBIT NUMBER	DESCRIPTION
3.1 <sup>(1)</sup>	Amended and Restated Certificate of Incorporation of the Registrant.
3.2 <sup>(2)</sup>	Amended and Restated Bylaws of the Registrant.
3.3 <sup>(3)</sup>	Amendment No. 1 to the Amended and Restated Bylaws of the Registrant.
3.4 <sup>(4)</sup>	Amendment No. 2 to the Amended and Restated Bylaws of the Registrant.
3.5 <sup>(5)</sup>	Amendment No. 3 to the Amended and Restated Bylaws of the Registrant.
3.6 <sup>(6)</sup>	Amendment No. 4 to the Amended and Restated Bylaws of the Registrant.
3.7 <sup>(7)</sup>	Amendment No. 5 to the Amended and Restated Bylaws of the Registrant.
3.8 <sup>(8)</sup>	Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Registrant.
4.1 <sup>(9)</sup>	Specimen Common Stock Certificate of the Registrant.
4.2 <sup>(10)</sup>	Preferred Stock Rights Agreement dated as of March 27, 2007, between the Registrant and Computershare Investor Services, LLC.
4.3 <sup>(11)</sup>	Indenture dated as of May 21, 2013, by and between the Registrant and Deutsche Bank Trust Company Americas, as trustee.
4.4 <sup>(12)</sup>	Form of 4.50% Convertible Senior Note due May 1, 2020.
10.1	Letter Regarding Termination Notice dated as of August 29, 2016, from Auxilium Pharmaceuticals, LLC and Endo Ventures Limited to the Registrant.
10.2	First Amendment to Lease effective August 30, 2016, between the Registrant and MV Campus Owner, LLC, the successor in interest to SFERS Real Estate Corp. U.
10.3	Office Lease effective September 2, 2016, between the Registrant and AG-SW Hamilton Plaza Owner, L.P.
10.4††	License and Commercialization Agreement dated as of September 30, 2016, by and between the Registrant and Metuchen Pharmaceuticals LLC.
10.5††	Commercial Supply Agreement dated as of September 30, 2016, by and between the Registrant and Metuchen Pharmaceuticals LLC.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.

- 32 Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101 The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, formatted in eXtensible Business Reporting Language (XBRL), include: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) related notes.
- †† Confidential portions of this exhibit have been redacted and filed separately with the SEC pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.
- (1) Incorporated by reference to Exhibit 3.2 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1996, filed with the SEC on March 28, 1997.
- (2) Incorporated by reference to Exhibit 3.2 filed with the Registrant's Current Report on Form 8-K filed with the SEC on April 20, 2012.
- (3) Incorporated by reference to Exhibit 3.3 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013, filed with the SEC on May 8, 2013.
- (4) Incorporated by reference to Exhibit 3.4 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013, filed with the SEC on May 8, 2013.
- (5) Incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on May 13, 2013.
- (6) Incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on July 24, 2013.
- (7) Incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on September 18, 2015.
- (8) Incorporated by reference to Exhibit 3.3 filed with the Registrant's Registration Statement on Form 8-A filed with the SEC on March 28, 2007.
- (9) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 1996, filed with the SEC on April 16, 1997.
- (10) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Registration Statement on Form 8-A filed with the SEC on March 28, 2007.
- (11) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on May 21, 2013.
- (12) Incorporated by reference to Exhibit 4.2 filed with the Registrant's Current Report on Form 8-K filed with the SEC on May 21, 2013.

August 29, 2016

Via email:

John Slebir  
General Counsel  
VIVUS, Inc.  
351 E. Evelyn Ave.  
Mountain View, CA 94041

Re: Termination Notice

Dear Mr. Slebir:

This is to confirm our agreement that the date of termination of the License and Commercialization Agreement between VIVUS, Inc. and Auxilium Pharmaceuticals, LLC (formerly Auxilium Pharmaceuticals, Inc.), an Endo international company, dated October 10, 2013 (the "License Agreement"), is hereby extended to September 30, 2016.

Sincerely,

AUXILIUM PHARMACEUTICALS, LLC

ENDO VENTURES LIMITED

/s/ Deanne Voss  
Deanne Voss  
Assistant Secretary

/s/ Robert Cobuzzi  
Robert Cobuzzi  
Director

Accepted and agreed:

VIVUS, INC.

/s/ John L. Slebir  
John L. Slebir  
SVP, General Counsel

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## FIRST AMENDMENT TO LEASE

**THIS FIRST AMENDMENT TO LEASE** (this “**First Amendment**”) is made and entered into effective as of August 30, 2016 (the “**Effective Date**”), by and between **MV CAMPUS OWNER, LLC, a Delaware limited liability company** (“**Landlord**”), and **VIVUS, INC., a Delaware corporation** (“**Tenant**”).

## RECITALS

- A. Landlord, as successor-in-interest to SFERS Real Estate Corp. U, a Delaware corporation, and Tenant are parties to (i) that certain Lease dated December 11, 2012 (the “**Lease**”) and (ii) that certain Landlord Consent to Sublease dated as of April 30, 2014 (the “**Consent Agreement**”). Subject to the terms and conditions of the Lease, Landlord has leased to Tenant space currently containing approximately **45,240** rentable square feet (the “**Premises**”), located at 351 East Evelyn Avenue, Mountain View, California (the “**Building**”). The Building is part of an office campus at the intersection of East Evelyn Avenue and Ferry Morse Way in Mountain View (the “**Project**”).
- B. Subject to the terms and conditions of the Consent Agreement, Landlord has consented to Tenant’s sublease of a portion of the Premises to Adara, Inc., a California corporation (“**Subtenant**”), pursuant to that certain Sublease Agreement dated as of April 30, 2014 by and between Tenant and Subtenant (the “**Sublease**”).
- C. Tenant and Landlord mutually desire that the Lease be amended on and subject to the following terms and conditions.

**NOW, THEREFORE**, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

1. **Amendment.** Effective as of the Effective Date, Landlord and Tenant hereby agree that the Lease shall be amended in accordance with the following terms and conditions:
    - 1.1 **Term and Termination Date.** The Termination Date is hereby amended to be November 30, 2016 for all purposes under the Lease. All references to the “Termination Date” in the Lease shall refer to the Termination Date as amended by this First Amendment. The Term of Lease is hereby amended to be the period beginning on the Commencement Date and ending on the Termination Date as amended by this First Amendment. All references to the “Term” in the Lease shall refer to the Term of Lease as amended by this First Amendment. Article 40 of the Lease (Option to Renew) is hereby deleted in its entirety and replaced with “Intentionally Omitted.” Notwithstanding the foregoing, the Termination Date (as modified by this First Amendment) shall be extended to December 31, 2016 for all purposes under the Lease only if (a) the Tri-Party Agreement (as hereinafter defined) has not been executed and delivered by the parties thereto on or prior to
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November 30, 2016, or (b) Tenant delivers written notice to Landlord on or prior to October 1, 2016 of Tenant's election, in its sole discretion, to extend the Termination Date to December 31, 2016; *provided, however*, that if Landlord has not received such written notice on or prior to October 1, 2016, Tenant's right to extend the Termination Date hereunder shall be null and void and of no further force or effect. Except as expressly set forth in the immediately preceding sentence or as otherwise expressly agreed in a writing executed by Landlord and Tenant, Tenant shall have no right or option to renew the Lease or to extend the Termination Date.

- 1.2 **Vacation of the Premises.** On or prior to the Termination Date, Tenant shall vacate the Premises in accordance with the terms of the Lease. Notwithstanding anything in the Lease to the contrary, Landlord and Tenant hereby agree that Tenant shall not be required to remove any Alterations made by Tenant during the Term; *provided, however*, that Tenant shall be required to remove all Personalty, Building Signage and names or logos on the Monument Sign at its sole cost and expense and to otherwise comply with the terms and conditions of the Lease, including, without limitation, Sections 26, 42 and 43 thereof, with respect to the surrender and vacation of the Premises. From and after the Effective Date, Tenant shall not make, install or cause to be made or installed any Alterations to the Premises without the consent of Landlord, which consent may be granted or withheld in Landlord's sole and absolute discretion.

- 1.3 **Inspection.** In addition to, and not in limitation of, any other inspection rights contemplated under the Lease, including Section 26.1 thereof, from and after the Effective Date, Landlord shall have the right upon reasonable prior written notice to Tenant to enter the Premises to examine the current condition thereof, to conduct measurements and to perform other preliminary investigations related to the re-letting of the Premises. Such inspections shall not unreasonably interfere with the operation of Tenant's business on the Premises.

1.4 **Termination of Sublease.**

- 1.4.1 Tenant shall obtain Subtenant's surrender and vacation of the Sublet Premises (as defined in the Consent Agreement) on or prior to the Termination Date. In connection therewith, Tenant shall take all actions as may be required by the terms and conditions of the Sublease and the Consent Agreement, including, without limitation, providing written notice of the amended Termination Date to Subtenant in accordance with the terms and conditions of the Sublease, but in all events on or before August 31, 2016, and all such other actions as may be reasonably necessary, in order to obtain such surrender and vacation of the Sublet Premises from Subtenant. Tenant shall use diligent, good faith efforts to obtain, at Tenant's sole cost and expense, Subtenant's execution and delivery of a tri-party agreement by and among Tenant, Subtenant and Landlord (the "**Tri-Party Agreement**") prior to November 30, 2016, which such Tri-Party Agreement shall include, *inter alia*, (a) Subtenant's agreement to (i) peaceably and promptly vacate and surrender the Sublet Premises on before
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November 30, 2016, and (ii) release Landlord from any and all liability and waive any and all claims Subtenant may have against Landlord in connection with the Sublease or Consent Agreement, and (b) such other terms and conditions as Landlord may reasonably require. Landlord shall reasonably cooperate with Tenant's efforts to obtain the Tri-Party Agreement prior to November 30, 2016. Notwithstanding the foregoing, Tenant hereby acknowledges and agrees that Tenant's obligations under this First Amendment, including, without limitation, Tenant's obligation to obtain Subtenant's vacation and surrender of the Sublet Premises on or prior to the Termination Date, are in no way conditioned or contingent upon Tenant's ability to obtain such Tri-Party Agreement, and the failure to timely do so shall not relieve Tenant of any of its obligations hereunder.

1.4.2 Tenant acknowledges and agrees that Landlord shall have no obligations to Tenant or Subtenant with respect to the termination of the Sublease and Tenant hereby agrees to indemnify, defend, protect and hold harmless Landlord and its agents, employees, officers, directors, affiliates, advisors, asset managers and its permitted successors and assigns under the Lease (as amended hereby) from and against any and all claims, losses, damages, liabilities, costs or expenses of any kind or character (including, without limitation, attorneys' fees) arising out of, relating to or resulting from the termination of the Lease and the Sublease as contemplated herein and/or any disputes, liens or litigation in connection therewith, including, without limitation, any failure of Subtenant to have (a) received sufficient prior written notice of termination of the Sublease in accordance with the terms and conditions of the Sublease or (b) surrendered the Sublet Premises prior to the Termination Date. The failure of Subtenant to vacate the Sublet Premises prior to the Termination Date shall constitute holding over by Tenant under the Lease and Landlord shall be entitled to exercise all rights and remedies available to it under the Lease (including, without limitation, Article 14 thereof) or at law or in equity. This Section 1.4 shall survive the Termination Date (as amended hereby).

1.

**Miscellaneous.**

1.1 This First Amendment sets forth the entire agreement between the parties with respect to the matters set forth herein. There have been no additional oral or written representations or agreements. Under no circumstances shall Tenant be entitled to any rent abatement, improvement allowance, leasehold improvements, or other work to the Premises, or any similar economic incentives that may have been provided Tenant in connection with entering into the Lease, unless specifically set forth in this First Amendment. Time is of the essence with respect of each and every term and provision of this Agreement.

1.2 Except as herein modified or amended, the provisions, conditions and terms of the Lease are hereby ratified and confirmed and shall remain unchanged and in full force and effect. In the case of any inconsistency between the provisions of the Lease and this First Amendment, the provisions of this First Amendment shall

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govern and control. The capitalized terms used in this First Amendment shall have the same definitions as set forth in the Lease to the extent that such capitalized terms are defined therein and not redefined in this First Amendment.

- 1.3 Submission of this First Amendment by Landlord is not an offer to enter into this First Amendment but rather is a solicitation for such an offer by Tenant. Landlord shall not be bound by this First Amendment until Landlord has executed and delivered the same to Tenant.
- 1.4 Tenant hereby represents to Landlord that Tenant has dealt with no broker in connection with this First Amendment. Tenant agrees to indemnify and hold Landlord and Landlord Entities harmless from all claims of any brokers claiming to have represented Tenant in connection with this First Amendment.
- 1.5 This First Amendment may be executed in any number of original counterparts, including facsimile, PDF or other electronic counterparts. Any such counterpart, when executed, shall constitute an original of this First Amendment, and all such counterparts together shall constitute one and the same First Amendment. Signatures to this First Amendment executed and transmitted by copies of physically signed documents exchanged via email attachments in PDF format or equivalent shall be valid and effective to bind the party so signing. Each party agrees to deliver promptly an executed original of this First Amendment with its actual signature to the other party, but a failure to do so shall not affect the enforceability of this First Amendment, it being expressly agreed that each party to this First Amendment shall be bound by its own electronically transmitted signature and shall accept the electronically transmitted signature of the other party to this Agreement.
- 1.6 Subject to the terms and provisions of Article 9 of the Lease, the terms, covenants and conditions contained in this First Amendment shall be binding upon and inure to the benefit of the heirs, successors, executors, administrators and assigns of the parties to this First Amendment.
- 1.7 Redress for any claim against Landlord under the Lease and this First Amendment shall be limited to and enforceable only against and to the extent of Landlord's interest in the Building. The obligations of Landlord under the Lease are not intended to and shall not be personally binding on, nor shall any resort be had to the private properties of, any of its trustees or board of directors and officers, as the case may be, its investment manager, the general partners thereof, or any beneficiaries, stockholders, employees, or agents of Landlord or the investment manager, and in no case shall Landlord be liable to Tenant hereunder for any lost profits, damage to business, or any form of special, indirect or consequential damage.

*[Signature page follows]*

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IN WITNESS WHEREOF, Landlord and Tenant have entered into and executed this First Amendment as of the Effective Date.

**LANDLORD:**

**MV CAMPUS OWNER, LLC,**  
**a Delaware limited liability company**

By: /s/ Peter A. Kaye  
Name: Peter A. Kaye  
Its: Authorized Signatory  
Dated: August 30, 2016

**TENANT:**

**VIVUS, INC.,**  
**a Delaware corporation**

By: /s/ Mark Oki  
Name: Mark Oki  
Title: CFO  
Dated: August 25, 2016

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**HAMILTON PLAZA OFFICE LEASE**

**AG-SW HAMILTON PLAZA OWNER, L.P.,**  
a Delaware limited partnership as Landlord,

and

**VIVUS, INC.,**  
a Delaware corporation as Tenant

HAMILTON PLAZA  
Vivus, Inc.

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**OFFICE LEASE**

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<a href="#">ARTICLE 2 LEASE TERM</a>	<a href="#">2</a>
<a href="#">ARTICLE 3 BASE RENT</a>	<a href="#">2</a>
<a href="#">ARTICLE 4 ADDITIONAL RENT</a>	<a href="#">3</a>
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**EXHIBITS**

Exhibit A OUTLINE OF PREMISES

Exhibit B WORK LETTER

Exhibit C AMENDMENT TO LEASE Exhibit D RULES AND REGULATIONS

**RIDERS**

Rider 1 EXTENSION OPTION RIDER

**SUMMARY OF BASIC LEASE INFORMATION**

This Summary of Basic Lease Information ("Summary") is hereby incorporated into and made a part of the attached Office Lease. Each reference in the Office Lease to any term of this Summary shall have the meaning as set forth in this Summary for such term. In the event of a conflict between the terms of this Summary and the Office Lease, the terms of the Office Lease shall prevail. Any capitalized terms used herein and not otherwise defined herein shall have the meaning as set forth in the Office Lease.

**TERMS OF LEASE**

(References are to the Office Lease)

**DESCRIPTION**

1.Date:	August 9, 2016
2.Landlord:	<b>AG-SW HAMILTON PLAZA OWNER, L.P.</b> , a Delaware limited partnership
3.Address of Landlord (Section 24.19):	AG-SW Hamilton Plaza Owner, L.P. c/o SteelWave, Inc. 4000 E. Third Avenue, Suite 500 Foster City, California 94404 Attention: Senior Vice President, Asset Management
4.Tenant:	<b>VIVUS, INC.</b> , a Delaware corporation
5.Address of Tenant (Section 24.19):	Vivus, Inc. 351 Evelyn Avenue Mountain View, California 94041 Attention: Chief Financial Officer With an informational copy to: JLL 4085 Campbell Avenue, #150 Menlo Park, California 94025 Attention: Rich Branning and Cole Smith  and  Vivus, Inc. 900 E. Hamilton Avenue, Suite 525 Campbell, California 95008 Attention: Chief Financial Officer (After Lease Commencement Date)
6.Premises (Article 1):	
6.1Premises:	13,981 rentable square feet of space located on the fifth (5 <sup>th</sup> ) floor of the Building (as defined below), designated as Suites 525 and 550, as set forth in <b>Exhibit A</b> attached hereto.
6.2Building:	The Premises are located in that certain building (sometimes referred to herein as the " <b>Building</b> "), whose address is 900 E. Hamilton Avenue, Campbell, California 95008.
7.Term (Article 2):	
7.1Lease Term:	Fifty-eight (58) full calendar months.
7.2Lease Commencement Date:	The earlier of (i) the date Tenant commences business operations in the Premises, or (ii) the later to occur of: (a) December 1, 2016, or (b) the date the Premises are Ready for Occupancy (as defined in the Tenant Work Letter attached hereto as <b>Exhibit B</b> ).
7.3Lease Expiration Date:	The last day of the fifty-eighth (58 <sup>th</sup> ) full calendar month following the Lease Commencement Date.



<b>TERMS OF LEASE</b> (References are to the Office Lease)		<b>DESCRIPTION</b>
7.4Amendment to Lease:		Landlord and Tenant may confirm the Lease Co of the Office Lease.
8.Base Rent (Article 3):		
<u>Months of Lease Term</u>	<u>Annual Base Rent</u>	Monthly Installment <u>of</u>
1 – 16	\$520,093.20	\$43,341.10*
17 – 28	\$535,192.68	\$44,599.39
29 – 40	\$551,969.88	\$45,997.49
41 – 52	\$568,747.08	\$47,395.59
53 – 58	\$585,524.28	\$48,793.69
*Tenant shall not be obligated to pay monthly Base Rent for the first four (4) months of the Lease Term so long as Tenant is not in monetary or other material default under the Lease, as more particularly described in or provision of this Lease beyond applicable notice and grace periods, to the fullest extent permitted by law, any express or implicit waiver by Landlord of Tenant’s requirement to pay monthly Base Rent during any Base Rent so expressly or implicitly waived by Landlord.		
9. Tenant’s Share of Operating Expenses, Tax Expenses and Utilities Costs ( <u>Article 4</u> ):		7.74% (13,981 rentable square feet within the Pi
10.Security Deposit (Article 20):		\$198,000.00.
11.Parking (Article 23):		3.4 unreserved parking spaces within the parkin (48) parking spaces at no charge by Landlord, oi
12.Brokers (Section 24.25):		Cornish & Carey Commercial Newmark Knight
Vivus, Inc. Vivus, Inc.		

**OFFICE LEASE**

This Office Lease, which includes the preceding Summary and the exhibits attached hereto and incorporated herein by this reference (the Office Lease, the Summary and the exhibits to be known sometimes as the "Office Lease"), is made this 1st day of January, 2024, by and between AG-SW HAMILTON PLAZA OWNER, L.P., a Delaware limited partnership ("Landlord"), and VIVUS, INC., a Delaware corporation ("Tenant").

**ARTICLE 1**

**PROJECT, BUILDING AND PREMISES**

**1.1 Project, Building and Premises.**

1.1.1 Premises. Upon and subject to the terms, covenants and conditions hereinafter set forth in this Lease, Landlord hereby leases to Tenant and Tenant hereby leases from Landlord the premises set forth in Section 6.1 of the Summary (the "**Premises**"), which Premises are located in the Building defined in Section 6.2 of the Summary and located within the Project (as defined below). The outline of the floor plan of the Premises is set forth in Exhibit A attached hereto.

1.1.2 Building and Project. The Building is part of a multi-building commercial project currently containing two (2) office buildings and known as "Hamilton Plaza". The term "Building" shall include the areas and underground garage servicing the Building and the Other Existing Building (the "**Parking Facilities**"); (iv) any outside plaza areas, walkways, and/or the Other Existing Building, which are designated from time to time by Landlord as common areas appurtenant to or servicing the Building, the Other Existing Building and any such other improvements; (v) within or as part of the Project; and (vi) the land upon which any of the foregoing obligation to expand or otherwise make any improvements within the Project, including, without limitation, any of the outside plaza areas, walkways, driveways, courtyards, public and private streets, transportation facilities and (2) Landlord shall have the right from time to time to include or exclude any improvements or facilities within the Project, at such party's reasonable election, as more particularly set forth in Section 1.1.3 below.

1.1.3 Tenant's and Landlord's Rights. Tenant is hereby granted the right to the nonexclusive use of the common corridors and hallways, stairwells, elevators, restrooms and other public or common areas located within the Building, and the non-exclusive use of those areas located on the Project that are designated by Landlord from time to time as common areas for the Building (the "**Common Areas**"); provided, however, that (x) the manner in which such public and Common Areas are maintained and operated shall be at the sole discretion of Landlord, (ii) Tenant's use thereof shall be subject to (A) the provisions of any covenants, conditions and restrictions regarding the use thereof now or hereafter recorded against the Project, and (B) such reasonable, non-discriminatory rules, regulations and restrictions as Landlord may make from time to time, and (iii) Tenant may not go on the roof of the Building or the Other Existing Building without Landlord's prior consent (which may be withheld in Landlord's sole and absolute discretion) and without otherwise being accompanied by a representative of Landlord. Landlord reserves the right from time to time to use any of the Common Areas, and the roof, risers and conduits of the Building and the Other Existing Building for telecommunications and/or any other purposes, and to do any of the following: (1) make any changes, additions, improvements, repairs and/or replacements in or to the Project or any portion or elements thereof, including, without limitation, (x) changes in the location, size, shape and number of driveways, entrances, loading and unloading areas, ingress, egress, direction of traffic, landscaped areas, walkways, public and private streets, plazas, courtyards, transportation facilitation areas and common areas, and (y) expanding or decreasing the size of the Project and any Common Areas and other elements thereof, including adding, deleting and/or excluding buildings (including the Other Existing Building) thereon and therefrom; (2) close temporarily any of the Common Areas while engaged in making repairs, improvements or alterations to the Project; (3) retain and/or form a common area association or associations under covenants, conditions and restrictions to own, manage, operate, maintain, repair and/or replace all or any portion of the landscaping, driveway of the Building and the Other Existing Building and, subject to Article 4 below, include the Common Area assessments, fees and taxes charged by the association(s) and the cost of maintaining, managing, administering and operating the association(s), in Operating Expenses or Tax Expenses; and (4) perform such other acts and make such other changes with respect to the Project as Landlord may, in the exercise of good faith business judgment, deem to be appropriate. In connection with any work by Landlord in, and alterations or improvements to the common areas for the Building and/or Project, Landlord shall use commercially reasonable efforts to minimize any material adverse interference with Tenant's business at the Premises, and any unreasonable interference with Tenant's access to the Premises, as a result thereof.

25.1 Condition of Premises. Except as expressly set forth in this Lease and in the Tenant Work Letter attached hereto as Exhibit B, Landlord shall not be obligated to provide or pay for any improvement, remodeling or

refurbishment work or services related to the improvement, remodeling or refurbishment of the Premises, and Tenant shall accept the Premises in its "AS IS" condition on the Lease Commencement Date, provided that without limiting Landlord's obligations under the Work Letter, Landlord shall (a) repair any damage caused by Landlord's removal of furniture, fixtures and equipment from the Premises prior to delivery of possession (b) cause the Premises to be in a broom clean condition on the Lease Commencement Date. On the Lease Commencement Date, Landlord shall deliver the Premises with the existing Systems and Equipment in good working condition, in writing, of any of the foregoing items that are not in good working condition, Landlord shall cause such items to be promptly repaired to the extent that any deficiencies to such systems are not caused by the wrongful or negligent acts or omissions of Tenant or any of Tenant's Representatives (as defined in the Lease). If Tenant fails to timely deliver to Landlord such written notice of Systems or Equipment not in good working condition within the Review Period, Landlord shall have no obligation to perform any such work thereafter, except as otherwise expressly provided in the Lease.

25.2 **Rentable Square Feet.** The rentable square feet for the Premises are approximately as set forth in Section 6.1 of the Summary. For purposes hereof, the "rentable square feet" shall be calculated by Landlord with respect to rentable square footage pursuant to Landlord's standard rentable area measurements for the Project, to include, among other calculations, a portion of the Common Area of the Building and the Other Existing Building. The rentable square feet of the Premises and the Building are not subject to adjustment or remeasurement by Tenant, but the rentable square feet of the Premises are subject to verification from time to time. Landlord's planner/designer and such verification shall be made in accordance with the provisions of this Section 1.3. Tenant's architect may consult with Landlord's planner/designer regarding such verification, except that the determination of Landlord's planner/designer shall be conclusive and binding upon the parties. In the event that Landlord's planner/designer determines that the rentable square feet set forth in this Lease, all amounts, percentages and figures appearing or referred to in this Lease based upon such incorrect rentable square feet (including, without limitation, the amount of the Base Rent in accordance with such determination. If such determination is made, it will be confirmed in writing by Landlord to Tenant. Notwithstanding the foregoing, Landlord hereby agrees that, during the initial Lease Term, shall only be redetermined upon a physical change to the size of the Premises or as the result of a new load factor applicable to tenants of the Building due to new common area amenities.

**ARTICLE 2**

**LEASE TERM**

This Lease shall be effective as of the date of this Lease. The term of this Lease (the "**Lease Term**") shall be as set forth in Section 7.1 of the Summary and shall commence on the date (the "**Lease Commencement Date**") set forth in Section 7.2 of the Summary (subject, however, to the terms of the Tenant Work Letter and Landlord's delivery obligations set forth in Section 1.2), and shall terminate on the date (the "**Lease Expiration Date**") set forth in Section 7.3 of the Summary, unless this Lease is sooner terminated as hereinafter provided. For purposes of this Lease, the term "**Lease Year**" shall mean each consecutive twelve (12) month period during the Lease Term, provided that the last Lease Year shall end on the Lease Expiration Date. If Landlord does not deliver possession of the Premises to Tenant on or before the anticipated Lease Commencement Date (as set forth in Section 7.2(ii) of the Summary), Landlord shall not be subject to any liability nor shall the validity of this Lease nor the obligations of Tenant hereunder be affected, provided that Landlord shall use all commercially reasonable effort to deliver possession of the Premises to Tenant as soon as practicable. In the event that Landlord does not deliver such amendment to Tenant, the Lease Commencement Date shall be deemed to be the anticipated Lease Commencement Date set forth in Section 7.2(ii) of the Summary.

**ARTICLE 3**

**BASE RENT**

Tenant shall pay, without notice or demand, to Landlord or Landlord's agent at the management office of the Project, or at such other place as Landlord may from time to time designate in writing, in currency or a check for currency which, at the time of payment, is legal tender for private or public debts in the United States of America, base rent ("**Base Rent**") as set forth in Section 8 of the Summary, payable in equal monthly installments as set forth in Section 8 of the Summary in advance on or before the first day of each and every month during the Lease Term, without any setoff or deduction whatsoever. The Base Rent and estimated Additional Rent for the first (1st) full month of the Lease Term (in the aggregate amount of \$60,537.73) shall be paid at the time of Tenant's execution of this Lease. If any rental payment date (including the Lease Commencement Date) falls on a day of the month other than the first day of such month or if any rental payment is for a period which is shorter than one month, then the rental for any such fractional month shall be a proportionate amount of a full calendar month.

proportion that the number of days in such fractional month bears to the number of days in the calendar month during which such fractional month occurs. All other payments or adjustments required to be made under the terms of this Lease that require proration on a time basis shall be prorated on the same basis. If, at any time, Tenant is in default of any monetary or other material term, condition or provision of this Lease beyond periods, to the fullest extent permitted by law, any express or implicit waiver by Landlord of Tenant's requirement to pay Base Rent during any period of time from and after the Lease Commencement Date shall be null and void and Tenant shall immediately pay to Landlord all Base Rent so expressly or implicitly waived by Landlord.

ARTICLE 4

ADDITIONAL RENT

25.1 Additional Rent. In addition to paying the Base Rent specified in Article 3 of this Lease, Tenant shall pay as additional rent the sum of the following: (i) Tenant's Share (as such term is defined in Section 4.3.4 below); plus (ii) Tenant's Share of the Tax Expenses allocated to the Building (pursuant to Section 4.3.4 below); plus (iii) Utilities Costs allocated to the Building (pursuant to Section 4.3.4 below). Such additional rent, together with any and all other amounts payable by Tenant to Landlord pursuant to the terms of this Lease (including pursuant to Article 6), shall be hereinafter collectively referred to as the "**Additional Rent**." The Base Rent and Additional Rent are herein collectively referred to as the "**Rent**." All amounts due under this Rent shall be payable for the same periods and in the same manner, time and place as the Base Rent. Without limitation on other obligations of Tenant which shall survive the expiration of the Lease Term, the obligations of Tenant under this Article 4 shall survive the expiration of the Lease Term.

forth:  
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25.2.5 "Tax Expenses" shall mean all federal, state, county, or local governmental or municipal taxes, fees, assessments, charges or other impositions of every kind and nature, whether general or special, including leasehold taxes or taxes based upon the receipt of rent, including gross receipts or sales taxes applicable to the receipt of rent, personal property taxes, and taxes on ownership, leasing and operation of the Project or Landlord's interest therein. For purposes of this Lease, Tax Expenses shall be calculated as if (i) the tenant improvements in the Building, the Other Existing Buildings, and the Other Improvements were fully assessed for real estate tax purposes.

25.2.5.1 Tax Expenses shall include, without limitation:

- (i) Any tax on Landlord's rent, right to rent or other income from the Project or as against Landlord's business of leasing any of the Project;
- (ii) Any assessment, tax, fee, levy or charge in addition to, or in substitution, partially or totally, of any assessment, tax, fee, levy or charge previously included within the definition of Tax Expenses, being acknowledged by Tenant and Landlord that Proposition 13 was adopted by voters of the State of California in the June 1978 election ("**Proposition 13**") and that assessments, taxes, fees, levies and charges may be imposed by governmental agencies for such services as fire protection, street cleaning, refuse removal and for other governmental services formerly provided without charge to property owners or occupants. It is the intention of Tenant and Landlord that all such new and increased assessments, taxes, fees, levies and charges be included within the definition of Tax Expenses for purposes of this Lease;
- (iii) Any assessment, tax, fee, levy, or charge allocable to or measured by the area of the Premises or the rent payable hereunder, including, without limitation, any gross income tax upon or with respect to the possession, leasing, operating, management, maintenance, alteration, repair, use or occupancy by Tenant of the Premises, or any portion thereof;
- (iv) Any assessment, tax, fee, levy or charge, upon this transaction or any document to which Tenant is a party, creating or transferring an interest or an estate in the Premises; and

reduce or minimize Tax Expenses.

(v)

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3.4 Taxes and Other Charges for Which Tenant Is Directly Responsible. Tenant shall reimburse Landlord within thirty (30) days after receipt of written notice for any and all taxes or assessments required to be paid by Landlord (except to the extent included in Tax Expenses by Landlord) and chargeable to Tenant hereunder, excluding state, local and federal personal or corporate income taxes measured by the net income of Landlord from all sources and estate and inheritance taxes, whether or not now customary or within the contemplation of the parties hereto, when:

3.4.1 said taxes are measured by or reasonably attributable to the cost or value of Tenant's equipment, furniture, fixtures and other personal property located in the Premises, or by the cost or value of any leasehold improvement as determined by Landlord regardless of whether title to such improvements shall be vested in Tenant or Landlord;

3.4.2 said taxes are assessed upon or with respect to the possession, leasing, operation, management, maintenance, alteration, repair, use or occupancy by Tenant of the Premises or any portion of the Project (including the Parking Facilities); or

3.4.3 said taxes are assessed upon this transaction or any document to which Tenant is a party creating or transferring an interest or an estate in the Premises.

3.5 Late Charges. If any installment of Rent or any other sum due from Tenant shall not be received by Landlord or Landlord's designee by the due date therefor, then Tenant shall pay to Landlord a late charge equal to five percent (5%) of the amount due plus any attorneys' fees incurred by Landlord by reason of Tenant's failure to pay Rent and/or other charges when due hereunder. The late charge shall be deemed Additional Rent and the right to require it shall be in addition to all of Landlord's other rights and remedies hereunder, at law and/or in equity and shall not be construed as liquidated damages or as limiting Landlord's remedies in any manner. In addition to the late charge described above, any Rent or other amounts owing hereunder which are not paid by the date that they are due shall thereafter bear interest until paid at a rate (the "**Interest Rate**") equal to the lesser of (i) the "Prime Rate" or "Reference Rate" announced from time to time by the Bank of America (or such reasonable comparable national banking institution as selected by Landlord in the event Bank of America ceases to exist or publish a Prime Rate or Reference Rate), plus four percent (4%), or (ii) the highest rate permitted by applicable law. Notwithstanding the foregoing, in the first instance each calendar year wherein Tenant is late in making a payment to Landlord of Rent or any other sums payable by Tenant hereunder, the foregoing late charge shall not be assessed until five (5) days after such Rent or other amount is past due.

3.6 Audit. After delivery to Landlord of at least thirty (30) days' prior written notice delivered no later than one hundred twenty (120) days after and/or audit the books and records evidencing such costs and expenses for the previous one (1) calendar year, during Landlord's reasonable business hours but not more frequently than once during any calendar year, thereto) shall be maintained strictly confidential by Tenant and its accounting firm and shall not be disclosed, published or otherwise disseminated to any other party other than to Landlord and its authorized agents such costs and expenses. If Tenant fails to timely deliver written notice of Tenant's desire to audit a Statement pursuant to this Section 4.6 or Tenant fails to commence and complete such audit within six (6) months :

## **ARTICLE 5**

### **USE OF PREMISES**

Tenant shall use the Premises solely for general office purposes consistent with the character of the Building, and Tenant shall not use or permit the Premises to be used for any other purpose or purposes whatsoever. Tenant further covenants and agrees that it shall not use, or suffer or permit any person or persons to use, the Premises or any part thereof for any use or purpose contrary to the provisions of Exhibit D, attached hereto, or in violation of the laws of the United States of America, the state in which the Project is located over the Project. Tenant shall comply with all recorded covenants, conditions, and restrictions, and the provisions of all ground or underlying leases, now or hereafter affecting the Project. Tenant shall not use or allow another person or entity to use any part of the Premises for the storage, use, treatment, manipulation, remove, restore and otherwise remediate (including, without limitation, preparation of any feasibility studies or reports and the performance of any and all closures) any spills, releases or discharges of Hazardous Materials arising from or related to the acts or omissions of Tenant or Tenant's agents, or



SERVICES AND UTILITIES

3.1 Standard Tenant Services. Landlord shall provide the following services on all days during the Lease Term, unless otherwise stated below.

3.1.1

Subject to reasonable changes implemented by Landlord and to all governmental rules, regulations and guidelines applicable thereto, Landlord shall provide heating and air conditioning when necessary for normal comfort for normal office use in the Premises, from Monday through Friday, during the period from 7:00 a.m. to 6:00 p.m., except for the date of observation of New Year's Day, Presidents' Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, Christmas Day and other locally or nationally recognized holidays as designated by Landlord (collectively, the "**Holidays**"). Landlord acknowledges that Tenant may require HVAC and electricity for the portion of the Premises other than the Server Room (defined below) during hours both before and after the Building Hours and, subject to the terms of this Lease and any rules, regulations and procedures reasonably adopted by Landlord, Landlord agrees that such services shall be made available to Tenant and the Premises before and after Building Hours, at Tenant's sole cost. The initial hourly rate is \$65.00 (with a minimum of two (2) hours), which hourly rate is subject to change at any time upon written notice from Landlord based upon reasonable changes in costs to Landlord in providing such after hours HVAC.

3.1.2

Landlord shall provide adequate electrical wiring and facilities and power for normal general office use as reasonably determined by Landlord.

3.1.3

As part of Operating Expenses or Utilities Costs (as reasonably determined by Landlord), Landlord shall replace lamps, starters and ballasts for Building standard lighting fixtures within the Premises. Tenant shall bear the cost of replacement of lamps, starters and ballasts for non-Building standard lighting fixtures within the Premises.

3.1.4

Landlord shall provide city water for drinking, lavatory and toilet purposes.

3.1.5

Landlord shall provide janitorial services five (5) days per week, except the date of observation of the Holidays, in and about the Premises and window washing services in a manner consistent with other comparable "Class A" buildings in the vicinity of the Project.

3.1.6

Landlord shall provide nonexclusive automatic passenger elevator service at all times.

Landlord.

3.1.7

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Landlord shall provide nonexclusive freight elevator service subject to scheduling by

3.2 Overstandard Tenant Use Except in other than normal fractional horsepower office machines, or equipment or lighting other than building standard lights in the Premises, which may affect the temperature otherwise maintained by the air conditioning system, shall not exceed two (2) watts connected load per square foot of rentable area of the Premises, calculated on a monthly basis for the hours described in Section 6.1.1 above. Tenant shall pay for the cost of metering devices. If Tenant desires to use heat, ventilation or air conditioning during hours other than those for which Landlord is obligated to supply such utilities pursuant to the terms of Section 6.1 of this Lease, (i)

3.3 Interruption of Use. Tenant agrees that Landlord shall not be liable for damages, by abatement of Rent or otherwise, for failure to furnish or delay in furnishing any service (including but not limited to heat, ventilation or air conditioning) if the delay or diminution is occasioned, in whole or in part, by repairs, replacements, or improvements, by any strike, lockout or other labor trouble, by inability to secure electricity, gas, water, or other fuel at the Building or by any other cause beyond Landlord's reasonable control; and such failures or delays or diminution shall never be deemed to constitute an eviction or disturbance of Tenant's use and possession of the Premises or any circumstances for a loss of, or injury to, property or for injury to, or interference with, Tenant's business, including, without limitation, loss of profits, however occurring, through or in connection with or incident to any such failure, delay or diminution.

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contrary contained herein, Tenant shall be entitled to abate Base Rent due hereunder, to the extent that utility services to the Premises are interrupted or suspended solely as a result of Landlord's or its authorized representatives' gross negligence or willful misconduct, for a period of ten (10) or more consecutive business days, provided that Tenant is prevented from using the Premises as a result thereof.

3.4 Additional Services. Landlord shall also have the exclusive right, but not the obligation, to provide any additional services which may be requested by Tenant, including, without limitation, locksmithing, lamp replacement, additional janitorial service, and additional repairs and maintenance, provided that Tenant shall pay to Landlord upon billing, the sum of all costs to Landlord of such additional services plus an administration fee. Charges for any utilities or services for which Tenant is required to pay from time to time hereunder, shall be deemed Additional Rent hereunder and shall be billed on a monthly basis.

3.5 Server Room. Landlord and Tenant acknowledge that a portion of the Premises may be used as a server room (the "Server Room") five (365) days per year. In the event that Tenant elects to use a portion of the Premises as a Server Room, (i) Landlord agrees that, subject to the terms of this Lease, Landlord shall provide cooling, heating, ventilation, air conditioning, and humidity control to the Server Room and a separate monitoring device to measure such Server Room usage and Tenant shall pay all such costs of usage pursuant to regular monthly invoicing, and (iii) notwithstanding the foregoing, Tenant shall not be responsible for the cost of such usage.

3.6 Separate Metering; Compliance with Energy Regulations. Notwithstanding anything to the contrary contained herein, if any utility services to the Premises are separately metered, or which are billed directly to Tenant, within ten (10) business days after invoice. Tenant acknowledges that Landlord and/or Tenant may from time to time be requested in writing or required to provide information regarding the consumption of utilities at the Premises as may be required to comply with applicable laws, regulations, codes, and standards.

**ARTICLE 7**

**REPAIRS**

3.1 Tenant's Repairs. Subject to Landlord's repair obligations in Sections 7.2 and 11.1 below, Tenant shall, at Tenant's own expense, keep the Premises, including all improvements, fixtures and equipment, in good order, repair and condition at all times during the Lease Term, which repair obligations shall include, without limitation, the obligation to promptly and adequately repair all damage to the Premises, including all improvements, fixtures and equipment, and to repair all damaged or broken fixtures and appurtenances; provided however, that, at Landlord's option, or if Tenant fails to make such repairs after reasonable written notice from Landlord to Tenant, Landlord may, at its sole discretion, make such repairs and replacements, and Tenant shall pay Landlord the cost thereof, including a percentage of the cost thereof (not to exceed ten percent (10%)) sufficient to reimburse Landlord for all overhead, general conditions, fees and other costs or expenses arising from Landlord's involvement with such repairs and replacements. Landlord shall not be liable for the cost of such repairs and replacements.

3.2 Landlord's Repairs. Anything contained in this Lease, notwithstanding, and subject to Articles 11 and 12 of this Lease, Landlord shall repair and maintain the exterior landscaping, Common Areas, structural portions of the Building, including the foundations, roof, base, and other structural elements, and shall be responsible for the repair and maintenance of the same. Tenant shall pay to Landlord as additional rent, the reasonable cost of such maintenance and repairs. Landlord shall not be liable for alterations or improvements in or to any portion of the Project, Building or the Premises or in or to fixtures, appurtenances and equipment therein. Tenant hereby waives and releases its right to make repairs at Landlord's expense.

**ARTICLE 8**

**ADDITIONS AND ALTERATIONS**

3.1 Landlord's Consent to Alterations. Tenant may not make any improvements, alterations, additions or changes to the Premises (collectively, the "Alterations") without first procuring the prior written consent of Landlord to such Alterations, which consent shall be requested by Tenant not less than fifteen (15) days prior to the commencement thereof, and which consent shall not be unreasonably withheld or delayed by Landlord; provided,

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3.2. Manner of Construction. Landlord may impose, as a condition of its consent to all Alterations or repairs of the Premises or about the Premises, such requirements as Landlord in its reasonable including, but not limited to, the requirement that Tenant utilize for such purposes only contractors, materials, mechanics and materialmen approved by Landlord; provided, however, Landlord may impose such determine, in its sole good faith business judgement, with respect to any work affecting the structural components of the Building or Systems and Equipment (including designating specific contractors to perform such such Alterations and perform such repairs in conformance with any and all applicable rules and regulations of any federal, state, county or municipal code or ordinance (including California Energy Code, Title 24) permit, issued by the city in which the Project is located, and in conformance with Landlord's construction rules and regulations. In the event that any proposed Alterations trigger the need for repairs, maintenance outside of the Premises for any reason, Tenant shall be solely responsible for the performance of all such work at Tenant's sole cost and expense. Landlord's approval of the plans, specifications and working drawings shall create no responsibility or liability on the part of Landlord for their completeness, design compliance with all laws, rules and regulations of governmental agencies or authorities. All work with respect to any Alterations must be done in a good and workmanlike manner and diligently prosecuted to completion shall at all times be a complete unit except during the period of work. In performing the work of any such Alterations, Tenant shall have the work performed in such manner as not to obstruct access to the Building or for any other tenant of the Project, and as not to obstruct the business of Landlord or other tenants of the Project, or interfere with the labor force working at the Project. If Tenant makes any Alterations, Tenant agrees to obtain insurance covering the construction of such Alterations, and such other insurance as Landlord may require, it being understood and agreed that all of such Alterations shall be insured by Tenant pursuant to Article 10 completion thereof. In addition, Landlord may, in its reasonably discretion, require Tenant to obtain a lien and completion bond or some alternate form of security satisfactory to Landlord in an amount free completion of such Alterations and naming Landlord as a co-obligee. Upon completion of any Alterations, Tenant shall submit a set of Completion to be recorded in the office of the Recorder of the county in which the Project is located in accordance with Section 3093 of the Civil Code of the State of California or any successor statute, (ii) deliver the Project a reproducible copy of the "as built" drawings of the Alterations, and (iii) deliver to Landlord evidence of payment, contractors' affidavits and full and final waivers of all liens for labor, services or materials.

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rates, and Tenant shall reimburse Landlord within twenty (20) days following submission to Tenant of an invoice from Landlord. This reimbursement obligation is independent of any rights or remedies Landlord may have in the event of a breach or default by Tenant under this Lease.

3.4 **Landlord's Property.** All Alterations, improvements, fixtures (other than Tenant's trade fixtures that may be removed without damage to the Premises) and/or equipment which may be installed on the Premises, including any cabling and wiring associated with the Wi-Fi Network, and all signs installed in, on or about the Premises, from time to time, shall be at the sole cost of Tenant and shall be and become the property of Landlord. Furthermore, Landlord may require that Tenant remove any improvement or Alteration (including any cabling and wiring associated with the Wi-Fi Network) upon the expiration or termination of the Lease Term, and repair any damage to the Premises and Building caused by such removal; provided, Landlord shall advise Tenant at the time of granting consent if Landlord requires such Alterations to be removed upon termination of the Lease. If Tenant fails to complete such removal and/or to repair any damage caused by the removal of any Alterations (including any cabling and wiring associated with the Wi-Fi Network), Landlord shall charge the cost thereof to Tenant (together with a five percent (5%) supervision/administration fee), and Tenant shall pay such cost to Landlord within thirty (30) days of being billed for the same.

**ARTICLE 9**

**COVENANT AGAINST LIENS**

Tenant has no authority or power to cause or permit any lien or encumbrance of any kind whatsoever, whether created by act of Tenant, operation of law or otherwise, to attach to or be placed upon the Project, Building or Premises, and any and all liens and encumbrances created by Tenant shall attach to Tenant's interest only. Landlord shall have the right at all times to post and keep posted on the Premises any notices for protection from such liens. Tenant covenants and agrees not to suffer or permit any lien of mechanics or materialmen or others to be placed against the Project, the Building or the Premises with respect to work or services claimed to have been performed for or materials claimed to have been furnished to Tenant or the Premises, and, in case of any such lien attaching or notice of any lien, Tenant covenants and agrees to cause it to be immediately released and removed of record. Notwithstanding anything to the contrary set forth in this Lease, if any such lien is not released and removed on or before the date that is ten (10) days after notice of such lien is delivered by Landlord to Tenant, Landlord, at its sole option, may immediately take all action necessary to release and remove such lien, without any duty to investigate the validity thereof, and all sums, costs and expenses, including reasonable attorneys' fees and costs, incurred by Landlord in connection with such lien shall be deemed Additional Rent under this Lease and shall immediately be due and payable by Tenant.

**ARTICLE 10**

**INDEMNIFICATION AND INSURANCE**

3.1 **Indemnification and Waiver.** Tenant hereby assumes all risk of damage to property and from any cause whatsoever and agrees that Landlord, and its partners and subpartners, and their respective officers, agents, property managers, servants, employees, and independent contractors (collectively, "Landlord") shall defend, protect, and hold harmless the Landlord Parties from any and all claims, damages, losses, and expenses, including reasonable attorneys' fees and costs, incurred by Landlord Parties, arising out of or from the use of the Premises or the fitness center located on or about the Premises (including, without limitation, Tenant's installation, placement and removal of Alterations, improvements, fixtures and/or equipment in, on or about the Premises) or the fitness center located on the Project, the Building and Project; provided, however, that the terms of the foregoing indemnity shall not apply to the gross negligence or willful misconduct of Landlord. The provisions of this Section shall not be construed to limit or restrict the obligations of Landlord Parties under any applicable law, regulation, or contract.

3.2 **Tenant's Compliance with Landlord's Fire and Casualty Insurance.** Tenant shall, at Tenant's expense, comply as to the Premises with all insurance company requirements pertaining to the use of the Premises. If Tenant's conduct or use of the Premises for other than ordinary office use causes any increase in the premium for such insurance policies, then Tenant shall reimburse Landlord for any such increase. Tenant, at Tenant's expense, shall comply with all rules, orders, regulations or requirements of the American Insurance Association (formerly the National Board of Fire Underwriters) and with any similar body.

3.3 **Tenant's Insurance.** Tenant shall maintain the following coverages in the following amounts.

3.3.1 Commercial General Liability Insurance covering the insured against claims of bodily injury, personal injury and property damage arising out of Tenant's operations, assumed liabilities or use of the Premises, including the performance by Tenant of the indemnity agreements set forth in **Section 10.1** of this Lease, (and with owned and non-owned automobile liability coverage, and liquor liability coverage in the event applicable).

Bodily Injury and Property Damage Liability	\$5,000,000 each occurrence \$5,000,000 annual aggregate
Personal Injury Liability	\$5,000,000 each occurrence \$5,000,000 annual aggregate

3.3.2 Physical Damage Insurance covering (i) all furniture, trade fixtures, equipment, merchandise and all other items of Tenant's property on the Premises installed by, for, or at the expense of Tenant, and (ii) all improvements, alterations and additions to the Premises, including any improvements, alterations or additions installed at Tenant's request above the ceiling of the Premises or below the floor of the Premises. Such insurance shall be written on a "physical loss or damage" basis under a "special form" policy, for the full replacement cost value new without deduction for depreciation of the covered items and in amounts that meet any co-insurance clauses of the policies of insurance and shall include a vandalism and malicious mischief endorsement, sprinkler leakage coverage and earthquake sprinkler leakage coverage.

3.3.3 Workers' compensation insurance as required by law.

3.3.4 Loss-of-income, business interruption and extra-expense insurance in such amounts as will reimburse Tenant for direct and indirect loss of earnings attributable to all perils commonly insured against by prudent tenants or attributable to prevention of loss of access to the Premises or to the Building as a result of such perils.

3.3.5 Tenant shall carry comprehensive automobile liability insurance having a combined single limit of not less than Two Million Dollars (\$2,000,000.00) per occurrence and insuring Tenant against liability for claims arising out of ownership, maintenance or use of any owned, hired or non-owned automobiles.

3.3.6 The minimum limits of policies of insurance required of Tenant under this Lease shall in no event limit the liability of Tenant under this Lease. Such insurance shall: (i) name Landlord, and any other party with a material connection to the Premises it so specifies, as an additional insured; (ii) specifically cover the liability assumed by Tenant under this Lease, including, but not limited to, Tenant's obligations under Section 10.1 of this Lease; (iii) be issued by an insurance company having a rating of not less than A-; VIII in Best's Insurance Guide or which is otherwise acceptable to Landlord and licensed to do business in the state in which the Project is located; (iv) be primary insurance as to all claims thereunder and provide that any insurance carried by Landlord is excess and is non-contributing with any insurance requirement of Tenant; (v) contain a credit in Sections 10.3.1 and 10.3.2 above, have deductible amounts not exceeding Fifty Thousand Dollars (\$50,000.00). Tenant shall deliver said policy or policies or certificates thereof to Landlord on or before nonrenewal or modification of insurance coverage from any insurer. Tenant shall send such notice to Landlord within five (5) business days of receipt. If Tenant shall fail to procure such insurance, or to deliver such policies of insurance with notice and cure periods set forth in Section 19.1, procure such policies for the account of Tenant, and the cost thereof shall be paid to Landlord as Additional Rent within ten (10) days after

4.1 Subrogation. Landlord and Tenant agree to have their respective insurance companies issuing property damage insurance waive any rights of subrogation that such companies may have against Landlord or Tenant, as the case may be, so long as the insurance carried by Landlord and Tenant, respectively, is not invalidated thereby. Landlord and Tenant hereby waive any right that either may have against the other on account of any loss or damage to their respective property to the extent such loss or damage is insurable under policies of insurance for fire and all risk coverage, theft, public liability, or other similar insurance.

4.2 Additional Insurance Obligations. Tenant shall carry and maintain during the entire Lease Term, at Tenant's sole cost and expense, increased amounts of the insurance required to be carried by Tenant pursuant to this Article 10, and such other reasonable types of insurance coverage and in such reasonable amounts covering the Premises and Tenant's operations therein, as may be reasonably requested by Landlord, provided such additional insurance is consistent with the amounts and types of insurance then being required by reasonably prudent landlords of comparable buildings in the vicinity of the Building or as otherwise required by Landlord's lenders.

## ARTICLE 11

### DAMAGE AND DESTRUCTION

4.1 Repair of Damage to Premises by Landlord. Tenant shall promptly notify Landlord of any damage to the Premises resulting from fire or any other casualty. If the Premises or any Common Areas are damaged by fire or other casualty, Landlord shall, and diligently, subject to reasonable delays for insurance adjustment or other matters beyond Landlord's reasonable control, and subject to all other terms of this Article 11, restore the base, shell, and core of the Premises. Such restoration shall be to substantially the same condition of the base, shell, and core of the Premises and Common Areas prior to the casualty, except for modifications required by zoning laws or by the holder of a mortgage on the Building and/or Project, or the lessor of a ground or underlying lease with

respect to the Project and/or the Building, or any other modifications to the Common Areas deemed desirable by Landlord, provided access to the Premises and any common restrooms serving the Premises shall not be materially impaired. Notwithstanding any other provision of this Lease, upon the occurrence of any damage to the Premises, Tenant shall assign to Landlord (or to any party designated by Landlord) all insurance Tenant's insurance required under Section 10.3 of this Lease, and Landlord shall repair any injury or damage to the tenant improvements and alterations installed in the Premises and shall return such tenant improvements and alterations to their original condition; provided that if the cost of such repair by Landlord exceeds the amount of insurance proceeds received by Landlord from Tenant's insurance carrier, as assigned to Tenant, such as any cabling, wiring, supplemental utility system, telephone system or wireless/Wi-Fi Network. In connection with such repairs and replacements, Tenant shall, prior to the commencement of construction, submit to Landlord, for Landlord's review and approval, all plans, specifications and working drawings relating thereto, and Landlord shall select the contractors to perform such improvement work. Landlord shall not be liable for any inconvenience or annoyance to Tenant or its visitors, or injury to Tenant's business resulting in any way from such damage or the repair thereof; provided however, if the damage to the Premises or Common Areas is necessary to Tenant's occupancy, Landlord shall allow Tenant a proportionate abatement of Base Rent and Tenant's Share of Operating Expenses, Tax Expenses and Utilities Costs, during the time and to the extent the Premises are unfit for occupancy for the this Lease, and not occupied by Tenant as a result thereof.

4.2 Landlord's Option to Repair. Notwithstanding the terms and instead terminate this Lease by notifying Tenant in writing of such termination within sixty (60) days after the date of damage, such notice to include a termination date giving Tenant ninety (90) days to vacate the portion thereof be used to retire the mortgage debt, or shall terminate the ground or underlying lease, as the case may be and shall exercise that right; or (iii) the damage is not fully covered, except for deductible amount, 11.2, Tenant shall pay the Base Rent and Additional Rent, properly apportioned up to such date of termination, and both parties hereto shall thereafter be freed and discharged of all further obligations hereunder, except as otherwise provided herein.

4.3 Waiver of Statutory Provisions. The provisions of this Lease, including this Article 11, constitute an express agreement between Landlord and Tenant with respect to any and all damage to, or destruction of, any part of the Premises, the Building or any other portion of the Project, and any statute or regulation in which the Project is located, including, without limitation, Sections 1932(2) and 1933(4) of the California Civil Code, with respect to any rights or obligations concerning damage or destruction in the absence of such statute or regulation, between the parties, and any other statute or regulation, now or hereafter in effect, shall have no application to this Lease or any damage or destruction to all or any part of the Premises, the Building or any other portion of the Project.

**ARTICLE 12**

**CONDEMNATION**

4.1 Permanent Taking. If the whole or any part of the Premises, Building or Project shall be taken by power of eminent domain or condemned by any competent authority for any public or quasi-public use, or condemned, or reconfigured or vacated by such authority in such manner as to require the use, reconstruction or remodeling of any part of the Premises, Building or Project, or if Landlord shall grant condemnation, Landlord shall have the option to terminate this Lease upon ninety (90) days' notice, provided such notice is given no later than one hundred eighty (180) days after the date of such taking, condemnation or taking, five percent (25%) of the rentable square feet of the Premises is taken, or if access to the Premises is substantially impaired, Tenant shall have the option to terminate this Lease upon ninety (90) days' notice, provided such notice is given no later than one hundred eighty (180) days after the date of such taking. Landlord shall be entitled to receive the entire award or payment in connection therewith, except that Tenant shall have the right to file any separate claim available to Tenant for any taking of Tenant's personal property or loss of business by reason of the taking, lessor with respect to the Project or its mortgagee, and such claim is payable separately to Tenant. All Rent shall be apportioned as of the date of such termination, or the date of such taking, whichever shall first occur. If any part of the Premises shall be taken, and this Lease shall not be so terminated, the Base Rent and Tenant's Share of Operating Expenses, Tax Expenses and Utilities Costs shall be proportionately abated. Tenant hereby waives any and all rights it might otherwise have pursuant to Section 1265.130 of the California Code of Civil Procedure.

4.2 Temporary Taking. Notwithstanding anything to the contrary contained in this Article 12, in the event of a temporary taking (180) days or less, then this Lease shall not terminate but the Base Rent and Tenant's Share of Operating Expenses, Tax Expenses and Utilities Costs shall be abated for the period of such taking in proportion to the rent then payable. If the temporary taking exceeds (180) days, then this Lease shall terminate on the date of the expiration of the temporary taking and Tenant shall be entitled to receive the entire award made in connection with any such temporary taking.

#### ARTICLE 13

##### COVENANT OF QUIET ENJOYMENT

Landlord covenants that Tenant, on paying the Rent, charges for services and other payments herein reserved and on keeping, observing and performing all the other terms, covenants, conditions, provisions and agreements herein contained on the part of Tenant to be kept, observed and performed, shall, during the Lease Term, peaceably and quietly have, hold and enjoy the Premises subject to the terms, covenants, conditions, provisions and agreements hereof without interference by any persons lawfully claiming by or through Landlord. The foregoing covenant is in lieu of any other covenant express or implied.

#### ARTICLE 14

##### ASSIGNMENT AND SUBLETTING

4.1 Transfers. Tenant shall not, without the prior written consent of Landlord, assign, mortgage, pledge, hypothecate, encumber, or permit any lien to attach to, or otherwise transfer, this Lease or any part thereof, or permit the use of the Premises by any persons other than Tenant and its employees (all of the foregoing are hereinafter sometimes referred to collectively as a "**Transferee**"). If Tenant shall desire Landlord's consent to any Transfer, Tenant shall notify Landlord in writing, which notice (the "**Transfer Notice**") shall include (i) the proposed effective date of the Transfer, (ii) a description of the portion of the Premises to be transferred (the "**Subject Space**"), (iii) all of the terms of the proposed Transfer, the name and address of the proposed Transferee, and a copy of the proposed Transfer, and (iv) current financial statements of the proposed Transferee certified by an officer, partner or owner of the proposed Transferee. Landlord's consent shall, at Landlord's option, be null, void and of no effect, and shall, at Landlord's option, constitute a default by Tenant under this Lease. Each time Tenant requests Landlord's consent to a proposed Transfer, Tenant shall pay to Landlord One Thousand Five Hundred Dollars (\$1,500.00) to reimburse Landlord for its review and processing fees, and Tenant shall also reimburse Landlord for any reasonable costs incurred by Landlord in connection with the proposed Transfer. Section 14.1, so long as Tenant delivers to Landlord (i) at least fifteen (15) business days prior written notice of its intention to assign or sublease the Premises to any Permitted Transferee, which notice shall be effectuated, and (iii) such other information concerning the Permitted Transferee as Landlord may reasonably require, including without limitation, information regarding any change in the proposed use of the proposed subject portion of the Premises is in made under this Lease and do not involve the use or storage of any Hazardous Materials (other than nominal amounts of ordinary household cleaners, office supplies and janitorial supplies which are not regulated by with standard commercial real estate accounting practices (but excluding goodwill as an asset), which is equal to or greater than Tenant as of the date of this Lease, then Tenant may assign this Lease or sublease any of Tenant, without having to obtain the prior written consent of Landlord thereto (each such transfer shall be referred to herein as a "**Permitted Transfer**" and each transferee pursuant to a Permitted Transfer shall be jointly and severally liable to Tenant in the event of any default by the transferee under this Lease and such assignee or sublessee shall be jointly and severally liable to Tenant in the event of any default by the transferee under this Lease. The term "control" as used in the immediately preceding sentence shall mean having direct ownership of fifty percent (50%) or more of the capital stock of the entity controlled by, under control with, or in control of Tenant.

4.2 Landlord's Consent. Landlord shall not unreasonably withhold its consent to any proposed Transfer of the Subject Space to the Transferee on the terms specified in the Transfer Notice. The parties hereby agree that it shall be reasonable under this Lease and under any applicable law for Landlord to withhold its consent to any proposed Transfer where one or more of the following apply, without limitation as to other reasonable grounds for withholding consent:

- 4.2.1 The Transferee is of a character or reputation or engaged in a business which is not consistent with the quality of the Building or Project;

under this Lease;  
4.2.2

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The Transferee intends to use the Subject Space for purposes which are not permitted

4.2.3 The Transferee is either a governmental agency or instrumentality thereof;

4.2.4 The Transfer will result in more than a reasonable and safe number of occupants per floor within the Subject Space;

4.2.5 The Transferee is not a party of reasonable financial worth stability that has and will continue to have sufficient financial strength to perform all of the remaining obligations of Tenant under the Lease (or under the sublease in the case of a sublease) from and after the date of by Landlord taking into account all relevant facts and circumstances;

4.2.6 The proposed Transfer would cause Landlord to be in violation of another lease or agreement to which Landlord is a party, or would give an occupant of the Project a right to cancel its lease;

4.2.7 The terms of the proposed Transfer will allow the Transferee to exercise a right of renewal, right of expansion, right of first offer, or other similar right held by Tenant (or will allow the Transferee to occupy space leased by Tenant pursuant to any such right);

4.2.8 Either the proposed Transferee, or any person or entity which directly or indirectly, controls, is controlled by, or is under common control with, the proposed Transferee, (i) is negotiating with Landlord to lease space preceding the Transfer Notice; or

4.2.9 The Transfer occurs at a time that less than eighty-five percent (85%) of the rentable square feet of the Project is leased and the rent charged by Tenant to such Transferee during the term of such Transfer, calculated by using a present value analysis, is less than eighty-five percent (85%) of the rent being quoted by Landlord at the time of such Transfer, for comparable space in the Project for a comparable term, calculated using a present value system.

If Landlord consents to any Transfer pursuant to the terms of this Section 14.2 (and does not exercise any recapture rights Landlord may have under Section 14.4 of this Lease), Tenant may within six (6) months, enter into such Transfer of the Premises or portion thereof, upon substantially the same terms and conditions as are set forth in the Transfer Notice furnished by Tenant to Landlord pursuant to Section 14.1 of this Lease, provided that if there are any changes in the terms and conditions from those specified in the Transfer Notice (i) such that Landlord would initially have been entitled to refuse its consent to such Transfer under this Section 14.2, or (ii) which would cause the proposed Transfer to be more favorable to the Transferee than the terms set forth in Tenant's original Transfer Notice, Tenant shall again submit the Transfer to Landlord for its approval and other action under this Article 14 (including Landlord's right of recapture, if any, under Section 14.4 of this Lease).

4.3 **Transfer Premium.** If Landlord consents to a Transfer, as a condition thereto which the parties hereby agree is reasonable, Tenant shall pay to Landlord fifty percent (50%) of any "Transfer Premium," as that term is defined in this Section 14.3, received by Tenant from such Transferee. "Transfer Premium" shall mean all rent, additional rent or other consideration payable by such Transferee in excess of the Rent and Additional Rent payable by Tenant under this Lease on a per rentable square foot basis if less than all of the Premises is transferred, after deducting the reasonable expenses incurred by Tenant for (i) any reasonable changes, alterations and improvements to the Premises in connection with the Transfer (but only to the extent approved by Landlord), and (ii) any reasonable brokerage commissions and reasonable legal fees in connection with the Transfer. "Transfer Premium" shall also include, but not be limited to, key money and bonus money paid by Transferee to Tenant in connection with such Transfer, and any payment in excess of fair market value for or for assets, fixtures, inventory, equipment, or furniture transferred by Tenant to Transferee in connection with such Transfer. No Transfer Premium shall be due or payable with respect to a Transfer to a Permitted Transferee.

4.4 **Landlord's Option as to Subject Space.** Notwithstanding anything to the contrary contained in this Article 14, except in the case of Permitted Transfer Landlord shall have the option, by giving of fifty percent (50%) or more of the Premises, the entirety of the Premises, as determined in Landlord's sole discretion. Such recapture notice shall cancel and terminate this Lease with respect to either termination shall be effective on the date that is sixty (60) days after Landlord's delivery of a recapture notice. of the number of rentable square feet retained by Tenant in proportion to the number of rentable square feet contained in the Premises, and this Lease as so amended shall continue thereafter in full force and effect, in to the proposed Transfer, Tenant shall be entitled to proceed to transfer the Subject Space to the proposed Transferee, subject to provisions of the last paragraph of Section 14.2 of this Lease.

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4.5 **Effect of Transfer.** If Landlord consents to a Transfer, (i) the terms and conditions of this Lease shall in execution, an original executed copy of all documentation pertaining to the Transfer in form reasonably acceptable to Landlord, and (iv) no Transfer relating to this Lease or agreement entered into with respect thereto any Transfer shall be found understated by more than three percent (3%), Tenant shall, within thirty (30) days after demand, pay the deficiency and Landlord's costs of such audit.

4.6 **Additional Transfers.** For purposes of this Lease, the term "Transfer" shall also include (i) if Tenant is a partnership, the withdrawal or change, voluntary, involuntary or by operation of law, of fifty percent (50%) or more of five percent or more of partnership interests, within a twelve (12) month period, or the dissolution of the partnership without immediate reconstitution thereof, and (ii) if Tenant is a closely held corporation (i.e., whose stock is not publicly held and not traded through an exchange or over the counter), (A) the dissolution, merger, consolidation or other reorganization of Tenant, (B) the sale or other transfer of more than an aggregate of fifty percent (50%) of the voting shares of Tenant (other than to immediate family members by reason of gift or death), within a twelve (12)-month period, or (C) the sale, mortgage, hypothecation or pledge of more than an aggregate of fifty percent (50%) of the value of the unencumbered assets of Tenant within a twelve (12) month period. No such deemed transfer shall give Landlord rights to recapture the Premises or receive any Transfer Premium. Notwithstanding the foregoing provisions of this Section 14.6, the sale of Tenant's common stock on a national stock exchange shall not be deemed a Transfer pursuant to this Section 14.6.

## ARTICLE 15

### **SURRENDER; OWNERSHIP AND REMOVAL OF TRADE FIXTURES**

4.1 **Surrender of Premises.** No act or thing done by Landlord or any agent or employee of Landlord during the Lease Term shall be deemed to constitute an acceptance by Landlord of a surrender of the Premises unless such intent is specifically acknowledged in a writing signed by Landlord. The delivery of keys to the Premises to Landlord or any agent or employee of Landlord shall not constitute a surrender of the Premises or effect a termination of this Lease, whether or not the keys are thereafter retained by Landlord, and notwithstanding such delivery Tenant shall be entitled to the return of such keys at any reasonable time upon request until this Lease shall have been properly terminated. The voluntary or other surrender of this Lease by Tenant, whether accepted by Landlord or not, or a mutual termination hereof, shall not work a merger, and at the option of Landlord shall operate as an assignment to Landlord of all subleases or subtenancies affecting the Premises.

4.2 **Removal of Tenant Property by Tenant.** Upon the expiration of the Lease Term, or upon any earlier termination of this Lease, Tenant shall, subject to the provisions of this Article 15, quit and sue the Premises to Landlord in as good order and condition as when Tenant took possession and as thereafter improved by Landlord and/or Tenant, reasonable wear and tear, casualty, condemnation, and repairs which the responsibility of Landlord hereunder excepted. Upon such expiration or termination, Tenant shall, without expense to Landlord, remove or cause to be removed from all debris and rubbish, and such items of furniture, equipment, standing cabinet work, and other articles of personal property owned by Tenant or installed or placed by Tenant at its expense in the Premises, and cabling, wiring or conduit (including any such cabling or wiring as Fi Network, if any) which may have been placed at the Project or within the Building by or on behalf of Tenant (including any cabling or wiring installed above the ceiling of the Premises or below the floor of the similar articles of any other persons claiming under Tenant, as Landlord may, in its sole discretion, require to be removed, and Tenant shall repair at its own expense all damage to the Premises and Building resulting

## ARTICLE 16

### **HOLDING OVER**

If Tenant holds over after the expiration of the Lease Term hereof, with or without the express or implied consent of Landlord, such tenancy shall be a tenancy at sufferance only, and shall not constitute a renewal hereof or an extension for any further term, and in such case Base Rent shall be payable at a monthly rate equal to one hundred fifty percent (150%) of the Base Rent applicable during the last rental period of the Lease Term under this Lease. Such tenancy shall be subject to every other term, covenant and agreement contained herein. Landlord hereby expressly reserves the right to require Tenant to surrender possession of the Premises to Landlord as provided in this Lease upon the expiration or other termination of this Lease. The provisions of this Article 16 shall not be deemed to limit or constitute a waiver of any other rights or remedies of Landlord provided herein or at law. If Tenant fails to surrender the Premises upon the termination or expiration of this Lease, in addition to any other liabilities to Landlord accruing therefrom, Tenant shall protect,



defend, indemnify and hold Landlord harmless from all loss, costs (including reasonable attorneys' fees) and liability resulting from such failure, including, without limiting the generality of the foregoing, any claims made by any succeeding tenant four and any lost profits to Landlord resulting therefrom.

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## ARTICLE 17

### ESTOPPEL CERTIFICATES

Within ten (10) business days following a request in writing by Landlord, Tenant shall execute and deliver to Landlord an estoppel certificate, which, as submitted by Landlord, shall be in the form as may be required by any prospective mortgagee or purchaser of the Project (or any portion thereof), indicating therein any exceptions thereto that may exist at that time, and shall also contain any other information reasonably requested by Landlord or Landlord's mortgagee or prospective mortgagee. Tenant shall execute and deliver whatever other instruments may be reasonably required for such purposes. If Tenant fails to deliver such certificate within three (3) days after Landlord's second (2<sup>nd</sup>) written request therefor, failure by Tenant to so deliver such estoppel certificate shall be a material default of the provisions of this Lease. In addition, Tenant shall be liable to Landlord, and shall indemnify Landlord from and against any loss, cost, damage or expense, incidental, consequential, or otherwise, including attorneys' fees, arising or accruing directly or indirectly, from any failure of Tenant to execute or deliver to Landlord any such estoppel certificate.

## ARTICLE 18

### SUBORDINATION

This Lease is subject and subordinate to all present and future ground or underlying leases of the Project and to the lien of any mortgages or trust deeds, now or hereafter in force against the Project, if any, extensions, modifications, consolidations and replacements thereof, and to all advances made or hereafter to be made upon the security of such mortgages or trust deeds, unless the holders of such mortgages or trust deeds, or the lessors under such ground lease or underlying leases, require in writing that this Lease be superior thereto. Tenant covenants and agrees in the event any proceedings are brought for the foreclosure of any such mortgage, or if any ground or underlying lease is terminated, to attorn, without any deductions or set-offs whatsoever, to the purchaser upon any such foreclosure sale, or to the lessor of such ground or underlying lease, as the case may be, if so requested to do so by such purchaser or lessor and to recognize such purchaser or lessor as the lessor under this Lease. Tenant shall, within five (5) days of request by Landlord, execute such further instruments or assurances as Landlord may reasonably deem necessary to evidence or confirm the subordination or superiority of this Lease to any such mortgages, trust deeds, ground leases or underlying leases. Tenant waives the provisions of any current or future statute, rule or law which may give or purport to give Tenant any right or election to terminate or otherwise adversely affect this Lease and the obligations of the Tenant hereunder in the event of any foreclosure proceeding or sale.

## ARTICLE 19

### TENANT'S DEFAULTS; LANDLORD'S REMEDIES

4.1 Events of Default by Tenant. All covenants and agreements to be kept or performed by Tenant under this Lease shall be performed by Tenant at Tenant's sole cost and expense and without any reduction of Rent. The occurrence of any of the following shall constitute a default of this Lease by Tenant:

4.1.1 Any failure by Tenant to pay any Rent or any other charge required to be paid under this Lease, or any part thereof, when due where such failure continues for three (3) days after written notice thereof from Landlord to Tenant; provided however, that any such notice shall be in lieu of, and not in addition to, any notice required under California Code of Civil Procedure Section 1161 or any similar or successor law; or

4.1.2 Any failure by Tenant to observe or perform any other provision, covenant or condition of this Lease to be observed or performed by Tenant where such failure continues for twenty (20) days after written notice thereof from Landlord to Tenant; provided however, that any such notice shall be in lieu of, and not in addition to, any notice required under California Code of Civil Procedure Section 1161 or any similar or successor law; and provided further that if the nature of such default is such that the same cannot reasonably be cured within a twenty (20) day period, Tenant shall not be deemed to be in default if it diligently commences such cure within such period and thereafter diligently proceeds to rectify and cure said default as soon as possible; or

4.1.3 Abandonment of the Premises by Tenant. Abandonment is herein defined to include, but is not limited to, any absence by Tenant from the Premises for three (3) business days or longer while in default of any material provision of this Lease.

4.2 Landlord's Remedies Upon Default. Upon the occurrence of any such default by Tenant, Landlord shall have, in addition to any other remedies available to Landlord at law or in equity, the option to pursue any one or more of the following remedies, each and all of which shall be cumulative and nonexclusive, without any notice or demand whatsoever.

4.2.1 Terminate this Lease, in which event Tenant shall immediately surrender the Premises to Landlord, and if Tenant fails to do so, Landlord may, without prejudice to any other remedy which it may have for possession or arrearages in rent, enter upon and take possession of the Premises and expel or remove Tenant and any other person who may be occupying the Premises or any part thereof, without being liable for prosecution or any claim or damages therefor; and Landlord may recover from Tenant the following:

- (i) The worth at the time of award of any unpaid rent which has been earned at the time of such termination; plus

(ii) The worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; plus

(iii) The worth at the time of award of the amount by which the unpaid rent for the balance of the Lease Term after the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; plus

(iv) Any other amount necessary to compensate Landlord for all the detriment proximately caused by Tenant's failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result therefrom, specifically including but not limited to, brokerage commissions and advertising expenses incurred, expenses of remodeling the Premises or any portion thereof for a new tenant, whether for the same or a different use, and any special concessions made to obtain a new tenant, including, without limitation, any rent abatement; and

(v) At Landlord's election, such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time by applicable law.

The term "rent" as used in this Section 19.2 shall be deemed to be and to mean all sums of every nature required to be paid by Tenant pursuant to the terms of this Lease, whether to Landlord or to others. As used in Sections 19.2.1(i) and (ii), above, the "worth at the time of award" shall be computed by allowing interest at the Interest Rate set forth in Section 4.5 of this Lease. As used in Section 19.2.1(iii) above, the "worth at the time of award plus one percent (1%)".

4.2.2 Landlord shall have the remedy described in California Civil Code Section 1951.4 (lessor may continue lease in effect after lessee's breach and abandonment and recover rent as it becomes due, if lessee has the right to sublet or assign, subject only to reasonable limitations). Accordingly, if Landlord does not elect to terminate this Lease on account of any default by Tenant, Landlord may, from time to time, without terminating this Lease, enforce all of its rights and remedies under this Lease, including the right to recover all rent as it becomes due.

4.2.3 Landlord may, but shall not be obligated to, make any such payment or perform or otherwise cure any such obligation, provision, covenant or condition on Tenant's part to be observe enter the Premises for such purposes). In the event of Tenant's failure to perform any of its obligations or covenants under this Lease, and such failure to perform poses a material risk of injury or harm to person property, then Landlord shall have the right to cure or otherwise perform such covenant or obligation at any time after such failure to perform by Tenant, whether or not any such notice or in Section 19.1 above has expired. Any such actions undertaken by Landlord pursuant to the foregoing provisions of this Section 19.2.3 shall not be deemed a waiver of Landlord's rights and remedies as a result of T and shall not release Tenant from any of its obligations under this Lease.

4.3 Payment by Tenant. Tenant shall pay to Landlord, within fifteen (15) days after delivery by Landlord to Tenant of statements therefor: (i) sums equal to expe obligations incurred by Landlord in connection with Landlord's performance or cure of any of Tenant's obligations pursuant to the provisions of Section 19.2.3 above; and (ii) sums equal to all expenditures made and in collecting or attempting to collect the Rent or in enforcing or attempting to rights of Landlord under this Lease or pursuant to law, including, without limitation, all legal fees and other amounts so expended. Tenant's obligations under this Section 19.3 shall survive the expiration or sooner te

4.4 Sublessees of Tenant. Whether or not Landlord elects to terminate this Lease of any default by Tenant, as set forth in this Article 19, Landlord shall have the right to terminate any and all subleases, licenses, concessions or other consensual arrangements for possession entered into by Tenant a or may, in Landlord's sole discretion, succeed to Tenant's interest in such subleases, licenses, concessions or arrangements. In the event of Landlord's election to succeed to Tenant's subleases, licenses, concessions or arrangements, Tenant shall, as of the date of notice by Landlord of such election, have no further right to or interest in the rent or other consideration receivable thereunder.

4.5 Waiver of Default. No waiver by Landlord of any violation or breach by Tenant of any of the terms, provisions and covenants herein contained shall be deemed or construed to constitute a wa violation or breach by Tenant of the same or any other of the terms, provisions, and covenants herein contained. Forbearance by Landlord in enforcement of one or more of the remedies a default by Tenant shall not be deemed or construed to constitute a waiver of such default. The acceptance of any Rent hereunder by Landlord following the occurrence of any default, whether or not known to Landl a waiver of any such default, except only a default in the payment of the Rent so accepted.

4.6 Efforts to Relet. For the purposes of this Article 19, Tenant's right to possession shall not be deemed to have been terminated by efforts of Landlord to relet the Premises, by its acts of maintenance or preservation with respect to the Premises, or by appointment of a receiver to protect Landlord's interests hereunder. The foregoing enumeration is not exhaustive, but merely illustrative of acts which may be performed by Landlord without terminating Tenant's right to possession.

ARTICLE 20

SECURITY DEPOSIT

Concurrent with Tenant's execution of this Lease, Tenant shall deposit with Landlord a security deposit (the "**Security Deposit**") in the amount set forth in Section 10 of the Summary. The Security Deposit as security for the faithful performance by Tenant of all the terms, covenants, and conditions of this Lease to be kept and performed by Tenant during the Lease Term. If Tenant defaults with respect to any provisions of this Lease, including, but not limited to, the provisions relating to the payment of Rent, Landlord may, but shall not be required to, use, apply or retain all or any part of the Security Deposit for the payment of any Rent or any other sum in default, or for the payment of any amount that Landlord may spend or become obligated to spend by reason of Tenant's default, or to compensate Landlord for any other loss or damage that Landlord in default. If any portion of the Security Deposit is so used or applied, Tenant shall, within five (5) business days after written demand therefor, deposit cash with Landlord in an amount sufficient to restore the Security Deposit to its original amount, and Tenant's failure to do so shall be a default under this Lease. If Tenant shall fully and faithfully perform every provision of this Lease to be performed by it, the Security Deposit, or any balance thereof, shall be returned to Tenant, or, at Landlord's option, to the last assignee of Tenant's interest hereunder, within sixty (60) days following the expiration of the Lease Term. Tenant shall not be entitled to any interest on the Security Deposit. Tenant hereby waives the provisions of Section 1950.7 of the California Civil Code, and all other provisions of law, now or hereafter in force, which provide that Landlord may claim from a security deposit only those sums reasonably necessary to remedy defaults in the payment of rent, to repair damage caused by Tenant or to clean the Premises, it being agreed that Landlord may, in addition, claim those sums reasonably necessary to compensate Landlord for any other loss or damage, foreseeable or unforeseeable, caused by the act or any officer, employee, agent or invitee of Tenant. Subject to the provisions of this Section 20, effective as of (a) the third anniversary of the Lease Commencement Date (the "**First Reduction Date**"), Tenant shall have the right to reduce the Security Deposit by the amount of Sixty-Four Thousand Six Hundred Sixty-Six Dollars (\$64,666.00), so that the from and after the First Reduction Date, the amount of the Security Deposit (as reduced hereby) shall be One Hundred Twenty-Nine Thousand Three Hundred Thirty-Four Dollars (\$129,334.00) and (b) the fourth anniversary of the Lease Commencement Date (the "**Second Reduction Date**"), Tenant shall have the right to reduce the Security Deposit by the amount of Sixty-Four Thousand Six Hundred Sixty-Six Dollars (\$64,666.00), so that the from and after the Second Reduction Date, the amount of the Security Deposit (as reduced hereby) shall be Sixty-Four Thousand Six Hundred Sixty-Eight Dollars (\$64,668.00). Notwithstanding anything to the contrary contained herein, any reduction of the Security Deposit shall only occur (i) upon the written request delivered by Tenant to Landlord on or prior to the applicable reduction date, and (ii) upon Landlord's confirmation that no default by Tenant has occurred under the Lease, after the expiration of any applicable notice and cure period, as of or prior to such reduction date. Notwithstanding anything to the contrary herein, if at any time, Tenant is in default of any of the terms, covenants or conditions of this Lease, then Tenant's right to further force or effect.

ARTICLE 21

COMPLIANCE WITH LAW

Tenant shall not do anything or suffer anything to be done in or about the Premises which will in any way conflict with any law, statute, ordinance or other governmental rule, regulation or requirement now in force or which may hereafter be enacted or promulgated. At its sole cost and expense, Tenant shall promptly comply with all such governmental measures, other than the making of structural changes or changes to the Building's life safety system (collectively the "**Excluded Changes**") except to the extent such Excluded Changes are required specifically due to Tenant's alterations to or particular manner of use of the Premises for other than general office use. In addition, Tenant shall fully comply with all present or future programs intended to manage parking, transportation or traffic in and around the Project, and in connection therewith, Tenant shall take responsible action for the transportation planning and management of all employees located at the Premises by working directly with Landlord, any governmental transportation management organization or any other transportation-related committees or entities. The judgment of any court of competent jurisdiction or the admission of Tenant in any judicial action, regardless of whether Landlord is a party thereto, that Tenant has violated any of said governmental measures, shall be conclusive of that fact as between Landlord and Tenant. For purposes of Section 1938 of the California Civil Code, Landlord hereby discloses to Tenant, and Tenant hereby acknowledges, that the Premises have not undergone inspection by a Certified Access Specialist (CASp). Subject to reimbursement as a component of Operating Expenses, Landlord shall comply with all laws that pertain to the common areas unless such item is Tenant's respons

ARTICLE 22

ENTRY BY LANDLORD

Landlord reserves the right at all reasonable times and upon reasonable notice to Tenant to enter the Premises upon at least twenty-four (24) hours advance notice to Tenant to: (i) inspect them; (ii) show the Premises to prospective purchasers, mortgagees or tenants, or to the ground or underlying lessors; (iii) to post notices of nonresponsibility; or (iv) alter, improve or repair the Premises or the Building if necessary to codes or other applicable laws, or for structural alterations, repairs or improvements to the Building, or as Landlord may otherwise reasonably desire or deem necessary. Notwithstanding anything to the contrary contained in this Article 22, Landlord may enter the Premises at any time, without notice to Tenant, in emergency situations and/or to perform janitorial or other services required of Landlord pursuant to this Lease. Any such entries shall be without the abatement of Rent and shall include the right to take such reasonable steps as required to accomplish the

stated purposes provided, however, Landlord shall use commercially reasonable efforts to minimize any unreasonable interference with Tenant's use and occupancy of the Premises as a result of any entry by Landlord under this Article 22. Tenant hereby waives any claims for damages or for any injuries or inconvenience to or interference with Tenant's business, lost profits, any loss of occupancy or quiet enjoyment of the Premises, and any other loss occasioned thereby. For each of the above purposes, Landlord shall at all times have a key with which to unlock all the doors in the Premises, excluding Tenant's vaults, safes and special security areas designated in advance by Tenant. In an emergency, Landlord shall have the right to enter without notice and use any means that Landlord may deem proper to open the doors in and to the Premises. Any entry into the Premises in the manner hereinbefore described shall not be deemed to be a forcible or unlawful entry into, or a detainer of, the Premises, or an actual or constructive eviction of Tenant from any portion of the Premises. Tenant shall have the right to have a representative of Tenant accompany Landlord during any such entry, provided, however, Landlord shall not be required to delay its entry if Tenant does not have a representative available to accompany Landlord at its intended time of entry.

**ARTICLE 23**

**TENANT PARKING**

Tenant shall have the right at all times, but not the obligation, to rent throughout the Lease Term the number of parking spaces set forth in Section 11 of the Summary, located in those portions of the Parking Facilities as may be reasonably designated by Landlord from time to time. Tenant shall pay to Landlord for the use of such parking spaces, on a monthly basis, the prevailing rate charged from time to time by Landlord or Landlord's parking operator for parking spaces in the Parking Facilities where such parking spaces are located, which prevailing rate is currently free. Notwithstanding anything to the contrary contained herein and provided that Tenant faithfully performs all of the terms and conditions of this Lease, Landlord hereby agrees to abate Tenant's obligation for any extension term. Tenant's continued right to use the parking spaces is conditioned upon Tenant abiding by all rules and regulations which are prescribed from time to time for the orderly operation and use of the Parking Facilities. Tenant shall cooperate in seeing that Tenant's employees and visitors also comply with such rules and regulations. In addition, Landlord may assign any parking spaces and/or make all or a portion of such spaces reserved or institute an attendant-assisted tandem parking program and/or valet parking program if Landlord determines in its sole discretion that such is necessary or desirable for orderly and efficient parking. Landlord specifically reserves the right, from time to time, to change the size, configuration, design, layout, location and all other aspects of the Parking Facilities, and Tenant acknowledges and agrees that Landlord, from time to time, may, without incurring any liability to Tenant and without any abatement of Rent under this Lease temporarily close-off or restrict access to the Parking Facilities, or temporarily relocate Tenant's parking spaces to other parking structures and/or surface parking areas within a reasonable distance from the Parking Facilities, for purposes of permitting or facilitating any such construction, alteration or improvements or to accommodate or facilitate renovation, alteration, construction or other modification of other improvements or structures located on the Real Property. Landlord may delegate its responsibilities hereunder to a parking operator in which case such parking operator shall have all the rights of control attributed hereby to Landlord (as well as the parking fee abatement obligation provided for above). The parking rates charged by Landlord for Tenant's parking spaces shall be exclusive of any parking tax or other charges imposed by governmental authorities in connection with the use of such parking, which taxes and/or charges shall be paid directly by Tenant or the parking users, or, if directly imposed against Landlord, Tenant shall reimburse Landlord for all such taxes and/or charges within ten (10) days after Tenant's receipt of the invoice from Landlord. The parking spaces provided to Tenant pursuant to this Article 23 are provided solely for use by Tenant's own personnel and such parking rights may not be transferred, assigned, subleased or otherwise alienated by Tenant without Landlord's prior approval.

**ARTICLE 24**

**MISCELLANEOUS PROVISIONS**

- 4.1 **Terms; Captions.** The necessary grammatical changes required to make the provisions hereof apply either to corporations or partnerships or individuals, men or women, as the case may require, shall in all cases be assumed as though in each case fully expressed. The captions of Articles and Sections are for convenience only and shall not be deemed to limit, construe, affect or alter the meaning of such Articles and Sections.
- 4.2 **Binding Effect.** Each of the provisions of this Lease shall extend to and shall, as the case may require, bind or inure to the benefit not only of Landlord and of Tenant, but also of their respective successors or assigns,
- 4.3 **No Waiver.** No waiver of any provision of this Lease shall be implied by any failure of a party to enforce any remedy on account of the violation of such provision, even if such violation shall continue subsequently, any waiver by a party of any provision of this Lease may only be in writing, and no express waiver shall affect any provision other than the one specified in such waiver and that one only for the terms specifically stated. No receipt of monies by Landlord from Tenant after the termination of this Lease shall in any way alter the length of the Lease Term or of Tenant's right of possession hereunder. If any notice shall reinstate, continue or extend the Lease Term or affect any notice given Tenant prior to the receipt of such monies, it being agreed that after the service of notice or the commencement of a suit or action for possession of the Premises, Landlord may receive and collect any Rent due, and the payment of said Rent shall not waive or affect said notice, suit or judgment.

4.4 Modification of Lease; Financials. Should any current or prospective ground lessor for the Project require a modification or modifications of this Lease, which modification or modifications will not cause an increased cost or expense to Tenant or in any other way materially and adversely affect the performance of Tenant hereunder, then and in such event, upon written notice to Tenant, Tenant agrees that this Lease may be so modified and agrees to execute whatever documents are reasonably required therefor and deliver the same to Landlord within ten (10) days following the request therefor. Should Landlord or any such current or prospective mortgagee or ground lessor require execution of a short form of Lease for recording, containing, among other customary provisions, a description of the Premises and the Lease Term, Tenant agrees to execute such short form of Lease and to deliver the same to Landlord within ten (10) days following the request therefor. In addition, upon request, Tenant shall provide to Landlord, within ten (10) days of written request (unless Tenant's stock is publically traded on a national stock exchange based in the United States of America) current financial statements for Tenant, dated as of the date of such request, certified as accurate by Tenant or, if available, audited financial statements prepared by a certified public accountant with copies of the auditor's statement. All such financial statements will be delivered to Landlord and any such lender or purchaser in confidence and shall only be used for the financial strength of Tenant.

4.5 Transfer of Landlord's Interest. Tenant acknowledges that Landlord has the right to transfer all or any portion of its interest in the Project, and Tenant shall look solely to such transferee for the performance of Landlord's obligations hereunder after the date of transfer, upon such transferee's written assumption of the matters accruing during its actual period of ownership of title to the Project. The liability of any transferee of Landlord shall be limited to the interest of such transferee in the Project and such transferee shall be entitled to look to a mortgage lender as additional security and agrees that such an assignment shall not release Landlord from its obligations hereunder and that Tenant shall continue to look to Landlord for the performance of its obligations.

4.6 Prohibition Against Recording. Except as provided in Section 24.4 of this Lease, neither this Lease, nor any memorandum, affidavit or other writing with respect thereto, shall be recorded by Tenant or by anyone acting on its behalf.

4.7 Landlord's Title; Air Rights. Landlord's title is and always shall be paramount to the title of Tenant. Nothing herein contained shall empower Tenant to do any act which can, shall or may encumber the title of Landlord. No rights to any view or to light or air over any property, whether belonging to Landlord or any other person, are granted to Tenant by this Lease.

4.8 Tenant's Signs. Tenant shall be entitled to (i) one (1) identification sign on or near the entry doors of the Premises, and (ii) for multi-tenant floors, one (1) identification or directional sign, as designated by Landlord. Landlord shall pay for the initial installation of such signs and Tenant shall pay for any changes consistent with the Landlord's Building standard signage program and shall be subject to Landlord's prior written approval, in its reasonable discretion. Upon the expiration or earlier termination of this Lease, Tenant shall remove all such signs. Except for such identification signs, Tenant may not install any signs on the exterior or roof of the Building, the Other Existing Building or the Common Areas. Any signs, window coverings or other exterior features of the Building are subject to the prior approval of Landlord, in its sole and absolute discretion.

4.9 Relationship of Parties. Nothing contained in this Lease shall be deemed or construed by the parties hereto or by any third party to create the relationship of principal and agent, partnership or any association between Landlord and Tenant, it being expressly understood and agreed that neither the method of computation of Rent nor any act of the parties hereto shall be deemed to create any relationship between Landlord and Tenant other than the relationship of landlord and tenant.

4.10 Application of Payments. Landlord shall have the right to apply payments received from Tenant pursuant to this Lease, regardless of Tenant's designation of such payments, to satisfy any accrued obligations of Tenant hereunder, in such order and amounts as Landlord, in its sole discretion, may elect.

4.11 Time of Essence. Time is of the essence of this Lease and each of its provisions.

4.12 Partial Invalidity. If any term, provision or condition contained in this Lease shall, to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such term, provision or condition to persons or circumstances other than those with respect to which it is invalid or unenforceable, shall not be affected thereby, and each and every other term, provision and condition of this Lease shall be valid and enforceable to the fullest extent possible permitted by law.

4.13 No Warranty. In executing and delivering this Lease, Tenant has not relied on any representation, including, but not limited to, any representation whatsoever as to the amount of any item comprising Additional Rent or the amount of the Additional Rent in the aggregate or that Landlord is furnishing the same services to other tenants, at all, on the same level or on the same basis, or any warranty or any statement of Landlord which is not set forth herein or in one or more of the Exhibits attached hereto.

4.14 Landlord Exculpation. It in this Lease to the contrary, and notwithstanding any applicable law to the contrary, the liability of Landlord and the Landlord Parties hereunder (including any successor landlord) and any recourse by Tenant again

4.15 Entire Agreement. It is understood and acknowledged that there are no oral agreements between the parties hereto affecting this Lease and this Lease supersedes and cancels any and all previous brochures, agreements and understandings, if any, between the parties hereto or displayed by Landlord to Tenant with respect to the subject matter thereof, and none thereof or construe this Lease. This Lease and any side letter or separate agreement executed by Landlord and Tenant in connection with this Lease and dated of even date herewith contain all of the terms, covenants, conditions of the parties relating in any manner to the rental, use and occupancy of the Premises, shall be considered to be the only agreement between the parties hereto and their representatives of the terms, covenants, conditions or provisions of this Lease can be modified, deleted or added to except in writing signed by the parties hereto. All negotiations and oral agreements acceptable to both parties included herein. There are no other representations or warranties between the parties, and all reliance with respect to representations is based totally upon the representations and agreements contained in this Lease.

4.16 Right to Lease. Landlord reserves the absolute right to effect such other tenancies in the Building, the Other Existing Building and/or in any other buildings and/or any other portions of the Project in the exercise of its sole business judgment shall determine to best promote the interests of the Project. Tenant does not rely on the fact, nor does Landlord represent, that any specific tenant or type or number of tenants shall occupy any space in the Building, the Other Existing Building or Project.

4.17 Force Majeure. Any prevention, delay or stoppage due to strikes, lockouts, labor disputes, acts of God, inability to obtain services, labor, or materials or reasonable substitutes therefor, governmental actions, civil commotions, fire or other casualty, and other causes beyond the reasonable control of the party obligated to perform, except with respect to the obligations imposed with regard to Rent and other charges to be paid by Tenant pursuant to this Lease and except with respect to Tenant's obligations under the Tenant Work Letter (collectively, the "**Force Majeure**"), notwithstanding anything to the contrary contained in this Lease, shall excuse the performance of such party for a period equal to any such prevention, delay or stoppage and, therefore, if this Lease specifies a time period for performance of an obligation of either party, that time period shall be extended by the period of any delay in such party's performance caused by a Force Majeure.

4.18 Waiver of Redemption by Tenant. Tenant hereby waives for Tenant and for all those claiming under Tenant all right now or hereafter existing to redeem by order or judgment of any court or by any legal process or writ, Tenant's right of occupancy of the Premises after any termination of this Lease.

4.19 Notices. All notices, demands, statements or communications (collectively, "**Notices**") given or required to be given by either party to the other hereunder shall be in writing, shall be sent by United States registered mail, postage prepaid, return receipt requested, or delivered personally (i) to Tenant at the appropriate address set forth in Section 5 of the Summary, or to such other place as Tenant may from time to time designate to Landlord; or (ii) to Landlord at the addresses set forth in Section 3 of the Summary, or to such other place as Landlord may from time to time designate in a Notice to Tenant. Any Notice will be deemed given on the date it is mailed as provided in this Section 24.19 or upon the date person notified of the identity and address of Landlord's mortgagee or ground or underlying lessor, Tenant shall give to such mortgagee or ground or underlying lessor written notice of any default by Tenant of this Lease by registered or certified mail, and such mortgagee or ground or underlying lessor shall be given a reasonable opportunity to cure such default prior to Tenant's exercising any remedy available to it.

4.20 Joint and Several. If there is more than one Tenant, the obligations imposed upon Tenant under this Lease shall be joint and several.

4.21 Authority. If Tenant is a corporation or partnership, each individual executing this Lease on behalf of Tenant hereby represents and warrants that Tenant is a duly formed and existing entity qualified to do business in the state in which the Project is located and that Tenant has full right and authority to execute and deliver this Lease and that each person signing on behalf of Tenant is authorized to do so. Tenant confirms that it is not in violation of any executive order or similar governmental regulation or law, which prohibits terrorism or transactions with suspected or confirmed terrorists or terrorist entities or with persons or organizations that are associated with, or that provide any form of support to, terrorists. Tenant further confirms that it will comply throughout the Term of this Lease, with all governmental laws, rules or regulations governing transactions or business dealings with any suspected or confirmed terrorists or terrorist entities, as identified from time to time by the U.S. Treasury Department's Office of Foreign Assets Control or any other applicable governmental entity.

4.22 Jury Trial; Attorneys' Fees. IF EITHER PARTY COMMENCES LITIGATION AGAINST THE OTHER FOR THE SPECIFIC PERFORMANCE OF THIS LEASE, FOR THE PARTIES HERETO AGREE TO AND HEREBY DO WAIVE ANY RIGHT TO A TRIAL BY JURY. In the event of any such commencement of litigation, the prevailing party shall be entitled to recover from the other party its reasonable attorneys' fees and costs, including reasonable costs of litigation, in connection with such litigation, and the costs of preparing and filing this Lease, and executing such judgment.

4.23 Governing Law. This Lease shall be construed and enforced in accordance with the laws of the state in which the Project is located.

4.24 Submission of Lease. Submission of this instrument for examination or signature by Tenant does not constitute a reservation of or an option for lease, and it is not effective as a lease or otherwise until execution and delivery by both Landlord and Tenant.

4.25 Brokers. Landlord and Tenant hereby warrant to each other that they have had no dealings with any real estate broker or agent in connection with the negotiation of this Lease, excepting only agents specified in Section 12 of the Summary (the "**Brokers**"), and that they know of no other real estate broker or agent who is entitled to a commission in connection with this Lease. Each party shall defend the other party against and hold the other party harmless from any and all claims, demands, losses, liabilities, lawsuits, judgments, and costs and expenses (including without limitation reasonable attorneys' fees and costs) in connection with any such claim, demand, loss, liability, lawsuit, judgment, or costs and expenses, including without limitation reasonable attorneys' fees and costs, in respect to any leasing commission or equivalent compensation alleged to be owing on account of the indemnifying party's dealings with any real estate broker or agent other than the Brokers. Tenant further represents and warrants that Tenant will not receive (i) any portion of any potential brokerage commission or finder's fee payable to the Broker in connection with this Lease, or (ii) any other form of compensation from the Broker with respect to this Lease.

4.26 Independent Covenants. This Lease shall be construed as though the covenants herein between Landlord and Tenant are independent and not dependent and Tenant hereby expressly waives the right to set aside or rescind this Lease on the basis of any breach of any covenant hereunder by Landlord or Tenant. Landlord and Tenant agree that the foregoing shall in no way impair the right of Tenant to commence a separate action against Landlord for any violation by Landlord of the provisions hereof so long as notice is first given to Landlord and any other party in writing as provided above.

4.27 Building Name and Signage. Landlord shall have the right at any time to change the name of the Building, the Other Existing Building and/or Project and to install, affix and maintain any and all signs, including without limitation signs on the exterior of the Building, the Other Existing Building and/or Project, and any signs on the interior of the Building, the Other Existing Building and/or Project, and any signs on the Project as Landlord may, in Landlord's sole discretion, desire. Tenant shall not use the names of the Building, the Other Existing Building and/or Project or use pictures or illustrations of the Building, the Other Existing Building and/or Project in advertising or other publicity, without the prior written consent of Landlord.

4.28 Building Directory. At Landlord's cost, Landlord shall include Tenant's name and location in the Building on one (1) line of the Building directory.

4.29 Landlord's Construction. It is specifically understood and agreed that Landlord has no obligation and has made no representation or warranty that the Other Existing Building, Project, or any part thereof and that no representations or warranties respecting the condition of the Premises, the Building, the Other Existing Building, and/or Project have been made by Landlord or Tenant. Landlord's sole option, renovate, improve, alter, or modify (collectively, the "**Renovations**") the Building, Premises, the Other Existing Building and/or Project, limit or eliminate access to portions of the Project, including portions of the Common Areas, or perform work in the Building, the Other Existing Building and/or Project, which work may create noise, dust or leave debris in the Building, the Other Existing Building and/or Project. Tenant hereby agrees that such Renovations and Landlord's actions in connection with such Renovations shall in no way constitute a constructive eviction of Tenant nor entitle Tenant to any abatement of Rent. Landlord shall not be liable to Tenant for any direct or indirect injury to or interference with Tenant's business arising from the Renovations, nor shall Tenant be entitled to any compensation or damages from Landlord for loss of the use of the whole or any part of the Premises or of Tenant's personal property or impairment of Tenant's business.

///continued on next page///



IN WITNESS WHEREOF, Landlord and Tenant have caused this Lease to be executed the day and date first above written.

"LANDLORD":

AG-SW HAMILTON PLAZA OWNER, L.P.,  
a Delaware limited partnership

By: AG-SW Hamilton Plaza GP, L.L.C., a Delaware limited liability company, its general partner

By: AG-SW Hamilton Plaza Holdings, L.P., a Delaware limited partnership,  
its sole member

By: AG CP IV Hamilton Plaza GP, L.L.C., a Delaware limited liability company, its general partner

By: AG Real Estate Manager, Inc., a Delaware corporation,  
its manager

By: /s/ Steven G. White Name: Steven G. White  
Vice President

Title:

"TENANT": VIVUS, INC.,  
a Delaware corporation

By: /s/ Mark Oki Name: Mark Oki

Its: CFO

By: . Name: \_\_\_\_\_

Its: \_\_\_\_\_

\*\*\* If Tenant is a CORPORATION, the authorized officers must sign on behalf of the corporation and indicate the capacity in which they are signing. The Lease must be executed by the chairman of the board, president or vice president and the chief financial officer, secretary, assistant treasurer or assistant secretary, unless the bylaws or a resolution of the board of directors shall otherwise provide, in which event, the bylaws or a resolution of the board of directors, as the case may be, must be attached to this Lease.

**EXHIBIT A**

**OUTLINE OF FLOOR PLAN OF PREMISES**

[see attached]

EXHIBIT A

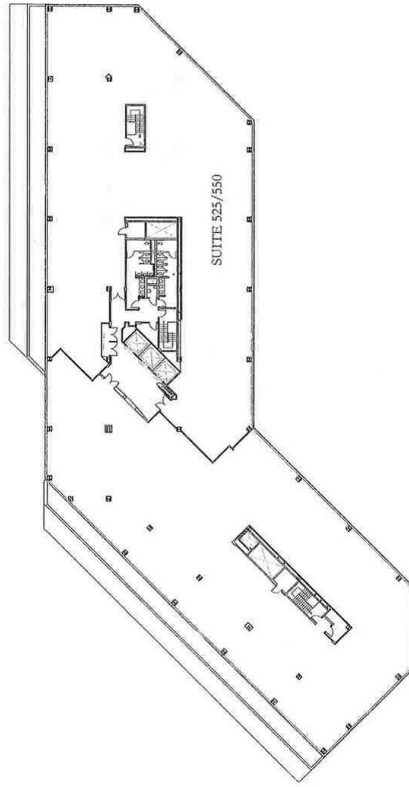
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EXHIBIT A

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EXHIBIT A  
OUTLINE OF FLOOR PLAN OF PREMISES  
900 EAST HAMILTON AVE. SUITE 525/550  
CAMPBELL, CALIFORNIA



TENANT INITIALS HERE: Wur

**EXHIBIT B**

**TENANT WORK LETTER**

This Tenant Work Letter ("**Tenant Work Letter**") sets forth the terms and conditions relating to the construction of improvements for the Premises. All references in this Tenant Work Letter to the "**Lease**" shall mean the relevant portions of the Lease to which this Tenant Work Letter is attached as Exhibit B.

**SECTION 1**

**BASE, SHELL AND CORE**

Landlord has previously constructed the base, shell and core (i) of the Premises and (ii) of the floor(s) of the Building on which the Premises are located (collectively, the "**Base, Shell and Core**"), and Tenant shall accept the Base, Shell and Core in its current "**AS-IS**" condition existing as of the date of the Lease and the Lease Commencement Date. Except for the Tenant Improvement Allowance set forth below, Landlord shall not be obligated to make or pay for any alterations or improvements to the Premises, the Building or the Project.

**SECTION 2**

**TENANT IMPROVEMENTS**

4.1 Tenant Improvement Allowance. Tenant shall be entitled to a one-time tenant improvement allowance (the "**Tenant Improvement Allowance**") in the amount of Twenty Dollars (\$20.00) per rentable square foot of the Premises (i.e., up to \$20.00 per rentable square foot). The Tenant Improvement Allowance shall be Nine Thousand Six Hundred Twenty and 00/100 Dollars (\$279,620.00), based on 13,981 rentable square feet in the Premises), for the costs relating to the initial design and construction of Tenant's improvements within the Tenant Improvement Allowance (the "**Tenant Improvements**"). In no event shall Landlord be obligated to make disbursements pursuant to this Tenant Work Letter in a total amount which exceeds the Tenant Improvement Allowance. Tenant shall not be entitled to a credit against Rent or otherwise for any portion of the Tenant Improvement Allowance which is not used to pay for the Tenant Improvement Allowance Items (as such term is defined below).

4.2 Disbursement of the Tenant Improvement Allowance. Except as otherwise set forth in this Tenant Work Letter, the Tenant Improvement Allowance shall be disbursed by Landlord (each of which disbursement shall be made pursuant to Landlord's standard disbursement process), only for the following items and costs (collectively, the "**Tenant Improvement Allowance Items**");

4.2.1 payment of the fees of the "**Architect**" and the "**Engineers**," as those terms are defined in Section 3.1 of this Tenant Work Letter, and payment of the fees incurred by, and the cost of documents and materials supplied by, Landlord and Landlord's consultants in connection with the preparation and review of the "**Construction Drawings**," as that term is defined in Section 3.1 of this Tenant Work Letter;

Improvements;

4.2.2

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the payment of plan check, permit and license fees relating to construction of the Tenant

4.2.3 the cost of construction of the Tenant Improvements, including, without limitation, contractors' fees and general conditions, testing and inspection costs, costs of utilities, trash removal, parking and hoists, and the costs of after-hours freight elevator usage;

4.2.4 the cost of any changes in the Base, Shell and Core when such changes are required by the Construction Drawings (including if such changes are due to the fact that such work is prepared on an unoccupied basis), such cost to include all direct architectural and/or engineering fees and expenses incurred in connection therewith;

4.2.5 the cost of any changes to the Construction Drawings or Tenant Improvements required by Code or any other applicable laws;

4.2.6 sales and use taxes and Title 24 fees;

4.2.7 the costs and expenses associated with complying with all national, state and local codes, including California Energy Code, Title 24, including, without limitation, all costs associated with any lighting or HVAC retrofits required thereby;

Work Letter; and

4.2.8

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EXHIBIT B  
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the "Landlord Supervision Fee," as that term is defined in Section 4.3.2 of this Tenant

4.2.9 all other costs to be expended by Landlord in connection with the construction of the Tenant Improvements.

4.3 Specifications for Building Standard Components. Landlord has established specifications (the "**Specifications**") for the Building standard components to be used in the construction of the Tenant Improvements in the Premises, which Specifications have been received by Tenant. Unless otherwise agreed to by Landlord, the

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Tenant Improvements shall comply with the Specifications. The Specifications for the Building are attached hereto as Schedule 1; provided, however, Landlord may make changes to the Specifications from time to time.

### SECTION 3

#### CONSTRUCTION DRAWINGS

4.1 Selection of Architect/Construction Drawings. Landlord shall retain an architect/space planner (the "**Architect**") to prepare the "Construction Drawings," as that term is defined in this Section consultants (the "**Engineers**") to prepare all plans and engineering working drawings relating to the structural, mechanical, electrical, plumbing, HVAC, lifesafety, and sprinkler work in the Premises. The plans Engineers hereunder shall be known collectively as the "**Construction Drawings**." Notwithstanding that any Construction Drawings are reviewed by Landlord or prepared by its Architect, Engineers and consult which may be rendered to Tenant by Landlord or Landlord's Architect, Engineers, and consultants, liability whatsoever in connection therewith and shall not be responsible for any omissions or errors contained in the Construction Drawings, and Tenant's waiver and indemnity set forth in Article 10 of the Lease sh

4.2 Final Space Plan. Within three (3) business days of the full execution and delivery of the Lease by Landlord and Tenant, Tenant shall meet with Landlord's Architect and provide Landlord's Arc preliminary layout and designation of all proposed offices, other partitioning, and their intended use and equipment to be contained therein (the "**Information**"). Landlord and Architect shall, based on such Information (subject to changes reasonably required by Landlord), Improvements in the Premises (collectively, the "**Final Space Plan**"), which Final Space Plan shall include a layout and designation of all offices, rooms and other partitioning, their intended use, and equipment to the Final Space Plan to Tenant for Tenant's approval. Tenant shall approve or reasonably disapprove the Final Space Plan or any revisions thereto within three (3) business days after Landlord delivers the Final S provided, however, that Tenant may only disapprove the Final Space Plan to the extent the same is not (subject to changes reasonably required by Landlord) in substantial conformance with the Information provide **Design Problem**). failure to disapprove the Final Space Plan for any Space Plan Design Problem or any revisions thereto by written notice to Landlord (which notice shall specify in detail the reasonable reasons for Tenant's dis Design Problem) within said three (3) business day period shall be deemed to constitute Tenant's approval of the Final Space Plan or such revisions.

4.3 Final Working Drawings. Based on the Final Space Plan, Landlord compile a fully coordinated set of architectural, structural, mechanical, electrical and plumbing working drawings in a form which is complete to allow subcontractors to bid on the work and to obtain all applicable p set forth in the Final Space Plan for any portion of the Tenant Improvements depicted thereon, the actual specifications and finish work shall be in accordance with the Specifications. Tenant shall approve or reason conformance with the Final Space Plan ("**Working Drawing Design Problem**"). Tenant's failure to reasonably disapprove the Final Working Drawings or any revisions thereto by written notice to Landlord (which r

4.4 Approved Working Drawings. The Final Working Drawings shall be approved or deemed approved by Tenant (the "**Approved Working Drawings**") prior to the commencement of t Improvements. Landlord shall cause the Architect to submit the Approved W to the applicable local governmental agency for all applicable building permits necessary to allow "Contractor," as that term is defined in Section 4.1 of this Tenant Work Letter, to commence and fully complete Improvements (the "**Permits**"). No changes, modifications or alterations in Working Drawings may be made without the prior written consent of Landlord, provided that Landlord may withhold its consent, in its sole discretion, to any change in the Approved Working Drawings, if such cha delay the Substantial Completion of the Premises and/or would result in an Over-Allowance Cap (as defined below).

4.5 Time Deadlines. Landlord and Tenant shall each use its best efforts to cooperate with Architect, the Engineers, and each other, to complete all phases of the Construction Drawings and the permitting process and to receive the Permits, and with Contractor, for approval of the "Cost Proposal," as that term is defined in Section 4.2 below as soon as possible after the execution of the Lease and, in this regard, to the extent Landlord considers such meeting(s) to be reasonably necessary, Tenant shall meet with Landlord on a weekly basis to discuss Tenant's progress in connection with the same.

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## SECTION 4

### CONSTRUCTION OF THE TENANT IMPROVEMENTS

4.1 Contractor. A contractor, under the supervision of and selected by Landlord, shall construct the Tenant Improvements (the "**Contractor**"). Selection of the Contractor shall be subject to Tenant's approval, such approval not be to unreasonably withheld, conditioned or delayed. Landlord shall give copies to Tenant of all bids for construction of the Tenant Improvements received from Contractor and all sub-contractors (to the extent sub-contractor bids are not included in the bids received from the Contractor).

4.2 Cost Proposal. After the Approved Working Drawings are signed by Landlord and Tenant, Landlord shall provide Tenant with a cost proposal in accordance with the Approved Working Drawings, which cost proposal shall include, as nearly as possible, the cost of all Tenant Improvement Allowance Items to be incurred by Tenant in connection with the construction of the Tenant Improvements (the "**Cost Proposal**"). Notwithstanding the foregoing, portions of the cost of the Tenant Improvements may be delivered to Tenant as such portions of the Tenant Improvements are priced by Contractor (on an individual item-by-item or trade-by-trade basis), even before the Approved Working Drawings are completed (the "**Partial Cost Proposal**"). Tenant shall approve and deliver the Cost Proposal to Landlord within five (5) business days of the receipt of the same (or, as to a Partial Cost Proposal, within two (2) business days of receipt of the same). The date by which Tenant must approve and deliver the Cost Proposal, or the last Partial Cost Proposal to Landlord, as the case may be, shall be known hereafter as the "**Cost Proposal Delivery Date**." The total of all Partial Cost Proposals, if any, shall be known as the Cost Proposal. Notwithstanding anything above to the contrary, if upon Landlord's delivery of any Partial or final Cost Proposal to Tenant, the Over-Allowance Amount (as defined below) is determined to be greater than an amount equal to twenty-five percent (25%) of the Tenant Improvement Allowance (the "**Over-Allowance Cap**"), then Landlord, in Landlord's sole discretion, shall have the right to revise the Approved Working Drawings and/or any other Construction Drawings (and resubmit the same to Tenant for Tenant's approval to be provided pursuant to the approval procedures and standards set forth in Section 3.3 above) to reduce the Over-Allowance Amount to an amount less than the Over-Allowance Cap and Landlord may refuse to sign any construction contract until such revisions to the Approved Working Drawings and/or any other Construction Drawings are approved by Tenant.

#### 4.3 Construction of Tenant Improvements by Landlord's Contractor under the Supervision of Landlord

4.3.1 Over-Allowance Amount. On the Cost Proposal Delivery Date, Tenant shall deliver to Landlord cash in an amount (the "**Over-Allowance Amount**") equal to the difference thereof already disbursed by Landlord, or in the process of being disbursed by Landlord, on or before the Cost Proposal Delivery Date of any then remaining portion of the Tenant Improvement Allowance, and such disbursement shall be pursuant to the same procedure as the Tenant Improvement Allowance. In the event that, after the Cost Proposal which arise in connection with such revisions, changes or substitutions shall be added to the Cost Proposal and shall be paid by Tenant to Landlord immediately upon Landlord's request to the extent such the Tenant Improvements, Landlord shall deliver to Tenant a final cost statement which shall indicate the final costs of the Tenant Improvement Allowance Items, and if such cost statement indicates that Tenant shall deliver to Landlord the amount of such underpayment or Landlord shall return to Tenant the amount of such overpayment, as the case may be.

4.3.2 Landlord Supervision. After Landlord selects the Contractor, Landlord shall independently retain Contractor to construct the Tenant Improvements in accordance with the Approved Working Drawings and the Cost Proposal and Landlord shall supervise the construction by Contractor, and Tenant shall pay a construction supervision and management fee (the "**Landlord Supervision Fee**") to Landlord in an amount equal to the product of (i) five percent (5%) and (ii) an amount equal to the Tenant Improvement Allowance plus the Over-Allowance Amount (as such Over-Allowance Amount may increase pursuant to the terms of this Tenant Work Letter). Notwithstanding the foregoing, in the event SteelWave CDS, Inc. is selected as the Contractor, then no Landlord Supervision Fee shall be payable by Tenant pursuant to this Section 4.3.2.

4.3.3 Contractor's Warranties and Guarantees. Landlord hereby assigns to Tenant all warranties and guarantees by Contractor relating to the Tenant Improvements, which assignment shall be on a non-exclusive basis such that the warranties and guarantees may be enforced by Landlord and/or Tenant, and Tenant hereby waives all claims against Landlord relating to, or arising out of the construction of, the Tenant Improvements.

## SECTION 5

### SUBSTANTIAL COMPLETION; LEASE COMMENCEMENT DATE

4.1 Substantial Completion. For purposes of the Lease, including for purposes of determining the Lease Commencement Date (as set forth in Section 7.2 of the Summary), the Premises shall be "**Ready for Occupancy**" upon Substantial Completion of the Premises. For purposes of this Lease, "**Substantial Completion**" of the Premises shall occur upon the completion of construction of the Tenant Improvements in the Premises pursuant to the Approved Working Drawings and receipt of final permit sign offs for the Tenant Improvements, with

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the exception of any punchlist items and any tenant fixtures, work-stations, built-in furniture, or equipment to be installed by Tenant or under the supervision of Contractor.

4.2 Tenant Delays. If there shall be a delay or there are delays in the Substantial Completion of the Premises (as a direct, indirect, partial, or total result of any of the following (collectively, "**Tenant Delays**")):

4.2.1  
Tenant's failure to timely approve any matter requiring Tenant's approval, including a Partial Cost Proposal or the Cost Proposal and/or Tenant's failure to timely perform any other obligation or act required of Tenant hereunder;

4.2.2 a breach by Tenant of the terms of this Tenant Work Letter or the Lease;

4.2.3 Tenant's request for changes in the Construction Drawings;

4.2.4 Tenant's requirement for materials, components, finishes or improvements which are not available in a reasonable time (based upon the anticipated date of the Lease Commencement Date);

4.2.5 changes to the Base, Shell and Core required by the Approved Working Drawings;

4.2.6 any changes in the Construction Drawings and/or the Tenant Improvements required by  
(i) applicable laws if such changes are directly attributable to Tenant's particular use of the Premises (e.g. for other than general office use) or Tenant's specialized tenant improvement(s) (as determined by Landlord), and/or  
(ii) Landlord pursuant to Section 4.2 above; or

2.2.1 any other acts or omissions of Tenant, or its agents, or employees;

then, notwithstanding anything to the contrary set forth in the Lease and regardless of the actual date of the Substantial Completion of the Premises, the Lease Commencement Date (as set forth in Section 7.2 of the Summary) shall be deemed to be the date the Lease Commencement Date would have occurred if no Tenant Delay or Delays, as set forth above, had occurred.

## **SECTION 6**

### **MISCELLANEOUS**

2.1 Tenant's Representative. Tenant has designated Roger Luong as its sole representative with respect to the matters set forth in this Tenant Work Letter, who shall have full authority and responsibility to act on behalf of the Tenant as required in this Tenant Work Letter.

2.2 Landlord's Representative. Landlord has designated Alexandra Arsenlis as its sole representative with respect to the matters set forth in this Tenant Work Letter, who, until further notice to Tenant, shall have full authority and responsibility to act on behalf of the Landlord as required in this Tenant Work Letter.

2.3 Time of the Essence in This Tenant Work Letter. Unless otherwise indicated, all references herein to a "**number of days**" shall mean and refer to calendar days. In all instances where Tenant is required to approve or deliver an item, if no written notice of approval is given or the item is not delivered within the stated time period, at Landlord's sole option, at the end of said period the item shall automatically be deemed approved or delivered by Tenant and the next succeeding time period shall commence.

2.4 Tenant's Lease Default. Notwithstanding any provision to the contrary contained in the Lease, if an event of default by Tenant as described in Section 19.1 of the Lease or any default by Tenant rights and remedies granted to Landlord pursuant to the Lease, at law and/or in equity, Landlord shall have the right to withhold payment of all or any portion of the Tenant Improvement Allowance for any delay in the Substantial Completion of the Premises caused by such work stoppage as set forth in Section 5.2 of this Tenant Work Letter, and (ii) all other obligations of Landlord under the terms of this Tenant Work Letter for any delay in the Substantial Completion of the Premises caused by such inaction by Landlord. In addition, if the Lease is terminated prior to the Lease Commencement Date, for any reason other remedies available to Landlord under the Lease, at law and/or in equity, Tenant shall pay to Landlord, as Additional Rent under the Lease, within five (5) days of receipt of a statement thereof reimbursed or otherwise paid by Tenant through the date of such termination in connection with the Tenant Improvements to the extent planned, installed and/or constructed as of such date of termination, including, but not limited to, the cost of the Leasehold Improvements.

2.5 Termination. Notwithstanding anything in the Lease (including this Tenant Work Letter) to the contrary, Tenant shall have the option to terminate the Lease by giving Tenant written notice of the exercise of such option (in which event the Lease shall cease and terminate as of the date of such notice) in the event Landlord is unable to obtain the Permits for the Tenant's use of the Premises. Upon such termination, the parties

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shall be relieved of all further obligations under the Lease except for those obligations under the Lease which expressly survive the expiration or sooner termination of the Lease.

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AMENDMENT TO LEASE

THIS AMENDMENT TO LEASE ("Amendment") is made and entered into effective as of \_\_\_\_\_, 2016, by and between AG-SW HAMILTON PLAZA OWNER, L.P., a Delaware limited partnership ("Landlord") and VIVUS, INC., a Delaware corporation ("Tenant").

RECITALS:

A. Landlord and Tenant entered into that certain Office Lease dated as of August 9, 2016 (the "Lease") pursuant to which Landlord leased to Tenant and Tenant leased from Landlord certain "Premises", as described in the Lease, in that certain Building located at 900 E. Hamilton Avenue, Campbell, California 95008.

B. Except as otherwise set forth herein, all capitalized terms used in this Amendment shall have the same meaning as such terms have in the Lease.

C. Landlord and Tenant desire to amend the Lease to confirm the commencement and expiration dates of the term, as hereinafter provided.

NOW, THEREFORE, in consideration of the foregoing Recitals and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Confirmation of Dates. The parties hereby confirm that (a) the Premises are Ready for Occupancy, and (b) the term of the Lease commenced as of \_\_\_\_\_ (the "Lease Commencement

Date") for a term of \_\_\_\_\_ terminated as provided in \_\_\_\_\_ ending on \_\_\_\_\_ the Lease).

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(unless sooner

2. No Further Modification. Except as set forth in this Amendment, all of the terms and provisions of the Lease shall remain unmodified and in full force and effect.

written.

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EXHIBIT C  
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IN  
WITNESS  
WHEREOF  
, this  
Amendmen  
t to Lease  
has been  
executed as  
of the day  
and year  
first above

"LANDLORD":

AG-SW HAMILTON PLAZA OWNER, L.P.,  
a Delaware limited partnership

By: AG-SW Hamilton Plaza GP, L.L.C., a Delaware limited liability company, its general partner

By: AG-SW Hamilton Plaza Holdings, L.P., a Delaware limited partnership,  
its sole member

By: AG CP IV Hamilton Plaza GP, L.L.C., a Delaware limited liability company, its general partner

By: AG Real Estate Manager, Inc., a Delaware corporation,  
its manager

By: Name: Title:

"TENANT": VIVUS, INC.,  
a Delaware corporation

By: **DO NOT SIGN**  
Name: Its:

By: **DO NOT SIGN**  
Name: Its:

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EXHIBIT C  
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**EXHIBIT D**

**RULES AND REGULATIONS**

Tenant shall faithfully observe and comply with the following Rules and Regulations. Landlord shall not be responsible to Tenant for the nonperformance of any of said Rules and Regulations by or otherwise with respect to the acts or omissions of any other tenants or occupants of the Building or Real Property.

1. Tenant shall not place any lock(s) on any door, or install any security system (including, without limitation, card key systems, alarms or security cameras), in the Premises or Building without Landlor to use keys or other access codes or devices to all locks and/or security system within and into the Premises, other than secured areas and vaults. A reasonable number of keys to the locks on the entry doors in the Pre to Landlord at the expiration or early termination of this Lease. Further, if and to the extent Tenant re-keys, re-programs or otherwise changes any locks at the Project, Tenant shall be obligated to restore all such lock
2. All doors opening to public corridors shall be kept closed at all times except for normal ingress and egress to the Premises, unless electrical hold backs have been installed. Sidewalks, doorways, vestibules, halls, stairways and other similar areas shall not be obstructed by Tenant or used by Tenant for any purpose other than ingress and egress to and from the Premises.
3. Landlord reserves the right to close and keep locked all entrance and exit doors of the Building during such hours as are customary for comparable buildings in the vicinity of the Building. Tenant, its employees and agents must be sure that the doors to the Building are securely closed and locked when leaving the Premises if it is after the normal hours of business for the Building. Any tenant, its employees, agents or any other persons entering or leaving the Building at any time when it is so locked, or any time when it is considered to be after normal business hours for the Building, may be required to sign the Building register when so doing. After-hours access by Tenant's authorized employees may be provided by hard-key, card-key access or other procedures adopted by Landlord from time to time; Tenant shall pay for the costs of all access cards provided to Tenant's employees and all replacements thereof for lost, stolen or damaged cards. Access to the Building and/or Real Property may be refused unless the person seeking access has proper identification or has a previously arranged pass for such access. Landlord and its agents shall in no case be liable for damages for any error with regard to the admission to or exclusion from the Building and/or Real Property of any person. In case of invasion, mob, riot, public excitement, or other commotion, Landlord reserves the right to prevent access to the Building and/or Real Property during the continuance of same by any means it deems appropriate for the safety and protection of life and property.
4. Landlord shall have the right to prescribe the weight, size and position of all safes and other heavy property brought into the Building. Safes and other heavy objects shall, if considered necessary by L thickness as is necessary to properly distribute the weight. Landlord will not for loss of or damage to any such safe or property in any case. All damage done to any part of the Building, its contents, occupants or visitors by moving or maintaining any such safe or other property shall and any expense of said damage or injury shall be borne by Tenant.
5. No furniture, freight, packages, supplies removed from the Building or carried up or down in the elevators, except upon prior notice to Landlord, and in such manner, in such specific elevator, and between such hours as shall be designated by Lanc shall assume all risk for damage to articles moved and injury to any persons resulting from the activity. If equipment, property, or personnel of Landlord or of any other party is damaged or injured as a resul
6. Landlord shall have the right to control and operate the public portions of the Building and Real Property, the public facilities, the heating and air conditioning, and any other facilities furnished for the common use of tenants, in such manner as is customary for comparable buildings in the vicinity of the Building.
7. No signs, advertisements or notices shall be painted or affixed to windows, doors or other parts of the Building, except those of such color, size, style and in such places as are first approved in writing by Landlord. All tenant identification and suite numbers at the entrance to the Premises shall be installed by Landlord, at Tenant's cost and expense, using the standard graphics for the Building. Landlord may provide and maintain in the first floor (main lobby) of the Building an alphabetical directory board or other directory device listing tenants, and no other directory shall be permitted unless previously consented to by Landlord in writing.
8. The requirements of Tenant will be attended to only upon application at the management office of the Real Property or at such office location designated by Landlord.
9. Tenant shall not disturb, solicit, or canvass any occupant of the Building or Real Property and shall cooperate with Landlord or Landlord's agents to prevent same.

10. The toilet rooms, urinals, wash bowls and other apparatus shall not be used for any purpose other than that

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for which they were constructed, and no foreign substance of any kind whatsoever shall be thrown therein. The expense of any breakage, stoppage or damage resulting from the violation of this rule shall be borne by the tenant who, or whose employees or agents, shall have caused it.

11. Tenant shall not overload the floor of the Premises. Tenant shall not mark, drive nails or screws, or drill into the partitions, woodwork or plaster or in any way deface the Premises or any part thereof without Landlord's prior written consent. Tenant shall not place pictures and other normal office wall hangings on the interior walls of the Premises (but at the end of the Term, Tenant shall repair any holes and other damage to the Premises resulting therefrom subject to the prior written consent of Landlord).
12. Except for vending machines intended for the sole use of Tenant's employees and invitees, no vending machine or machines of any description other than fractional horsepower office machines shall be installed, maintained or operated upon the Premises without the written consent of Landlord. Tenant shall not install, operate or maintain in the Premises or in any other area of the Building, electrical equipment that would overload the electrical system beyond its capacity for proper, efficient and safe operation as determined solely by Landlord.
13. Tenant shall not use any method of heating or air conditioning other than that which may be supplied by Landlord, without the prior written consent of Landlord. Tenant shall not furnish cooling or heating to the Premises, including, without limitation, the use of electronic or gas heating devices, portable coolers (such as "move n cools") or space heaters, without Landlord's prior written consent, and any such approval will be for devices that meet federal, state and local code.
14. No inflammable, explosive or dangerous fluids or substances shall be used or kept by Tenant in the Premises, Building or about the Property, except for those substances as are typically found in similar premises used for general office purposes and are being used by Tenant in a safe manner and in accordance with all applicable Laws, rules and regulations. Tenant shall not, without Landlord's prior written consent, use, store, install, spill, remove, release or dispose of, within or about the Premises or any other portion of the Property, any asbestos- containing materials or any solid, liquid or gaseous material now or subsequently considered toxic or hazardous under the provisions of 42 U.S.C. Section 9601 et seq. or any other applicable environmental Laws which may now or later be in effect. Tenant shall comply with all Laws pertaining to and governing the use of these materials by Tenant, and shall remain solely liable for the costs of abatement and removal.
15. Tenant shall not use, keep or permit to be used or kept, any foul or noxious gas or substance in or on the Premises, or permit or allow the Premises to be occupied or used in a manner offensive or objectionable to Landlord or other occupants of the Building or Real Property by reason of noise, odors, or vibrations, or interfere in any way with other tenants or those having business therewith.
16. Tenant shall not bring into or keep within the Real Property, the Building or the Premises any animals (except those assisting handicapped persons), birds, fish tanks, bicycles or other vehicles.
17. Tenant shall not use or occupy the Premises in any manner or for any purpose which might injure the reputation or impair the present or future value of the Premises or the Building. Tenant shall not use, or permit any part of the Premises to be used, for lodging, sleeping or for any illegal purpose.
18. No cooking shall be done or permitted by Tenant on the Premises, nor shall the Premises be used for the storage of merchandise, for lodging or for any improper, approved equipment and microwave ovens may be used in the Premises for heating food and brewing coffee, tea, hot chocolate and similar beverages, provided that such use is in accordance with all applicable Laws and Regulations.
19. Landlord will approve where and how telephone and telegraph wires and other equipment shall be introduced to the Premises. No boring or cutting for wires shall be allowed without the consent of Landlord. The location of telephone, call boxes and other office equipment and/or systems affixed to the Premises shall be subject to the prior written consent of Landlord. Tenant shall not use more than its proportionate share of telephone lines and other telecommunication facilities available to service the Building.
20. Landlord reserves the right to exclude or expel from the Building and/or Real Property any person who, in the judgment of Landlord, is intoxicated or under the influence of liquor or drugs, or who shall in any manner do any act in violation of any of these Rules and Regulations or cause harm to Building occupants and/or property.
21. All contractors, contractor's representatives and installation technicians performing work in the Building shall be subject to Landlord's prior approval, which approval shall not be unreasonably withheld, and shall be required to comply with Landlord's standard rules, regulations, policies and procedures, which may be revised from time to time.
22. Tenant, its employees and agents shall not loiter in the entrances or corridors, nor in any way obstruct the sidewalks, lobby, halls, stairways or elevators, and shall use the same only as a means of ingress and egress for the Premises.
23. Tenant at all times shall maintain the entire Premises in a neat and clean, first class condition, free of debris. Tenant shall not place items, including, without limitation, any boxes, files, trash receptacles or loose cabling or wiring, in or near any window to the Premises which would be visible anywhere from the exterior of the Building.

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Premises.

24. Tenant shall not waste electricity, water or air conditioning and agrees to cooperate fully with Landlord to ensure the most effective operation of the Building's heating, including, without limitation, the use of window blinds to block solar heat load, and shall refrain from attempting to adjust any controls. Tenant shall comply with and participate in any program for metering or other and services, including, without limitation, programs requiring the disclosure or reporting of the use of any utilities or services. Tenant shall also cooperate and comply with, participate in, and assist in the implementation of any conservation, sustainability, recycling, energy efficiency, and waste reduction programs, environmental protection efforts and/or other programs from time to time at the Building and/or the Real Property, including, without limitation, any required reporting, disclosure, rating or compliance system or program (including LEED [Leadership in Energy and Environmental Design] rating or compliance system, including those currently coordinated through the U.S. Green Building Council).

25. Tenant shall store all its recyclables, trash and garbage within the interior of the Premises. No material shall be placed in the trash boxes or receptacles if such material is of such nature that it may not be disposed of in the ordinary and customary manner of removing and disposing of recyclables, trash and garbage in the building in which the Real Property is located without violation of any law or ordinance governing such disposal. All trash, garbage and refuse disposal shall be made only through entry-ways and elevators provided for such purposes at such times as Landlord shall designate.

26. Tenant shall comply with all safety, fire protection and evacuation procedures and regulations established by Landlord or any governmental agency.

27. Tenant shall assume any and all responsibility for protecting the Premises from theft, robbery and pilferage, which includes keeping doors locked and other means of entry to the Premises closed, when the Premises is unoccupied or when the Premises' entry is not manned by Tenant on a regular basis.

28. No awnings or other projection shall be attached to the outside walls of the Building without the prior written consent of Landlord. No curtains, blinds, shades or screens shall be attached to or hung in, or placed on the windowsills. All electrical ceiling fixtures hung in offices or spaces along the perimeter of the Building must be fluorescent and/or of a quality, type, design and bulb color approved by Landlord.

29. The washing and/or detailing of or, the installation of windshields, radios, telephones in or general work on, automobiles shall not be allowed on the Real Property, except under specific arrangement with Landlord.

30. Food vendors shall be allowed in the Building upon receipt of a written request from the Tenant. The food vendor shall service only the tenants that have a written request on file in the management office. The food vendor shall display their products in a public or Common Area including corridors and elevator lobbies. Any failure to comply with this rule shall result in immediate permanent withdrawal of the vendor's access to the Building. The food vendor shall obtain ice, drinking water, barbering, shoe polishing, floor polishing, cleaning, janitorial, plant care or other similar services only from vendors who have registered with the Building office and who have been approved by Landlord.

31. Tenant must comply with requests by the Landlord concerning the informing of their employees of items of importance to the Landlord.

32. Tenant shall comply with any non-smoking ordinance adopted by any applicable governmental authority. Neither Tenant nor its agents, employees, contractors, guests or invitees shall smoke or permit smoking in the Common Areas, unless the Common Areas have been declared a designated smoking area by Landlord, nor shall the above parties allow smoke from the Premises to emanate into the Common Areas or any other part of the Building. Landlord shall have the right to designate the Building (including the Premises) as a non-smoking building.

33. Tenant shall not take any action which would violate Landlord's labor contracts or which would cause a work stoppage, picketing, labor disruption or dispute, or interfere with Landlord's or any other tenant's or occupant's business or with the rights and privileges of any person lawfully in the Building ("**Labor Disruption**"). Tenant shall take the actions necessary to resolve the Labor Disruption, and shall have pickets removed and, at the request of Landlord, immediately terminate any work in the Premises that gave rise to the Labor Disruption, until Landlord gives its written consent for the work to resume. Tenant shall have no claim for damages against Landlord or and its trustees, members, principals, beneficiaries, partners, officers, directors, employees, Mortgagees, or agents.

34. No tents, shacks, temporary or permanent structures of any kind shall be allowed on the Real Property. No personal belongings may be left unattended in any Common Areas.

35. Landlord shall have the right to prohibit the use of the name of the Building or any other publicity by Tenant that in Landlord's sole opinion may impair the reputation of the Building or its desirability. Upon request from Landlord, Tenant shall refrain from and discontinue such publicity immediately.

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36. Landlord shall have the right to designate and approve standard window coverings for the Premises and to establish rules to assure that the Building presents a uniform exterior appearance. Tenant shall ensure, to the extent reasonably practicable, that window coverings are closed on windows in the Premises while they are exposed to the direct rays of the sun.

37. The work of cleaning personnel shall not be hindered by Tenant after 5:30 P.M., and cleaning work may be done at any time when the offices are vacant. Windows, doors and fixtures may be cleaned at any time. Tenant shall provide adequate waste and rubbish receptacles to prevent unreasonable hardship to the cleaning service.

**PARKING RULES AND REGULATIONS**

- (i) Landlord reserves the right to establish and reasonably change the hours for the parking areas, on a non- discriminatory basis, from time to time. Tenant shall not store or permit its employees to store any a with prior notice thereof designating the license plate number and model of such automobile.
- (ii) Tenant (including Tenant's agents) will use the parking spaces solely for the purpose of parking passenger model cars, small vans and small trucks and will comply in all respects with any rules and regulations that may be promulgated by Landlord from time to time with respect to the Parking Facilities.
- (iii) Cars must be parked entirely within the stall lines painted on the floor, and only small cars may be parked in areas reserved for small cars.
- (iv) All directional signs and arrows must be observed.
- (v) The speed limit shall be 5 miles per hour.
- (vi) Parking spaces reserved for handicapped persons must be used only by vehicles properly designated.
- (vii) Parking is prohibited in all areas not expressly designated for parking, including without limitation:
  - (a) areas not striped for parking;
  - (b) aisles;
  - (c) where "no parking" signs are posted;
  - (d) ramps; and
  - (e) loading zones.
- (viii) Parking stickers, key cards or any other devices or forms of identification or entry supplied by the operator shall remain the property of the operator. Such device must be displayed as requested and may not be mutilated in any manner. The serial number of the parking identification device may not be obliterated. Parking passes and devices are not transferable and any pass or device in the possession of an unauthorized holder will be void.
- (ix) Parking managers or attendants are not authorized to make or allow any exceptions to these Rules.
- (x) Every parker is required to park and lock his/her own car.
- (xi) Loss or theft of parking pass, identification, key cards or other such devices must be reported to Landlord and to the parking manager immediately. Any parking devices reported lost or stolen found on any a be confiscated and the illegal holder will be subject to prosecution. Lost or stolen passes and devices found by Tenant or its employees must be reported to the office of the parking manager immediately.
- (xii) Washing, waxing, cleaning or servicing of any vehicle by the customer and/or his agents is prohibited. Parking spaces may be used only for parking automobiles.
- (xiii) Tenant agrees to acquaint all persons to whom Tenant assigns a parking space with these Rules.
- (xiv) Neither Landlord nor any operator of the Parking Facilities within the Project, as the same are designated and modified by Landlord, in its sole discretion, from time to time will be liable for loss of o contents of such vehicle or accessories to any such vehicle, or any property left the Parking Facilities, resulting from fire, theft, vandalism, accident, conduct of other users of the Parking Facilities and other persons, or any other casualty or cause. Further, Tenant understands and agrees that: (i) to provide any traffic control, security protection or operator for the Parking Facilities; (ii) Tenant uses the Parking Facilities at its own risk; and (iii) Landlord will not be liable for personal i of or damage to property. Tenant indemnifies and agrees to hold Landlord, any operator of the Parking Facilities and their respective agents harmless from and against any and all claims, demands, and actions arisi Facilities by Tenant and its agents, whether brought by any of such persons or any other person.
- (xv) Tenant will ensure that any vehicle parked in any of the parking spaces will be kept in proper repair and will not leak excessive amounts of oil or grease or any amount of gasoline. If any of the parking spaces are a used: (i) for any purpose other than parking as provided above; (ii) in any way or manner reasonably objectionable to Landlord; or (iii) by Tenant after default by Tenant under the Lease, Landlord, in addition to rights otherwise available to Landlord, may consider such default an event of default under the Lease.

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- (xvi) Tenant's right to use the Parking Facilities will be in common with other tenants of and reassign, from time to time, particular parking spaces for use by persons selected by Landlord, provided that Tenant's rights under the Lease are preserved. Landlord will not be liable to Tenant for any TIME PARKING (or similar designation).
- (xvii) If the Parking Facilities are damaged or destroyed, or if the use of the Parking Facilities is limited or prohibited by any governmental authority, or the use or operation of the Parking Facilities is limited or prevented by strikes or other labor difficulties or other causes beyond Landlord's control, Tenant's inability to use the parking spaces will not subject Landlord or any operator of the Parking Facilities to any liability to Tenant and will not relieve Tenant of any of its obligations under the Lease and the Lease will remain in full force and effect. Tenant will pay to Landlord upon demand, and Tenant indemnifies Landlord against, any and all loss or damage to the Parking Facilities, or any equipment, fixtures, or signs used in connection with the Parking Facilities and any adjoining buildings or structures caused by Tenant or any of its agents.
- (xviii) Tenant has no right to assign or sublicense any of its rights in the parking passes, except as part of a permitted assignment or sublease of the Lease; however, Tenant may allocate the parking passes among its employees.
- (xix) Tenant shall be responsible for the observance of all of the foregoing rules by Tenant's employees, agents, clients, customers, invitees or guests. Landlord may waive for the benefit of any particular tenant or tenants, but no such waiver by Landlord shall be construed as a waiver of such Rules and Regulations in favor of any other tenant or tenants, nor prevent Landlord as a condition of its occupancy of the Premises.

**RIDER 1**

**EXTENSION OPTION**

This Rider 1 (the "**Rider**") is incorporated as a part of that certain Office Lease dated August 9, 2016, (the "**Lease**"), by and between **AG-SW HAMILTON PLAZA OWNER, L.P.**, a Delaware limited partnership ("**Landlord**"), and **VIVUS, INC.**, a Delaware corporation ("**Tenant**"), for the leasing of those certain premises located at 900 E. Hamilton Avenue, Suites 525 and 550, Campbell, California , as more particularly described in the Lease (the "**Premises**"). Any capitalized terms used herein and not otherwise defined herein shall have the meaning ascribed to such terms as set forth in the Lease.

1. **Grant of Extension Option.** Subject to the provisions, limitations and conditions set forth in this Rider, Tenant shall have one (1) option (the "**Extension Option**") to extend the initial Lease Term for two (2) years (the "**Extension Term**").

2.

**Tenant's Extension Option Notice.** Tenant shall have the right to deliver written notice to Landlord of its intent to exercise this Extension Option (the "**Extension Option Notice**"). If Landlord does not receive the Extension Option Notice from Tenant on a date which is no earlier than fifteen (15) months and no less than twelve (12) months prior to the expiration of the initial Lease Term, all rights under this Extension Option shall automatically terminate and shall be of no further force or effect. Upon the proper exercise of this Extension Option, subject to the provisions, limitations and conditions set forth in this Rider, the Lease Term shall be extended for the Extension Term.

3. **Establishing the Initial Base Rent for the Extension Term.** The initial Base Rent for the Extension Term shall be equal to the then Fair Market Rental Rate, as hereinafter defined. As used herein, the "**Fair Market Rental Rate**" payable by Tenant for the Extension Term shall mean the Base Rent for the highest and best use for comparable space at which non-equity tenants, as of the commencement of the lease term for the Extension Term, will be leasing non-sublease, non-equity, unencumbered space comparable in size, location and quality to the Premises for a comparable term, which comparable space is located in the Building and in other comparable first- class buildings in the West Valley market area, taking into consideration all out-of-pocket concessions generally being granted at such time for such comparable space, including the condition and value of existing tenant improvements in the Premises. The Fair Market Rental Rate shall include the periodic rental increases that would be included for space leased for the period of the Extension Term.

If Landlord and Tenant are unable to agree on the Fair Market Rental Rate for the Extension Term within ten (10) days of receipt by Landlord of the Extension Option Notice for the Extension Term, Landlord or Tenant, by giving ten (10) days' written notice to the other party, can apply to the Presiding Judge of the Superior Court of the county in which the Premises is located for the selection of a third broker who meets the qualifications stated in this paragraph. Landlord and Tenant each shall bear one-half (½) of the cost of appointing the third broker and of paying the third broker's fee. The third broker, however selected, shall be a person who has not previously acted in any capacity for either Landlord or Tenant. Within fifteen (15) days after the selection of the third broker, the third broker shall select one of the two Fair Market Rental Rates submitted by the first two brokers as the Fair Market Rental Rate for the space and term at issue. The determination of the Fair Market Rental Rate by the third broker shall be conclusive and binding upon Landlord and Tenant. In no event shall the monthly Base Rent for any period of the Extension Term as determined pursuant to this Rider, be less than the highest monthly Base Rent charged during the initial term of the Lease plus an escalation amount equal to the increase in the Fair Market Rental Rate charged during the preceding term of the Lease.

Upon determination of the initial monthly Base Rent for the Extension Term in accordance with the terms outlined above, Landlord and Tenant shall immediately execute an amendment to the Lease. Such amendment shall set forth among other things, the initial monthly Base Rent for the Extension Term and the actual commencement date and expiration date of the Extension Term. Tenant shall have no other right to extend the Lease. Landlord and Tenant otherwise agree in writing.

4. **Condition of Premises and Brokerage Commissions for the Extension Term.** If Tenant timely and properly exercises this Extension Option, in strict accordance with the terms contained herein: (1) Tenant shall accept the Premises in its then "**AS-IS**" condition and, accordingly, Landlord shall not be required to perform any additional improvements to the Premises; and (2) Tenant hereby agrees that it will be solely responsible for any and all brokerage commissions and finder's fees payable to any broker now or hereafter procured or hired by Tenant or

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who otherwise claims a commission based on any act or statement of Tenant ("Tenant's Broker") in connection with the Extension Option. Tenant hereby further agrees that Landlord shall in no event or circumstance be responsible for the payment of any such commissions and fees to Tenant's Broker, and Tenant shall indemnify, defend and hold Landlord free and harmless against any liability, claim, judgment, or damages with respect thereto, including attorneys' fees and costs.

5. Limitations On, and Conditions To, Extension Option. This Extension Option is or involuntarily, separate from or as part of the Lease. At Landlord's option, all rights of Tenant under this Extension Option shall terminate and be of no force or effect if any of the following individual events occur of the Lease on the date Landlord receives the Extension Option Notice; and/or (2) Tenant has assigned its rights and obligations under all or part of to Landlord at the time the Extension Option Notice is delivered to Landlord; provided, however, that if Landlord determines that Tenant's financial condition is unacceptable, such determination must be based on g Premises pursuant to the Lease, or if the Lease has been terminated earlier, pursuant to the terms and provisions of the Lease.

6. Time is of the Essence. Time is of the essence with respect to each and every time period described in this Rider.

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EXECUTION VERSION

CONFIDENTIAL

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

LICENSE AND COMMERCIALIZATION AGREEMENT

dated as of September 30, 2016

by and between

VIVUS, INC.

and

METUCHEN PHARMACEUTICALS LLC

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## LICENSE AND COMMERCIALIZATION AGREEMENT

THIS LICENSE AND COMMERCIALIZATION AGREEMENT (the “**Agreement**”) is dated as of the 30th day of September, 2016, by and between **VIVUS, INC.**, a Delaware corporation having its principal offices at 351 E. Evelyn Ave., Mountain View, CA 94041 (“**VIVUS**”), and Metuchen Pharmaceuticals LLC, a limited liability company organized under the laws of Delaware, having a place of business at 11 Commerce Drive, 1st Floor, Cranford, New Jersey 07016 (“**Licensee**”). VIVUS and Licensee are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

### Recitals

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

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

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

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

### ARTICLE 1 DEFINITIONS

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

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

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

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

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

1.5 “**Assigned Trademarks**” means the trademark registrations and applications for registration set forth on Exhibit A.

1.6 “**Auxilium Agreement**” means the License and Commercialization Agreement, dated as of October 10, 2013, by and between VIVUS, Inc. and Auxilium Pharmaceuticals, Inc., as amended from time to time.

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

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

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 the Product, including activities directed to obtaining Pricing Approval. “**Commercialize**” has a correlative meaning.

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

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

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

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

1.15 “**Compound**” means all the compounds which are selective phosphodiesterase type-5 inhibitor, 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

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filed which is being prosecuted in good faith by or on behalf of VIVUS, MTPC or its respective Affiliate, including without limitation the compound coded as T -1790 by MTPC, chemically known as (S)-4-(3-Chloro-4-methoxybenzylamino)-2-(2-hydroxymethylpyrrolidin-1-yl)-N- pyrimidin-2-ylmethyl-5-pyrimidinecarboxamide and identified by the International Non Proprietary Name avanafil (each, a “**Compound**” and collectively, the “**Compounds**”).

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

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

1.18 “**Debtor**” has the meaning set forth in Section 12.7.

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

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

1.21 “**Effective Date**” means October 1, 2016.

1.22 “**Equity Investor**” shall have the meaning set forth in Section 2.8(a).

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

1.24 “**FDA Assessment**” has the meaning set forth in Section 5.2(b).

1.25 “**FDA-Required Studies**” has the meaning set forth in Section 4.1(a).

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

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

1.28 “**Field**” means any therapeutic use in humans.

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

1.30 “**Financing Default**” means (a) Licensee’s default under the Financing Documents, or the occurrence of an event of default under the Financing Documents, if such default or event of default gives rise to a right by a Financing Entity to exercise remedies under the Financing Documents, and (b) any of (i) a consensual resolution of such default or event of default whereby Licensee agrees to assign this Agreement and Licensee’s rights and obligations arising hereunder to a Financing Entity or a Qualified Assignee (with written notice of such resolution provided jointly by Licensee and such Financing Entity or Qualified Assignee to VIVUS), (ii) the entry of a final, non-appealable order by a court of competent jurisdiction authorizing the sale and/or assignment of this Agreement and Licensee’s rights and obligations arising hereunder to a Financing Entity or Qualified Assignee, or (iii) the exercise by a Financing Entity of its rights and remedies as a secured creditor in respect of the Debt Facility under the Financing Documents in accordance with applicable law, provided that such Financing Entity provides written notice to VIVUS of such exercise of such rights and remedies.

1.31 “**Financing Document**” means any loan, security or other agreement or agreements pursuant to which a Financing Entity provides a Debt Facility to Licensee.

1.32 “**Financing Entity**” means any Person that provides Licensee with debt financing secured by an assignment of Licensee’s contractual rights under this Agreement (including the License granted to Licensee hereunder, Licensee’s rights in and to the Product Marketing Authorization, Licensee’s right to grant sublicenses, and Licensee’s rights to appoint JSC representatives and Alliance Managers) as collateral (a “**Debt Facility**”) and each successor and assign of such Person’s rights in and to such Debt Facility (but excluding any such Person and/or such Person’s successors and/or assignees upon the exercise of remedies by such Person pursuant to the related Financing Documents). The Parties acknowledge that (i) Hercules Capital, Inc., as “Agent”, and each of the “Lenders” (as such terms are defined in the Loan and Security Agreement dated as of September 30, 2016, by and between Licensee and Hercules Capital, Inc., as Agent, and the related Loan Documents as defined therein (the “**Hercules Loan Agreements**”)), are Financing Entities and (ii) the Hercules Loan Agreements are Financing Documents.

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

1.34 “**Generic Product**” means, with respect to a Product in a given country of the Licensee Territory, any product sold in such country by a Third Party (other than a sublicensee of Licensee or any other Third Party authorized to sell such product by, or otherwise in the chain of distribution of, Licensee or a Licensee Affiliate or sublicensee) that (a) contains the same active ingredient(s) as the Product, or any base form, salt form, prodrug form, isomer, crystalline polymorph, hydrate or solvate of such active ingredients (but no additional pharmaceutically active

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ingredients beyond what is contained in the Product), and (b) is approved or registered for use in such country pursuant to any drug approval process based on reference to a Regulatory Approval for such Product held by VIVUS, Licensee or any of their respective Affiliates or sublicensees in such country or in another country.

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

1.36 “**Hetero Litigation**” means the lawsuit filed on July 27, 2016 by VIVUS in the U.S. District Court for the District of New Jersey against Hetero USA, Inc., and Hetero Labs Limited (collectively with Hetero USA, Inc. (“**Hetero**”).

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

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

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

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

1.41 “**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.

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

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

1.44 “**Joint Invention**” has the meaning set forth in Section 8.1.

1.45 “**Joint Patent**” has the meaning set forth in Section 8.3(b).

1.46 “**JSC**” has the meaning set forth in Section 3.1.

1.47 “**Knowledge of Licensee**” or any similar phrase means, with respect to any fact or matter, the actual knowledge of Greg Ford, Keith Lavan and Keith Rotenberg, after reasonable consultation with their direct reports.

1.48 “**Knowledge of VIVUS**” or any similar phrase means, with respect to any fact or matter, the actual knowledge of Seth H.Z. Fischer (Chief Executive Officer), John L. Slebir (Senior Vice President Business Development and General Counsel), Mark K. Oki (Chief Financial Officer and Chief Accounting Officer), Santosh T. Varghese (Chief Medical Officer), Ted Broman (Vice President, Chemistry, Manufacturing and Control), Deborah Larsen (Vice President, Marketing) and Sandra E. Wells (Vice President, Patents and Assistant General Counsel), after reasonable consultation with their direct reports.

1.49 “**Licensed Party**” means a Party in its capacity as licensee under the applicable licenses set forth in ARTICLE 2.

1.50 “**Licensee Indemnitees**” has the meaning set forth in Section 10.1.

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

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

1.53 “**Licensee Technology**” means the Licensee Patents and Licensee Know-How.

1.54 “**Licensee Territory**” means the United States of America and its territories and possessions, including Puerto Rico and U.S. military bases abroad (collectively, the “**United States**”), Canada, South America and India.

1.55 “**Licensee Trademarks**” has the meaning set forth in Section 8.6.

1.56 “**Licensing Party**” means a Party in its capacity as licensor under the applicable licenses set forth in ARTICLE 2.

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1.57 “**Losses**” means (a) all damages, judgments, or settlements payable to Third Parties; and (b) all legal expenses (including reasonable attorneys’ fees and disbursements, reasonable expert and witness fees, reasonable fees and costs associated with any investigations, court costs and appeal bonds).

1.58 “**Manufacturing and Supply Agreement**” means that certain Manufacturing and Supply Agreement, dated as of September 1, 2013 by and between VIVUS and Sanofi Winthroe Industrie, as amended, including, for purposes of this definition, all agreements with Sanofi Winthroe Industrie or any of its Affiliates in support of the activities contemplated by such agreement.

1.59 “**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.

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

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

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

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

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

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

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

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

(b) credits, refunds, returns or allowances actually allowed, paid, received or given, including credits, allowances, discounts and rebates to, and chargebacks from the account

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of customers for nonconforming, damaged, rejected, out-dated and returned, withdrawn or recalled Product or on account of retroactive price reductions affecting the Product;

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

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

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

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

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

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

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

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

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

1.69 "**PDE-5 Inhibitor**" means any product that operates as a phosphodiesterase type-5 inhibitor.

1.70 "**Permitted Assignment**" has the meaning set forth in Section 14.5.

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- 1.71 **“Person”** means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.
- 1.72 **“Pricing Approval”** means the approval, agreement, determination, or governmental decision establishing the price or level of reimbursement for the Product, as required in a given jurisdiction.
- 1.73 **“Product”** means pharmaceutical compositions containing the Compound, including but not limited to that drug product known as STENDRA™, in the form, formulation, and dosage strength(s) as defined in the NDA approved by the FDA as of the Effective Date and any other improvements, line extensions, delivery mechanisms, dosage strengths, formulations, or forms as may be approved in the future by the FDA, Health Canada or any other relevant Regulatory Authority in the Licensee Territory that, in each case, contain a Compound.
- 1.74 **“Product Infringement”** has the meaning set forth in Section 8.4(a).
- 1.75 **“Product Launch”** means, on a country-by-country basis, the first commercial sale of the Product in a country by Licensee 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 Licensee Territory, excluding any transfer of Product for research, test marketing, clinical trial purposes, compassionate use, or named patient arrangements.
- 1.76 **“Product Marketing Authorization”** has the meaning set forth in Section 5.1(a).
- 1.77 **“Promotion”** means those activities, including advertising, Detailing, and distributing samples of a product, normally undertaken by a pharmaceutical company that are aimed at legally marketing and promoting, and encouraging the appropriate use of, a particular prescription pharmaceutical product. **“Promote”** and **“Promotional”** have correlative meanings.
- 1.78 **“Promotional Materials”** means all training materials and all written, printed, graphic, electronic, audio or video matter, including journal advertisements, sales visual aids, leave items, formulary binders, reprints, direct mail, direct-to-consumer (**“DTC”**) advertising, Internet postings and broadcast advertisements, in each case created by Licensee or its Affiliates or on its behalf, and used or intended for use in connection with any Promotion of the Product in the Licensee Territory under this Agreement.
- 1.79 **“Prosecuting Party”** has the meaning set forth in Section 8.3(b).
- 1.80 **“PV Agreement”** has the meaning set forth in Section 5.6.
- 1.81 **“Qualified Assignee”** means a Person (a) operating in the pharmaceuticals industry that has the financial resources, technological and regulatory expertise, and operational capabilities reasonably required to perform all of Licensee’s obligations under this Agreement, and (b) for which the Licensee (or a Financing Entity or such Person) has, at least five (5) Business Days prior

to any transfer or assignment of this Agreement in accordance with the terms hereof, provided VIVUS with such information reasonably necessary to determine such Person's resources, expertise, and capabilities to perform under this Agreement.

1.82 **"Quality Agreement"** has the meaning set forth in Section 6.1.

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

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

1.85 **"Regulatory Materials"** means regulatory applications, submissions, notifications, registrations, and/or other filings made to or with a Regulatory Authority that are necessary or reasonably desirable in order to Develop, use, import, sell, offer to sell, register, market, manufacture, or otherwise Commercialize the Product in the Field for the Licensee Territory, along with any documents related to Regulatory Approval and Pricing Approvals issued by a Regulatory Authority for the Licensee Territory. Regulatory Materials include, but are not limited to, INDs, NDAs, post-marketing reports submitted to a Regulatory Authority such as those described in 21 CFR 314.81, supplemental applications, and all correspondence to or from a Regulatory Authority which reference an IND or NDA.

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

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

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

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

1.90 **"SOPS"** has the meaning set forth in Section 5.5(c).

1.91 **"Supply Chain Transfer"** has the meaning set forth in Section 6.2.

1.92 **"Supply Chain Transfer Plan"** has the meaning set forth in Section 6.2.

1.93 **"Taxes"** has the meaning set forth in Section 7.4.

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- 1.94 “**Term**” has the meaning set forth in Section 12.1.
- 1.95 “**Territory**” means the VIVUS Territory and the Licensee Territory, respectively.
- 1.96 “**Third Party**” means any legal person, entity or organization other than VIVUS, Licensee or an Affiliate of either Party, including any Governmental Authority.
- 1.97 “**Trademark Royalty Payments**” has the meaning set forth in Exhibit C.
- 1.98 “**Transition Services Agreement**” means the Transition Services Agreement, dated as of September 30th, 2016, by and between VIVUS, Inc. and Auxilium Pharmaceuticals, Inc.
- 1.99 “**United States Bankruptcy Code**” has the meaning described in Section 12.4.
- 1.100 “**VIVUS Indemnitees**” has the meaning set forth in Section 10.2.
- 1.101 “**VIVUS Know-How**” means all Information (excluding any Patents) that (a) is Controlled as of the Effective Date or during the Term by VIVUS or its Affiliates and (b) relates to any Product in the Field or the research, development, manufacture, use or sale of the Product in the Field in the Licensee Territory.
- 1.102 “**VIVUS Patents**” means the patents which are set forth in Exhibit G, and any other valid U.S. and foreign patents relating thereto, including without limitation, all substitutions, reissues, renewals, reexaminations, patents of addition, extensions, registrations, confirmations, and all pending patent applications, (including provisional applications, continuations, divisionals and continuation-in-part), which are owned or controlled by VIVUS, MTPC or their respective affiliates as of the Effective Date or during the term of this Agreement. The “VIVUS Patents” shall also include but not be limited to patents directed to new uses of the compounds claimed within the VIVUS Patents in the FIELD, and patents directed to manufacturing and formulation of the compounds claimed within the VIVUS Patents in the field unless otherwise set forth herein, which are owned or controlled by VIVUS, MTPC or their respective affiliates as of the Effective Date or during the term of this Agreement.
- 1.103 “**VIVUS Technology**” means the VIVUS Patents and VIVUS Know-How.
- 1.104 “**VIVUS Territory**” means the entire world other than the Licensee Territory.

## **ARTICLE 2**

### **LICENSES**

2.1 **License to Licensee.** Subject to the terms and conditions of this Agreement, VIVUS hereby grants to Licensee an exclusive (even as to VIVUS), royalty-bearing (subject in all respects to Section 7.2), sublicensable (subject to ARTICLE 6) license under the VIVUS Technology, (i) to use, distribute, import, Promote, market, sell, offer for sale, and otherwise Commercialize Products in the Field in the Licensee Territory; (ii) make and have made Products

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in the Manufacturing Territory, where such Product is solely for use or sale in the Field in the Licensee Territory (subject to Section 2.2), and (iii) to conduct certain Development activities on the Product in the Field pursuant to ARTICLE 4 solely in support of Regulatory Approval in the Licensee Territory (collectively, the “**License**”).

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

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

(b) In the event of a Supply Chain Transfer pursuant to Section 6.2, Licensee’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 Licensee, from time to time, until the completion of the Supply Chain Transfer pursuant to Section 6.2), in any event in accordance with and subject to the terms of the Supply Agreement.

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

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

**2.4 VIVUS Retained Rights.** Notwithstanding the rights granted to Licensee under the License, VIVUS shall retain its rights under the VIVUS Technology within the Field in the Licensee Territory, but solely to the extent necessary to (a) fulfill its obligations under this Agreement, including its manufacturing and supply obligations under ARTICLE 6 and (b) conduct research, Development, and manufacturing activities in the Licensee Territory solely in support of

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the Regulatory Approval, Pricing Approval, or Commercialization of the Product in the VIVUS Territory (including the right to grant licenses to Affiliates or Third Parties with respect to such activities); provided that any such activities in the Licensee Territory do not have, and are not reasonably expected to have, an adverse impact on the Commercialization of the Product in the Field in the Licensee Territory. VIVUS retains all rights to the VIVUS Technology outside the Field.

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

2.6 **Sublicense Agreements.**

(a) **Sublicensing by Licensee.** Licensee acknowledges that the License includes sublicenses under the rights licensed to VIVUS under the MTPC Agreement and that VIVUS is required to notify and consult with MTPC with respect to the selection of sublicensees. Consequently, the License may only be further sublicensed on condition that (i) Licensee shall have used Commercially Reasonable Efforts to promptly notify, consult with, provide all reasonably requested information and cooperate with VIVUS in good faith prior to any such sublicensing in connection with the ongoing obligation of VIVUS to notify and consult with MTPC in respect of the selection of sublicensees, (ii) provide VIVUS reasonable opportunity to so notify and consult with MTPC in respect of the selection of sublicensees, (iii) each sublicensee agrees, in writing, to use Commercially Reasonable Efforts to maximize the sale of Products, and (iv) each sublicensee agrees, in writing, to be bound by the same obligations as Licensee under this Agreement (including Section 2.8(a)); provided, further, however, that notwithstanding anything to the contrary herein or otherwise, Licensee may sublicense the License to \*\*\* at any time, subject to clauses (iii) and (iv) above. At Licensee's request, VIVUS shall use Commercially Reasonable Efforts to obtain any consents or approvals from MTPC that are required for Licensee to grant such a sublicense, it being understood that, so long as VIVUS uses such Commercially Reasonable Efforts, VIVUS shall not be responsible for any denials or delays resulting from MTPC's action or inaction. Any agreement granting a sublicense under the License shall be consistent with the terms of this Agreement and shall include confidentiality and non-use obligations no less stringent than those set forth in ARTICLE 11. Notwithstanding any sublicenses granted by Licensee hereunder, Licensee shall remain responsible for and guarantee the performance of its obligations under this Agreement.

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

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VIVUS shall remain responsible for and guarantee the performance of its obligations under this Agreement.

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

2.8 **Exclusivity.**

(a) Licensee hereby covenants that for a period of \*\*\* from the Effective Date, neither it nor its Affiliates will, directly or indirectly (including via a license to a Third Party), develop, commercialize or in-license any Competing Product in the Licensee Territory; provided, that such covenant shall not apply to any entity that is (i) an Affiliate by virtue of its equity investment in Licensee (an “**Equity Investor**”) or any Affiliate of such Equity Investor which is not otherwise an Affiliate of Licensee, and (ii) does not control the management of Licensee. For the avoidance of doubt, neither an individual non-executive member of the board of directors of Licensee, nor any entity affiliated with such individual shall, be deemed an Affiliate of Licensee for purposes of this Section 2.8(a) solely by virtue of such individual’s membership on the board of directors of Licensee. VIVUS hereby covenants that for a period of \*\*\* from the Effective Date, neither it nor its Affiliates will, directly or indirectly (including via a license to a Third Party), develop, commercialize, or in-license any Competing Product in the Licensee Territory.

(b) In the event that, during the Term, either Party or any of such Party’s Affiliates experiences a \*\*\* that results in a Third Party either (i) \*\*\* or (ii) \*\*\* (\*\*\*), and \*\*\*, immediately prior to such \*\*\*, \*\*\*, then the \*\*\* shall not be prohibited from \*\*\*, provided that the \*\*\*.

2.9 **Covenant Not To Sue.** VIVUS hereby grants to Licensee a covenant not to sue on any VIVUS Technology on account of (i) the Development, manufacture, or Commercialization of the Product in the Field in the Licensee Territory by or on behalf of Licensee, its Affiliates or sublicensees and (ii) the manufacture of the Product in the Manufacturing Territory for purposes of the activities described in the foregoing sub-clause (i), during the Term.

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

2.11 **Notice Right.** VIVUS shall provide Licensee with prompt written notice of any breach or alleged breach, including without limitation any notice of such breach or alleged breach provided by MTPC or its successor under the MTPC Agreement, of the MTPC Agreement, or by any Third Party manufacturer under any manufacturing agreement between such Third Party manufacturer and VIVUS, and shall provide Licensee with copies of any documentation and correspondence between MTPC or such Third Party manufacturer and VIVUS regarding such

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breach including written summaries of any oral discussions. In the event that VIVUS is in breach of the MTPC Agreement or such manufacturing agreement, it shall promptly provide to Licensee a written plan of action to remedy or cure such breach and shall keep Licensee promptly informed of its progress or any changes to such plan of action. VIVUS may condition disclosure of attorney-client privileged information or attorney work product on the Parties' execution of a joint defense agreement, common interest agreement, or similar agreement intended to preserve attorney-client and attorney work product privileges under Applicable Law, in a form reasonably acceptable to VIVUS.

**2.12 Transition Services.** Subject to the terms and conditions of this Agreement (including Section 12.5(e)), VIVUS hereby sells, assigns, conveys, transfers and delivers to Licensee, and Licensee hereby receives, acquires and accepts from VIVUS with effect as of the Effective Date, all of VIVUS' right, title and interest in, to and under the Transition Services Agreement, and shall assume, and shall timely perform, pay and discharge in accordance with the terms of the Transition Services Agreement all of VIVUS' liabilities and obligations thereunder. Between the execution of the Transition Services Agreement and the assignment of the Transition Services Agreement to Licensee pursuant to this Section 2.12, VIVUS will not agree to any amendment, waiver of rights, or modification of the Transition Services Agreement that has, or would reasonably be expected to have, any material negative effect or material adverse impact on the Licensee, without the prior written consent of Licensee. If the assignment of the Transition Services Agreement to Licensee pursuant to this Section 2.12 occurs after the execution date thereof, VIVUS shall use Commercially Reasonable Efforts to assist and cooperate with Licensee in connection with such assignment (including providing Licensee with the benefit of all transitional services received by VIVUS from the date of execution of the Transition Services Agreement through the Effective Date).

### **ARTICLE 3 GOVERNANCE**

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

**3.2 Meetings of the JSC.** The JSC shall meet at least once every \*\*\*, 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 written notice to the other Party. Subject to the foregoing, the JSC shall meet on such dates and at such times as agreed by the JSC and shall meet via teleconference or videoconference or, if mutually agreed by the Parties, at a location determined by the JSC. Upon prior written notice to, and approval of, the JSC, each Party may permit visitors to attend meetings of the JSC, provided that any approved visitor shall be subject to confidentiality and non-use obligations no less stringent than the terms of ARTICLE 11. Each Party shall be responsible for its own expenses for participating in the JSC. Meetings of the JSC shall be effective only if at least (1) representative of each Party is present or participating, subject to the following sentence. The Parties acknowledge and agree that VIVUS shall have the right to opt out of its

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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 Licensee shall have the right to make the decisions and take the actions previously reserved to the JSC, and shall keep VIVUS reasonably informed of its plans and activities on at least a semi-annual basis.

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

- (a) review and comment on any Development being conducted by either Party;
- (b) provide a forum for discussing any development relating to the Product being conducted by VIVUS (or its sublicensees) outside the Licensee Territory;
- (c) review and comment on marketing and sales activities being carried out by Licensee in the Licensee Territory, including review of the Commercialization and Medical Affairs Plans;
- (d) provide a forum for discussing marketing and sales activities being conducted by VIVUS (or its sublicensees) outside the Licensee Territory;
- (e) review and discuss any manufacturing or supply issues that may arise (including any issues relating to a potential Supply Disruption (as defined in the Commercial Supply Agreement), pursuant to Section 2.8 of the Commercial Supply Agreement);
- (f) 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
- (g) Perform such other functions as the Parties may agree in writing.

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

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

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

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

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

#### **ARTICLE 4 DEVELOPMENT AND COMMERCIALIZATION**

##### **4.1 Development Obligations.**

(a) **Post-Approval Studies.** Licensee shall be responsible for conducting any post-Regulatory Approval studies of Product (i) that are required by the FDA in the Licensee Territory (“**FDA-Required Studies**”) or (ii) that Licensee determines to conduct with respect to the Product in the Field in the Licensee Territory. Any and all such post-Regulatory Approval studies shall be conducted by Licensee as its sole expense. Licensee shall not be under any obligation to conduct any such additional post-Regulatory Approval studies of Product (other than the FDA-Required Studies).

(b) **Use of Data.** Each Party shall have the right, without any additional payment, to use any clinical or non-clinical data developed by or on behalf of the other Party or its Affiliates relating to the Product solely (i) to support the Regulatory Approval of Products in its

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territory (*i.e.*, the Licensee Territory for Licensee and the VIVUS Territory for VIVUS) and (iii) for Promotional, marketing, and medical education purposes in support of the Commercialization of the Product in its territory. The rights set forth in this section may be sublicensed by each Party to any Third Party collaborator or licensee in such Party's territory (or a portion thereof) who also holds Development or Commercialization rights to the Product in the Party's respective Territory.

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

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

4.3 **Commercialization Plan.**

(a) Without limiting the generality of Licensee's sole responsibility and decision-making authority for Commercializing the Product in the Field in the Licensee Territory as set forth in Section 4.2, Licensee will use its Commercially Reasonable Efforts to carry out the Commercialization of the Product in accordance with a written Commercialization Plan, as such may be amended or revised by Licensee from time to time, that describes the anticipated Commercialization activities to be performed with respect to Product in the Licensee Territory by Licensee or on its behalf by permitted Third Parties (the "**Commercialization Plan**"). Each Commercialization Plan shall address, in reasonable detail, to the extent applicable, \*\*\*.

(b) Within \*\*\* of the Effective Date, Licensee shall deliver to VIVUS a Commercialization Plan covering activities to be conducted in preparation of any Product Launch in the Licensee Territory on a country-by-country basis and during the first full calendar year following such Product Launch.

(c) Licensee shall thereafter update the Commercialization Plan (together with the Medical Affairs Plan described in Section 4.7) on an annual basis as follows: Licensee shall provide the JSC (or VIVUS in the absence of a JSC) with preliminary drafts of the Commercialization Plan and Medical Affairs Plan no later than \*\*\* of each year for the JSC's (or VIVUS' in the absence of a JSC) review and comment and Licensee shall provide the JSC (or VIVUS in the absence of a JSC) with the final Commercialization Plan and Medical Affairs Plan no later than \*\*\* of the year immediately following such year. In preparing the updated versions of the Commercialization Plan and Medical Affairs Plan, Licensee shall \*\*\*.

Licensee agrees to give due consideration to the input provided by the JSC (or VIVUS in the absence of a JSC) but Licensee at all times will retain responsibility and decision-making authority for the Commercialization of the Product in the Field in the Licensee Territory. Licensee may, at its



election, update the Commercialization Plan and Medical Affairs Plan between annual updates by following this same procedure.

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

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

#### **4.4 Commercialization by Licensee.**

(a) Licensee, itself or through its Affiliates or sublicensees, shall use Commercially Reasonable Efforts to Commercialize the Product in the Field in each country of the Licensee Territory. Without limiting the generality of the foregoing, on a country-by-country basis, Licensee shall commence a Product Launch in each country (except for the United States) of the Licensee Territory no later than the date that is \*\*\* following Licensee's receipt of Regulatory Approval in such country.

(b) Licensee shall commence a Product Launch in the United States in accordance with the quantities set forth on Schedule 4.4(b) within \*\*\* of the Effective Date. In the event that Licensee, due solely to reasons outside of its reasonable control, is unable to commence a Product Launch in the United States on or before such date, due to VIVUS, or any supplier or subcontractor of VIVUS, failing to ship to Licensee Product for sale reasonably in advance of such date, and \*\*\*, then, in addition to any other rights or remedies of Licensee under this Agreement, Licensee shall have the right to terminate this Agreement and promptly receive a return of the license fee paid by Licensee under Section 7.1. If VIVUS has complied with the terms of the above and in the event Licensee fails to commence a Product Launch in the United States within \*\*\* of the Effective Date and as a result of the failure to launch, \*\*\*, VIVUS shall, in addition to any other rights or remedies of VIVUS under this Agreement, have the right to retain the license fee paid by Licensee under Section 7.1, and VIVUS shall have no liability to Licensee as a result of \*\*\*.

#### **4.5 Sales Force.**

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

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(b) **Qualifications.** Unless otherwise agreed by the Parties, Licensee 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 Licensee Territory.

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

#### 4.6 **Promotional Materials.**

(a) Licensee shall be responsible, at its expense, for preparing and producing the then current Promotional Materials. Up to two (2) times per year Licensee shall make its core Promotional Materials available to the JSC (or VIVUS in the absence of a JSC) for its review. The Promotional Materials used by Licensee or its Affiliates or sublicensees in a particular market in the Licensee Territory shall be consistent with the Regulatory Approval in the Licensee Territory and shall in any event comply in all material respects with Applicable Law. Licensee shall use and distribute the Promotional Materials in accordance with the terms of this Agreement. To the extent that VIVUS disagrees with Promotional message or tactics proposed by Licensee for Product in the Licensee Territory, it may raise such issues with the JSC (or VIVUS in the absence of a JSC) for discussion. Licensee shall be solely responsible for timely submitting, as applicable, any Promotional Materials to the FDA's Office of Prescription Drug Promotion ("OPDP"), or to any equivalent Regulatory Authority elsewhere in the Licensee Territory (including to any applicable state governmental authorities therein). Promptly following the Effective Date, VIVUS will take such actions necessary to confirm with OPDP that Licensee is responsible for such submissions on behalf of VIVUS.

(b) Licensee shall not use or distribute in connection with Promotion of the Product any materials bearing VIVUS' name or trademarks without VIVUS' prior written approval.

(c) All Promotional Materials used or intended for use in the United States shall include MTPC's name in a form that references MTPC as the licensor, to the extent permitted by Applicable Law and is customary for such materials in the United States. Licensee shall directly provide MTPC with copies of all such Promotional Materials used or intended for use in the United States as soon as reasonably practicable after such Promotional Materials are first used. For all other countries (except for the United States) in the Licensee Territory, Licensee shall, on a country-by-country basis, first request and obtain written confirmation from VIVUS as to whether (and how) the Promotional Materials used or intended for use in each such country shall include MTPC's name, before using any such Promotional Materials in such country.

4.7 **Medical Affairs Activities.** Without limiting the generality of Licensee's sole responsibility and decision-making authority for Commercializing the Product in the Field in the Licensee Territory as set forth in Section 4.2, Licensee will use its Commercially Reasonable Efforts to carry out medical affairs activities for the Product in accordance with a written Medical Affairs Plan, as such may be amended or revised by Licensee from time to time, that describes the

anticipated medical affairs activities to be performed with respect to Product in the Licensee Territory by Licensee or on its behalf by permitted Third Parties (the "**Medical Affairs Plan**"). Each Medical Affairs Plan shall address, in reasonable detail and to the extent applicable, \*\*\*. Within \*\*\* of the Effective Date, Licensee shall deliver to VIVUS a Medical Affairs Plan covering those medical affairs activities anticipated to be conducted in preparation of any Product Launch in the Licensee Territory on a country-by-country basis and during the first full calendar year following such Product Launch.

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

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

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

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

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

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**ARTICLE 5  
REGULATORY**

**5.1 Transfer of Marketing Authorization.**

(a) **Transfer.** Subject to the terms and conditions of this Agreement, VIVUS hereby undertakes to transfer to Licensee NDA #202276 (the “**Product Marketing Authorization**”) and all other regulatory filings previously made with any Governmental Authorities in any country within the Licensee Territory that remain pending approval as of the date hereof. VIVUS shall, as soon as practicable following VIVUS’ receipt of full payment of the license fee pursuant to Section 7.1, and in any event, no later than three (3) Business Days thereafter, notify the FDA of the transfer to Licensee of the Product Marketing Authorization, and shall promptly provide a correct and complete copy of such notice of transfer to Licensee. Promptly following VIVUS’ receipt of full payment of the license fee pursuant to Section 7.1, and in any event, no later than \*\*\* thereafter, VIVUS shall provide Licensee with a complete copy of NDA #202276 and all related correspondence with the FDA. VIVUS shall use Commercially Reasonable Efforts to complete any and all other regulatory requirements necessary for such transfer in accordance with Applicable Laws. Licensee shall assist and cooperate with VIVUS in connection with such transfer. Licensee shall be responsible for out of pocket costs and expenses incurred by either Licensee or VIVUS or their Affiliates in connection with the transfer of the Product Marketing Authorization. Such payments shall be based on written invoices submitted to Licensee by VIVUS from time to time. For clarity, only the Product Marketing Authorization will be transferred to Licensee, and no patents, patent applications, or other intellectual property of VIVUS (except for the Assigned Trademarks) shall be transferred to Licensee hereunder.

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

(c) **Restriction on Further Transfer.** Licensee may not assign or transfer the Product Marketing Authorization without the prior written consent of VIVUS, except that, in connection with an assignment of this Agreement pursuant to Section 14.5 hereof, Licensee may make any such assignment or transfer without VIVUS’ consent to Licensee’s Affiliate or to a successor to all or substantially all of the assets or business of Licensee to which this Agreement pertains or to a Financing Entity (and such Financing Entity may make a further assignment to a Qualified Assignee, only in connection with an assignment of this Agreement pursuant to Section 14.5). Licensee acknowledges that a breach of this Section 5.1(c) by Licensee would constitute a material breach of this Agreement.

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

## 5.2 **Regulatory Materials and Regulatory Approvals.**

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

(b) **Costs.** Except as otherwise provided in this Agreement, each Party shall bear its own costs in connection with its performance of regulatory activities hereunder. Notwithstanding the foregoing, (i) VIVUS shall reimburse Licensee \*\*\* percent (\*\*\*) of the user fee assessed by the FDA in connection with a supplemental application for updates to the Product label to reflect the results of the spermatogenesis post-marketing required study (the “**FDA Assessment**”); provided that VIVUS’ payment hereunder shall not exceed \$\*\*\*, and (ii) VIVUS shall be responsible for any other fees payable to the FDA or any other Regulatory Authority in the Licensee Territory with respect to the Product prior to the transfer of the Product Marketing Authorization to Licensee, and Licensee shall be responsible for any fees payable to the FDA or any other Regulatory Authority in the Licensee Territory with respect to the Product after the transfer of the Product Marketing Authorization to Licensee. With respect to any fees paid by VIVUS prior to the transfer of the Product Marketing Authorization to Licensee as prepayments to the FDA or any other Regulatory Authority in the Licensee Territory with respect to the Product, Licensee shall reimburse VIVUS for the pro rata portion of such fees that are allocable to the Term of this Agreement.

(c) **Notifications; Communications with Regulatory Authorities.** During the Term, each Party shall keep the other reasonably and regularly informed of such Party’s submission to Regulatory Authorities of all material Regulatory Materials, meetings with

Regulatory Authorities, and receipt of, or any material changes to existing, Regulatory Approvals, in each case for the Product in the Licensee Territory, pursuant to procedures to be developed by the JSC (or VIVUS in the absence of a JSC). Prior to completion of the transfer of the Product Marketing Authorization to Licensee in accordance with Section 5.1, VIVUS and Licensee shall jointly make decisions with respect to the content of any communications that VIVUS makes to Regulatory Authorities regarding the Product. Following completion of transfer of the Product Marketing Authorization to Licensee in accordance with Section 5.1, Licensee 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 Licensee Territory that would reasonably be expected to have a material impact on the Commercialization of the Product in the VIVUS Territory shall require VIVUS' prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. Without limiting the first sentence of this Section 5.2(c), following completion of transfer of the Product Marketing Authorization to Licensee in accordance with Section 5.1, at VIVUS' reasonable request, Licensee shall promptly provide copies of then-current versions of any and all such Regulatory Materials and Regulatory Approvals.

### 5.3 Other Regulatory Obligations.

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

(b) Each Party shall fully cooperate with and assist the other Party in complying with any regulatory obligations with respect to the Product, or the manufacturing thereof, in the Licensee Territory.

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

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5.4 **Rights of Reference.** VIVUS hereby grants to Licensee an exclusive right of reference to all Regulatory Materials and Regulatory Approvals owned or Controlled by VIVUS solely for the purpose of obtaining or maintaining, during the Term, the Product Marketing Authorization. Licensee hereby grants to VIVUS an exclusive right of reference to all Regulatory Materials, Regulatory Approvals (including the Product Marketing Authorization), and Pricing Approvals owned or Controlled by Licensee solely for the purpose of obtaining or maintaining Regulatory Approval for Product in 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 of non-compliance with Applicable Laws that might reasonably be expected to have an impact on the Commercialization of the Product in the Territory, including any notices relating to the manufacture of the Product.

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

(c) **Product Withdrawals and Recalls.** The Parties shall exchange their internal standard operating procedures ("SOPs") for conducting product recalls reasonably in advance of Product Launch, and shall discuss and resolve any conflicts between such SOPs and issues relating thereto promptly after such exchange. In the event of any disagreement as to how to resolve any such conflicts with respect to the Product, VIVUS's SOP shall control unless and until VIVUS transfers ownership of the Product Marketing Authorization to Licensee, and Licensee's SOP shall control thereafter. If either Party becomes aware of information relating to

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the Product that indicates that a unit or batch of such Product may not conform to the specifications therefor, or that potential adulteration, misbranding, and/or other issues have arisen that relate to the safety or efficacy of Products, it shall promptly so notify the other Party. To the extent practicable, the Parties shall discuss the circumstances of any potential product recall, field correction, or withdrawal of any Product and possible appropriate courses of action. If Licensee decides to initiate a recall, field correction, or withdrawal of Product in the Licensee Territory, Licensee shall have the right and responsibility, at its expense but without limiting any claims Licensee may have against VIVUS or any other Person, to control such recall, field correction, or withdrawal in a manner consistent with its internal SOPs (as revised pursuant to the first sentence of this Section 5.5(c), if applicable); provided, however, Licensee shall consider in good faith the views of VIVUS as to whether a recall, field correction, or withdrawal is necessary or appropriate. For clarity, as between the Parties, VIVUS shall have the right, at its expense, to control all recalls, field corrections, and withdrawals of any Product in the VIVUS Territory. Each Party shall maintain complete and accurate records of any recall, field correction, or withdrawal in its territory for such periods as may be required by Applicable Laws, but in no event for less than \*\*\*. For purposes of clarity, for Product supplied by VIVUS under the Commercial Supply Agreement, the Parties' respective responsibilities for the costs of any Product recall, field correction, or withdrawal of such Product shall be as set forth in the Commercial Supply Agreement.

5.6 **PV Agreement.** Within \*\*\* of the Effective Date, the Parties shall use commercially reasonable efforts to enter into a separate pharmacovigilance agreement (the "**PV Agreement**"), containing the specific terms, conditions and obligations of the Parties with respect to the collection, reporting and monitoring of all adverse drug reactions, adverse events, medical inquiries with safety concerns, and other relevant drug safety matters with respect to Products during the Term. From the Effective Date until the date that the Parties have entered into the PV Agreement, but in no event for any period longer than \*\*\* following the Effective Date, VIVUS shall handle medical inquiries, complaints and adverse experience reporting for the Product in the United States in accordance with VIVUS' customary practice for handling such activities and using VIVUS' existing resources (including call centers).

## **ARTICLE 6 MANUFACTURING**

6.1 **Commercial Supply Agreement.** Concurrent with the execution of this Agreement, the Parties have executed (a) the manufacturing and supply agreement (the "**Commercial Supply Agreement**") attached hereto as Exhibit B, under which VIVUS has agreed to supply, itself or through \*\*\* Third Party manufacturers, bulk tablets of Product to Licensee, its Affiliates, and/or its sublicensees for Commercialization in the Field in the Licensee Territory, and (b) the quality agreement (the "**Quality Agreement**"), attached hereto as Exhibit F, which governs the agreed-upon specifications and other technical aspects of supply of such Product for Commercialization in the Field in the Licensee Territory. For the avoidance of doubt, none of VIVUS' agreements with Third Party manufacturers and suppliers for the Product shall be assigned to Licensee on the Effective Date.

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6.2 **Transition of Supply Chain.** At a time selected by Licensee, but in any event no later than \*\*\* following the Effective Date, Licensee may elect to have VIVUS transfer control of the supply chain for the Product to Licensee or its designee for the supply of Product for the Licensee Territory by assigning to Licensee VIVUS' agreement(s) with the contract manufacturer(s) in such supply chain (the "**Supply Chain Transfer**"). As promptly as practicable following written notice from Licensee that it will exercise its right to a Supply Chain Transfer, the Parties shall discuss and agree on a written plan for the Supply Chain Transfer (the "**Supply Chain Transfer Plan**"). Following agreement on such Supply Chain Transfer Plan, the Parties shall each use Commercially Reasonable Efforts to carry out their respective obligations thereunder in a timely fashion; provided, however, the Supply Chain Transfer shall only occur if and when Licensee makes the applicable election. Notwithstanding the foregoing, Licensee acknowledges that in order for VIVUS to carry out its obligations under the Supply Chain Transfer Plan, VIVUS will need to obtain certain third party consents that are outside of the control of VIVUS. Following the Supply Chain Transfer, Licensee shall pay the Third Party manufacturer of Product directly for such supply. Notwithstanding anything to the contrary herein or otherwise, VIVUS hereby acknowledges and agrees that it shall not agree or consent to any amendment, waiver of rights, or modification of any agreements that pertain to the current supply chain for the Product, including without limitation the Manufacturing and Supply Agreement, (a) that would reasonably be expected to result in (i) any non-routine increase in the Price (as defined in the Commercial Supply Agreement), (ii) any early termination of the Commercial Supply Agreement, or (iii) any increase in the Licensee's Minimum Purchase Obligations (as defined in the Commercial Supply Agreement), (b) that has, or would reasonably be expected to have, any other material negative effect or material adverse impact on the rights granted to Licensee hereunder or under the Commercial Supply Agreement or (c) that would impose additional material obligations on Licensee hereunder or under the Commercial Supply Agreement, in each case without the prior written consent of Licensee (which consent shall not to be unreasonably withheld, conditioned or delayed).

## ARTICLE 7 FINANCIALS

7.1 **License Fee.** No later than \*\*\* on \*\*\*, Licensee shall pay to VIVUS a one-time, non-refundable (subject to Section 4.4(b)), non-creditable license fee of seventy million dollars (\$70,000,000) by wire transfer of immediately available funds into an account designated in writing by VIVUS.

7.2 **Royalties under MTPC Agreement.** Licensee shall be responsible for paying the amounts and payments set forth on Exhibit C owed by VIVUS to MTPC under the MTPC Agreement on account of Net Sales of Licensee or its Affiliates or sublicensees, including the royalties on net sales owed to MTPC during the MTPC Royalty Period, trademark royalties owed to MTPC after the end of the MTPC Royalty Period, and Licensee's pro-rata share of the sales milestone, all of which are set forth in Exhibit C (the "**MTPC Payments**"). For the avoidance of doubt, the Parties acknowledge that (i) such payments to VIVUS are intended to match payments owed by VIVUS to MTPC under the MTPC Agreement, (ii) that to the extent royalties owed to MTPC are terminated or reduced (temporarily or permanently) for any reason, any royalties owed

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by Licensee to VIVUS hereunder shall be terminated or reduced (temporarily or permanently, as applicable) in an equivalent manner (and for an equivalent duration, as applicable) in all respects, (iii) except as expressly provided herein, such royalties shall not be subject to any step-down, and (iv) that the definition of “net sales” under the MTPC Agreement is different than the definition of Net Sales hereunder, and that, as a result, Licensee’s payment obligations under this Section 7.2 and Exhibit C that are based on net sales shall be determined using the definition of MTPC Agreement Net Sales contained in the MTPC Agreement.

7.3 **Royalty Payments and Reports.** Within \*\*\* after the end of each calendar \*\*\*, Licensee shall provide VIVUS with a statement of (a) the amount of gross sales of Products during the applicable calendar \*\*\*, (b) an itemized calculation of Net Sales showing Net Sales Deductions during such calendar \*\*\*, and (c) the calculation of the amount of any payment due pursuant to Section 7.2. Together with each \*\*\* statement provided pursuant to this Section 7.3, Licensee shall provide VIVUS with any payments due. All amounts payable to VIVUS under this Section 7.3 shall be paid by wire transfer of immediately available funds into an account designated in writing by VIVUS. Promptly, but no later than \*\*\*, after VIVUS’ receipt of any such payments, VIVUS shall remit such payments by wire transfer to MTPC in accordance with the terms of the MTPC Agreement, and provide Licensee with confirmation of such wire transfer.

7.4 **Taxes.** All payments made under this Agreement shall be made free and clear of withholding for Taxes (“**Withholding Taxes**”) unless such withholding is otherwise required under Applicable Law. To the extent such withholding is required under Applicable Law, Licensee shall pay such Taxes to the applicable taxing authority and shall be permitted to deduct such Taxes from applicable payments under this Agreement. Licensee will timely provide VIVUS with reasonable documentation evidencing the payment of any such Taxes to the applicable taxing authority and shall comply with any tax reporting obligations that are required under Applicable Law so as to enable VIVUS to obtain a credit of any such Tax. Notwithstanding the foregoing, to the extent that a deduction or withholding of Taxes hereunder arises as a result of any action taken by Licensee after the Effective Date that has at the time of such action the effect of modifying the Tax treatment of, or increasing the Taxes applicable to, payments hereunder, in each case relative to the Tax treatment existing as of the Effective Date (a “**Licensee Withholding Tax Action**”), including without limitation an assignment of this Agreement by Licensee or any failure on the part of Licensee to comply with Applicable Law, then, and only to the extent VIVUS is not eligible to obtain a credit of any such withholding taxes, (a) the payment by Licensee 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 Licensee Withholding Tax Action occurred, and (b) obligations set forth above with respect to making payments to the applicable taxing authority and reporting such payments to VIVUS shall apply with respect to such Additional Tax; provided that, to the extent any Additional Tax is attributable in whole or in part to any action taken by VIVUS after the Effective Date, the payment increase in subsection (a) shall be proportionately reduced to reflect the relative responsibilities of the Parties for causing the deduction or withholding of Taxes. Solely for purposes of this Section 7.4, “**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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7.5 **Late Payments.** In the event any payment due hereunder is not made when due, the payment shall accrue interest (beginning on the date such payment is due) calculated at the rate of \*\*\* percent (\*\*\*\*%) per month or the maximum rate allowable by Applicable Law, whichever is less. Such payment when made shall be accompanied by all interest so accrued.

7.6 **Records; Audits.** Licensee shall maintain complete and accurate books and records in accordance with GAAP in sufficient detail to permit VIVUS to confirm the accuracy of milestone payments, royalty payments, and any other compensation payable under this Agreement, for a period of \*\*\* from the creation of individual records or any longer period required by Applicable Law. At VIVUS' request, such records shall be available for review at Licensee's headquarters located at 11 Commerce Drive, 1st Floor, Cranford, New Jersey 07016, or a mutually agreeable location determined by Parties not more than once each calendar year covering the \*\*\* immediately preceding calendar \*\*\* (during normal business hours on a mutually agreed date with reasonable advance notice) by an independent Third Party auditor selected by VIVUS and approved by Licensee (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 Licensee pursuant to this Agreement or of any payments made by Licensee to VIVUS pursuant to this Agreement. Any such auditor shall not disclose Licensee's Confidential Information to VIVUS, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Licensee or the amount of payments due by Licensee under this Agreement. Any undisputed amounts finally determined to be owed but unpaid shall be paid within \*\*\* from the accountant's report, plus interest (as set forth in Section 7.5) from the original due date. Any amounts finally determined to have been overpaid may be credited by Licensee against future payments to VIVUS hereunder. Licensee may carry forward any unused credits to future calendar quarters; provided, that in the event there are unused credit amounts upon the termination of this Agreement or expiration of the MTPC Royalty Period, VIVUS shall promptly pay to Licensee such amounts. VIVUS shall bear the full cost of such audit unless such audit reveals an underpayment or under-reporting error of \*\*\* percent (\*\*\*\*%) or more during the applicable audit period, in which case Licensee shall bear the full cost of such audit.

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

## **ARTICLE 8 INTELLECTUAL PROPERTY**

8.1 **Ownership of Inventions.** Each Party shall own all inventions and Information made solely by its respective employees, agents, and independent contractors and its Affiliates in the course of conducting such Party's activities under this Agreement (collectively, "**Sole Inventions**"), along with any Patents covering such Sole Inventions. All inventions and Information that are made jointly by employees, Affiliates, agents, or independent contractors of both Parties in the course of performing activities under this Agreement (collectively, "**Joint Inventions**"), along with any Joint Patents, shall be owned jointly by the Parties. Subject to the licenses granted pursuant to Section 2.1 or 2.3, each Party shall have the right to practice, license

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and exploit the Joint Inventions and Joint Patents worldwide, without consent of the other Party (and where consent is required by Applicable Law, such consent is hereby deemed granted) and without a duty of accounting to the other Party. For the avoidance of doubt and for purposes of this Agreement, to the extent that any Joint Inventions relate to any Product, such Joint Inventions shall be deemed to constitute VIVUS Know-How and Licensee Know-How, and to the extent that any Joint Patents relate to any Product, such Joint Patents shall be deemed to constitute VIVUS Patents and Licensee Patents.

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

8.3 **Prosecution of Patents.**

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

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

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#### 8.4 Enforcement of Patents.

(a) **Notification.** If a Party becomes aware of any infringement, threatened infringement, or alleged infringement of the VIVUS Patents or Joint Patents on account of a Third Party's manufacture, use or sale of a product that includes the Compound as the sole active ingredient in the Field in the Licensee Territory (in each case, a "**Product Infringement**"), then such Party shall promptly notify the other Party in writing of such Product Infringement, including any evidence in such Party's possession demonstrating such Product Infringement. Any "patent certification" filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) (or similar provisions in other jurisdictions) that asserts that infringement of a VIVUS Patent or Joint Patent will not arise from the manufacture, use or sale of a product that includes the Compound as the sole active ingredient in the Field in the Licensee Territory by a Third Party or that asserts that any claims of a VIVUS Patent or Joint Patent covering product that includes the Compound as the sole active ingredient in the Field in the Licensee Territory is invalid or unenforceable shall be deemed to be a Product Infringement hereunder, and each Party shall provide written notice to other Party of any such filed certification within \*\*\* of becoming aware thereof. Notwithstanding the foregoing, VIVUS shall bear all fees, costs and expenses associated in any manner with the Hetero Litigation and VIVUS shall not consent to any settlement with respect to the Hetero Litigation without the prior written consent of Licensee (which consent shall not be unreasonably withheld, conditioned or delayed), provided that (i) Licensee's consent shall not be required for any settlement with respect to the Hetero Litigation that (A) does not include any admission of the invalidity of, or waiver or forfeiture of any claims of, the VIVUS Patents and (B) includes any entry date for a Generic Product that is on or after the date that is \*\*\* prior to the expiration date of \*\*\*, and (ii) if (A) VIVUS, in good faith, recommends a settlement proposal to Licensee, in writing, that (x) does not include any admission of the invalidity of, or waiver or forfeiture of any claims of, the VIVUS Patents and (y) includes any entry date for a Generic Product that is earlier than the date that is \*\*\* prior to the expiration date of \*\*\*, but no earlier than the date that is \*\*\* prior to the expiration date of \*\*\*, and (B) Licensee does not deliver to VIVUS a written consent to such settlement proposal within \*\*\* of Licensee's receipt of VIVUS' recommendation, then Licensee will immediately assume full responsibility for the Hetero Litigation (including any and all costs and expenses related to, arising from, or otherwise associated therewith) from the date of such written recommendation from VIVUS, and VIVUS will reasonably cooperate with Licensee, at Licensee's sole cost and expense, to facilitate any transition of the Hetero Litigation from VIVUS to Licensee.

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

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the applicable VIVUS Patents with respect to such Product Infringement in the Licensee 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 Licensee, VIVUS agrees to exercise its right under the MTPC Agreement to require MTPC to cooperate in any enforcement by or on behalf of Licensee 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.

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

(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 Licensee is the enforcing Party, the Remainder shall be included in Net Sales for purposes of calculating royalties owed to VIVUS hereunder.

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

obligation, to take action to enforce such Joint Patents against such infringement at its own cost and expense and such other Party may retain all recoveries with respect thereto.

8.5 **Patent Marking.** Licensee 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.** Subject to the terms and conditions of this Agreement, including Section 12.5(c), VIVUS hereby sells, assigns, conveys, transfers and delivers to Licensee, and Licensee hereby receives and accepts from VIVUS, with effect as of the Effective Date, all of its right, title and interest in and to the Assigned Trademarks, any and all goodwill associated therewith, and all rights in and to any of the foregoing. Licensee shall be responsible for the selection, adoption, registration, maintenance and defense of the (a) Assigned Trademarks and (b) any other trademarks Licensee uses in connection with the sale or marketing of Products in the Licensee Territory (such other trademarks, collectively, the "**Licensee Trademarks**"), as well as all expenses associated therewith. Notwithstanding the foregoing, if Licensee determines that it is no longer interested in maintaining (or defending against any cancellation proceedings) a particular Assigned Trademark, Licensee shall provide VIVUS with written notice of such determination at least sixty (60) days before any deadline for taking action to avoid any cancellation of, abandonment of, or other loss of rights relating to such Assigned Trademark, and at VIVUS' request, shall promptly transfer and assign such Assigned Trademark, any goodwill associated therewith, and all rights in and to any of the foregoing, to VIVUS, at no cost to VIVUS. Licensee shall own all Licensee Trademarks.

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

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

## **ARTICLE 9 REPRESENTATIONS, WARRANTIES AND COVENANTS**

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

(a) **Corporate Existence and Power.** It is a corporation, duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated

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or formed, and has all requisite power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder.

(b) **Authority and Binding Agreement.** It has the requisite power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and this Agreement has been duly executed and delivered on its behalf, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject as to enforcement of remedies to applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting generally the enforcement of creditors' rights and subject to a court's discretionary authority with respect to the granting of a decree ordering specific performance or other equitable remedies.

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

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

9.2 **VIVUS Representations, Warranties and Covenants.** VIVUS hereby represents, warrants, and covenants to Licensee as of the Effective Date that, except as disclosed in Schedule 9.2:

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

(b) except for the Auxilium Agreement, VIVUS has granted no rights to a Third Party under the VIVUS Technology with respect to the Commercialization of Product in the Field in the Licensee Territory, and as of the Effective Date, no Third Party has any right or license to clinically develop Product in the Field in the Territory at any time during the Term;

(c) to the Knowledge of VIVUS as of the Effective Date, the manufacture, Development, and Commercialization of the Product in the Field in the Licensee Territory does not infringe any issued Third Party patents or any claims of any pending patent applications in the Licensee Territory that are reasonably likely to issue as filed. To the Knowledge of VIVUS, no Third Party is infringing any VIVUS Patents. VIVUS has not received any written notice from

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any Third Party asserting that the VIVUS Patents are invalid, unenforceable, or not infringed. VIVUS has not, and, to the Knowledge of VIVUS, MTPC has not, alleged that any Third Party infringes or has infringed the VIVUS Patents or misappropriated or used without authorization the VIVUS Know-How;

(d) there are no material liens, encumbrances, charges, security interests, mortgages or other similar restrictions currently existing on or to the VIVUS Technology and VIVUS has not granted any outstanding liens, encumbrances, charges, security interests, mortgages or other similar restrictions on the VIVUS Technology in the Territory;

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

(f) VIVUS has disclosed, shown or made available (e.g., through the electronic data room) to Licensee all material information and data (including without limitation all communications with or from the FDA or any other Regulatory Authority) relating to the results of all preclinical studies and clinical trials of the Product;

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

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

(i) VIVUS has obtained the Product Marketing Authorization. True and complete copies of such Product Marketing Authorization and all correspondence with the FDA and any other Regulatory Authority relating to the Product Marketing Authorization have been provided to Licensee. As of the Effective Date, the Product Marketing Authorization remains valid, and VIVUS has not received any notices from the FDA or any other Regulatory Authority regarding any possible modifications or withdrawals;

(j) the MTPC Agreement is valid, binding and in full force and effect and is enforceable by VIVUS in accordance with its terms. Except as would not reasonably be expected to result in the termination, or material limitation, restriction or adverse change, in the rights granted to Licensee by the terms of this Agreement, (i) VIVUS has performed all obligations required to be performed by it to date under the MTPC Agreement and is not in breach of or in default under the MTPC Agreement, and no event has occurred which with the passage of time or

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giving of notice or both would constitute such a breach or default, (ii) there is no existing breach or default by MTPC and (iii) no event has occurred which with the passage of time or giving notice of or both would constitute such a breach or default by MTPC. VIVUS has not received any written notice of breach under the MTPC Agreement, whether or not cured or disputed. MTPC has not exercised its rights under Section 2.4 of the MTPC Agreement. To the Knowledge of VIVUS, VIVUS' rights under the VIVUS Technology with respect to the Development, manufacture or Commercialization of the Product in the Field for the Licensee Territory are exclusive as to MTPC. VIVUS has provided to Licensee a complete and accurate copy of the MTPC Agreement as of the Effective Date;

(k) with respect to the Product covered by the Product Marketing Authorization, VIVUS has paid in full the milestones due to date under the MTPC Agreement;

(l) VIVUS will not at any time during the Term take any action that it knows or should know, will result in a breach of the MTPC Agreement and will throughout the Term comply with the terms and provisions of the MTPC Agreement in all material respects. VIVUS will not at any time during the Term terminate the MTPC Agreement without the prior written consent of Licensee. VIVUS will not agree to any amendment, waiver of rights, or modification of the MTPC Agreement that (i) would reasonably be expected to result in (A) any non-routine increase in the Price (as defined in the Commercial Supply Agreement), (B) any early termination of the Commercial Supply Agreement, or (C) any increase in the Licensee's Minimum Purchase Obligations (as defined in the Commercial Supply Agreement), (ii) has, or would reasonably be expected to have, any other material negative effect or other material adverse impact on (A) any financial or reporting obligation of Licensee or (B) on the rights granted to Licensee under this Agreement or the material obligations imposed on Licensee under this Agreement, without the prior written consent of Licensee;

(m) VIVUS has not knowingly failed to furnish Licensee with any information requested by Licensee, or intentionally concealed from Licensee any information in VIVUS' possession which would be reasonably likely to be material to Licensee's decision to enter into this Agreement and undertake the commitments and obligations set forth herein;

(n) as of the Effective Date, VIVUS represents and warrants that (i) there is no actual, pending, alleged or, to the Knowledge of VIVUS, threatened product liability action with respect to any Product anywhere in the United States or the European Union; (ii) to the Knowledge of VIVUS, there is no actual, pending, alleged or threatened product liability action with respect to any Product anywhere else the world; and (iii) to the Knowledge of VIVUS, there are no facts or circumstances that would cause VIVUS to believe that there is a basis for such a product liability claim;

(o) to the Knowledge of VIVUS, VIVUS, its Affiliates, its sublicensees, and their respective authorized distributors and agents, in each case in respect of the Product, have shipped and sold at all times during the nine (9) month period prior to the Effective Date, the Product in the ordinary course of business and consistent with past Product shipment and sales practices and, in particular, have not, directly or indirectly: (a) engaged in "channel stuffing" or

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“load” selling of Product, (b) encouraged or required customers to “buy in” Product, (c) encouraged customers to make payments earlier than would otherwise reasonably be expected (based on historical patterns) to be made, or otherwise (d) engaged in the process of positioning inventory of the Product with distributors, wholesalers, retailers or customers materially in excess of requirements or initiated or engaged in any program, activity or other action (including any rebate, discount, chargeback or refund policy or practice) that could reasonably be expected to result, directly or indirectly, in sales or profits materially in excess of purchasing patterns that have been normal for the Product;

(p) to the Knowledge of VIVUS, Auxilium has not taken any action or failed to take any action which would constitute a material breach or default under Section 4.8, Section 5.3(a), and Section 5.3(b) of the Auxilium Agreement;

(q) as of the Effective Date, all product fees, establishment fees and other fees for amounts greater than \$10,000 invoiced by any Governmental Authority in the Licensee Territory with respect to the Product and the Product Marketing Authorizations have been paid; and

(r) as of the Effective Date, VIVUS has not elected to assume responsibility over any existing patient assistance programs pursuant to Section 4.2 of the Transition Services Agreement.

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

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

(b) except as disclosed in Schedule 9.3, attached hereto, 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 Licensee Territory with respect to any of the Assigned Trademarks;

(c) the Assigned Trademarks are the only trademarks that, prior to the consummation of the transactions contemplated herein, were 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 Licensee Territory (other than VIVUS’ corporate name and/or logo);

(d) to the Knowledge of VIVUS, prior to the consummation of the transactions contemplated herein, it had all rights necessary to use the Assigned Trademarks with respect to the Product in the Licensee Territory and to assign and transfer to Licensee the Assigned Trademarks as set forth above; and

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(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 Assigned Trademarks in the Licensee Territory.

#### **9.4 Licensee Representations, Warranties and Covenants.**

(a) Licensee hereby represents and warrants to VIVUS as of the Effective Date that, except as disclosed by VIVUS in Schedules 9.2 and 9.3, to the actual knowledge of Greg Ford, Keith Lavan and Keith Rotenberg, there are no misrepresentations or breaches of any of VIVUS' representations or warranties under this Agreement.

(b) Licensee hereby covenants not to sue the VIVUS Indemnitees (as defined in Section 10.2 hereof), and shall defend, indemnify and hold harmless the VIVUS Indemnitees from and against any and all Losses incurred by the VIVUS Indemnitees, for any such VIVUS Indemnitees' compliance with any Financing Entity's notice of its exercise of rights and remedies under the Financing Documents in connection with any Financing Default (including during the pendency of any dispute between Licensee and the Financing Entity relating to or arising under the Financing Documents, provided that the Financing Entity provides written notice to VIVUS of such exercise of such rights and remedies).

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

#### **9.6 Representations Regarding Debarment and Compliance.**

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

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

(ii) have been charged with, or convicted of, any felony or misdemeanor under Applicable Laws related to any of the following: (A) the development or approval of any drug product or the regulation of any drug product under the FD&C Act; (B) a conspiracy to commit, aid or abet the development or approval of any drug product or regulation of any drug product; (C) health care program-related crimes (involving Medicare or any state health care program); (D) patient abuse, controlled substances, bribery, payment of illegal gratuities, fraud,

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perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records; (E) interference with, obstruction of an investigation into, or prosecution of, any criminal offense; or (F) a conspiracy to commit, aid or abet any of these listed felonies or misdemeanors; and

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

(b) Each Party will notify the other Party promptly, but in no event later than \*\*\*, after knowledge of any exclusion, debarment, suspension or other ineligibility set forth in Section 9.6(a)(iii) occurring during the Term, or if such Party concludes based on its good faith business judgment that a pending action or investigation is likely to lead to the exclusion, debarment, suspension or other ineligibility of such Party.

9.7 **New Generation Compounds.** Pursuant to Section 2.6 of the MTPC Agreement, VIVUS has been granted a right of first refusal and certain related rights by MTPC in connection with New Generation Compounds, as defined in the MTPC Agreement. VIVUS hereby agrees that, at Licensee's written request, VIVUS shall exercise such rights with respect to the Licensee Territory, and shall negotiate with MTPC in good faith to obtain the right to sublicense such rights to Licensee, and Licensee shall be responsible for any and all monetary obligations associated therewith, including (i) any and all payment obligations to MTPC or any third party under any arrangement for such rights and (ii) out-of-pocket costs incurred by VIVUS in connection with the exercise of such rights and related negotiations, provided, however, that (x) in the case of the foregoing clause (i), VIVUS shall have provided Licensee ample opportunity to review any such proposed arrangements, and consulted and reasonably cooperated with Licensee in connection with the negotiation of any such arrangements, and (y) in the case of the foregoing clause (ii), all such out-of-pocket costs shall have been expressly approved by Licensee prior to the incurrence thereof by VIVUS. All additional sublicensable rights obtained by VIVUS through exercise of such rights shall be sublicensed to Licensee and governed by the terms of this Agreement, subject to the terms of any relevant arrangement between VIVUS and MTPC.

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

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**ARTICLE 10**  
**Indemnification**

10.1 **Indemnification by VIVUS.** VIVUS shall defend, indemnify, and hold harmless Licensee, 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 “**Licensee Indemnitees**”) from and against any and all Losses incurred by such Licensee Indemnatee based on or arising out of:

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

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

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

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

The foregoing indemnity obligation shall not apply to the extent that the Losses of such VIVUS Indemnatee 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 Indemnatee.

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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 thirty (30) days 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 and control the defense of the Indemnified Claim with counsel of its choice so long as the Indemnifying Party is conducting a good faith and diligent defense. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance in connection with the defense of the Indemnified Claim. The Indemnified Party may monitor such defense with counsel of its own choosing at its sole expense; provided, that if under applicable standards of professional conduct a conflict of interest exists between the Indemnifying Party and the Indemnified Party in respect of such claim, such Indemnified Party shall have the right to employ separate counsel to represent such Indemnified Party with respect to the matters as to which a conflict of interest exists and in that event the reasonable fees and expenses of such separate counsel shall be paid by the Indemnifying Party. The Indemnifying Party may not settle the Indemnified Claim without the prior written consent of the Indemnified Party, such consent shall not be unreasonably withheld, delayed or conditioned. If the Indemnifying Party does not assume and conduct the defense of the Indemnified Claim as provided above: (a) the Indemnified Party may assume and conduct the defense of the Indemnified claim at the Indemnifying Party’s expense; (b) the Indemnified Party may consent to the entry of any judgment or enter into any settlement with respect to the Indemnified Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith); and (c) the Indemnifying Party will remain responsible to indemnify the Indemnified Party for Losses as provided in this ARTICLE 10.

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

10.5 **Insurance.** Licensee shall procure and maintain insurance during the Term of this Agreement and for a period of \*\*\* following the termination or expiration of this Agreement, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Such insurance shall be written by insurance companies with a rating of at least an “A-” in the latest addition of A.M. Best or its equivalent.

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Without limiting the generality of the foregoing, Licensee's insurance shall include, at minimum, the following coverages:

- (a) commercial general liability coverage with minimum per claim limits of at least \$\*\*\* per occurrence and \$\*\*\* annual aggregate, the policy(ies) for which shall (A) name VIVUS as an additional insured, and (B) be primary and non-contributory;
- (b) automobile liability coverage covering all owned, hired and non-owned automobile equipment with minimum per claim limits of \$\*\*\* per occurrence and annual aggregate, the policy(ies) for which shall name VIVUS as an additional insured;
- (c) excess liability/umbrella coverage with minimum per claim limits of at least \$\*\*\* per occurrence and annual aggregate;
- (d) products liability coverage with minimum per claim limits of at least \$\*\*\* per occurrence and annual aggregate with a \*\*\* extended reporting period endorsement, the policy(ies) for which shall name VIVUS as an additional insured; and
- (e) property coverage having limits adequate for Product inventory in Licensee's care, custody, and/or control and for Product in transit to and from Licensee.

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

#### **ARTICLE 11** **Confidentiality**

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

- (a) was already known to the receiving Party or its Affiliate, other than under, an obligation of confidentiality, at the time of disclosure by the disclosing Party;
- (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

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(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 disclosing Party; provided that unless otherwise prohibited by Applicable Law, the receiving Party first advises the disclosing Party of such intended disclosure and provides the disclosing Party with the opportunity to seek appropriate judicial or administrative relief to avoid, or obtain confidential treatment of, such disclosure at the disclosing Party's sole cost and expense.

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

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

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

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

(d) disclosure to the receiving Party's Affiliates' and their respective directors, officers, employees, consultants, attorneys, professional advisors, bankers, lenders, insurers, sublicensees, suppliers and distributors only on a need-to-know basis and solely as necessary in connection with this Agreement; provided that each such Person must be bound by obligations of

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confidentiality and non-use on substantially similar terms as those set forth in Section 11.1 prior to any such disclosure (it being understood that receiving Party shall be liable for any breach of such confidentiality and non-use obligations by any such Person);

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

(f) disclosure to any Financing Entity (and/or their respective consultants, attorneys, professional advisors) on a need-to-know basis and solely for the purpose of evaluating a potential Debt Financing or similar transaction or the enforcement thereof; provided that each such Person must be bound by written obligations of confidentiality and non-use on terms that are no less protective than those set forth in Section 11.1 prior to any such disclosure (it being understood that the receiving Party shall be solely liable for any breach of such confidentiality and non-use obligations by any such Person).

### 11.3 Publicity; Terms of Agreement.

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

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

(c) Either Party or any of its Affiliates (the “**Filing Party**”) may publicly disclose without violation of this Agreement, such terms of this Agreement as are, on the advice of such Filing Party’s counsel, required by the rules and regulations of the SEC or any other applicable entity having regulatory authority over such Filing Party’s securities; provided that such Filing Party shall advise the other Party of such intended disclosure and request confidential treatment of certain commercial terms and technical terms hereof to the extent such confidential treatment is reasonably available to such Filing Party. In the event of any such filing, such Filing Party will provide such other Party, a reasonable time prior to filing, with a copy of the Agreement

marked to show provisions for which such Filing Party intends to seek confidential treatment and shall reasonably consider and incorporate such other Party's comments thereon to the extent consistent with the legal requirements applicable to such Filing Party and that govern redaction of information from material agreements that must be publicly filed. Such other Party shall provide the Filing Party any such comments as promptly as practicable. The intention of the Parties is to agree upon a single redacted version of the Agreement to be filed with the SEC or any other applicable entity.

## **ARTICLE 12**

### **Term and Termination**

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

#### **12.2 Termination For Cause, Convenience, or Generic Entry.**

(a) **Material Breach.** Either Party shall have the right to terminate this Agreement, upon written notice to the other Party if such other Party, after receiving written notice from the terminating Party identifying a material breach by such other Party of its obligations under this Agreement, fails to cure (or if not curable within such time period, adopt a plan for cure during such time period) such material breach within \*\*\* from the date of such notice (or, in the case of payment obligations, \*\*\* from the date of such notice); provided, however, that in the event the non-terminating Party contests any such asserted breach in good faith and diligently pursues the dispute resolution procedures set forth in ARTICLE 13, such \*\*\* or \*\*\* cure period shall be tolled or suspended until the final resolution of such dispute pursuant to the terms of, and in accordance with, the terms and provisions of ARTICLE 13, subject to any exercise by MTPC of its right of termination of the MTPC Agreement due to any material breach of the provisions or conditions of the MTPC Agreement arising from the facts or circumstances that resulted in the material breach by such non-terminating Party hereunder. Notwithstanding the foregoing, in the event of any uncured material breach by Licensee of its obligations hereunder, VIVUS shall only exercise its right to terminate this Agreement under this Section 12.2(a) to the extent that MTPC exercises its right of termination of the MTPC Agreement due to a material breach of the MTPC Agreement. For the avoidance of doubt (and without limiting VIVUS' remedies for any other breaches by Licensee), Licensee's uncured failure to pay the amounts set forth in Section 7.1 by the deadlines set forth therein shall each be deemed to be a material breach of this Agreement.

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

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(c) **Licensee Termination for Convenience.** Licensee shall have the right to terminate this Agreement for any reason upon one hundred eighty (180) days prior written notice to VIVUS.

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

12.3 **Termination for Patent Challenge.** VIVUS may terminate this Agreement in its entirety upon written notice to Licensee if Licensee or any Affiliate, directly or indirectly, individually or in association with any other person or entity, commences any action or proceeding that challenges the validity or enforceability of any VIVUS Patent in the Licensee Territory, except if such action or proceeding is commenced in response to a claim asserted by VIVUS against Licensee or the Licensee Affiliate for infringement of such VIVUS Patent. In the event Licensee 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 Licensee Territory, Licensee shall promptly terminate the applicable sublicense. If Licensee does not terminate such sublicense within \*\*\* of Licensee being made aware of such challenge by VIVUS, VIVUS may terminate this Agreement in its entirety upon written notice to Licensee.

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

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

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

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

(c) **Marks.** Upon any expiration or early termination of this Agreement, Licensee shall and hereby agrees to sell, assign, convey, transfer and deliver all rights in the Assigned Trademarks, any goodwill associated therewith, and all rights in and to any of the foregoing, to VIVUS, and Licensee shall assign to VIVUS any Licensee Trademarks incorporating the mark STENDRA that are Controlled by Licensee and then being used to Commercialize Product in the Licensee Territory, but expressly excluding (i) Licensee's corporate name, (ii) any other mark that incorporates or is derived from Licensee's corporate names, and (iii) any other proprietary mark of Licensee that is used by Licensee independently of the Product, provided that in the event of expiration of this Agreement, to the extent that Licensee continues to Commercialize the Product in the Licensee Territory under the Assigned Trademarks, then upon written request by Licensee, VIVUS agrees to waive the right to have the ownership of the Assigned Trademarks transferred to VIVUS so long as Licensee pays the Trademark Royalty Payments in accordance with Exhibit C.

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

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(e) **Transition Assistance.** In the event of any early termination of this Agreement, to the extent the Transition Services Agreement has not expired, at VIVUS' request, Licensee shall promptly transfer and assign to VIVUS all of Licensee's rights, title, interest in, liabilities and obligations under the Transition Services Agreement; provided that, Licensee shall be responsible for any liabilities and obligations accrued by Licensee under the Transition Services Agreement prior to the effective date of such transfer and assignment, subject to VIVUS' indemnification obligations under Section 10.1 hereof. In the event of any termination of this Agreement other than termination by Licensee pursuant to Section 12.2(a) or 12.4, Licensee 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 Licensee Territory, including without limitation, upon request of VIVUS, using commercially reasonable efforts to transfer any agreements or arrangements with distributors that apply solely to the sale or supply of Product in the Licensee Territory.

(f) **Sell-Through of Inventory.** For a period of \*\*\* following the effective date of termination, Licensee, its Affiliates, and its sublicensees may sell or otherwise dispose of the inventory of Product then on hand or in production or for which substantial preparation for manufacture has been made or which they are legally obligated to supply, provided that this provision shall not limit, and Licensee shall satisfy, Licensee's obligations under the Commercial Supply Agreement with respect to any minimum purchase requirements or related obligations thereunder.

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

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

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

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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 Licensee are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of rights to “intellectual property” as defined under Section 101 of the United States Bankruptcy Code. The Parties agree that each Party, as licensee of certain rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the United States Bankruptcy Code. The Parties further agree that, in the event of (i) the commencement of a case by or against a Party (such Party, the “**Debtor**”) under the United States Bankruptcy Code, (ii) the rejection of this Agreement by the Debtor pursuant to section 365 of the United States Bankruptcy Code, and (iii) the election of the other Party to retain its rights under section 365(n)(1)(B) of the United States Bankruptcy Code, then 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 following the rejection of this Agreement by the Debtor upon written request therefor by the other Party.

12.8 **Survival.** The following provisions shall survive any expiration or termination of this Agreement: ARTICLE 1, 10, 11, 13, 14 and Sections 7.6, 8.1, 12.5, 12.6, 12.7, and 12.8.

### **ARTICLE 13**

#### **Dispute Resolution**

13.1 **Disputes.** The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party’s rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this ARTICLE 13 if and when a dispute arises under this Agreement.

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

(b) **Good Faith Resolution.** Any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement, including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, then upon the request of either Party, the Parties agree to meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one (1) in-person meeting between the chief executive officers of each Party. If

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the matter is not resolved within \*\*\* following the request for discussions, either Party may then invoke the provisions of Section 13.2.

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

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

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

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

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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; Financing Entity Disputes.**

(a) Notwithstanding anything to the contrary in this ARTICLE 13, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of the VIVUS Patents, Assigned Trademarks, Licensee Patents, Licensee Trademarks or Joint Patents shall be submitted to a court of competent jurisdiction in the country in which such patent or trademark rights were granted or arose.

(b) Notwithstanding anything to the contrary in this ARTICLE 13, any Financing Entity may bring a proceeding in a court of competent jurisdiction located in the State of New York solely to enforce its rights under Sections 5.1(c), 13.10(b), 14.1, 14.5 and 14.8 hereof. Such courts of competent jurisdiction located in the State of New York shall have the sole and exclusive jurisdiction to hear and adjudicate any claims pursuant to this Section 13.10(b).

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**ARTICLE 14**  
**Miscellaneous**

14.1 **Entire Agreement; Amendment.** This Agreement, including the Exhibits hereto, together with the letter agreement dated September 30th, 2016 between VIVUS and Hercules Capital, Inc., and the terms of the MTPC Agreement which are incorporated herein by reference, 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 anything to the contrary in this Section 14.1, no amendment of the definitions of "Financing Entity," "Financing Default," "Qualified Assignee," or "Permitted Assignment" or Sections 5.1(c), 13.1013.10(b), 14.1, 14.5 and 14.8 hereof that effects the rights of any Financing Entity shall be effective without the prior written consent of each Financing Entity.

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

14.3 **Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 14.3, and shall be deemed to have been given for all purposes when received, if hand-delivered or by means of facsimile, or one (1) Business Day after being sent by a reputable overnight delivery service.

If to VIVUS:	VIVUS, Inc. 351 E. Evelyn Ave. Mountain View, CA 94041 Fax: (650) 934-5320
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Attention: General Counsel  
Email: generalcounsel@vivus.com

With a copy to: Weil, Gotshal & Manges LLP  
767 Fifth Avenue  
New York, NY 10153  
Fax: (212) 310-8007  
Attention: Michael A. Epstein  
Email: michael.epstein@weil.com

If to Licensee: Metuchen Pharmaceuticals LLC  
11 Commerce Drive, 1st Floor  
Cranford, NJ 07016  
Facsimile: (908) 272-3084  
Attention: Greg Ford  
Email: GFord@kfe-llc.com

With a copy to: Mist Pharmaceuticals, LLC  
11 Commerce Drive, 1st Floor  
Cranford, NJ 07016  
Facsimile: (908) 272-3084  
Attention: Keith Rotenberg, President  
Email: krotenberg@mistpharma.com

With a copy to: Lowenstein Sandler LLP  
65 Livingston Avenue  
Roseland, New Jersey 07068  
Facsimile: (973) 597-2400  
Attention: Michael J. Lerner  
Email: MLerner@lowenstein.com

**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

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as referring to such laws and any rules or regulations promulgated thereunder as from time to time enacted, repealed or amended, (c) any reference herein to any Person will be construed to include such Person's successors and assigns (including any Financing Entity or Qualified Assignee, as applicable), (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 Party, except that (a) 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, (b) Licensee may assign this Agreement and any of Licensee's rights or obligations hereunder as collateral to any Financing Entity pursuant to one or more Financing Documents without the consent of VIVUS or any other Person, (c) neither the consent of VIVUS nor any other Person shall be required for the assignment of this Agreement and all of Licensee's rights, obligations and liabilities hereunder (including any and all liabilities that accrued prior to such assignment, but excluding liabilities under Sections 9.4(b) and 10.2 hereof) to any Financing Entity upon the occurrence of a Financing Default, provided that at least five (5) Business Days prior to any transfer or assignment of this Agreement in accordance with the terms of this clause (c), such Financing Entity provides VIVUS with a general description of the Financing Entity's business and operations or equivalent documentation, and (d) neither the consent of VIVUS nor any other Person shall be required for the assignment of this Agreement and all of Licensee's rights, obligations and liabilities hereunder by Licensee (with the consent of the Financing Entity, provided that the Licensee and the Financing Entity jointly provide timely notice to VIVUS of such consent) or any Financing Entity upon the occurrence of a Financing Default to any Qualified Assignee that is a successor to or assignee of all or substantially all of the assets or business of Licensee to which this Agreement pertains; provided that any assignment to a Financing Entity or a Qualified Assignee in connection with a Financing Default must also include an agreement, in writing, signed by such Financing Entity or Qualified Assignee, as applicable, to assume performance of all of Licensee's rights and obligations, and assume all of Licensee's outstanding liabilities (including any and all liabilities that accrued prior to such assignment, but excluding liabilities under Sections 9.4(b) and 10.2 hereof), provided that in the case of clauses (c) and (d) above, with respect to any liabilities accrued by Licensee (including Licensee's liabilities under Sections 9.4(b) and 10.2 hereof), such Financing Entity and/or such Qualified Assignee, as applicable, shall, at VIVUS' request and expense (which shall be limited to such Financing Entity's or Qualified Assignee's, as applicable, reasonable out-of-pocket-expenses), cooperate and provide reasonable assistance to VIVUS (including the providing, subject to a customary confidentiality agreement, of any relevant information to VIVUS in such Person's possession) in

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connection with, and to support, VIVUS' efforts to seek recovery for any Losses under Licensee's insurance policy), thereunder (any of the foregoing assignments, a "**Permitted Assignment**"). Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Any assignment or attempted assignment by either Party in violation of the terms of this Section 14.5 shall be null, void and of no legal effect. The VIVUS Technology shall exclude any intellectual property held or developed by a permitted successor of VIVUS prior to the transaction in which it became a successor of such Party, and the Licensee Technology shall exclude any intellectual property held or developed by a permitted successor of Licensee prior to the transaction in which it became a successor of such Party.

**14.6 Records Retention.** Each of VIVUS and Licensee 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 Licensee will retain such records for a duration prescribed by Applicable Law, but not in any event for less than \*\*\* after the Effective Date (or longer if a Party is notified, ordered or otherwise required to maintain such records for a longer period in connection with a legal proceeding or government investigation).

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

**14.8 Successors and Assigns; No Third Party Beneficiaries.** This Agreement will be binding upon and inure to the benefit of the Parties and their successors and permitted assigns. No provision of this Agreement, express or implied, is intended to or will be deemed to confer upon Third Parties any right, benefit, remedy, claim, liability, reimbursement, claim of action or other right of any nature whatsoever under or by reason of this Agreement other than (i) the Parties and, to the extent provided in Sections 10.1 and 10.2, the Indemnified Parties and (ii) any Financing Entity solely with respect to Sections 5.1(c), 13.10(b), 14.1, 14.5, and this Section 14.8 (and the Parties hereto acknowledge and agree that each Financing Entity (including Hercules Capital, Inc.) is an express third-party beneficiary of such Sections 5.1(c), 13.10(b), 14.1, 14.5, and this Section 14.8). 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' 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 Licensee under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at Licensee's sole and exclusive

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

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

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

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

**14.13 Independent Contractors.** Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

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

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In Witness Whereof, the Parties have caused this Agreement to be duly executed as of the date last signed below.

VIVUS, INC.

METUCHEN PHARMACEUTICALS LLC

By: /s/ Seth H. Z. Fischer \_\_\_\_\_

By: /s/ J. Gregory Ford \_\_\_\_\_

Name: Seth H. Z. Fischer \_\_\_\_\_

Name: J. Gregory  
Ford \_\_\_\_\_

Title: CEO \_\_\_\_\_

Title: CEO \_\_\_\_\_

Date: 9/30/2016 \_\_\_\_\_

Date: 9/30/2016 \_\_\_\_\_

**Acknowledged and Agreed:**

HERCULES CAPITAL, INC.

By: /s/ Melanie Grace \_\_\_\_\_

Name: Melanie Grace \_\_\_\_\_

Title: GC/CCO \_\_\_\_\_

Date: 9/30/2016 \_\_\_\_\_

*[Signature Page to License and Commercialization Agreement]*

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## **SCHEDULES**

<b>Schedule 4.4(b)</b>	<b>U.S. Product Launch Quantities</b>
<b>Schedule 9.2</b>	<b>Disclosures to VIVUS' Representations and Warranties</b>
<b>Schedule 9.3</b>	<b>Disclosures to Assigned Trademarks Representations and Warranties</b>

## **EXHIBITS**

<b>Exhibit A</b>	Assigned Trademarks
<b>Exhibit B</b>	Commercial Supply Agreement
<b>Exhibit C</b>	Additional Financial Terms
<b>Exhibit D</b>	Press Release
<b>Exhibit E</b>	Letter Agreement
<b>Exhibit F</b>	Quality Agreement
<b>Exhibit G</b>	VIVUS Patents

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Schedule 4.4(b)

U.S. Product Launch Quantities, by dosage strength:

50 mg dosage strength – \*\*\* tablets;

100 mg dosage strength – \*\*\* tablets; and

200 mg dosage strength – \*\*\* tablets.

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## Schedule 9.2

### **Disclosures to VIVUS Representations, Warranties and Covenants**

Certain matters listed herein are for informational purposes only, and no disclosure herein shall be deemed an acknowledgment that such fact, item, matter, circumstance, transaction or event is required to be so disclosed pursuant to the Agreement. The inclusion of any fact, item, matter, circumstance, transaction or event in this Schedule 9.2 shall not be deemed to be an admission or representation that the fact, item, matter, circumstance, transaction or event is or is not “material” or would or would not have, individually or in the aggregate, a material adverse impact. Additionally, matters reflected in this Schedule 9.2 shall not be used as a basis for interpreting the terms “material,” “materially,” “materiality,” “material adverse impact” or any other similar definition in the Agreement. The fact that certain information is contained herein is not an admission of liability under any applicable law or otherwise. Further, any disclosure in this Schedule 9.2 relating to any possible breach or violation of any agreement, law or regulation shall not be construed as an admission or indication that any such breach or violation exists or has actually occurred.

This Schedule 9.2 shall not be deemed or interpreted to broaden any representations or warranties of VIVUS and is qualified in its entirety by reference to the specific provisions of the Agreement.

#### Section 9.2

1. **Hetero ANDA Filing**

On June 20, 2016, VIVUS received a Paragraph IV certification notice from Hetero USA, Inc. indicating that it filed an ANDA with the FDA, requesting approval to market a generic version of STENDRA and contending that patents listed for STENDRA in the Orange Book at the time of the notice (U.S. Patents 6,656,935, and 7,501,409) (collectively “Patents-in-suit”) are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of a generic form of STENDRA as described in their ANDA. On July 27, 2016, VIVUS filed the Hetero Litigation addressed in Section 8.4(b) on the basis that Hetero’s submission of their ANDA to obtain approval to manufacture, use, sell, or offer for sale generic versions of STENDRA prior to the expiration of the Patents-in-suit constitutes infringement of one or more claims of those patents.

2. **Supplement Request**

The FDA Assessment addressed in Section 5.2(b) remains unpaid.

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### Schedule 9.3

#### **Disclosures to Assigned Trademark Representations and Warranties**

Certain matters listed herein are for informational purposes only, and no disclosure herein shall be deemed an acknowledgment that such fact, item, matter, circumstance, transaction or event is required to be so disclosed pursuant to the Agreement. The inclusion of any fact, item, matter, circumstance, transaction or event in this Schedule 9.3 shall not be deemed to be an admission or representation that the fact, item, matter, circumstance, transaction or event is or is not “material” or would or would not have, individually or in the aggregate, a material adverse impact. Additionally, matters reflected in this Schedule 9.3 shall not be used as a basis for interpreting the terms “material,” “materially,” “materiality,” “material adverse impact” or any other similar definition in the Agreement. The fact that certain information is contained herein is not an admission of liability under any applicable law or otherwise. Further, any disclosure in this Schedule 9.3 relating to any possible breach or violation of any agreement, law or regulation shall not be construed as an admission or indication that any such breach or violation exists or has actually occurred.

This Schedule 9.3 shall not be deemed or interpreted to broaden any representations or warranties of VIVUS and is qualified in its entirety by reference to the specific provisions of the Agreement.

#### Section 9.3

1. The SPEDRA mark in India is the subject of an opposition by Sun Pharma. Sun Pharma did not pursue the opposition beyond an initial filing, but the Indian patent office has not yet indicated that the opposition is abandoned.
2. There was previously an opposition to the STENDRA mark in Peru, which has since been resolved in VIVUS’ favor.

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EXHIBIT A  
ASSIGNED TRADEMARKS

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**EXHIBIT B**  
**COMMERCIAL SUPPLY AGREEMENT**

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## COMMERCIAL SUPPLY AGREEMENT

THIS COMMERCIAL SUPPLY AGREEMENT (this “**Agreement**”) is dated as of September 30, 2016, 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 Metuchen Pharmaceuticals LLC, a limited liability company organized under the laws of Delaware, having its principal place of business at 11 Commerce Drive, 1st Floor, Cranford, New Jersey 07016 (“**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 (the “**License Agreement**”), effective as of the date of this Agreement, pursuant to which VIVUS granted to Purchaser an exclusive license in the Purchaser Territory for, among other things, the development and commercialization of the therapeutic drug known as Stendra® (avanafil);

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

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

### 1. DEFINITIONS

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

“**API**” has the meaning set forth in [Section 2.10](#).

“**Binding Forecast**” has the meaning set forth in [Section 2.3](#).

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

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

“**Effective Date**” means October 1, 2016.

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**“Financing Default”** means (a) Purchaser’s default under the Financing Documents, or the occurrence of an event of default under the Financing Documents, if such default or event of default gives rise to a right by a Financing Entity to exercise remedies under the Financing Documents, and (b) any of (i) a consensual resolution of such default or event of default whereby Purchaser agrees to assign this Agreement and Purchaser’s rights and obligations arising hereunder to a Financing Entity or a Qualified Assignee (with written notice of such resolution provided jointly by Purchaser and such Financing Entity or Qualified Assignee to VIVUS), (ii) the entry of a final, non-appealable order by a court of competent jurisdiction authorizing the sale and/or assignment of this Agreement and Purchaser’s rights and obligations arising hereunder to a Financing Entity or a Qualified Assignee, or (iii) the exercise by a Financing Entity of its rights and remedies as a secured creditor in respect of the Debt Facility under the Financing Documents in accordance with applicable law, provided that such Financing Entity provides written notice to VIVUS of such exercise of such rights and remedies.

**“Financing Document”** means any loan, security or other agreement or agreements pursuant to which a Financing Entity provides a Debt Facility to Purchaser.

**“Financing Entity”** means any Person that provides Purchaser with debt financing secured by an assignment of Purchaser’s contractual rights under this Agreement as collateral (a **“Debt Facility”**) and each successor and assign of such Person’s rights in and to such Debt Facility (but excluding any such Person and/or such Person’s successors and/or assignees upon the exercise of remedies by such Person pursuant to the related Financing Documents). The Parties acknowledge that (i) Hercules Capital, Inc., as “Agent”, and each of the “Lenders” (as such terms are defined in the Loan and Security Agreement dated as of September 30, 2016, by and between Purchaser and Hercules Capital, Inc., as Agent, and the related Loan Documents as defined therein (the **“Hercules Loan Agreements”**)), are Financing Entities and (ii) the Hercules Loan Agreements are Financing Documents.

**“Finished Product”** means Product that is fully packaged and labeled in accordance with the FDA-approved NDA (or foreign equivalent, as applicable in the countries of the Purchaser Territory).

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

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

**“Initial Period”** means the period beginning on the Effective Date and ending on the \*\*\* of the Effective Date.

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

**“Manufacturing Cost”** means VIVUS’ actual out-of-pocket costs in obtaining, transporting, and storing raw materials for manufacturing Product and in having the Product manufactured, tested, and supplied to Purchaser hereunder, including transfer prices paid to Sanofi

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and other Third Party manufacturers. The current Manufacturing Cost for Product manufactured by Sanofi shall be as set forth in Exhibit B. The Manufacturing Cost may be adjusted on a periodic basis (at least annually) to reflect variances between actual and estimated costs, and such adjusted Manufacturing Cost shall be calculated based on estimated costs (including, Sanofi's (or any other Third Party manufacturer's) price increases, currency exchange rate fluctuations, yield loss adjustments, and other variables in cost), as determined by VIVUS in good faith and in accordance with its standard procedures. VIVUS will use Commercially Reasonable Efforts to (i) consult with Purchaser prior to the implementation of any non-routine Manufacturing Cost adjustment that is beyond the scope of any cost adjustments contemplated under the relevant supply arrangement between VIVUS and Sanofi, and (ii) provide all relevant supporting documentation detailing any such Manufacturing Cost adjustments.

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

**"Permitted Assignment"** has the meaning set forth in Section 16.6.

**"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 (\*\*\*) \*\*\*.

**"Product"** means formulated tablets containing Compound in bulk form which, if appropriately packaged and labeled would constitute the pharmaceutical product known as Stendra, as described in the FDA-approved NDA for such product (as such NDA may be modified in the future in accordance with this Agreement and/or the License Agreement).

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

**"Product Shortage"** means a circumstance, whether or not the result of a force majeure, in which VIVUS is unable to supply Product to Purchaser in compliance with the terms and conditions of this Agreement in the quantities sufficient to meet Purchaser's requirements of Product as set forth in outstanding Purchase Orders and/or the Binding Forecast.

**"Purchase Orders"** has the meaning set forth in Section 2.3.

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

**"Qualified Assignee"** means a Person (a) operating in the pharmaceuticals industry that has the financial resources, technological and regulatory expertise, and operational capabilities reasonably required to perform all of Purchaser's obligations under this Agreement, and (b) for which Purchaser (or a Financing Entity or such Person, as applicable) has, at least five (5) Business Days prior to any transfer or assignment of this Agreement in accordance with the terms hereof,

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provided VIVUS with such information reasonably necessary to determine such Person's resources, expertise, and capabilities to perform under this Agreement.

"Quality Agreement" has the meaning set forth in [Section 5.4](#).

"Renewal Period" means each successive two-year renewal period beginning upon the expiration of the Initial Period.

"Sanofi" means the following affiliated manufacturing entities: (a) for API, Sanofi Chimie and (b) for bulk tablet of Products, Sanofi Winthrop Industrie.

"\*\*\*" has the meaning set forth in [Section 2.5\(b\)](#).

"Specifications" means the specifications, standards, limits, criteria and other requirements for or related to the Product provided hereunder, as set forth in [Exhibit A](#) or otherwise agreed to by the Parties in writing.

"Supply Disruption" has the meaning set forth in [Section 2.8](#).

"Term" has the meaning set forth in [Section 9.1](#).

## 2. SUPPLY OF PRODUCTS

### 2.1 Supply of Product.

(a) Supply and Purchase of Product. During the Term, and subject to the provisions herein, VIVUS shall manufacture, test, and supply the Product to Purchaser or its designee, directly or through one or more Third Party subcontractors. Purchaser shall purchase the Product from VIVUS, and VIVUS shall supply Product to Purchaser, pursuant to Purchase Orders submitted to VIVUS by Purchaser, from time to time in accordance with [Section 2.3](#). VIVUS shall ensure that the Product manufactured by Sanofi on behalf of VIVUS and delivered to Purchaser (other than shipments out of the Current Inventory pursuant to [Section 2.5](#)) has a minimum remaining shelf life of not less than \*\*\*.

(b) VIVUS' Third Party Supplier. Without limiting or modifying any of VIVUS' obligations under this Agreement, Purchaser acknowledges that, as of the Effective Date, VIVUS obtains Product solely from Sanofi and that VIVUS will continue to obtain Product solely from Sanofi unless and until VIVUS, with the assistance and cooperation of Purchaser, is able to qualify with the FDA a Third Party manufacturer with the ability to manufacture Product in accordance with the Specifications, cGMP, and Applicable Law as a manufacturer of Compound and bulk tablets of Product. Purchaser agrees to cooperate and provide any such assistance at VIVUS' reasonable request.

(c) Exclusive Arrangement. Subject to the terms and conditions of this Agreement, Purchaser agrees to purchase from VIVUS, and VIVUS agrees to manufacture and provide to Purchaser, all of Purchaser's requirements for Product. VIVUS shall be free to supply Product to any Third Party worldwide, subject to the exclusive rights granted to Purchaser and obligations assumed by VIVUS pursuant to the License Agreement.

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2.2 **Forecasts.** Purchaser will submit to VIVUS, no later than the \*\*\* preceding the start of every \*\*\* (i.e., \*\*\*) 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. Such Forecast shall not be binding on either Party except as provided in this Agreement.

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 calendar quarter, Purchaser shall be required to submit Purchase Orders for at least \*\*\* percent (\*\*\*) of the quantities in the Forecast for such \*\*\* 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, but will use Commercially Reasonable Efforts to supply such excess Product. 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. If a new Third Party manufacturer has been appointed by VIVUS, then the lead times (i.e. the time between the finalizing of a Purchase Order and the delivery of the Product) for Purchase Orders set forth above may not be lengthened without the prior written consent of Purchaser, not to be unreasonably withheld, conditioned, or delayed.

2.4 **Minimum Purchase Requirements.** For 2016 and for each subsequent calendar year during the Term, Purchaser shall be required to either (a) purchase no less than the Minimum Purchase Obligation from VIVUS in accordance with the terms of this Agreement or (b) \*\*\* as it relates to \*\*\* to \*\*\*. For clarity, upon any termination of this Agreement other than by Purchaser under Section 9.2(a) or pursuant to Section 9.4, Purchaser’s obligations under Section 2.4 shall accelerate for the entire then-current Initial Period or Renewal Period, as applicable, and become due, and Purchaser shall be required \*\*\* to \*\*\* for the entire then-current Initial Period or Renewal Period, as applicable. VIVUS acknowledges and agrees that VIVUS’ sole remedy for Purchaser’s failure to meet its Minimum Purchase Obligation is set forth in this Section 2.4 and that the Minimum Purchase Obligation is not a guarantee by Purchaser that any specific sales level will be obtained with respect to the Product. With respect to the minimum purchase requirements for 2016 only, any quantities of bulk Product purchased in excess of the Minimum Purchase Obligation for 2016 shall be credited against the Minimum Purchase Obligation for 2017 as set forth in Exhibit C. Purchaser’s orders of Current Inventory (including the order made pursuant to Section 2.5(b) below) shall not be counted towards the satisfaction of the Minimum Purchase Obligation.

2.5 **Initial Shipments of Product.**

(a) The Current Inventory of Product is, as of the Effective Date, being stored at \*\*\* at \*\*\*. Upon payment in full to VIVUS of the lesser of (i) the aggregate Manufacturing Cost for the full quantities of Product in the Current Inventory and (ii) \$\*\*\*, VIVUS shall transfer to Purchaser ownership of the Current Inventory, in accordance with this Section 2.5.

(b) Purchaser hereby submits a binding order for the full quantities of the Current Inventory. As set forth in Section 3.1, the transfer price for the quantities of Product ordered pursuant to this Section 2.5(b), shall be the Price. Upon payment in full to VIVUS of the Price for the full quantities of

Product in the Current Inventory, Current Inventory will be sold to Purchaser EXW (Incoterms 2010) \*\*\* facilities and title to such quantities of Product shall automatically pass to Purchaser.

(c) For all Product transferred to Purchaser under this Section 2.5, Purchaser shall be responsible, at Purchaser's sole cost, for transport and distribution of such Product. Purchaser may use any Third Party that it designates for Product packaging, but Purchaser shall be responsible for the cost of validation if the packager is any Third Party other than \*\*\*, as well as any costs associated with transporting Product to such other packager. VIVUS shall ensure that all Current Inventory delivered to Purchaser under this Agreement has a minimum remaining shelf life of not less than \*\*\*.

**2.6 Delivery and Shipping Terms.** Product supplied hereunder shall be shipped EXW (Incoterms 2010) Sanofi's manufacturing facility (or, if applicable, the manufacturing facility of any other manufacturer being utilized by VIVUS for manufacturing Product) directly to the packaging facility or other location designated by Purchaser. Title to the Product and risk of loss shall pass to Purchaser at the time of delivery of the Product to the Third Party shipper at the loading dock of the manufacturing facility. Purchaser shall arrange for all shipping, insurance freight, custom duties, and other charges associated with, the shipment, and the cost of the foregoing will be paid by Purchaser. VIVUS shall issue (or shall have its manufacturer issue) to Purchaser in advance of shipment a Certificate of Analysis (each, a "COA") and Certificate of Compliance (each, a "COC") for each shipment of Product (including Current Inventory) delivered to Purchaser. Each COA shall be accompanied by batch documentation for each lot of delivered Product and shall certify that the Product conforms to the Specifications, this Agreement, and the Quality Agreement along with the results of such analysis and any supporting data. Purchaser will be under no obligation to accept any shipment of Product for which VIVUS has not provided a COA and/or COC or which Purchaser reasonably believes does not comply with the COA or COC at the time the Product was delivered to Purchaser. VIVUS will be responsible for any out-of-pocket costs incurred by Purchaser with respect to the storage, shipment, return, or at VIVUS' direction, destruction, of such non-conforming shipment.

**2.7 Packaging and Labeling.** VIVUS will supply Product to Purchaser in the form of bulk tablets. Purchaser shall be responsible, at its sole expense, for packaging and labeling the Product for commercial sale. Any labels, product inserts, and other packaging for the Product shall be consistent with then-current approved NDA for the Product and with Applicable Law. VIVUS' name will not appear on the label or anywhere else on the commercial packaging of the Product unless: (a) required by any Applicable Laws; (b) VIVUS consents in writing to the use of its name; or (c) such Product is in the Current Inventory.

**2.8 Supply Disruption.** If VIVUS is unable to supply confirmed orders to Purchaser with respect to the quantity or the delivery date (a "Supply Disruption"), or if VIVUS believes that a Supply Disruption is reasonably likely to occur based on Purchaser's confirmed and/or forecasted orders, VIVUS shall provide Purchaser with prompt written notice of such inability or belief. In the event of a Supply Disruption, VIVUS shall be obliged to allocate the available Product among Purchaser and any other licensees and/or authorized distributors of Product worldwide, \*\*\* based on the volume of Product orders of Purchaser and such other licensees and distributors. The "volume of Product orders" will be calculated based on (a) orders for Product that were delivered during the preceding \*\*\* or that are then in transit (excluding in each case any orders where payment therefor is delinquent), and (b) the binding portion of any outstanding purchase orders or forecasts. In the event of a Supply Disruption, notwithstanding Section 2.1(c), Purchaser shall be permitted to obtain from another source the quantities of Product that VIVUS is unable to supply. In the absence of gross negligence or willful misconduct, this Section 2.8 describes Purchaser's sole and exclusive remedy, and VIVUS' sole and exclusive liability, for any Supply

Disruption; provided, that if VIVUS actually recovers direct contract damages from its Third Party manufacturer or supplier in connection with a Supply Disruption, VIVUS shall pass through to Purchaser its allocable portion (which shall be calculated and allocated \*\*\* based on the volume of Product orders of Purchaser and such other licensees and distributors, as described above in this Section 2.8) of such recovery amount. In the event of any Supply Disruption that results in more than \*\*\* percent (\*\*\*) of ordered Product in any \*\*\* period arriving at the delivery location more than \*\*\* after the intended delivery date, Purchaser shall be relieved of any further obligation during the then-current \*\*\* to purchase the Minimum Purchase Obligation for \*\*\*; provided that to the extent any such Supply Disruption results in the delivery of any such quantity of Product after \*\*\* of the relevant \*\*\*, such late-delivered quantities shall be credited against the Minimum Purchase Obligation of the immediately following \*\*\*. In the event a Supply Disruption affects the quantities of Product available for Commercialization in a subsequent \*\*\*, the Parties will meet and negotiate in good faith a possible reduction of the Minimum Purchase Obligation for such subsequent \*\*\*, which reduction shall take into account (i) the reasonably likely commercial effect of the Supply Disruption and (ii) VIVUS' respective minimum purchase obligations under any arrangements or agreements with any Third Parties (including Sanofi).

2.9 **Post-Delivery Handling and Release.** After delivery of the Product to Purchaser in accordance with the terms of this Agreement and the Quality Agreement, any handling, storage, quality control, quality assurance, and the release of the Product shall be the sole responsibility of Purchaser or its designated Third Party.

2.10 **Stability Testing.** VIVUS shall be responsible for conducting all stability testing required under the NDA with respect to the active pharmaceutical ingredient in the Compound ("API") and the bulk Product, and Purchaser shall be responsible for conducting such stability testing with respect to the Finished Product. VIVUS shall, at Purchaser's reasonable request and expense, use Commercially Reasonable Efforts to (a) make relevant VIVUS personnel available for consultation during normal business hours and (b) provide underlying documentation, in each case (a) and (b), for analytical methods transfer, including supply of API standard and impurities per Product specification.

2.11 **Technology Transfer.**

(a) Cooperation. Upon (i) termination of this Agreement by Purchaser as a result of VIVUS' uncured material breach, (ii) in the event of a Supply Disruption, (iii) upon mutual agreement of the Parties on a Supply Chain Transfer Plan in accordance with Section 6.2 of the License Agreement, (iv) in the event that VIVUS provides a notice to Purchaser under Section 2.8, (v) upon an event of Force Majeure preventing the timely supply of Product hereunder for a period anticipated to exceed \*\*\*, or (vi) upon a breach by VIVUS which permits Purchaser to terminate this Agreement, VIVUS shall provide Purchaser with such assistance and any VIVUS Know-How Controlled by VIVUS, as reasonably necessary for manufacturing, formulating and/or packaging of the Product, as the case may be (a "Technology Transfer"). In connection with the foregoing, Purchaser shall be permitted to consult with VIVUS' technical personnel on the specified manufacturing activities and, to the extent necessary, VIVUS shall use Commercially Reasonable Efforts to permit Purchaser to consult with VIVUS' Third Party manufacturers. Purchaser, in its sole discretion, shall choose whether to exercise its rights in connection with a Technology Transfer.

(b) Manufacturing Rights. Notwithstanding any Technology Transfer pursuant to Section 2.11(a), Purchaser's right to manufacture or have manufactured Product shall be limited to the rights described in Section 2.2 of the License Agreement, plus the additional manufacturing rights described in Section 2.8 in connection with a Supply Disruption.

(c) Technology Transfer Costs. In connection with a Technology Transfer pursuant to Section 2.11(a)(iii), Purchaser shall be responsible for paying VIVUS' actual costs and expenses incurred in connection with such Technology Transfer, including FTE costs, out-of-pocket expenses and any technology transfer fees payable to any other Third Party; provided, however, VIVUS shall bear all costs related to any Method Transfer and any other transfer costs, for which the related work has been performed prior to the Effective Date (collectively, "**Technology Transfer Costs**"). In connection with a Technology Transfer pursuant to Section 2.11(a)(i), (ii), or (v), VIVUS shall be responsible for the Technology Transfer Costs. In connection with a Technology Transfer pursuant to Section 2.11(a)(iv), Purchaser shall be responsible for the Technology Transfer Costs unless and until a Supply Disruption shall have occurred, in which event VIVUS shall be responsible for such Technology Transfer Costs, including reimbursing Purchaser for those already paid by Purchaser.

2.12 **Notice Right; Step-In Right**. VIVUS shall provide Purchaser with prompt written notice of any breach or alleged breach, including without limitation any notice of such breach or alleged breach provided by any Third Party manufacturer of API or bulk Product and shall provide Purchaser with copies of any documentation and correspondence between any Third Party manufacturer and VIVUS regarding such breach including written summaries of any oral discussions. In the event that VIVUS is in breach of any such manufacturing or supply agreement with a Third Party manufacturer, it shall promptly provide to Purchaser a written plan of action to remedy or cure such breach and shall keep Purchaser promptly informed of its progress or any changes to such plan of action. If VIVUS is unable to cure such breach, then, unless VIVUS is disputing such breach in good faith, at Purchaser's election VIVUS shall use Commercially Reasonable Efforts to cause such Third Party manufacturer to \*\*\*. VIVUS may condition disclosure of attorney-client privileged information or attorney work product on the Parties' execution of a joint defense agreement, common interest agreement, or similar agreement intended to preserve attorney-client and attorney work product privileges under Applicable Law, in a form reasonably acceptable to VIVUS.

2.13 **Adjustments Related to Third Party Manufacturers**. VIVUS will not at any time during the Term take any action that could reasonably be expected to result in a breach of any agreement between VIVUS and any Third Party manufacturer or supplier. VIVUS shall provide Purchaser with advance written notice of any material amendment, waiver of rights, termination or modification of any agreement between VIVUS and any Third Party manufacturer or supplier, and VIVUS will not agree to any amendment, waiver of rights, termination or modification of any agreement between VIVUS and any Third Party manufacturer or supplier that (a) that would reasonably be expected to result in (i) any non-routine increase in the Price, (ii) any early termination of this Agreement, or (iii) any increase in the Purchaser's Minimum Purchase Obligations or (b) has, or would reasonably be expected to have, any other material negative effect on Purchaser, in each case (a) and (b), without the prior written consent of Purchaser, which shall not be unreasonably withheld, conditioned, or delayed.

2.14 **API Purchase Option**. If VIVUS obtains the right to satisfy its minimum purchase obligations under all relevant manufacturing and/or supply agreements with Sanofi and/or any other relevant Third Party manufacturer (as applicable) by purchasing a combination of API and Product in lieu of solely Product from Sanofi and/or such other relevant Third Party manufacturer (as applicable), then the Parties shall discuss in good faith an option for Purchaser to fulfill its obligations under this Agreement by purchasing API in lieu of or in addition to Product, and possible adjustments or supplements to this Agreement to provide for the supply of API on comparable terms and conditions as for the supply of Product contained herein, including (a) a price for API and quantities for the API minimum purchase obligations, which appropriately take into account both purchases of Product and API, and (b) revisions to Section 4.2 and ARTICLE 5 to reflect, on a basis substantially comparable to the provisions set forth herein, that

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Purchaser will be buying and VIVUS shall be supplying API in lieu of or in addition to Product. VIVUS shall use Commercially Reasonable Efforts to negotiate in good faith with Sanofi or any other Third Party manufacturer, as applicable, to obtain the rights to satisfy its minimum purchase obligations by purchasing a combination of API and Product.

### 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 re-sell the Product.

3.2 **Payment.** VIVUS shall provide to Purchaser written invoices setting forth the amount payable by Purchaser with respect to quantities of Product sold hereunder, including the Price applied by VIVUS to each dosage strength of Product. Purchaser shall pay VIVUS for Product in the amount invoiced by VIVUS within \*\*\* from the date of invoice, which invoice shall be issued at the delivery date. If Purchaser is legally required to withhold any Taxes from payments due hereunder, Purchaser shall (a) deduct such Taxes from the payment made to VIVUS, and (b) timely pay the taxes to the proper taxing authority. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect and shall discuss in good faith how to solve any situation where VIVUS may not deduct such payment for reasons beyond VIVUS' reasonable control. Solely for purposes of this Section, "Taxes" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including interest, penalties and additions thereto) that are imposed by the applicable government or other taxing authority.

3.3 **Records; Audit.** VIVUS shall maintain complete and accurate books and records in accordance with GAAP in sufficient detail to permit Purchaser to confirm the accuracy of the Manufacturing Costs, and any other financial measure relating to the Price of the Product payable under this Agreement, for a period of \*\*\* from the creation of individual records or any longer period required by Applicable Law. At Purchaser's request, such records shall be available for review at a Purchaser's headquarters located at 11 Commerce Drive, 1st Floor, Cranford, New Jersey 07016, or a mutually agreeable location determined by Parties not more than once each calendar year (during normal business hours on a mutually agreed date with reasonable advance notice) by an independent Third Party auditor selected by Purchaser and approved by VIVUS (such approval not to be unreasonably withheld, conditioned, or delayed) and subject to confidentiality and non-use obligations no less stringent than those set forth in Article 11 of the License Agreement for the sole purpose of verifying for Purchaser the accuracy of the Manufacturing Costs and Price paid by Purchaser pursuant to this Agreement or of any payments made by Purchaser to VIVUS pursuant to this Agreement. Any such auditor shall not disclose VIVUS' Confidential Information to Purchaser, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by VIVUS or the amount of payments due by VIVUS under this Agreement. Any undisputed amounts finally determined to be owed but unpaid shall be paid within \*\*\* from the accountant's report. Any amounts finally determined to have been overpaid will either be refunded to Purchaser or credited to Purchaser against future payments to VIVUS hereunder, at Purchaser's option. Purchaser shall bear the full cost of such audit unless such audit reveals an underpayment or under-reporting error of \*\*\* percent (\*\*\*%) or more during the applicable audit period, in which case VIVUS shall bear the full cost of such audit.

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#### 4. REPRESENTATIONS, WARRANTIES AND COVENANTS

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

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

(b) Authority and Binding Agreement. It has the requisite power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and this Agreement has been duly executed and delivered on its behalf, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject as to enforcement of remedies to applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting generally the enforcement of creditors' rights and subject to a court's discretionary authority with respect to the granting of a decree ordering specific performance or other equitable remedies.

(c) Consents. All necessary consents, approvals and authorizations of all governmental authorities and other Third Parties required to be obtained by it in connection with the execution, delivery and performance of this Agreement have been obtained by it. For the avoidance of doubt, Purchaser shall be solely responsible for obtaining any product and/or distribution license from the applicable Governmental Authority so as to be able to sell and market the Product in a particular jurisdiction.

#### 4.2 **Product Representations and Warranties of VIVUS.**

(a) Compliance. VIVUS warrants that it will ensure that all Product will be manufactured and tested in conformity with this Agreement, the License Agreement, cGMP, the Specifications, and the Quality Agreement.

(b) Conformity with Specifications. VIVUS warrants that it will and will cause its Third Party suppliers to ensure that all Product manufactured by or on behalf of VIVUS and sold to Purchaser pursuant to this Agreement will at the time of delivery to the common carrier for such Product (i) meet the Specifications, (ii) not be misbranded or adulterated and (iii) will be in compliance with all Applicable Laws.

(c) No Liens. VIVUS warrants that all Product delivered to Purchaser pursuant to this Agreement will, at the time of such delivery, be free and clear of all liens, encumbrances, security interests and other encumbrances.

VIVUS' 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.

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4.3 **Other Representations and Warranties of VIVUS.**

(a) **Performance.** VIVUS will perform its obligations under this Agreement, and will use Commercially Reasonable Efforts to cause any Third Party supplier to perform their manufacturing obligations with respect to the Product, in a professional manner with requisite skill, care and diligence and in accordance with the industry standards. VIVUS will maintain, and will use Commercially Reasonable Efforts to cause its Third Party suppliers to maintain, appropriately qualified and trained personnel, adequate premises and space, suitable equipment, correct materials, containers and labels, suitable storage and the knowledge and experience to carry out satisfactorily the work ordered by Purchaser.

(b) **Compliance with Applicable Laws.** During the Term of this Agreement, VIVUS will comply with, and will use Commercially Reasonable Efforts to cause its Third Party suppliers to comply with, all Applicable Laws to the conduct of its business and manufacture of Product in the performance of this Agreement and will hold, or will cause its Third Party manufacturers to hold, all permits and authorizations necessary to fulfill its obligations under this Agreement.

(c) **Compliance with Certain Agreements.** VIVUS is in compliance in all material respects with, and will at all times remain in compliance in all material respects with, and has not received any notice of breach pursuant to any agreement relating to the manufacture of Product. To the Knowledge of VIVUS, as of the Effective Date, (i) Sanofi is not in breach of the Manufacturing and Supply Agreement, and (ii) Sanofi is in compliance with such agreement in all material respects.

(d) **Debarment.** VIVUS represents and warrants that it has not been debarred, nor is it under consideration to be debarred, and that it will not knowingly use in any capacity in connection with the manufacturing or services hereunder any person (including Third Party manufacturers) who has been debarred, nor is under consideration to be debarred by the FDA and/or TPD, the subject of a pending debarment pursuant to the Act, or who is the subject of a conviction described in such section. VIVUS will inform Purchaser in writing immediately upon becoming aware thereof if it or any person (including Third Party manufacturers) who is performing manufacturing or any services hereunder is debarred or is the subject of a conviction described in section 306 of the Act, or if any action, suit, claim, investigation, or proceeding is pending, or to the best of VIVUS' knowledge, is threatened, relating to the debarment or conviction of VIVUS, or any person performing manufacturing or services pursuant to this Agreement.

4.4 **Covenants of Purchaser.** Purchaser hereby covenants not to sue the VIVUS Indemnified Parties (as defined in Section 10.2 hereof), and shall defend, indemnify and hold harmless the VIVUS Indemnified Parties from and against any and all Losses incurred by the VIVUS Indemnified Parties, for any such VIVUS Indemnified Parties' compliance with any Financing Entity's notice of its exercise of rights and remedies under the Financing Documents in connection with any Financing Default (including during the pendency of any dispute between Purchaser and the Financing Entity relating to or arising under the Financing Documents, provided that the Financing Entity provides written notice to VIVUS of such exercise of such rights and remedies).

4.5 **No Other Representations or Warranties.** EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 4 OR THE LICENSE AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF VIVUS. ALL OTHER REPRESENTATIONS AND

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5. **QUALITY**

5.1 **General.** VIVUS shall be responsible for establishing and maintaining such procedures for implementing corrective and preventive actions with respect to the manufacturing of the Product as required by Applicable Law, cGMP, and the Quality Agreement. VIVUS shall cooperate with Purchaser at VIVUS' expense in determining the cause of any quality problems involving the Product, identifying corrective actions, and ensuring the implementation and effectiveness thereof. VIVUS shall implement such corrective actions with respect to the Product, and shall provide Purchaser with written confirmation upon the completion thereof.

5.2 **Notice of Failure to Meet Specifications.** Each Party shall notify the other Party immediately after the discovery that any lot of Product sold to Purchaser failed to comply with its applicable Specifications at the time of delivery or was not manufactured in accordance with Applicable Laws, including without limitation cGMP. VIVUS will immediately make, at its sole expense, such further internal investigation of any failure to meet these requirements as is reasonable under the circumstances and otherwise consistent with its obligations hereunder and shall use its best efforts to remediate such failure, which shall include the replacement of the quantity of non-conforming Product at no cost to Purchaser, as promptly as reasonably practicable.

5.3 **Changes to Specifications.**

(a) Changes Requested by Purchaser. VIVUS will not be required to implement any requests by Purchaser to change the manufacturing process, Specifications, or any testing method with respect to the Product, but VIVUS shall consider any such requests in good faith.

(b) Changes Requested by VIVUS. VIVUS will provide Purchaser with advance notice of any material changes to procedures, Specifications, methods (including testing methods) or standard operating procedures relating to the manufacture or supply of the Product and VIVUS will not make or permit any such changes without the prior written consent of Purchaser if such change is (i) inconsistent with the then-current approved NDA for the Product, (ii) reasonably likely to have a material adverse effect on VIVUS' ability to comply with the terms of this Agreement, including any Product delivery timelines hereunder, or (iii) otherwise reasonably likely to have an adverse impact on the Commercialization of the Product in the Purchaser Territory.

(c) Changes Required by Applicable Law. VIVUS will promptly, at its own expense, implement any changes to any procedures, Specifications, methods (including testing methods) or standard operating procedures relating to the manufacture or supply of the Product required by Applicable Law or the NDA (collectively, "**Required Manufacturing Changes**"); provided that Purchaser shall be responsible for any and all expenses arising from any such changes required by any changes to the NDA submitted to any Regulatory Authority by the Purchaser without VIVUS' prior written consent.

(d) Cost of Manufacturing Changes. Prior to a Supply Chain Transfer, VIVUS will be solely responsible for all internal and external costs, including, without limitation, obsolete raw materials, regulatory filings, work-in-process, and Product, (i) associated with Required Manufacturing Changes, and (ii) all costs associated with any other manufacturing changes not requested by Purchaser. Prior to a Supply Chain Transfer, Purchaser shall be responsible for such costs only in the event such

manufacturing change is requested by Purchaser and is not otherwise required by Applicable Law or the NDA; provided that Purchaser shall also be responsible for any and all expenses arising from any such changes required by any changes to the NDA submitted to any Regulatory Authority by the Purchaser without VIVUS' prior written consent.

5.4 **Quality Agreement.** Concurrent with the execution of this Agreement, the Parties have entered into a separate quality agreement governing the agreed-upon Specifications and other technical aspects of supply of Products to Purchaser hereunder (the "**Quality Agreement**"). In the event of any inconsistency between this Agreement and the Quality Agreement, this Agreement shall control, except with respect to quality assurance matters. VIVUS agrees to use its Commercially Reasonable Efforts to have three-way quality agreements put into place with Purchaser and VIVUS' Third Party manufacturers.

## 6. ACCEPTANCE AND REJECTION PROCEDURES

6.1 **Inspection.** Purchaser or its designee shall promptly, upon arrival on its site, carefully inspect each shipment of Product for transport damages, losses and shortfalls. Apparent defects, such as, for instance, damaged containers or missing packages of Product, must be notified to the carrier promptly upon arrival of the shipment and the freight documents at Purchaser or its designee and, where possible, countersigned by the carrier's representative. Failure of Purchaser or its designee to notify such visually detectable defects to the carrier promptly upon arrival of the concerned shipment and freight documents shall exclude any liability of VIVUS for such defects. Purchaser shall have \*\*\* after receipt of a shipment of Product to determine if there is any defect in the Product or any non-compliance with the Specifications or Applicable Law, including without limitation cGMP, which is discoverable by diligent and customary inspection of the shipment and any accompanying documentation (the "**Inspection Period**"). Purchaser shall notify VIVUS of any such non-compliance prior to the end of the Inspection Period, describing in reasonable detail the non-compliance. Notwithstanding the preceding provisions of this Section 6.1, if with respect to any unexpired Product, the non-compliance could not reasonably be expected to have been found by diligent and customary inspection during the Inspection Period and Purchaser notifies VIVUS of such non-compliance, describing such Latent Defect in detail, within \*\*\* of Purchaser's knowledge of the Latent Defect and within the shelf life of the Product, such non-compliance shall be deemed to be a "**Latent Defect**" hereunder. Purchaser's notification of VIVUS of a non-compliance during the Inspection Period or of a Latent Defect as permitted above shall be referred to herein as a "**Claim**". For the sole purpose of application of Section 6.2, Purchaser shall be deemed to have accepted any Product if it fails to give a Claim in the periods permitted above; provided, however, that Purchaser's acceptance of Product shall not limit Purchaser's indemnification rights under Section 10.1 (which, for clarity, shall be fully subject to the exceptions recited therein). At VIVUS' 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 Sanofi and/or any other relevant Third Party manufacturer.

6.2 **Remedies.** Except for Claims disputed pursuant to Section 6.2(b) hereof, if Purchaser submits a Claim, then as promptly as practicable after the submission of the Claim to VIVUS (but in no event later than \*\*\* after the submission of the Claim), VIVUS shall instruct Purchaser whether to return or destroy the Product in question and provide Purchaser with replacement Product. In the event that:

(a) VIVUS agrees with the Claim, then VIVUS shall pay for all out-of-pocket costs of returning or destroying Product that is the subject of any accepted Claim. VIVUS shall bear the risk of loss for such Product, beginning at such time as such Product is taken at Purchaser's premises for return delivery. VIVUS shall replace all nonconforming Product as promptly as reasonably practicable and at no cost to Purchaser.

(b) VIVUS does not agree with the Claim, then the Parties agree to submit the Product in question to a mutually agreed independent Third Party that has the capability of testing the Product to determine whether or not it complies with the Quality Agreement, the Specifications and Applicable Law, including cGMP. The losing Party shall bear all costs and expenses related to such testing and pay for all shipping costs of returning the Product and/or sending the replacement Product, as the case may be.

6.3 **Cost of Product Recalls.** With respect to any Product supplied hereunder, VIVUS shall bear all Losses (including without limitation expenses related to communications and meetings with all required regulatory agencies, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those customers) related to any Product Recall in the event that such Product Recall is caused by or results from (a) the breach by VIVUS (including indirectly by any Third Party manufacturer) of any representation or warranty or covenant contained in this Agreement or the License Agreement, or (b) VIVUS' negligence or willful misconduct. Additionally, in the event the Product Recall is caused by or results from (a) or (b) above, VIVUS shall replace the units of recalled Products as promptly as practicable and at no cost to Purchaser. Except as provided above, Purchaser shall bear all Losses related to any Product Recall.

## 7. REGULATORY MATTERS.

7.1 **Regulatory Responsibilities.** The Parties' respective rights and obligations with respect to Regulatory Approvals in the Purchaser Territory, communications with Regulatory Authorities in the Purchaser Territory, and other regulatory matters relating to the Product in the Purchaser Territory are set forth in the License Agreement.

## 8. RECORD-KEEPING; AUDITS

8.1 **Recordkeeping.** VIVUS (and/or Sanofi or any other Third Party manufacturer) will keep complete and accurate records of the manufacture and testing of Product, and retain samples of bulk Product and the active pharmaceutical ingredient in the Compound as are necessary to comply with Applicable Laws, as well as to assist with resolving Product complaints and other similar investigations. Copies of the records and samples will be retained for a period of \*\*\* following the date of Product expiry, or longer if required by Applicable Laws. Purchaser is responsible for retaining samples of the fully packaged Product necessary to comply with the legal/regulatory requirements applicable to Purchaser.

### 8.2 Audits.

(a) Audit Right; Facility Access. From and after the commencement of supply hereunder directly or through an independent auditor reasonably acceptable to VIVUS, Purchaser shall have the right, upon reasonable advance notice and during regular business hours, to make an annual inspection and audit of the facilities being used by VIVUS or a VIVUS Affiliate for the production, storage, or testing of Product to assure compliance by or on behalf of VIVUS with cGMPs, the Specifications, and Applicable Law. At Purchaser's reasonable request, VIVUS agrees to use Commercially Reasonable Efforts to facilitate a similar inspection and audit of the facilities being used by Sanofi and/or any other Third Party manufacturer, such as, solely by way of example, by exercising VIVUS' audit right in its agreement with such manufacturer, at Purchaser's cost, and permitting Purchaser or its designee to attend such audit (subject to approval by the Third Party manufacturer to allow such attendance, which VIVUS shall use Commercially Reasonable Efforts to obtain) and in any event sharing the results of such audit with Purchaser.

(b) Third Party Audits. Without limiting VIVUS' obligations under this Agreement in any respect, Purchaser acknowledges that VIVUS' audit rights in its manufacturing and supply agreements with Sanofi are limited to periodic audits to ensure that cGMPs continue to be followed. In the event that VIVUS or any Third Party licensee of VIVUS outside the Purchaser Territory proposes to conduct or conducts an audit of the facilities used by or on behalf of VIVUS or a VIVUS Affiliate or Third Party for the production, storage, or testing of Product to be sold to Purchaser under this Agreement, then VIVUS will provide immediate notice to Purchaser of such audit and VIVUS shall use its Commercially Reasonable Efforts to permit Purchaser to be able to be present for and participate in such audit.

(c) Procedure. The inspection and audit provided for under Section 8.2(a) shall not be carried out by Purchaser more than \*\*\* per calendar year, but such inspection and audit shall not preclude Purchaser from conducting any "for cause" inspection or audit permitted under the Quality Agreement or otherwise for cause. Each inspection and audit shall be conducted in a manner so as to minimize disruption of the business operations of VIVUS, Sanofi and/or any other Third Party manufacturer. VIVUS representatives will be permitted to participate as observers during any such inspection and audit. To the extent that Purchaser requests an inspection or audit of the facilities of Sanofi and/or any other Third Party manufacturer, Purchaser acknowledges that VIVUS must coordinate the dates and schedule of such inspection and audit with Sanofi and/or such other Third Party manufacturer. The independent auditor, if any, shall enter into a written confidentiality agreement with VIVUS containing provisions regarding the disclosure of information obtained during the inspection and 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, Sanofi and/or any other Third Party manufacturer) failed to comply with the requirements of Section 8.1 (and shall not be permitted to disclose to Purchaser any other information). A copy of any such disclosure to Purchaser shall also be provided to VIVUS.

(d) Results. If an inspection or audit reveals a failure to comply with cGMP or Applicable Law in any material respect, then Purchaser shall promptly provide to VIVUS written notice of such fact, which notice shall contain in reasonable detail the deficiencies found in the applicable facilities and, if practicable, those steps Purchaser believes should be undertaken in order to remedy such deficiencies. The Parties shall discuss in good faith the deficiencies and VIVUS shall, at its own expense, use its best efforts to remedy such deficiencies, or implement a plan to remedy such deficiencies, as soon as reasonably practical following receipt of the notification thereof. In addition to the audit rights set forth in this Section 8.2, Purchaser will be entitled to perform reasonable follow-up inspections to monitor correction of such deficiencies or the circumstances giving rise to such deficiency, failure or notice.

8.3 **Analytical Method Transfer**. Upon the reasonable prior written request of Purchaser, VIVUS agrees to provide Purchaser or use Commercially Reasonable Efforts to cause its Third Party designee hereunder to provide Purchaser with all required documentation and support for analytical method transfer for the Product in order to enable Purchaser to analyze the Product in order to determine its suitability and stability under this Agreement and according to all applicable requirements of Regulatory Authorities or to ensure that the Products are in line with the Regulatory Approvals (a "**Method Transfer**"). VIVUS agrees to actively participate, or use Commercially Reasonable Efforts to cause its Third Party designee hereunder to participate, in such Method Transfer by, among other things, providing samples and conducting parallel testing. Purchaser shall pay for any out-of-pocket costs incurred by VIVUS in connection with such Method Transfer, except in connection with the first Method Transfer to establish stability testing.

8.4 **Regulatory Compliance.** VIVUS will advise Purchaser promptly if an authorized agent of a Regulatory Authority visits its facilities (or, to its knowledge, its Third Party designee's manufacturing facilities) where the API or the Product is being manufactured, stored, or tested. VIVUS will provide Purchaser with all material information in VIVUS' possession pertaining to actions taken by Regulatory Authorities (including any inspections, proposed regulatory actions, investigations or requests for information or a meeting by any Regulatory Authority) whether inside the Purchaser Territory or outside the Purchaser Territory in connection with the API or the Product in the Field, including any notice, audit notice, notice of initiation by Regulatory Authorities of investigations, inspections, detentions, seizures or injunctions concerning the API or the Product in the Field whether inside the Purchaser Territory or outside the Purchaser Territory, notice of violation letter (*i.e.*, an untitled letter), warning letter, service of process or other inquiry; provided, however, that VIVUS shall be entitled to redact those portions thereof to the extent not related to the API or the Product in the Field or to the extent disclosing Third Party confidential information. Without limiting the generality of the foregoing, each Party shall promptly, but in any event within two (2) Business Days, inform the other Party of any material inspections, proposed regulatory actions, investigations or requests for information or a meeting by any Regulatory Authority with respect to the API or the Product in the Field in the Manufacturing Territory. VIVUS or its Third Party designee will furnish to Purchaser all material information supplied to, or supplied by, any Regulatory Authority in the Manufacturing Territory, including the Form 483 observations and responses, to the extent that such information relates to the API or the Product or the ability of VIVUS to supply such API or the Product and could reasonably be expected to have a material negative effect on the Purchaser or the Commercialization of the Product in the Purchaser Territory, within \*\*\* of their receipt of such information, in each case to the extent that VIVUS is aware of such information and subject in each case to the redaction right described above. VIVUS or its Third Party designee will consult in advance with Purchaser prior to responding to any request from a Regulatory Authority to the extent such response relates to the API or the Product, and VIVUS will use Commercially Reasonable Efforts to permit Purchaser and/or its agents to be present at any inspection by any Regulatory Authority of any manufacturing facility where the API or the Product that is supplied to Purchaser hereunder is being manufactured or quality tested.

## 9. TERM; TERMINATION

9.1 **Term.** The term of this Agreement (the "**Term**") will commence on the Effective Date and will continue, unless otherwise agreed between the Parties, for a period ending on the fifth (5<sup>th</sup>) anniversary of the Effective Date. Thereafter, the Term shall be automatically renewed for successive two- (2) year periods, unless either Party provides a termination notice to the other Party at least \*\*\* in advance of the expiration of the then-current Term.

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; provided, however, that, except with respect to any breach of Section 2.4 hereof, in the event the non-terminating Party contests any such asserted breach in good faith and diligently pursues the dispute resolution procedures set forth in Article 14, such thirty (30) day cure period shall be tolled or suspended until the final resolution of such dispute pursuant to the terms of, and in accordance with, the terms and provisions of Article 14; 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

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

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which may be available to the non-defaulting Party, including any rights or remedies under the License Agreement.

9.3 **Termination Upon Termination of License Agreement.** In addition to the termination rights expressly provided for elsewhere in this Agreement, either Party may also terminate this Agreement upon written notice to the other Party if the License Agreement is terminated in accordance with its terms.

9.4 **Termination upon Transfer of Control of Supply Chain.** This Agreement shall automatically terminate upon the completion of the Supply Chain Transfer (as defined in the License Agreement).

9.5 **Effects of Termination.** Upon expiration or termination of this Agreement other than termination of this Agreement by Purchaser under Section 9.2(a), VIVUS shall manufacture and supply, and Purchaser shall purchase from VIVUS (a) any and all quantities of Product ordered by Purchaser pursuant to this Agreement prior to the date on which such notice is given, for the applicable Price, and (b) any and all materials held by VIVUS or Sanofi (or any other Third Party manufacturer of Product) for exclusive use in the manufacture of Compound or Product based on binding part of the Forecasts provided by Purchaser, for an amount equal to the \*\*\* with respect to such materials. Termination or expiration of this Agreement will not affect any outstanding obligations due hereunder prior to the termination or expiration. In the event of Purchaser's termination of this Agreement under Section 9.2(a), Purchaser shall not be required to purchase any additional quantities of Product from VIVUS and all orders of Product shall be immediately voided and of no effect with no further obligation of Purchaser to VIVUS with respect to materials held by VIVUS or a Third Party manufacturer for manufacture of the Compound or Product.

9.6 **Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to the effective date of such expiration or termination. The following sections shall survive termination or expiration of this Agreement for any reason: Sections 2.11, 3.3, 6.1, 6.3 and 8.1 and Articles 9 through 14 and 16.

## 10. INDEMNIFICATION

10.1 **Indemnification by VIVUS.** VIVUS shall defend and indemnify and hold Purchaser, its Affiliates and their respective directors, officers and employees (the "**Purchaser Indemnified Parties**") harmless against any and all Losses resulting from any Claim of a Third Party arising out of, based on, or caused by (i) alleged or actual bodily injury or property damage resulting from the manufacturing, packing, labeling, handling, storage, transportation, use, distribution of Products by or on behalf of VIVUS, its licensees (other than Purchaser) or Affiliates, including any product liability claim; (ii) liabilities arising from clinical trials conducted by or on behalf of VIVUS in connection with any Products; (iii) the breach by VIVUS of any representation or warranty or covenant contained in this Agreement; (iv) the Product supplied by VIVUS to Purchaser hereunder failing to meet the warranties set forth in Section 4.2; or (v) the negligence or willful misconduct of VIVUS or its Affiliates, sublicensees, or any of its agents, directors, officers or employees, except in each case to the extent that such Losses arise directly from the breach by Purchaser of any representation or warranty or covenant contained in this Agreement or any negligence or willful misconduct by a Purchaser Indemnified Party.

10.2 **Indemnification by Purchaser.** Purchaser agrees to defend and indemnify and hold VIVUS, its Affiliates and their respective directors, officers and employees (the "**VIVUS Indemnified Parties**") harmless against any and all Losses resulting from any Claim of a Third Party arising out of, based on, or caused by (i) the storage, sale, shipment, promotion or distribution of the Product by Purchaser

after Purchaser has taken title to the Product, or (ii) the breach by Purchaser of any representation or warranty or covenant contained in this Agreement, except in each case to the extent that such Losses arise (x) directly from the breach by VIVUS of any representation or warranty or covenant contained in this Agreement (including breach of Section 4.2), (y) any negligence or willful misconduct by a VIVUS Indemnified Party, or (z) and are directly attributable to any uncured breach, that is not the subject of a good faith dispute, by VIVUS of the License Agreement.

10.3 **Indemnification Procedures.** The Party claiming indemnity under this Article 10 (the “**Indemnified Party**”) shall give written notice to the Party from whom indemnity is being sought (the “**Indemnifying Party**”) promptly and in no event later than \*\*\* after learning of a written claim (“**Indemnified Claim**”). Failure by an Indemnified Party to give notice of an Indemnified Claim within \*\*\* of receiving a writing reflecting such Claim shall not relieve the Indemnifying Party of its indemnification obligations hereunder except and solely to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give such notice. The Indemnifying Party shall have the right to assume the conduct and defense of the Indemnified Claim with counsel of its choice so long as the Indemnifying Party is conducting a good faith and diligent defense; provided that, the Indemnifying Party shall not have the right to assume any Indemnified Claim if (x) the Indemnifying Party fails to provide reasonable evidence of its ability and willingness to satisfy such claim, or (y) such claim involves a criminal or regulatory enforcement action. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance in connection with the defense of the Indemnified Claim. The Indemnified Party may monitor such defense with counsel of its own choosing at its sole expense; provided, that if under applicable standards of professional conduct a conflict of interest exists between the Indemnifying Party and the Indemnified Party in respect of such claim, such Indemnified Party shall have the right to employ separate counsel to represent such Indemnified Party with respect to the matters as to which a conflict of interest exists and in that event the reasonable fees and expenses of such separate counsel shall be paid by the Indemnifying Party. The Indemnifying Party may not settle the Indemnified Claim without the prior written consent of the Indemnified Party, such consent shall not be unreasonably withheld, delayed or conditioned. In no event shall the Indemnifying Party settle the Indemnified Claim unless such settlement provides an unconditional and full release of the Indemnified Party. If the Indemnifying Party does not assume and conduct the defense of the Indemnified Claim as provided above: (a) the Indemnified Party may assume and conduct the defense of the Indemnified claim at the Indemnifying Party’s expense; (b) the Indemnified Party may consent to the entry of any judgment or enter into any settlement with respect to the Indemnified Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith); and (c) the Indemnifying Party will remain responsible to indemnify the Indemnified Party for Indemnified Amounts as provided in this Article 10.

## 11. LIMITATION OF LIABILITY

11.1 **Limitation.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY EXEMPLARY, SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES, COSTS OR EXPENSES (INCLUDING LOST PROFITS, LOST REVENUES AND/OR LOST SAVINGS) ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTHING IN THE PRECEDING SENTENCE IS INTENDED TO OR SHALL LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY IN CONNECTION WITH THIRD PARTY CLAIMS UNDER ARTICLE 10, (B) DAMAGES OR INJUNCTIVE RELIEF AVAILABLE FOR A PARTY’S BREACH OF ARTICLE 13, (C) DAMAGES TO THE EXTENT ARISING FROM OR RELATING TO WILLFUL MISCONDUCT OR FRAUDULENT ACTS OR OMISSIONS OF A PARTY

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OR (D) DIRECT DAMAGES. EXCEPT FOR WILLFUL MISCONDUCT OR LOSSES ASSOCIATED WITH PRODUCT RECALLS, 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 \*\*\*; PROVIDED, HOWEVER THAT THIS LIMITATION SHALL NOT APPLY TO (I) VIVUS' OBLIGATIONS IN CONNECTION WITH THIRD PARTY CLAIMS UNDER ARTICLE 10 OR (II) DAMAGES TO THE EXTENT ARISING FROM OR RELATING TO VIVUS' NEGLIGENCE, WILLFUL MISCONDUCT OR FRAUDULENT ACTS OR OMISSIONS. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS AGREEMENT SHALL LIMIT THE LIABILITY OF EITHER PARTY UNDER THE LICENSE AGREEMENT.

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

## **12. INSURANCE.**

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

- (a) commercial general liability coverage with minimum per claim limits of at least \$\*\*\* per occurrence and \$\*\*\* annual aggregate, the policy(ies) for which shall (A) name VIVUS as an additional insured, and (B) be primary and non-contributory;
- (b) automobile liability coverage covering all owned, hired and non-owned automobile equipment with minimum per claim limits of \$\*\*\* per occurrence and annual aggregate, the policy(ies) for which shall name VIVUS as an additional insured;
- (c) excess liability/umbrella coverage with minimum per claim limits of at least \$\*\*\* per occurrence and annual aggregate;
- (d) products liability coverage with minimum per claim limits of at least \$\*\*\* per occurrence and annual aggregate with a \*\*\* extended reporting period endorsement, the policy(ies) for which shall name VIVUS as an additional insured; and
- (e) property coverage having limits adequate for Product inventory in Purchaser's care, custody, and/or control and for Product in transit to and from Purchaser.

12.2 VIVUS shall procure and maintain insurance or self-insure during the Term of this Agreement and for a period of \*\*\* following the termination or expiration of this Agreement, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Upon written request, VIVUS shall provide proof of adequate coverage to Purchaser. VIVUS may substitute a self-insurance program to satisfy in whole or in part its obligations under this Article 12 on written notice to the Purchaser with information demonstrating the adequacy of such program.

12.3 It is understood that the insurance requirements in Sections 12.1 and 12.2 above shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under Article 10. Furthermore, it is understood that Purchaser's insurance requirements in Section 12.1 hereof are intended to be consistent with, and not to increase, the minimum insurance coverage obligations of the Purchaser under the License Agreement. Each Party shall provide the other Party with written evidence of such insurance upon written request. Each Party shall provide the other Party with written notice at least \*\*\* prior to the cancellation, non-renewal or material change in such insurance (or, in the case of VIVUS, self-insurance, as applicable) that materially adversely affects the rights of the other Party hereunder.

### 13. CONFIDENTIALITY; PROPRIETARY RIGHTS

13.1 **Confidentiality.** Each Party will maintain the Confidential Information of the other Party in accordance with Article 11 of the License Agreement. The Parties agree not to disclose any financial terms or conditions of this Agreement to any Third Party without the prior consent of the other Party, except as required by Applicable Law.

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

### 14. DISPUTE RESOLUTION

#### 14.1 Disputes.

(a) 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.

(b) Notwithstanding anything to the contrary in this Article 14, any Financing Entity may bring a proceeding in a court of competent jurisdiction located in the State of New York solely to enforce its rights under Sections 14.1, 16.1, 16.6, and 16.8 hereof. Such courts of competent jurisdiction located in the State of New York shall have the sole and exclusive jurisdiction to hear and adjudicate any claims pursuant to this Section 14.1(b).

14.2 **Arbitration.** Any dispute, controversy or claim arising out of or relating to the validity, construction, interpretation, enforceability, breach, performance, application or termination of this Agreement that is not resolved pursuant to Section 14.1, shall be settled by binding arbitration administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures of JAMS then in effect (the "**JAMS Rules**"), except as otherwise provided herein. The arbitration shall be governed by the United

States Federal Arbitration Act, 9 U.S.C. §§ 1-16 (the “**Federal Arbitration Act**”), to the exclusion of any inconsistent state laws. The United States Federal Rules of Civil Procedure shall govern discovery and the rules of evidence for the arbitration. The arbitration will be conducted in New York, New York, and the Parties consent to the personal jurisdiction of the United States federal courts, for any case arising out of or otherwise related to this arbitration, its conduct and its enforcement. Any situation not expressly covered by this Agreement shall be decided in accordance with the JAMS Rules.

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

14.4 **Decision.** The power of the arbitrator to fashion procedures and remedies within the scope of this Agreement is recognized by the Parties as essential to the success of the arbitration process. The arbitrator shall not have the authority to fashion remedies which would not be available to a federal judge hearing the same dispute. The arbitrator is encouraged to operate on this premise in an effort to reach a fair and just decision. Reasons for the arbitrator’s decisions should be set forth in accordance with the JAMS Rules. Such a written decision shall be rendered by the arbitrator following a full comprehensive hearing, no later than **\*\*\*** following the selection of the arbitrator as provided for in Section 14.3.

14.5 **Award.** Any award shall be promptly paid in United States dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by Applicable Law, be charged against the Party resisting enforcement. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Article 14, and agrees that, subject to the Federal Arbitration Act, judgment may be entered upon the final award in any court of competent jurisdiction and that other courts may award full faith and credit to such judgment in order to enforce such award. The award shall include interest from the date of the award until paid in full, at a rate fixed by the arbitrator and the arbitrator may, in his or her discretion, award pre-judgment interest. With respect to money damages, nothing contained herein shall be construed to permit the arbitrator or any court or any other forum to award punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for punitive or exemplary damages, subject to the exceptions set forth in Article 11.

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

14.7 **Injunctive Relief.** Provided a Party has made a sufficient showing under the rules and standards set forth in the Federal Rules of Civil Procedure and applicable case law, the arbitrator shall have the freedom to invoke, and the Parties agree to abide by, injunctive measures after either Party submits in writing for arbitration claims requiring immediate relief. Additionally, nothing in this Article 14 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

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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 disclosures and requests confidential treatment of certain commercial terms and technical terms hereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, such Party will provide the other Party, a reasonable time prior to filing, with a copy of the Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements applicable to such Party and that govern redaction of information from material agreements that must be publicly filed. The other Party shall provide any such comments as promptly as practicable. The intention of the Parties is to agree upon a single redacted version of the Agreement to be filed with the SEC or any other applicable entity.

15.2 **Use of Names.** Except as otherwise required by law or by the terms of this Agreement or the License Agreement, or as mutually agreed upon by the Parties, neither Party shall make any use of the name of the other Party in any advertising or promotional material, or otherwise, without the prior written consent of the other Party, which consent shall not be unreasonably withheld.

**16. MISCELLANEOUS**

16.1 **Entire Agreement; Amendment.** This Agreement, including the Exhibits hereto, together with the letter agreement dated September 30th, 2016 between VIVUS and Hercules Capital, Inc., and the terms of the License Agreement which are incorporated herein by reference, 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 anything to the contrary in this Section 16.1, no amendment of the definitions of "Financing Entity," "Financing Default," "Qualified Assignee," or "Permitted Assignment" or Sections 14.1, 16.1, 16.6, and 16.8 hereof that effects the rights of any Financing Entity shall be effective without the prior written consent of each Financing Entity.

**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 any or all 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; provided that, in the event of a force majeure impacting the Parties' rights and obligations under Section 2.8 and Section 2.11 of this Agreement, VIVUS shall use Commercially Reasonable Efforts to perform its obligations pursuant to Section 2.8 and Section 2.11 of this Agreement, as applicable. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party.

**16.4 Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 16.4, and shall be deemed to have been given for all purposes when received, if hand-delivered or by means of facsimile or other electronic transmission, or \*\*\* after being sent by a reputable overnight delivery service.

If to VIVUS:	VIVUS, Inc. 351 E. Evelyn Avenue Mountain View, CA 94041 Facsimile: (650) 934-5320 Attention: Chief Financial Officer Email: cfo@vivus.com
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With a copy to: Weil, Gotshal & Manges LLP  
767 Fifth Avenue  
New York, NY 10153  
Facsimile: (212) 310-8007  
Attention: Michael A. Epstein  
Email: michael.epstein@weil.com

If to Purchaser: Metuchen Pharmaceuticals, LLC  
11 Commerce Drive, 1st Floor  
Cranford, NJ 07016  
Facsimile: (908) 272-3084  
Attention: Greg Ford  
Email: GFord@kfe-llc.com

With a copy to: Mist Pharmaceuticals, LLC  
11 Commerce Drive, 1st Floor  
Cranford, NJ 07016  
Facsimile: (908) 272-3084  
Attention: Keith Rotenberg, President  
Email: krotenberg@mistpharma.com

With a copy to: Lowenstein Sandler LLP  
65 Livingston Avenue  
Roseland, New Jersey 07068  
Facsimile: (973) 597-2400  
Attention: Michael J. Lerner  
Email: MLerner@lowenstein.com

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 (including any Financing Entity or Qualified Assignee, as applicable), (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 any other agreement to Articles, Sections, or Exhibits will be construed to refer to Articles, Sections, and Exhibits of or to this Agreement.

16.6 **Assignment.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that (a) 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, (b) Purchaser may assign this Agreement and any of Purchaser’s rights or obligations hereunder as collateral to any Financing Entity pursuant to one or more Financing Documents without the consent of VIVUS or any other Person, (c) neither the consent of VIVUS nor any other Person shall be required for the assignment of this Agreement and all of Purchaser’s rights, obligations and liabilities hereunder (including any and all liabilities that accrued prior to such assignment, but excluding liabilities under Sections 4.4 and 10.2 hereof) to any Financing Entity upon the occurrence of a Financing Default, provided that at least five (5) Business Days prior to any transfer or assignment of this Agreement in accordance with the terms of this clause (c), such Financing Entity provides VIVUS with a general description of the Financing Entity’s business and operations or equivalent documentation, and (d) neither the consent of VIVUS nor any other Person shall be required for the assignment of this Agreement and all of Purchaser’s rights, obligations and liabilities hereunder by Purchaser (with the consent of the Financing Entity, provided that the Purchaser and the Financing Entity jointly provide timely notice to VIVUS of such consent) or any Financing Entity upon the occurrence of a Financing Default to any Qualified Assignee that is a successor to or assignee of all or substantially all of the assets or business of Purchaser to which this Agreement pertains; provided that any assignment to a Financing Entity or a Qualified Assignee in connection with a Financing Default must also include an agreement, in writing, signed by such Financing Entity or Qualified Assignee, as applicable, to assume performance of all of Purchaser’s rights and obligations, and assume all of Purchaser’s outstanding liabilities (including any and all liabilities that accrued prior to such assignment, but excluding liabilities under Sections 4.4 and 10.2 hereof), provided that in the case of clauses (c) and (d) above, with respect to any liabilities accrued by Purchaser (including Purchaser’s liabilities under Sections 4.4 and 10.2 hereof), such Financing Entity and/or Qualified Assignee, as applicable, shall, at VIVUS’ request and expense (which shall be limited to such Financing Entity’s or Qualified Assignee’s, as applicable, reasonable out-of-pocket-expenses), cooperate and provide reasonable assistance to VIVUS (including the providing, subject to a customary confidentiality agreement, of any relevant information to VIVUS in such Person’s possession) in connection with, and to support, VIVUS’ efforts to seek recovery for any Losses under Purchaser’s insurance policy), thereunder (any of the foregoing assignments, a “**Permitted Assignment**”). Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16.6 shall be null, void and of no legal effect.

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

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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 (i) the Parties and, to the extent provided in Sections 10.1 and 10.3, the Indemnified Parties and (ii) any Financing Entity solely with respect to Sections 14.1, 16.1, 16.6, and this Section 16.8 (and the Parties hereto acknowledge and agree that each Financing Entity (including Hercules Capital, Inc.) is an express third-party beneficiary of such Sections 14.1, 16.1, 16.6, and this Section 16.8. 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' sole and exclusive option, either by VIVUS directly or by any Affiliate or Third Party that VIVUS causes to satisfy, meet or fulfill such obligation, in whole or in part. Any obligation of Purchaser under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at Purchaser's sole and exclusive option, either by Purchaser directly or by any Affiliate of Purchaser or Third Party that Purchaser causes to satisfy, meet or fulfill such obligation, in whole or in part. Each of the Parties guarantees the performance of all actions, agreements and obligations to be performed by any Affiliates of such Party or a Third Party under the terms and conditions of this Agreement, and shall cause its Affiliates or such Third Party to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

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

*[Signature page follows]*

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed as of the date last signed below.

**Metuchen Pharmaceuticals LLC**

By: /s/ J. Gregory Ford  
Name: J. Gregory Ford  
Title: CEO  
Date: 9/30/2016

**Vivus, Inc.**

By: /s/ Seth H. Z. Fischer  
Name: Seth H. Z. Fischer  
Title: CEO  
Date: 9/30/2016

**Acknowledged and Agreed:**

**Hercules Capital, Inc.**

By /s/ Melanie Grace  
Name: Melanie Grace  
Title: GC/CCO  
Date: 9/30/2016

*[Signature Page to Commercial Supply Agreement]*

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EXHIBIT A

Table 1 Specifications for Commercial Bulk Avanafil Tablets

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**EXHIBIT B**  
**Current Manufacturing Cost**

For Product manufactured by Sanofi, the Manufacturing Cost shall be as follows, subject to an annual Sanofi price increase, currency exchange rate fluctuation and yield loss adjustment if significant:

<u>Dosage forms</u>	<u>Current Manufacturing Cost</u> (per tablet)
50mg tablet	US\$***/tablet
100mg tablet	US\$***/tablet
200mg tablet	US\$***/tablet

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EXHIBIT C  
Minimum Purchase Obligations\*

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\* For purposes of this Agreement, “\*\*\*” will be calculated as the number \*\*\* or \*\*\* the number of \*\*\*. Thus, for example, \*\*\* is \*\*\*, and \*\*\* equals \*\*\*.

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## EXHIBIT D

### Current Inventory

50 mg dosage strength – \*\*\* tablets;

100 mg dosage strength – \*\*\* tablets; and

200 mg dosage strength – \*\*\* tablets.

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**EXHIBIT D**  
**PRESS RELEASE**

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## VIVUS AND METUCHEN PHARMACEUTICALS ANNOUNCE LICENSE AGREEMENT FOR COMMERCIAL RIGHTS TO STENDRA

**VIVUS grants an exclusive license to Metuchen Pharmaceuticals for STENDRA® (avanafil) commercial rights in the U.S., Canada, South America and India**

MOUNTAIN VIEW, CA and CRANFORD, NJ – September 30, 2016 - VIVUS, Inc. (Nasdaq: VVUS; “VIVUS”) and Metuchen Pharmaceuticals LLC (“Metuchen”) today announced the signing of an agreement providing Metuchen, a fully-paid, perpetual license for exclusive rights to commercialize STENDRA® (avanafil) in the U.S., Canada, South America and India. The parties simultaneously signed a commercial supply agreement pursuant to which VIVUS will be responsible for the manufacture and supply of STENDRA to Metuchen for a mutually agreed term. For a period of 180 days, Metuchen has the option to assume the manufacturing and supply rights of STENDRA for its territories. Under the license agreement, VIVUS received \$70 million. Additionally, Metuchen will be responsible for royalties due to Mitsubishi Tanabe Pharma Corporation based on net sales.

STENDRA is an oral phosphodiesterase type 5 inhibitor. STENDRA was approved by the FDA in April 2012 for the treatment of erectile dysfunction (ED) in the United States and sold under the trade name SPEDRA in the European Union.

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“We are excited to announce our commercial collaboration with Metuchen. Metuchen management’s strong commercial experience positions them well to take advantage of STENDRA’s strong clinical profile within the \$3.5 billion erectile dysfunction market. With a 15 minute onset of action, the ability to be taken with food or alcohol and a strong side-effect profile, STENDRA commercialization with Metuchen will optimize the brand’s potential,” stated Seth H. Z. Fischer, VIVUS CEO. “This collaboration is the first announcement to arise out of the strategic business review process announced earlier this year, and we look forward to providing additional updates in the coming months.”

### About Avanafil

STENDRA® (avanafil) is approved in the U.S. by the FDA for the treatment of erectile dysfunction. Metuchen Pharmaceuticals LLC has exclusive marketing rights to STENDRA in the U.S., Canada, South America and India.

STENDRA is available through retail and mail order pharmacies.

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

VIVUS has granted an exclusive license to Sanofi to commercialize avanafil in Africa, the Middle East, Turkey, and the Commonwealth of Independent States (CIS) including Russia.

Avanafil is licensed from Mitsubishi Tanabe Pharma Corporation (MTPC). VIVUS owns worldwide development and commercial rights to avanafil for the treatment of sexual

dysfunction, with the exception of certain Asian-Pacific Rim countries. VIVUS is in discussions with other parties for the commercialization rights to its remaining territories.

For more information about STENDRA, please visit [www.STENDRA.com](http://www.STENDRA.com).

### Important Safety Information

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

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

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

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

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

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

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PDE5 inhibitors, including STENDRA, and call a doctor right away.

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

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

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

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

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

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

### About VIVUS

VIVUS is a biopharmaceutical company commercializing and developing innovative, next-generation therapies to address unmet needs in obesity and sexual health. For more information about the company, please visit [www.vivus.com](http://www.vivus.com).

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 and are subject to risks, uncertainties and other factors, including risks and uncertainties related to potential change in our business strategy to enhance long-term stockholder value; risks and uncertainties related to the timing, strategy, tactics and success of the commercialization of STENDRA (avanafil) by our sublicensee in the U.S., Canada, South America and India; risks and uncertainties related to our ability to successfully complete on acceptable terms, and on a timely basis, avanafil partnering discussions for territories under our license with MTPC in which we do not have a commercial collaboration; and risks and uncertainties related to our ability to protect our intellectual property



and litigation in which we are involved or may become involved. 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' Form 10-K for the year ended December 31, 2015 as filed on March 9, 2016 and as amended by the Form 10-K/A filed on April 22, 2016, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

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#### **About Metuchen**

Metuchen Pharmaceuticals LLC is a privately-held specialty pharmaceutical company dedicated to improving men's health through innovative proprietary pharmaceutical products that have unique and meaningful clinical benefits.

#### **VIVUS, Inc.**

Mark Oki  
Chief Financial Officer  
[oki@vivus.com](mailto:oki@vivus.com)  
650-934-5200

#### **VIVUS Investor Relations: The Trout Group**

Brian Korb  
Managing Director  
[bkorb@troutgroup.com](mailto:bkorb@troutgroup.com)  
646-378-2923

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#### **EXHIBIT E LETTER AGREEMENT**

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**EXHIBIT F**  
**QUALITY AGREEMENT**

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**QUALITY TECHNICAL AGREEMENT**

Between

**VIVUS, INC.**

And

**METUCHEN PHARMACEUTICALS LLC**

Dated as of

**September 30, 2016**

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## 1 APPROVALS

This Quality Technical Agreement is approved by:

VIVUS, INC.

/s/ Vincent Ho 9/30/2016

Vincent HoDate

Director, QA

/s/ John L. Slebir for Ted Broman 9/30/2016

Ted Broman Date

Vice President, Chemistry, Manufacturing and Control

METUCHEN PHARMACEUTICALS LLC

/s/ Greg Ford 9/30/2016

Greg FordDate

President and Chief Executive Officer

*[Signature Page to Quality Technical Agreement]*

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This Quality Technical Agreement (“**Agreement**”) is entered into by and between Metuchen Pharmaceuticals LLC, a limited liability company organized under the laws of Delaware, located at 11 Commerce Drive, 1st Floor, Cranford, New Jersey 07016 (“**Licensee**”), and VIVUS, Inc. located at 351 E. Evelyn Ave. Mountain View, CA 94041 (“**VIVUS**”), defines the parties’ quality responsibilities as they are related to the product(s) and services listed below. The products shall collectively be referred to herein as the “**Products**” and the services shall collectively be referred to herein as the “**Services**.”

Product(s)	Services provided by VIVUS
Stendra™ tablets 50mg, 100mg, 200mg	Manufacturing of bulk tablets.  Bulk product is manufactured for VIVUS by the CMO (as defined below)

Subject to the terms of this Agreement, any changes to this Agreement may be made solely by an amendment in writing signed by both parties. Main contacts at Licensee and VIVUS are listed in APPENDIX 1. Contacts, hereby incorporated herein by reference. APPENDIX 1 is subject to change without the need to re-sign this Agreement and assign a new version number. This Agreement is entered into as of September 30, 2016.

Licensee and VIVUS are parties to (i) that certain License and Commercialization Agreement dated as of the date hereof (the “**License Agreement**”), and (ii) that certain Commercial Supply Agreement dated as of the date hereof (the “**Supply Agreement**”, and together with the License Agreement, the “**Transaction Agreements**”). In the event of conflict between this Agreement and the Transaction Agreements, the Transaction Agreements shall govern except with respect to quality assurance matters.

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**1. Definitions**

For the purposes of this Agreement, the following terms, whether used in the singular or plural, shall have the meanings set forth in this Section 1. Capitalized terms not defined herein shall have the meaning as set forth in the Supply Agreement.

**cGMP:** The current guidelines for Good Manufacturing Practice for human pharmaceuticals and biologics, as amended from time to time, in force in the United States, the European Union, Canada and Japan, including the guidelines specifically referenced in Section 2.1 hereof.

**Change Control:** A system to ensure changes are reviewed, recorded, evaluated for impact, justified, and approved by the appropriate parties, prior to implementation.

**CMO:** means Sanofi or such other contract manufacturer of API or Product approved by the parties in accordance with the Transaction Agreements.

**Component:** Any ingredient intended for use in the Manufacture or packaging of a drug product, including those that may not appear in the final drug product.

**Deviation(s):** Any excursions from processes, Specifications, quality systems or nonconformities that may affect the safety, efficacy, identity, strength, purity, or quality of Product(s) or any regulatory submissions for the Product(s).

**Criticality Levels:**

**Level 1 (Minor):** a minor compliance deviation that has no potential of product impact.

**Level 2 (Major):** a deviation that may have the potential of product quality impact and may have the potential to have an adverse effect on the identity, strength, quality, purity, potency, safety or effectiveness of a drug product, validated test method, process, system or equipment.

**Level 3 (Critical):** a deviation that has the potential for significant product or quality impact. These critical deviations relate to a failure to meet in-process or final (finished) product specifications from approved procedures, test methods validated processes, facilities and utilities and equipment.

**Governmental Authority:** Any national, federal, state or local governmental authority, agency, commission or other instrumentality that has jurisdiction over the Manufacturing, packaging, testing, marketing, use, sale, handling, storage or distribution of the Product(s).

**License Agreement:** shall have the meaning set forth in the preamble of this Agreement.

**Manufacturing:** All operations related to the manufacture of a product, including receipt of materials, production, packaging, quality control, release, storage and shipping of such product.

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**Out-of-Specification (“OOS”):** A test result that does not meet pre-determined specifications or standards and must be investigated in accordance with internal procedures that comply with applicable Governmental Authority regulations.

**Out-of-Trend (“OOT”):** A test result that does not meet the definition of OOS, but that demonstrates an unusual trend toward the lower or higher end of a Specification range.

**Qualification:** Action of proving and documenting that equipment, materials, systems and suppliers satisfy predetermined conditions or requirements and are fit for their respective purposes.

**Specifications:** All specifications relating to product including the specifications for composition, storage, handling, packaging, testing and release of the product.

**Supply Agreement:** shall have the meaning set forth in the preamble of this Agreement.

**Third Party Subcontractor:** A company, individual or other entity contracted by VIVUS or Licensee to provide services in the manufacturing of product.

## **2. General Information**

As of October 1, 2016 (the “**Effective Date**”), Licensee is the NDA holder for Stendra- tablets 50mg, 100mg, 200mg.

All Confidential Information received during the term of this Agreement shall be subject to, and handled in accordance with, Article 11 of the License Agreement, which is hereby incorporated by reference.

### **2.1 Regulatory Compliance Requirements**

Licensee and VIVUS shall operate in compliance with all applicable laws, now in effect or hereinafter established, relating in any manner to the processing, Manufacturing, packaging, testing, inspection, storing, handling, delivery, shipping and disposal of the product.

Further, Licensee and VIVUS shall at all times be in compliance with the following regulations and guidelines, as amended from time to time and if applicable:

- a) 21 CFR 210 Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General and 21 CFR 211 Current Good Manufacturing Practice for Finished Pharmaceuticals;
- b) Current Good Manufacturing Practices Guidelines, Health Products and Food Branch Inspectorate, Health Canada;
- c) Finalized guidelines published by the International Conference on Harmonization;

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- d) Any other regulations promulgated by any Governmental Authority having jurisdiction over the Manufacture of the Product(s) or its/their processing.

The parties agree to work together in good faith to resolve any differences in interpretation of the aforementioned regulations and guidelines.

## **2.2 Notification of Governmental Authorities**

Interactions with Governmental Authorities shall be handled in accordance with Sections 5.2(c) and 5.3(c) of the License Agreement and Section 8.4 of the Supply Agreement, which are hereby incorporated by reference.

## **2.3 Conflict Resolution**

Any disputes or conflicts relating to this Agreement shall be resolved by the contacts identified in APPENDIX 1 (each, a “**Contact**” and collectively, the “**Contacts**”) in a timely manner and in compliance with all applicable regulations and guidelines. Such resolutions shall be documented and signed by each party’s Contacts. In the event the issue cannot be resolved by the Contacts, each party’s senior corporate quality officials shall enter into good faith negotiations to reach a mutually agreeable resolution.

## **2.4 Responsibilities**

Each party’s specific responsibilities as they pertain to the Product(s) are set forth in APPENDIX 2. Such responsibilities are hereby incorporated herein by reference.

## **3. Quality Assurance**

### **3.1 Annual Product Review**

Licensee shall perform annual product reviews; provided, that VIVUS shall perform the annual product review for 2016. Each of VIVUS and Licensee shall, upon the other party’s reasonable request, provide such party with the relevant information in VIVUS’ or Licensee’s, as applicable, possession, including information from any CMO or other Third Party Subcontractors, necessary for the other party to perform the annual product reviews for which such party is responsible pursuant to the immediately preceding sentence. Such information shall include, without limitation, the following: all Product test results, OOS and Deviation reports, Change Control summaries, document revisions and any FDA audit responses that relate to the Product(s).

### **3.2 Quality Audits / Regulatory Inspections**

#### **3.2.1 Quality Audits**

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- a) Licensee's audit rights pursuant to Section 8.2 of the Supply Agreement are hereby incorporated by reference.
- b) VIVUS is responsible for auditing the CMO of bulk product for cGMP compliance and will share the outcome of the audit with Licensee.
- c) Licensee shall audit the third party used for packaging of the product (currently Sharp Corporation located in Allentown, PA and Conshohocken, PA) for cGMP compliance and will share the outcome of the audit with VIVUS.

#### **3.2.2 Audit Procedures**

Following each audit, the parties shall hold an exit meeting, with representatives from each party present, to discuss significant audit observations. Within \*\*\* (a) of any audit pursuant to Section 3.2.1a) or 3.2.1b), Licensee shall provide a written report of all observations relating to such audit to VIVUS, and (b) of any audit pursuant to Section 3.2.1c), VIVUS shall provide a written report of all observations relating to such audit to Licensee. Within thirty (30) days of receiving any such audit report, the receiving party shall provide a written response to all findings that details corrective action to be implemented and shall follow up as necessary with the appropriate individuals to ensure that all corrective actions are implemented. With respect to each written report, the party responsible for providing such written report shall have the right to conduct a follow-up review to confirm commencement and completion of such corrective actions.

#### **3.2.3 Lot Release**

VIVUS shall release the bulk product and shall issue to Licensee a Certificate of Analysis and a Certificate of Compliance, or its functional equivalent, in connection with the delivery of the bulk product. Licensee is responsible for packaging and release of the packaged product.

#### **3.2.4 Regulatory Inspections**

In addition to the obligations set forth under Sections 5.2 and 5.3 of the License Agreement and Section 8.4 of the Supply Agreement, which are incorporated by reference, the provisions of this Section 3.2.4 shall apply:

To the extent VIVUS receives advance notice, VIVUS shall notify Licensee \*\*\* in advance of any pending Governmental Authority inspections scheduled and relating to Product to be performed at any relevant facility (each, a "Facility") and shall provide Licensee with copies of any notices or communications relating to the Services or the Product(s) within \*\*\* of receipt.

Licensee representatives may be present when any Governmental Authority inspects VIVUS, provided such inspection directly relates to the Product(s), Services and/or common areas used in the provision of Services. Licensee representation shall be limited to two (2) individuals and

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Licensee's direct participation in the audit shall be limited to questions directly related to the Product(s) and/or the Services.

VIVUS shall provide Licensee with copies of any inspection reports from any Governmental Authorities that may impact the Product(s) within \*\*\* of receipt. VIVUS may redact proprietary and confidential information pertaining to other clients' products at VIVUS' discretion.

VIVUS shall consult Licensee when preparing responses to Governmental Authorities, provided such responses are directly related to the Product(s) and/or Services, and shall obtain Licensee's prior written consent (not to be unreasonably withheld, conditioned, or delayed) before submitting such responses.

VIVUS will notify Licensee promptly, but in no event later than \*\*\* after VIVUS' receipt of notice from any applicable CMO or other Third Party Subcontractor of, any action resulting in:

- a) Suspension or prohibition of the Services; or
- b) Closure of the Facility

### **3.3 Management Responsibilities**

VIVUS shall operate, or shall require that its CMO operates, a cGMP compliant Facility. VIVUS shall ensure that the procedures and Specifications employed at VIVUS or at such CMO, as applicable, comply with applicable regulations promulgated by Governmental Authorities. VIVUS shall ensure compliance with such procedures and Specifications when performing the Services.

### **3.4 Internal Audits**

VIVUS shall have a documented program and procedure for conducting internal quality audits (self-inspections). These internal quality audits shall be performed according to VIVUS' standard operating procedures ("SOPs"). Internal audit schedules and statuses shall be available for review during scheduled audits and, upon request, during "for cause" audits.

### **3.5 Training and Qualification**

VIVUS will provide an adequate number of personnel qualified and trained to perform and supervise the Services in accordance with VIVUS' SOPs. VIVUS shall assure that training, including training on cGMP and other applicable laws and regulations, is regularly conducted, assessed and documented by qualified individuals. VIVUS shall make its training program documents available for review during scheduled audits and, upon request, during "for cause" audits. VIVUS shall also provide written job descriptions, upon request, for each position that has responsibility for the Product(s).

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### 3.6 Supplier/Third Party Subcontractor Qualification

VIVUS shall be responsible for the approval of the suppliers of all Components and material(s) provided by VIVUS in connection with the Services, provided that (a) VIVUS shall consult with Licensee prior to approving any such suppliers, and (b) if, and only if, the approval of any particular supplier would require the advance approval of FDA pursuant to either 21 CFR 314.70(b) or (c), Licensee's consent shall be required before VIVUS may approve such supplier. If, with respect to any particular supplier, the parties disagree as to the applicability of subsection (b) of the preceding sentence, such disagreement shall be resolved in accordance with Section 2.3 hereof. VIVUS shall provide to Licensee a list of approved suppliers associated with the Services. Notwithstanding the foregoing, the parties agree that any and all suppliers identified in any and all regulatory submissions existing as of the Effective Date shall be deemed approved. For avoidance of doubt, VIVUS in its sole discretion may make changes that require advance or retroactive notice to FDA in accordance with 21 CFR 314.70(d).

Upon request, VIVUS or Licensee, as the case may be, shall provide the requesting party with documented evidence that each supplier providing Components and/or materials used in connection with the Services has been appropriately approved by the responsible party.

When either party is complying with such a request, such party shall provide this information to the other party in a format suitable for submission to Governmental Authorities (*e.g.*, as a formal report under cover of a signed letter on company letterhead).

Licensee has the right to request the use of a supplier that is not currently qualified/approved by VIVUS. Upon such requests, Licensee shall be responsible for Qualifying and approving the new supplier. Alternatively, Licensee and VIVUS may work together to Qualify the new supplier in order to add it to VIVUS' approved supplier list.

VIVUS shall notify Licensee in writing and obtain approval prior to outsourcing any Manufacturing services to Third Party Subcontractors. VIVUS shall provide Licensee with documented evidence that Third Party Subcontractors hired by VIVUS to perform outsourced services related to the Product(s) have been appropriately approved by VIVUS. VIVUS shall provide this information to Licensee in a format suitable for submission to Governmental Authorities (*e.g.*, as a formal report under cover of a signed letter on company letterhead).

VIVUS shall ensure that any suppliers and/or Third Party Subcontractors used by VIVUS are Qualified and in compliance with cGMP or equivalent standards, as defined in regulatory submissions for worldwide marketing authorizations.

Licensee shall notify VIVUS in writing prior to outsourcing any Packaging services to Third Party Subcontractors. Licensee shall provide VIVUS with documented evidence that Third Party Subcontractors hired by Licensee to perform outsourced services related to the Product(s) have been appropriately Qualified and approved by Licensee.

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Licensee shall ensure that any suppliers and/or Third Party Subcontractors used by Licensee are Qualified and in compliance with cGMP or equivalent standards, as defined in regulatory submissions for worldwide marketing authorizations.

### **3.7 Deviations Investigations**

VIVUS shall notify Licensee in writing (by fax or e-mail) within \*\*\* of receipt of any notification, subject to any subsequent updates or future clarification of the substance of such notification, or otherwise becoming aware, of any Level 2 or Level 3 Deviation that occurs during the provision of Services.

Licensee shall notify VIVUS, in writing, of the detection of any Deviation that is discovered following VIVUS' delivery of any Product(s) to Licensee, or to a Licensee designee, which may affect or impact the safety, identity, strength, purity or quality of the Product(s) or any regulatory submissions related to the Product(s) within \*\*\* following the discovery.

VIVUS shall have a controlled system to document, investigate and assess the impact of each Deviation relating to the Product(s), which actions shall be conducted in accordance with VIVUS' internal procedures, consistent with cGMP requirements.

VIVUS shall work with its subcontractor, Sanofi, in this case to undertake reasonable corrective actions to correct the cause of each Deviation and provide Licensee with documented evidence that such corrective actions have been completed. VIVUS shall monitor such corrective actions for effectiveness and Licensee may verify corrective actions during scheduled audits or, upon request, during "for cause" audits.

### **3.8 Buildings and Facilities / Utilities**

VIVUS shall ensure that the CMO that manufactures the bulk product uses and maintains an adequate Facility as required by cGMP.

VIVUS shall ensure that the CMO performs and documents qualification/validation, monitoring, calibration and maintenance (preventative and corrective) for all Facility utility systems, including, but not limited to the water system(s), as they relate to the manufacture of the product. Through routine periodic or for cause audits VIVUS shall ensure that the CMO routinely conduct such actions within the timeframes established by the CMO's internal procedures that are appropriate given the significance of the particular systems. Documentation of such work shall be available for review during scheduled audits and, otherwise, upon request. Re-qualifications shall be conducted by the CMO according to the CMO's SOPs and documentation of such re-qualifications shall be available for review during scheduled audits and, otherwise, upon request.

VIVUS shall ensure that the CMO shall maintain a pest control program for the storage and testing areas used for Product(s).

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VIVUS will notify Licensee within \*\*\* of any calibration and/or performance failures which may have an adverse impact on Product previously supplied to Licensee.

### **3.9 Equipment**

VIVUS shall ensure that the CMO uses and maintains adequate equipment for the manufacture of the bulk tables, as required by cGMP.

VIVUS shall ensure that the CMO performs and documents qualification/validation, monitoring, calibration and maintenance (preventative and corrective) for all CMO's equipment that will be used to manufacture the product and such work shall be conducted routinely within timeframes established by CMO's internal procedures that are appropriate given the significance of the equipment. Documentation of such work shall be available for review during scheduled audits and, otherwise, upon request. Re-Qualifications shall be established by the CMO according to the CMO's SOP and documentation of such re-qualifications shall be available for review during scheduled audits and, otherwise, upon request.

VIVUS will notify Licensee within \*\*\* of any calibration and/or performance failures which may have an adverse impact on Product previously supplied to Licensee.

### **3.10 Documentation**

Specifications for the Product(s) shall be consistent with the requirements set forth in VIVUS' regulatory applications.

VIVUS will retain original records and documentation related to the Services for a minimum of \*\*\* beyond the completion of the Services. VIVUS shall store such records in a limited access area and shall treat such records in accordance with the requirements set forth in the Supply Agreement. VIVUS shall restrict access to the records to personnel authorized by VIVUS. VIVUS shall ensure that these documents are readily accessible for review and inspection by Licensee and/or Governmental Authorities upon request. VIVUS shall notify Licensee at the end of the document retention period and Licensee shall direct VIVUS, in writing, to (i) provide the documents directly to Licensee and/or (ii) destroy some or all of the documents.

### **3.11 Change Control**

Changes to Specifications shall be in accordance with Section 5.3 of the Supply Agreement, which is hereby incorporated by reference.

VIVUS and Licensee shall, or shall require that their respective CMOs and other Third Party Subcontractors, as applicable, (a) maintain controls to assure that any changes to the Product Manufacturing and Packaging equipment, operations and/or SOPs are reviewed and approved prior to implementation, and (b) validate such changes when required by applicable regulations. VIVUS and Licensee shall, upon receipt of notice from their respective CMOs and other Third

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Party Subcontractors, as applicable, of all changes that are not like-for-like exchanges that impact or could potentially impact the Product(s) and/or Services prior to implementing such changes, notify each other, in writing, of the same.

VIVUS and Licensee shall, or shall require that their respective CMOs and other Third Party Subcontractors, as applicable, maintain a Change Control system for, among other things, equipment, utilities and documents that are compliant with cGMP requirements and VIVUS and Licensee shall, or shall use Commercially Reasonable Efforts to procure that their respective CMOs and other Third Party Subcontractors, as applicable, use its Change Control procedures to initiate all significant changes.

Licensee shall notify VIVUS in writing of any significant changes to the packaging of the Product, its Specifications, where the changes will affect VIVUS' activities, prior to the implementation of such changes.

**3.12 Product Complaints**

VIVUS shall use Commercially Reasonable Efforts to provide Licensee with the necessary information (in VIVUS', any CMO's or any Third Party Subcontractor's possession) about Manufacturing the Product to assist any investigations required by Licensee as a result of a Product complaint or adverse drug event.

**3.13 Recall of Marketed Product**

Recalls shall be handled in accordance with Section 5.5(c) of the License Agreement, which is hereby incorporated by reference.

**4. Revision History**

Version Number.	Changes
1.0	Original

**5. Assignment**

Notwithstanding anything to the contrary herein or otherwise, this Agreement or any rights or obligations hereunder may be assigned or transferred without the prior written consent of the other party only (i) in connection with a valid and proper assignment or transfer of the Supply Agreement in accordance with the terms and conditions set forth therein, and (ii) to the same extent and to the same entity as the Supply Agreement is so assigned or transferred.

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## 2 APPENDIX 1 – CONTACTS

Area	Metuchen Contact	VIVUS Contact
<b>Quality Technical Agreements</b>	Keith S. Rotenberg, Ph.D President Mist Pharmaceuticals LLC (973) 303-3507 krotenberg@mistpharma.com	Vincent Ho Director, QA T] 650.934.5272 ho@vivus.com
<b>Product Complaints</b>	Tammy Francoeur Director, Pharmacovigilance & Medical Information Accelovance (978) 568-4067 mistpharma@accelovance.com	Vincent Ho Director, QA T] 650.934.5272 ho@vivus.com
<b>General Quality Assurance</b>	John Gorski Director, CMC Mist Pharmaceuticals (862) 266-6028 jgorski@mistpharma.com	Vincent Ho Director, QA T] 650.934.5272 ho@vivus.com
<b>Audits</b>	John Gorski Director, CMC Mist Pharmaceuticals (862) 266-6028 jgorski@mistpharma.com	Vincent Ho Director, QA T] 650.934.5272 ho@vivus.com
<b>Regulatory Affairs</b>	Keith S. Rotenberg, Ph.D President Mist Pharmaceuticals LLC (973) 303-3507 krotenberg@mistpharma.com	Santosh Varghese Chief Medical Officer T] 650.934.5352 varghese@vivus.com

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**EXHIBIT G**  
**VIVUS PATENTS**

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## EXECUTION VERSION

## CONFIDENTIAL

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## COMMERCIAL SUPPLY AGREEMENT

THIS COMMERCIAL SUPPLY AGREEMENT (this “**Agreement**”) is dated as of September 30, 2016, 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 Metuchen Pharmaceuticals LLC, a limited liability company organized under the laws of Delaware, having its principal place of business at 11 Commerce Drive, 1st Floor, Cranford, New Jersey 07016 (“**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 (the “**License Agreement**”), effective as of the date of this Agreement, pursuant to which VIVUS granted to Purchaser an exclusive license in the Purchaser Territory for, among other things, the development and commercialization of the therapeutic drug known as Stendra® (avanafil);

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

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

# 1. DEFINITIONS

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

“**API**” has the meaning set forth in [Section 2.10](#).

“**Binding Forecast**” has the meaning set forth in [Section 2.3](#).

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

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

“**Effective Date**” means October 1, 2016.

“**Financing Default**” means (a) Purchaser’s default under the Financing Documents, or the occurrence of an event of default under the Financing Documents, if such default or event of default gives rise to a right by a Financing Entity to exercise remedies under the Financing Documents, and (b) any of (i) a consensual resolution of such default or event of default whereby Purchaser agrees to assign this

Agreement and Purchaser's rights and obligations arising hereunder to a Financing Entity or a Qualified Assignee (with written notice of such resolution provided jointly by Purchaser and such Financing Entity or Qualified Assignee to VIVUS), (ii) the entry of a final, non-appealable order by a court of competent jurisdiction authorizing the sale and/or assignment of this Agreement and Purchaser's rights and obligations arising hereunder to a Financing Entity or a Qualified Assignee, or (iii) the exercise by a Financing Entity of its rights and remedies as a secured creditor in respect of the Debt Facility under the Financing Documents in accordance with applicable law, provided that such Financing Entity provides written notice to VIVUS of such exercise of such rights and remedies.

**"Financing Document"** means any loan, security or other agreement or agreements pursuant to which a Financing Entity provides a Debt Facility to Purchaser.

**"Financing Entity"** means any Person that provides Purchaser with debt financing secured by an assignment of Purchaser's contractual rights under this Agreement as collateral (a **"Debt Facility"**) and each successor and assign of such Person's rights in and to such Debt Facility (but excluding any such Person and/or such Person's successors and/or assignees upon the exercise of remedies by such Person pursuant to the related Financing Documents). The Parties acknowledge that (i) Hercules Capital, Inc., as "Agent", and each of the "Lenders" (as such terms are defined in the Loan and Security Agreement dated as of September 30, 2016, by and between Purchaser and Hercules Capital, Inc., as Agent, and the related Loan Documents as defined therein (the **"Hercules Loan Agreements"**)), are Financing Entities and (ii) the Hercules Loan Agreements are Financing Documents.

**"Finished Product"** means Product that is fully packaged and labeled in accordance with the FDA-approved NDA (or foreign equivalent, as applicable in the countries of the Purchaser Territory).

**"Forecast"** has the meaning set forth in Section 2.2.

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

**"Initial Period"** means the period beginning on the Effective Date and ending on the \*\*\* of the Effective Date.

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

**"Manufacturing Cost"** means VIVUS' actual out-of-pocket costs in obtaining, transporting, and storing raw materials for manufacturing Product and in having the Product manufactured, tested, and supplied to Purchaser hereunder, including transfer prices paid to Sanofi and other Third Party manufacturers. The current Manufacturing Cost for Product manufactured by Sanofi shall be as set forth in Exhibit B. The Manufacturing Cost may be adjusted on a periodic basis (at least annually) to reflect variances between actual and estimated costs, and such adjusted Manufacturing Cost shall be calculated based on estimated costs (including, Sanofi's (or any other Third Party manufacturer's) price increases, currency exchange rate fluctuations, yield loss adjustments, and other variables in cost), as determined by VIVUS in good faith and in accordance with its standard procedures. VIVUS will use Commercially Reasonable Efforts to (i) consult with Purchaser prior to the implementation of any non-routine Manufacturing Cost adjustment that is beyond the scope of any cost adjustments contemplated under the relevant supply arrangement between VIVUS and Sanofi, and (ii) provide all relevant supporting documentation detailing any such Manufacturing Cost adjustments.

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

“**Permitted Assignment**” has the meaning set forth in Section 16.6.

“**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 (\*\*\*) \*\*\*.

“**Product**” means formulated tablets containing Compound in bulk form which, if appropriately packaged and labeled would constitute the pharmaceutical product known as Stendra®, as described in the FDA-approved NDA for such product (as such NDA may be modified in the future in accordance with this Agreement and/or the License Agreement).

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

“**Product Shortage**” means a circumstance, whether or not the result of a force majeure, in which VIVUS is unable to supply Product to Purchaser in compliance with the terms and conditions of this Agreement in the quantities sufficient to meet Purchaser’s requirements of Product as set forth in outstanding Purchase Orders and/or the Binding Forecast.

“**Purchase Orders**” has the meaning set forth in Section 2.3.

“**Purchaser Territory**” means the “**Licensee Territory**” as defined in the License Agreement.

“**Qualified Assignee**” means a Person (a) operating in the pharmaceuticals industry that has the financial resources, technological and regulatory expertise, and operational capabilities reasonably required to perform all of Purchaser’s obligations under this Agreement, and (b) for which Purchaser (or a Financing Entity or such Person, as applicable) has, at least five (5) Business Days prior to any transfer or assignment of this Agreement in accordance with the terms hereof, provided VIVUS with such information reasonably necessary to determine such Person’s resources, expertise, and capabilities to perform under this Agreement.

“**Quality Agreement**” has the meaning set forth in Section 5.4.

“**Renewal Period**” means each successive two-year renewal period beginning upon the expiration of the Initial Period.

“**Sanofi**” means the following affiliated manufacturing entities: (a) for API, Sanofi Chimie and (b) for bulk tablet of Products, Sanofi Winthrop Industrie.

“\*\*\*” has the meaning set forth in Section 2.5(b).

“**Specifications**” means the specifications, standards, limits, criteria and other requirements for or related to the Product provided hereunder, as set forth in Exhibit A or otherwise agreed to by the Parties in writing.

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“Supply Disruption” has the meaning set forth in [Section 2.8](#).

“Term” has the meaning set forth in [Section 9.1](#).

## 2. SUPPLY OF PRODUCTS

### 2.1 Supply of Product.

(a) Supply and Purchase of Product. During the Term, and subject to the provisions herein, VIVUS shall manufacture, test, and supply the Product to Purchaser or its designee, directly or through one or more Third Party subcontractors. Purchaser shall purchase the Product from VIVUS, and VIVUS shall supply Product to Purchaser, pursuant to Purchase Orders submitted to VIVUS by Purchaser, from time to time in accordance with [Section 2.3](#). VIVUS shall ensure that the Product manufactured by Sanofi on behalf of VIVUS and delivered to Purchaser (other than shipments out of the Current Inventory pursuant to [Section 2.5](#)) has a minimum remaining shelf life of not less than \*\*\*.

(b) VIVUS’ Third Party Supplier. Without limiting or modifying any of VIVUS’ obligations under this Agreement, Purchaser acknowledges that, as of the Effective Date, VIVUS obtains Product solely from Sanofi and that VIVUS will continue to obtain Product solely from Sanofi unless and until VIVUS, with the assistance and cooperation of Purchaser, is able to qualify with the FDA a Third Party manufacturer with the ability to manufacture Product in accordance with the Specifications, cGMP, and Applicable Law as a manufacturer of Compound and bulk tablets of Product. Purchaser agrees to cooperate and provide any such assistance at VIVUS’ reasonable request.

(c) Exclusive Arrangement. Subject to the terms and conditions of this Agreement, Purchaser agrees to purchase from VIVUS, and VIVUS agrees to manufacture and provide to Purchaser, all of Purchaser’s requirements for Product. VIVUS shall be free to supply Product to any Third Party worldwide, subject to the exclusive rights granted to Purchaser and obligations assumed by VIVUS pursuant to the License Agreement.

2.2 **Forecasts.** Purchaser will submit to VIVUS, no later than the \*\*\* preceding the start of every \*\*\* (i.e., \*\*\*) 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. Such Forecast shall not be binding on either Party except as provided in this Agreement.

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 calendar quarter, Purchaser shall be required to submit Purchase Orders for at least \*\*\* percent (\*\*\*) of the quantities in the Forecast for such \*\*\* 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, but will use Commercially Reasonable Efforts to supply such excess Product. 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. If a new Third Party manufacturer has been appointed by VIVUS, then the lead

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times (*i.e.* the time between the finalizing of a Purchase Order and the delivery of the Product) for Purchase Orders set forth above may not be lengthened without the prior written consent of Purchaser, not to be unreasonably withheld, conditioned, or delayed.

**2.4 Minimum Purchase Requirements.** For 2016 and for each subsequent calendar year during the Term, Purchaser shall be required to either (a) purchase no less than the Minimum Purchase Obligation from VIVUS in accordance with the terms of this Agreement or (b) \*\*\* as it relates to \*\*\* to \*\*\*. For clarity, upon any termination of this Agreement other than by Purchaser under Section 9.2(a) or pursuant to Section 9.4, Purchaser's obligations under Section 2.4 shall accelerate for the entire then-current Initial Period or Renewal Period, as applicable, and become due, and Purchaser shall be required \*\*\* to \*\*\* for the entire then-current Initial Period or Renewal Period, as applicable. VIVUS acknowledges and agrees that VIVUS' sole remedy for Purchaser's failure to meet its Minimum Purchase Obligation is set forth in this Section 2.4 and that the Minimum Purchase Obligation is not a guarantee by Purchaser that any specific sales level will be obtained with respect to the Product. With respect to the minimum purchase requirements for 2016 only, any quantities of bulk Product purchased in excess of the Minimum Purchase Obligation for 2016 shall be credited against the Minimum Purchase Obligation for 2017 as set forth in Exhibit C. Purchaser's orders of Current Inventory (including the order made pursuant to Section 2.5(b) below) shall not be counted towards the satisfaction of the Minimum Purchase Obligation.

**2.5 Initial Shipments of Product.**

(a) The Current Inventory of Product is, as of the Effective Date, being stored at \*\*\* at \*\*\*. Upon payment in full to VIVUS of the lesser of (i) the aggregate Manufacturing Cost for the full quantities of Product in the Current Inventory and (ii) \$\*\*\*, VIVUS shall transfer to Purchaser ownership of the Current Inventory, in accordance with this Section 2.5.

(b) Purchaser hereby submits a binding order for the full quantities of the Current Inventory. As set forth in Section 3.1, the transfer price for the quantities of Product ordered pursuant to this Section 2.5(b) shall be the Price. Upon payment in full to VIVUS of the Price for the full quantities of Product in the Current Inventory, Current Inventory will be sold to Purchaser EXW (Incoterms 2010) \*\*\* facilities and title to such quantities of Product shall automatically pass to Purchaser.

(c) For all Product transferred to Purchaser under this Section 2.5, Purchaser shall be responsible, at Purchaser's sole cost, for transport and distribution of such Product. Purchaser may use any Third Party that it designates for Product packaging, but Purchaser shall be responsible for the cost of validation if the packager is any Third Party other than \*\*\*, as well as any costs associated with transporting Product to such other packager. VIVUS shall ensure that all Current Inventory delivered to Purchaser under this Agreement has a minimum remaining shelf life of not less than \*\*\*.

**2.6 Delivery and Shipping Terms.** Product supplied hereunder shall be shipped EXW (Incoterms 2010) Sanofi's manufacturing facility (or, if applicable, the manufacturing facility of any other manufacturer being utilized by VIVUS for manufacturing Product) directly to the packaging facility or other location designated by Purchaser. Title to the Product and risk of loss shall pass to Purchaser at the time of delivery of the Product to the Third Party shipper at the loading dock of the manufacturing facility. Purchaser shall arrange for all shipping, insurance freight, custom duties, and other charges associated with, the shipment, and the cost of the foregoing will be paid by Purchaser. VIVUS shall issue (or shall have its manufacturer issue) to Purchaser in advance of shipment a Certificate of Analysis (each, a "COA") and Certificate of Compliance (each, a "COC") for each shipment of Product (including Current Inventory) delivered to Purchaser. Each COA shall be accompanied by batch documentation for each lot of delivered

Product and shall certify that the Product conforms to the Specifications, this Agreement, and the Quality Agreement along with the results of such analysis and any supporting data. Purchaser will be under no obligation to accept any shipment of Product for which VIVUS has not provided a COA and/or COC or which Purchaser reasonably believes does not comply with the COA or COC at the time the Product was delivered to Purchaser. VIVUS will be responsible for any out-of-pocket costs incurred by Purchaser with respect to the storage, shipment, return, or at VIVUS' direction, destruction, of such non-conforming shipment.

2.7 **Packaging and Labeling.** VIVUS will supply Product to Purchaser in the form of bulk tablets. Purchaser shall be responsible, at its sole expense, for packaging and labeling the Product for commercial sale. Any labels, product inserts, and other packaging for the Product shall be consistent with then-current approved NDA for the Product and with Applicable Law. VIVUS' name will not appear on the label or anywhere else on the commercial packaging of the Product unless: (a) required by any Applicable Laws; (b) VIVUS consents in writing to the use of its name; or (c) such Product is in the Current Inventory.

2.8 **Supply Disruption.** If VIVUS is unable to supply confirmed orders to Purchaser with respect to the quantity or the delivery date (a "Supply Disruption"), or if VIVUS believes that a Supply Disruption is reasonably likely to occur based on Purchaser's confirmed and/or forecasted orders, VIVUS shall provide Purchaser with prompt written notice of such inability or belief. In the event of a Supply Disruption, VIVUS shall be obliged to allocate the available Product among Purchaser and any other licensees and/or authorized distributors of Product worldwide, \*\*\* based on the volume of Product orders of Purchaser and such other licensees and distributors. The "volume of Product orders" will be calculated based on (a) orders for Product that were delivered during the preceding \*\*\* or that are then in transit (excluding in each case any orders where payment therefor is delinquent), and (b) the binding portion of any outstanding purchase orders or forecasts. In the event of a Supply Disruption, notwithstanding Section 2.1(c), Purchaser shall be permitted to obtain from another source the quantities of Product that VIVUS is unable to supply. In the absence of gross negligence or willful misconduct, this Section 2.8 describes Purchaser's sole and exclusive remedy, and VIVUS' sole and exclusive liability, for any Supply Disruption; provided, that if VIVUS actually recovers direct contract damages from its Third Party manufacturer or supplier in connection with a Supply Disruption, VIVUS shall pass through to Purchaser its allocable portion (which shall be calculated and allocated \*\*\* based on the volume of Product orders of Purchaser and such other licensees and distributors, as described above in this Section 2.8) of such recovery amount. In the event of any Supply Disruption that results in more than \*\*\* percent (\*\*\*\*%) of ordered Product in any \*\*\* period arriving at the delivery location more than \*\*\* after the intended delivery date, Purchaser shall be relieved of any further obligation during the then-current \*\*\* to purchase the Minimum Purchase Obligation for \*\*\*; provided that to the extent any such Supply Disruption results in the delivery of any such quantity of Product after \*\*\* of the relevant \*\*\*, such late-delivered quantities shall be credited against the Minimum Purchase Obligation of the immediately following \*\*\*. In the event a Supply Disruption affects the quantities of Product available for Commercialization in a subsequent \*\*\*, the Parties will meet and negotiate in good faith a possible reduction of the Minimum Purchase Obligation for such subsequent \*\*\*, which reduction shall take into account (i) the reasonably likely commercial effect of the Supply Disruption and (ii) VIVUS' respective minimum purchase obligations under any arrangements or agreements with any Third Parties (including Sanofi).

2.9 **Post-Delivery Handling and Release.** After delivery of the Product to Purchaser in accordance with the terms of this Agreement and the Quality Agreement, any handling, storage, quality control, quality assurance, and the release of the Product shall be the sole responsibility of Purchaser or its designated Third Party.

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2.10 **Stability Testing.** VIVUS shall be responsible for conducting all stability testing required under the NDA with respect to the active pharmaceutical ingredient in the Compound ("API") and the bulk Product, and Purchaser shall be responsible for conducting such stability testing with respect to the Finished Product. VIVUS shall, at Purchaser's reasonable request and expense, use Commercially Reasonable Efforts to (a) make relevant VIVUS personnel available for consultation during normal business hours and (b) provide underlying documentation, in each case (a) and (b), for analytical methods transfer, including supply of API standard and impurities per Product specification.

2.11 **Technology Transfer.**

(a) Cooperation. Upon (i) termination of this Agreement by Purchaser as a result of VIVUS' uncured material breach, (ii) in the event of a Supply Disruption, (iii) upon mutual agreement of the Parties on a Supply Chain Transfer Plan in accordance with Section 6.2 of the License Agreement, (iv) in the event that VIVUS provides a notice to Purchaser under Section 2.8, (v) upon an event of Force Majeure preventing the timely supply of Product hereunder for a period anticipated to exceed \*\*\*, or (vi) upon a breach by VIVUS which permits Purchaser to terminate this Agreement, VIVUS shall provide Purchaser with such assistance and any VIVUS Know-How Controlled by VIVUS, as reasonably necessary for manufacturing, formulating and/or packaging of the Product, as the case may be (a "Technology Transfer"). In connection with the foregoing, Purchaser shall be permitted to consult with VIVUS' technical personnel on the specified manufacturing activities and, to the extent necessary, VIVUS shall use Commercially Reasonable Efforts to permit Purchaser to consult with VIVUS' Third Party manufacturers. Purchaser, in its sole discretion, shall choose whether to exercise its rights in connection with a Technology Transfer.

(b) Manufacturing Rights. Notwithstanding any Technology Transfer pursuant to Section 2.11(a), Purchaser's right to manufacture or have manufactured Product shall be limited to the rights described in Section 2.2 of the License Agreement, plus the additional manufacturing rights described in Section 2.8 in connection with a Supply Disruption.

(c) Technology Transfer Costs. In connection with a Technology Transfer pursuant to Section 2.11(a)(iii), Purchaser shall be responsible for paying VIVUS' actual costs and expenses incurred in connection with such Technology Transfer, including FTE costs, out-of-pocket expenses and any technology transfer fees payable to any other Third Party; provided, however, VIVUS shall bear all costs related to any Method Transfer and any other transfer costs, for which the related work has been performed prior to the Effective Date (collectively, "**Technology Transfer Costs**"). In connection with a Technology Transfer pursuant to Section 2.11(a)(i), (ii), or (v), VIVUS shall be responsible for the Technology Transfer Costs. In connection with a Technology Transfer pursuant to Section 2.11(a)(iv), Purchaser shall be responsible for the Technology Transfer Costs unless and until a Supply Disruption shall have occurred, in which event VIVUS shall be responsible for such Technology Transfer Costs, including reimbursing Purchaser for those already paid by Purchaser.

2.12 **Notice Right; Step-In Right.** VIVUS shall provide Purchaser with prompt written notice of any breach or alleged breach, including without limitation any notice of such breach or alleged breach provided by any Third Party manufacturer of API or bulk Product and shall provide Purchaser with copies of any documentation and correspondence between any Third Party manufacturer and VIVUS regarding such breach including written summaries of any oral discussions. In the event that VIVUS is in breach of any such manufacturing or supply agreement with a Third Party manufacturer, it shall promptly provide to Purchaser a written plan of action to remedy or cure such breach and shall keep Purchaser promptly informed of its progress or any changes to such plan of action. If VIVUS is unable to cure such breach,

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then, unless VIVUS is disputing such breach in good faith, at Purchaser's election VIVUS shall use Commercially Reasonable Efforts to cause such Third Party manufacturer to \*\*\*. VIVUS may condition disclosure of attorney-client privileged information or attorney work product on the Parties' execution of a joint defense agreement, common interest agreement, or similar agreement intended to preserve attorney-client and attorney work product privileges under Applicable Law, in a form reasonably acceptable to VIVUS.

**2.13 Adjustments Related to Third Party Manufacturers.** VIVUS will not at any time during the Term take any action that could reasonably be expected to result in a breach of any agreement between VIVUS and any Third Party manufacturer or supplier. VIVUS shall provide Purchaser with advance written notice of any material amendment, waiver of rights, termination or modification of any agreement between VIVUS and any Third Party manufacturer or supplier, and VIVUS will not agree to any amendment, waiver of rights, termination or modification of any agreement between VIVUS and any Third Party manufacturer or supplier that (a) that would reasonably be expected to result in (i) any non-routine increase in the Price, (ii) any early termination of this Agreement, or (iii) any increase in the Purchaser's Minimum Purchase Obligations or (b) has, or would reasonably be expected to have, any other material negative effect on Purchaser, in each case (a) and (b), without the prior written consent of Purchaser, which shall not be unreasonably withheld, conditioned, or delayed.

**2.14 API Purchase Option.** If VIVUS obtains the right to satisfy its minimum purchase obligations under all relevant manufacturing and/or supply agreements with Sanofi and/or any other relevant Third Party manufacturer (as applicable) by purchasing a combination of API and Product in lieu of solely Product from Sanofi and/or such other relevant Third Party manufacturer (as applicable), then the Parties shall discuss in good faith an option for Purchaser to fulfill its obligations under this Agreement by purchasing API in lieu of or in addition to Product, and possible adjustments or supplements to this Agreement to provide for the supply of API on comparable terms and conditions as for the supply of Product contained herein, including (a) a price for API and quantities for the API minimum purchase obligations, which appropriately take into account both purchases of Product and API, and (b) revisions to Section 4.2 and ARTICLE 5 to reflect, on a basis substantially comparable to the provisions set forth herein, that Purchaser will be buying and VIVUS shall be supplying API in lieu of or in addition to Product. VIVUS shall use Commercially Reasonable Efforts to negotiate in good faith with Sanofi or any other Third Party manufacturer, as applicable, to obtain the rights to satisfy its minimum purchase obligations by purchasing a combination of API and Product.

### **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 re-sell the Product.

**3.2 Payment.** VIVUS shall provide to Purchaser written invoices setting forth the amount payable by Purchaser with respect to quantities of Product sold hereunder, including the Price applied by VIVUS to each dosage strength of Product. Purchaser shall pay VIVUS for Product in the amount invoiced by VIVUS within \*\*\* from the date of invoice, which invoice shall be issued at the delivery date. If Purchaser is legally required to withhold any Taxes from payments due hereunder, Purchaser shall (a) deduct such Taxes from the payment made to VIVUS, and (b) timely pay the taxes to the proper taxing authority. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect and shall discuss in good faith how to solve any situation where VIVUS may not deduct such payment for reasons beyond VIVUS'

reasonable control. Solely for purposes of this Section, “**Taxes**” means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including interest, penalties and additions thereto) that are imposed by the applicable government or other taxing authority.

3.3 **Records; Audit.** VIVUS shall maintain complete and accurate books and records in accordance with GAAP in sufficient detail to permit Purchaser to confirm the accuracy of the Manufacturing Costs, and any other financial measure relating to the Price of the Product payable under this Agreement, for a period of \*\*\* from the creation of individual records or any longer period required by Applicable Law. At Purchaser’s request, such records shall be available for review at a Purchaser’s headquarters located at 11 Commerce Drive, 1st Floor, Cranford, New Jersey 07016, or a mutually agreeable location determined by Parties not more than once each calendar year (during normal business hours on a mutually agreed date with reasonable advance notice) by an independent Third Party auditor selected by Purchaser and approved by VIVUS (such approval not to be unreasonably withheld, conditioned, or delayed) and subject to confidentiality and non-use obligations no less stringent than those set forth in Article 11 of the License Agreement for the sole purpose of verifying for Purchaser the accuracy of the Manufacturing Costs and Price paid by Purchaser pursuant to this Agreement or of any payments made by Purchaser to VIVUS pursuant to this Agreement. Any such auditor shall not disclose VIVUS’ Confidential Information to Purchaser, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by VIVUS or the amount of payments due by VIVUS under this Agreement. Any undisputed amounts finally determined to be owed but unpaid shall be paid within \*\*\* from the accountant’s report. Any amounts finally determined to have been overpaid will either be refunded to Purchaser or credited to Purchaser against future payments to VIVUS hereunder, at Purchaser’s option. Purchaser shall bear the full cost of such audit unless such audit reveals an underpayment or under-reporting error of \*\*\* percent (\*\*\*) or more during the applicable audit period, in which case VIVUS shall bear the full cost of such audit.

#### 4. REPRESENTATIONS, WARRANTIES AND COVENANTS

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

(a) Corporate Existence and Power. It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has all 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

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doubt, Purchaser shall be solely responsible for obtaining any product and/or distribution license from the applicable Governmental Authority so as to be able to sell and market the Product in a particular jurisdiction.

#### 4.2 Product Representations and Warranties of VIVUS.

(a) Compliance. VIVUS warrants that it will ensure that all Product will be manufactured and tested in conformity with this Agreement, the License Agreement, cGMP, the Specifications, and the Quality Agreement.

(b) Conformity with Specifications. VIVUS warrants that it will and will cause its Third Party suppliers to ensure that all Product manufactured by or on behalf of VIVUS and sold to Purchaser pursuant to this Agreement will at the time of delivery to the common carrier for such Product (i) meet the Specifications, (ii) not be misbranded or adulterated and (iii) will be in compliance with all Applicable Laws.

(c) No Liens. VIVUS warrants that all Product delivered to Purchaser pursuant to this Agreement will, at the time of such delivery, be free and clear of all liens, encumbrances, security interests and other encumbrances.

VIVUS' obligations as provided in Section 10.1 and Section 6.2 shall be the sole and exclusive remedies available to Purchaser with respect to Product that fails to meet the product warranties set forth in Section 4.2.

#### 4.3 Other Representations and Warranties of VIVUS.

(a) Performance. VIVUS will perform its obligations under this Agreement, and will use Commercially Reasonable Efforts to cause any Third Party supplier to perform their manufacturing obligations with respect to the Product, in a professional manner with requisite skill, care and diligence and in accordance with the industry standards. VIVUS will maintain, and will use Commercially Reasonable Efforts to cause its Third Party suppliers to maintain, appropriately qualified and trained personnel, adequate premises and space, suitable equipment, correct materials, containers and labels, suitable storage and the knowledge and experience to carry out satisfactorily the work ordered by Purchaser.

(b) Compliance with Applicable Laws. During the Term of this Agreement, VIVUS will comply with, and will use Commercially Reasonable Efforts to cause its Third Party suppliers to comply with, all Applicable Laws to the conduct of its business and manufacture of Product in the performance of this Agreement and will hold, or will cause its Third Party manufacturers to hold, all permits and authorizations necessary to fulfill its obligations under this Agreement.

(c) Compliance with Certain Agreements. VIVUS is in compliance in all material respects with, and will at all times remain in compliance in all material respects with, and has not received any notice of breach pursuant to any agreement relating to the manufacture of Product. To the Knowledge of VIVUS, as of the Effective Date, (i) Sanofi is not in breach of the Manufacturing and Supply Agreement, and (ii) Sanofi is in compliance with such agreement in all material respects.

(d) Debarment. VIVUS represents and warrants that it has not been debarred, nor is it under consideration to be debarred, and that it will not knowingly use in any capacity in connection with the manufacturing or services hereunder any person (including Third Party manufacturers) who has been

debarred, nor is under consideration to be debarred by the FDA and/or TPD, the subject of a pending debarment pursuant to the Act, or who is the subject of a conviction described in such section. VIVUS will inform Purchaser in writing immediately upon becoming aware thereof if it or any person (including Third Party manufacturers) who is performing manufacturing or any services hereunder is debarred or is the subject of a conviction described in section 306 of the Act, or if any action, suit, claim, investigation, or proceeding is pending, or to the best of VIVUS' knowledge, is threatened, relating to the debarment or conviction of VIVUS, or any person performing manufacturing or services pursuant to this Agreement.

4.4 **Covenants of Purchaser.** Purchaser hereby covenants not to sue the VIVUS Indemnified Parties (as defined in Section 10.2 hereof), and shall defend, indemnify and hold harmless the VIVUS Indemnified Parties from and against any and all Losses incurred by the VIVUS Indemnified Parties, for any such VIVUS Indemnified Parties' compliance with any Financing Entity's notice of its exercise of rights and remedies under the Financing Documents in connection with any Financing Default (including during the pendency of any dispute between Purchaser and the Financing Entity relating to or arising under the Financing Documents, provided that the Financing Entity provides written notice to VIVUS of such exercise of such rights and remedies).

4.5 **No Other Representations or Warranties.** EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 4 OR THE LICENSE AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF VIVUS. ALL OTHER REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

## 5. QUALITY

5.1 **General.** VIVUS shall be responsible for establishing and maintaining such procedures for implementing corrective and preventive actions with respect to the manufacturing of the Product as required by Applicable Law, cGMP, and the Quality Agreement. VIVUS shall cooperate with Purchaser at VIVUS' expense in determining the cause of any quality problems involving the Product, identifying corrective actions, and ensuring the implementation and effectiveness thereof. VIVUS shall implement such corrective actions with respect to the Product, and shall provide Purchaser with written confirmation upon the completion thereof.

5.2 **Notice of Failure to Meet Specifications.** Each Party shall notify the other Party immediately after the discovery that any lot of Product sold to Purchaser failed to comply with its applicable Specifications at the time of delivery or was not manufactured in accordance with Applicable Laws, including without limitation cGMP. VIVUS will immediately make, at its sole expense, such further internal investigation of any failure to meet these requirements as is reasonable under the circumstances and otherwise consistent with its obligations hereunder and shall use its best efforts to remediate such failure, which shall include the replacement of the quantity of non-conforming Product at no cost to Purchaser, as promptly as reasonably practicable.

5.3 **Changes to Specifications.**

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(a) Changes Requested by Purchaser. VIVUS will not be required to implement any requests by Purchaser to change the manufacturing process, Specifications, or any testing method with respect to the Product, but VIVUS shall consider any such requests in good faith.

(b) Changes Requested by VIVUS. VIVUS will provide Purchaser with advance notice of any material changes to procedures, Specifications, methods (including testing methods) or standard operating procedures relating to the manufacture or supply of the Product and VIVUS will not make or permit any such changes without the prior written consent of Purchaser if such change is (i) inconsistent with the then-current approved NDA for the Product, (ii) reasonably likely to have a material adverse effect on VIVUS' ability to comply with the terms of this Agreement, including any Product delivery timelines hereunder, or (iii) otherwise reasonably likely to have an adverse impact on the Commercialization of the Product in the Purchaser Territory.

(c) Changes Required by Applicable Law. VIVUS will promptly, at its own expense, implement any changes to any procedures, Specifications, methods (including testing methods) or standard operating procedures relating to the manufacture or supply of the Product required by Applicable Law or the NDA (collectively, "**Required Manufacturing Changes**"); provided that Purchaser shall be responsible for any and all expenses arising from any such changes required by any changes to the NDA submitted to any Regulatory Authority by the Purchaser without VIVUS' prior written consent.

(d) Cost of Manufacturing Changes. Prior to a Supply Chain Transfer, VIVUS will be solely responsible for all internal and external costs, including, without limitation, obsolete raw materials, regulatory filings, work-in-process, and Product, (i) associated with Required Manufacturing Changes, and (ii) all costs associated with any other manufacturing changes not requested by Purchaser. Prior to a Supply Chain Transfer, Purchaser shall be responsible for such costs only in the event such manufacturing change is requested by Purchaser and is not otherwise required by Applicable Law or the NDA; provided that Purchaser shall also be responsible for any and all expenses arising from any such changes required by any changes to the NDA submitted to any Regulatory Authority by the Purchaser without VIVUS' prior written consent.

5.4 **Quality Agreement.** Concurrent with the execution of this Agreement, the Parties have entered into a separate quality agreement governing the agreed-upon Specifications and other technical aspects of supply of Products to Purchaser hereunder (the "**Quality Agreement**"). In the event of any inconsistency between this Agreement and the Quality Agreement, this Agreement shall control, except with respect to quality assurance matters. VIVUS agrees to use its Commercially Reasonable Efforts to have three-way quality agreements put into place with Purchaser and VIVUS' Third Party manufacturers.

## 6. ACCEPTANCE AND REJECTION PROCEDURES

6.1 **Inspection.** Purchaser or its designee shall promptly, upon arrival on its site, carefully inspect each shipment of Product for transport damages, losses and shortfalls. Apparent defects, such as, for instance, damaged containers or missing packages of Product, must be notified to the carrier promptly upon arrival of the shipment and the freight documents at Purchaser or its designee and, where possible, countersigned by the carrier's representative. Failure of Purchaser or its designee to notify such visually detectable defects to the carrier promptly upon arrival of the concerned shipment and freight documents shall exclude any liability of VIVUS for such defects. Purchaser shall have \*\*\* after receipt of a shipment of Product to determine if there is any defect in the Product or any non-compliance with the Specifications or Applicable Law, including without limitation cGMP, which is discoverable by diligent and customary inspection of the shipment and any accompanying documentation (the "**Inspection Period**"). Purchaser

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shall notify VIVUS of any such non-compliance prior to the end of the Inspection Period, describing in reasonable detail the non-compliance. Notwithstanding the preceding provisions of this Section 6.1, if with respect to any unexpired Product, the non-compliance could not reasonably be expected to have been found by diligent and customary inspection during the Inspection Period and Purchaser notifies VIVUS of such non-compliance, describing such Latent Defect in detail, within \*\*\* of Purchaser's knowledge of the Latent Defect and within the shelf life of the Product, such non-compliance shall be deemed to be a "**Latent Defect**" hereunder. Purchaser's notification of VIVUS of a non-compliance during the Inspection Period or of a Latent Defect as permitted above shall be referred to herein as a "**Claim**". For the sole purpose of application of Section 6.2, Purchaser shall be deemed to have accepted any Product if it fails to give a Claim in the periods permitted above; provided, however, that Purchaser's acceptance of Product shall not limit Purchaser's indemnification rights under Section 10.1 (which, for clarity, shall be fully subject to the exceptions recited therein). At VIVUS' 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 Sanofi and/or any other relevant Third Party manufacturer.

6.2 **Remedies.** Except for Claims disputed pursuant to Section 6.2(b) hereof, if Purchaser submits a Claim, then as promptly as practicable after the submission of the Claim to VIVUS (but in no event later than \*\*\* after the submission of the Claim), VIVUS shall instruct Purchaser whether to return or destroy the Product in question and provide Purchaser with replacement Product. In the event that:

(a) VIVUS agrees with the Claim, then VIVUS shall pay for all out-of-pocket costs of returning or destroying Product that is the subject of any accepted Claim. VIVUS shall bear the risk of loss for such Product, beginning at such time as such Product is taken at Purchaser's premises for return delivery. VIVUS shall replace all nonconforming Product as promptly as reasonably practicable and at no cost to Purchaser.

(b) VIVUS does not agree with the Claim, then the Parties agree to submit the Product in question to a mutually agreed independent Third Party that has the capability of testing the Product to determine whether or not it complies with the Quality Agreement, the Specifications and Applicable Law, including cGMP. The losing Party shall bear all costs and expenses related to such testing and pay for all shipping costs of returning the Product and/or sending the replacement Product, as the case may be.

6.3 **Cost of Product Recalls.** With respect to any Product supplied hereunder, VIVUS shall bear all Losses (including without limitation expenses related to communications and meetings with all required regulatory agencies, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those customers) related to any Product Recall in the event that such Product Recall is caused by or results from (a) the breach by VIVUS (including indirectly by any Third Party manufacturer) of any representation or warranty or covenant contained in this Agreement or the License Agreement, or (b) VIVUS' negligence or willful misconduct. Additionally, in the event the Product Recall is caused by or results from (a) or (b) above, VIVUS shall replace the units of recalled Products as promptly as practicable and at no cost to Purchaser. Except as provided above, Purchaser shall bear all Losses related to any Product Recall.

## 7. REGULATORY MATTERS.

7.1 **Regulatory Responsibilities.** The Parties' respective rights and obligations with respect to Regulatory Approvals in the Purchaser Territory, communications with Regulatory Authorities in the

## 8. RECORD-KEEPING; AUDITS

8.1 **Recordkeeping.** VIVUS (and/or Sanofi or any other Third Party manufacturer) will keep complete and accurate records of the manufacture and testing of Product, and retain samples of bulk Product and the active pharmaceutical ingredient in the Compound as are necessary to comply with Applicable Laws, as well as to assist with resolving Product complaints and other similar investigations. Copies of the records and samples will be retained for a period of \*\*\* following the date of Product expiry, or longer if required by Applicable Laws. Purchaser is responsible for retaining samples of the fully packaged Product necessary to comply with the legal/regulatory requirements applicable to Purchaser.

### 8.2 Audits.

(a) Audit Right; Facility Access. From and after the commencement of supply hereunder directly or through an independent auditor reasonably acceptable to VIVUS, Purchaser shall have the right, upon reasonable advance notice and during regular business hours, to make an annual inspection and audit of the facilities being used by VIVUS or a VIVUS Affiliate for the production, storage, or testing of Product to assure compliance by or on behalf of VIVUS with cGMPs, the Specifications, and Applicable Law. At Purchaser's reasonable request, VIVUS agrees to use Commercially Reasonable Efforts to facilitate a similar inspection and audit of the facilities being used by Sanofi and/or any other Third Party manufacturer, such as, solely by way of example, by exercising VIVUS' audit right in its agreement with such manufacturer, at Purchaser's cost, and permitting Purchaser or its designee to attend such audit (subject to approval by the Third Party manufacturer to allow such attendance, which VIVUS shall use Commercially Reasonable Efforts to obtain) and in any event sharing the results of such audit with Purchaser.

(b) Third Party Audits. Without limiting VIVUS' obligations under this Agreement in any respect, Purchaser acknowledges that VIVUS' audit rights in its manufacturing and supply agreements with Sanofi are limited to periodic audits to ensure that cGMPs continue to be followed. In the event that VIVUS or any Third Party licensee of VIVUS outside the Purchaser Territory proposes to conduct or conducts an audit of the facilities used by or on behalf of VIVUS or a VIVUS Affiliate or Third Party for the production, storage, or testing of Product to be sold to Purchaser under this Agreement, then VIVUS will provide immediate notice to Purchaser of such audit and VIVUS shall use its Commercially Reasonable Efforts to permit Purchaser to be able to be present for and participate in such audit.

(c) Procedure. The inspection and audit provided for under Section 8.2(a) shall not be carried out by Purchaser more than \*\*\* per calendar year, but such inspection and audit shall not preclude Purchaser from conducting any "for cause" inspection or audit permitted under the Quality Agreement or otherwise for cause. Each inspection and audit shall be conducted in a manner so as to minimize disruption of the business operations of VIVUS, Sanofi and/or any other Third Party manufacturer. VIVUS representatives will be permitted to participate as observers during any such inspection and audit. To the extent that Purchaser requests an inspection or audit of the facilities of Sanofi and/or any other Third Party manufacturer, Purchaser acknowledges that VIVUS must coordinate the dates and schedule of such inspection and audit with Sanofi and/or such other Third Party manufacturer. The independent auditor, if any, shall enter into a written confidentiality agreement with VIVUS containing provisions regarding the disclosure of information obtained during the inspection and 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, Sanofi and/or any other Third Party manufacturer) failed to comply with the requirements of Section 8.1 (and shall not be permitted to disclose to Purchaser any other information). A copy of any such disclosure to Purchaser shall also be provided to VIVUS.

(d) Results. If an inspection or audit reveals a failure to comply with cGMP or Applicable Law in any material respect, then Purchaser shall promptly provide to VIVUS written notice of such fact, which notice shall contain in reasonable detail the deficiencies found in the applicable facilities and, if practicable, those steps Purchaser believes should be undertaken in order to remedy such deficiencies. The Parties shall discuss in good faith the deficiencies and VIVUS shall, at its own expense, use its best efforts to remedy such deficiencies, or implement a plan to remedy such deficiencies, as soon as reasonably practical following receipt of the notification thereof. In addition to the audit rights set forth in this Section 8.2, Purchaser will be entitled to perform reasonable follow-up inspections to monitor correction of such deficiencies or the circumstances giving rise to such deficiency, failure or notice.

8.3 **Analytical Method Transfer**. Upon the reasonable prior written request of Purchaser, VIVUS agrees to provide Purchaser or use Commercially Reasonable Efforts to cause its Third Party designee hereunder to provide Purchaser with all required documentation and support for analytical method transfer for the Product in order to enable Purchaser to analyze the Product in order to determine its suitability and stability under this Agreement and according to all applicable requirements of Regulatory Authorities or to ensure that the Products are in line with the Regulatory Approvals (a "**Method Transfer**"). VIVUS agrees to actively participate, or use Commercially Reasonable Efforts to cause its Third Party designee hereunder to participate, in such Method Transfer by, among other things, providing samples and conducting parallel testing. Purchaser shall pay for any out-of-pocket costs incurred by VIVUS in connection with such Method Transfer, except in connection with the first Method Transfer to establish stability testing.

8.4 **Regulatory Compliance**. VIVUS will advise Purchaser promptly if an authorized agent of a Regulatory Authority visits its facilities (or, to its knowledge, its Third Party designee's manufacturing facilities) where the API or the Product is being manufactured, stored, or tested. VIVUS will provide Purchaser with all material information in VIVUS' possession pertaining to actions taken by Regulatory Authorities (including any inspections, proposed regulatory actions, investigations or requests for information or a meeting by any Regulatory Authority) whether inside the Purchaser Territory or outside the Purchaser Territory in connection with the API or the Product in the Field, including any notice, audit notice, notice of initiation by Regulatory Authorities of investigations, inspections, detentions, seizures or injunctions concerning the API or the Product in the Field whether inside the Purchaser Territory or outside the Purchaser Territory, notice of violation letter (*i.e.*, an untitled letter), warning letter, service of process or other inquiry; provided, however, that VIVUS shall be entitled to redact those portions thereof to the extent not related to the API or the Product in the Field or to the extent disclosing Third Party confidential information. Without limiting the generality of the foregoing, each Party shall promptly, but in any event within two (2) Business Days, inform the other Party of any material inspections, proposed regulatory actions, investigations or requests for information or a meeting by any Regulatory Authority with respect to the API or the Product in the Field in the Manufacturing Territory. VIVUS or its Third Party designee will furnish to Purchaser all material information supplied to, or supplied by, any Regulatory Authority in the Manufacturing Territory, including the Form 483 observations and responses, to the extent that such information relates to the API or the Product or the ability of VIVUS to supply such API or the Product and could reasonably be expected to have a material negative effect on the Purchaser or the Commercialization of the Product in the Purchaser Territory, within \*\*\* of their receipt of such information, in each case to the extent that VIVUS is aware of such information and subject in each case to the redaction right described



above. VIVUS or its Third Party designee will consult in advance with Purchaser prior to responding to any request from a Regulatory Authority to the extent such response relates to the API or the Product, and VIVUS will use Commercially Reasonable Efforts to permit Purchaser and/or its agents to be present at any inspection by any Regulatory Authority of any manufacturing facility where the API or the Product that is supplied to Purchaser hereunder is being manufactured or quality tested.

## **9. TERM; TERMINATION**

9.1 **Term.** The term of this Agreement (the “**Term**”) will commence on the Effective Date and will continue, unless otherwise agreed between the Parties, for a period ending on the fifth (5<sup>th</sup>) anniversary of the Effective Date. Thereafter, the Term shall be automatically renewed for successive two- (2) year periods, unless either Party provides a termination notice to the other Party at least \*\*\* in advance of the expiration of the then-current Term.

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; provided, however, that, except with respect to any breach of Section 2.4 hereof, in the event the non-terminating Party contests any such asserted breach in good faith and diligently pursues the dispute resolution procedures set forth in Article 14, such thirty (30) day cure period shall be tolled or suspended until the final resolution of such dispute pursuant to the terms of, and in accordance with, the terms and provisions of Article 14; or (b) if (i) the other Party shall institute bankruptcy, insolvency, liquidation or receivership proceedings or proceedings for reorganization under bankruptcy or comparable laws; or (ii) a petition shall be filed against the other Party for any proceedings described in clause (i) above, the effectiveness of which is not stayed or dismissed within \*\*\* after the filing thereof; or (iii) the other Party shall make a general assignment of all or substantially all of its assets for the benefit of creditors. Termination of this Agreement pursuant to this Section 9.2 shall not affect any other rights or remedies which may be available to the non-defaulting Party, including any rights or remedies under the License Agreement.

9.3 **Termination Upon Termination of License Agreement.** In addition to the termination rights expressly provided for elsewhere in this Agreement, either Party may also terminate this Agreement upon written notice to the other Party if the License Agreement is terminated in accordance with its terms.

9.4 **Termination upon Transfer of Control of Supply Chain.** This Agreement shall automatically terminate upon the completion of the Supply Chain Transfer (as defined in the License Agreement).

9.5 **Effects of Termination.** Upon expiration or termination of this Agreement other than termination of this Agreement by Purchaser under Section 9.2(a), VIVUS shall manufacture and supply, and Purchaser shall purchase from VIVUS (a) any and all quantities of Product ordered by Purchaser pursuant to this Agreement prior to the date on which such notice is given, for the applicable Price, and (b) any and all materials held by VIVUS or Sanofi (or any other Third Party manufacturer of Product) for exclusive use in the manufacture of Compound or Product based on binding part of the Forecasts provided by Purchaser, for an amount equal to the \*\*\* with respect to such materials. Termination or expiration of this Agreement will not affect any outstanding obligations due hereunder prior to the termination or expiration. In the event of Purchaser’s termination of this Agreement under Section 9.2(a), Purchaser shall not be required to purchase any additional quantities of Product from VIVUS and all orders of Product shall be immediately voided and of no effect with no further obligation of Purchaser to VIVUS with respect to materials held by VIVUS or a Third Party manufacturer for manufacture of the Compound or Product.

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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: Sections 2.11, 3.3, 6.1, 6.3 and 8.1 and Articles 9 through 14 and 16.

## 10. INDEMNIFICATION

10.1 **Indemnification by VIVUS.** VIVUS shall defend and indemnify and hold Purchaser, its Affiliates and their respective directors, officers and employees (the “**Purchaser Indemnified Parties**”) harmless against any and all Losses resulting from any Claim of a Third Party arising out of, based on, or caused by (i) alleged or actual bodily injury or property damage resulting from the manufacturing, packing, labeling, handling, storage, transportation, use, distribution of Products by or on behalf of VIVUS, its licensees (other than Purchaser) or Affiliates, including any product liability claim; (ii) liabilities arising from clinical trials conducted by or on behalf of VIVUS in connection with any Products; (iii) the breach by VIVUS of any representation or warranty or covenant contained in this Agreement; (iv) the Product supplied by VIVUS to Purchaser hereunder failing to meet the warranties set forth in Section 4.2, or (v) the negligence or willful misconduct of VIVUS or its Affiliates, sublicensees, or any of its agents, directors, officers or employees, except in each case to the extent that such Losses arise directly from the breach by Purchaser of any representation or warranty or covenant contained in this Agreement or any negligence or willful misconduct by a Purchaser Indemnified Party.

10.2 **Indemnification by Purchaser.** Purchaser agrees to defend and indemnify and hold VIVUS, its Affiliates and their respective directors, officers and employees (the “**VIVUS Indemnified Parties**”) harmless against any and all Losses resulting from any Claim of a Third Party arising out of, based on, or caused by (i) the storage, sale, shipment, promotion or distribution of the Product by Purchaser after Purchaser has taken title to the Product, or (ii) the breach by Purchaser of any representation or warranty or covenant contained in this Agreement, except in each case to the extent that such Losses arise (x) directly from the breach by VIVUS of any representation or warranty or covenant contained in this Agreement (including breach of Section 4.2), (y) any negligence or willful misconduct by a VIVUS Indemnified Party, or (z) and are directly attributable to any uncured breach, that is not the subject of a good faith dispute, by VIVUS of the License Agreement.

10.3 **Indemnification Procedures.** The Party claiming indemnity under this Article 10 (the “**Indemnified Party**”) shall give written notice to the Party from whom indemnity is being sought (the “**Indemnifying Party**”) promptly and in no event later than \*\*\* after learning of a written claim (“**Indemnified Claim**”). Failure by an Indemnified Party to give notice of an Indemnified Claim within \*\*\* of receiving a writing reflecting such Claim shall not relieve the Indemnifying Party of its indemnification obligations hereunder except and solely to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give such notice. The Indemnifying Party shall have the right to assume the conduct and defense of the Indemnified Claim with counsel of its choice so long as the Indemnifying Party is conducting a good faith and diligent defense; provided that, the Indemnifying Party shall not have the right to assume any Indemnified Claim if (x) the Indemnifying Party fails to provide reasonable evidence of its ability and willingness to satisfy such claim, or (y) such claim involves a criminal or regulatory enforcement action. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance in connection with the defense of the Indemnified Claim. The Indemnified Party may monitor such defense with counsel of its own choosing at its sole expense; provided, that if under applicable standards of professional conduct a conflict of interest exists between the Indemnifying Party and the Indemnified Party in respect of such claim, such Indemnified Party shall have the right to employ separate counsel to represent such Indemnified Party with respect to the matters as to which a conflict of interest

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exists and in that event the reasonable fees and expenses of such separate counsel shall be paid by the Indemnifying Party. The Indemnifying Party may not settle the Indemnified Claim without the prior written consent of the Indemnified Party, such consent shall not be unreasonably withheld, delayed or conditioned. In no event shall the Indemnifying Party settle the Indemnified Claim unless such settlement provides an unconditional and full release of the Indemnified Party. If the Indemnifying Party does not assume and conduct the defense of the Indemnified Claim as provided above: (a) the Indemnified Party may assume and conduct the defense of the Indemnified claim at the Indemnifying Party's expense; (b) the Indemnified Party may consent to the entry of any judgment or enter into any settlement with respect to the Indemnified Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith); and (c) the Indemnifying Party will remain responsible to indemnify the Indemnified Party for Indemnified Amounts as provided in this Article 10.

**11. LIMITATION OF LIABILITY**

11.1 **Limitation.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY EXEMPLARY, SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES, COSTS OR EXPENSES (INCLUDING LOST PROFITS, LOST REVENUES AND/OR LOST SAVINGS) ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTHING IN THE PRECEDING SENTENCE IS INTENDED TO OR SHALL LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY IN CONNECTION WITH THIRD PARTY CLAIMS UNDER ARTICLE 10, (B) DAMAGES OR INJUNCTIVE RELIEF AVAILABLE FOR A PARTY'S BREACH OF ARTICLE 13, (C) DAMAGES TO THE EXTENT ARISING FROM OR RELATING TO WILLFUL MISCONDUCT OR FRAUDULENT ACTS OR OMISSIONS OF A PARTY OR (D) DIRECT DAMAGES. EXCEPT FOR WILLFUL MISCONDUCT OR LOSSES ASSOCIATED WITH PRODUCT RECALLS, IN NO EVENT SHALL VIVUS' AGGREGATE LIABILITY ARISING OUT OF OR RELATING TO THIS AGREEMENT UNDER ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT, STATUTORY OR OTHERWISE) EXCEED THE \*\*\*; PROVIDED, HOWEVER THAT THIS LIMITATION SHALL NOT APPLY TO (I) VIVUS' OBLIGATIONS IN CONNECTION WITH THIRD PARTY CLAIMS UNDER ARTICLE 10 OR (II) DAMAGES TO THE EXTENT ARISING FROM OR RELATING TO VIVUS' NEGLIGENCE, WILLFUL MISCONDUCT OR FRAUDULENT ACTS OR OMISSIONS. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS AGREEMENT SHALL LIMIT THE LIABILITY OF EITHER PARTY UNDER THE LICENSE AGREEMENT.

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

**12. INSURANCE.**

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

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- (a) commercial general liability coverage with minimum per claim limits of at least \$\*\*\* per occurrence and \$\*\*\* annual aggregate, the policy(ies) for which shall (A) name VIVUS as an additional insured, and (B) be primary and non-contributory;
- (b) automobile liability coverage covering all owned, hired and non-owned automobile equipment with minimum per claim limits of \$\*\*\* per occurrence and annual aggregate, the policy(ies) for which shall name VIVUS as an additional insured;
- (c) excess liability/umbrella coverage with minimum per claim limits of at least \$\*\*\* per occurrence and annual aggregate;
- (d) products liability coverage with minimum per claim limits of at least \$\*\*\* per occurrence and annual aggregate with a \*\*\* extended reporting period endorsement, the policy(ies) for which shall name VIVUS as an additional insured; and
- (e) property coverage having limits adequate for Product inventory in Purchaser's care, custody, and/or control and for Product in transit to and from Purchaser.

12.2 VIVUS shall procure and maintain insurance or self-insure during the Term of this Agreement and for a period of \*\*\* following the termination or expiration of this Agreement, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Upon written request, VIVUS shall provide proof of adequate coverage to Purchaser. VIVUS may substitute a self-insurance program to satisfy in whole or in part its obligations under this Article 12 on written notice to the Purchaser with information demonstrating the adequacy of such program.

12.3 It is understood that the insurance requirements in Sections 12.1 and 12.2 above shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under Article 10. Furthermore, it is understood that Purchaser's insurance requirements in Section 12.1 hereof are intended to be consistent with, and not to increase, the minimum insurance coverage obligations of the Purchaser under the License Agreement. Each Party shall provide the other Party with written evidence of such insurance upon written request. Each Party shall provide the other Party with written notice at least \*\*\* prior to the cancellation, non-renewal or material change in such insurance (or, in the case of VIVUS, self-insurance, as applicable) that materially adversely affects the rights of the other Party hereunder.

### 13. CONFIDENTIALITY; PROPRIETARY RIGHTS

13.1 **Confidentiality.** Each Party will maintain the Confidential Information of the other Party in accordance with Article 11 of the License Agreement. The Parties agree not to disclose any financial terms or conditions of this Agreement to any Third Party without the prior consent of the other Party, except as required by Applicable Law.

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

### 14. DISPUTE RESOLUTION

14.1 **Disputes.**

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(a) 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.

(b) Notwithstanding anything to the contrary in this Article 14, any Financing Entity may bring a proceeding in a court of competent jurisdiction located in the State of New York solely to enforce its rights under Sections 14.1, 16.1, 16.6, and 16.8 hereof. Such courts of competent jurisdiction located in the State of New York shall have the sole and exclusive jurisdiction to hear and adjudicate any claims pursuant to this Section 14.1(b).

**14.2 Arbitration.** Any dispute, controversy or claim arising out of or relating to the validity, construction, interpretation, enforceability, breach, performance, application or termination of this Agreement that is not resolved pursuant to Section 14.1, shall be settled by binding arbitration administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures of JAMS then in effect (the "**JAMS Rules**"), except as otherwise provided herein. The arbitration shall be governed by the United States Federal Arbitration Act, 9 U.S.C. §§ 1-16 (the "**Federal Arbitration Act**"), to the exclusion of any inconsistent state laws. The United States Federal Rules of Civil Procedure shall govern discovery and the rules of evidence for the arbitration. The arbitration will be conducted in New York, New York, and the Parties consent to the personal jurisdiction of the United States federal courts, for any case arising out of or otherwise related to this arbitration, its conduct and its enforcement. Any situation not expressly covered by this Agreement shall be decided in accordance with the JAMS Rules.

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

**14.4 Decision.** The power of the arbitrator to fashion procedures and remedies within the scope of this Agreement is recognized by the Parties as essential to the success of the arbitration process. The arbitrator shall not have the authority to fashion remedies which would not be available to a federal judge hearing the same dispute. The arbitrator is encouraged to operate on this premise in an effort to reach a fair and just decision. Reasons for the arbitrator's decisions should be set forth in accordance with the JAMS Rules. Such a written decision shall be rendered by the arbitrator following a full comprehensive hearing, no later than \*\*\* following the selection of the arbitrator as provided for in Section 14.3.

**14.5 Award.** Any award shall be promptly paid in United States dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by Applicable Law, be charged against the Party resisting enforcement. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Article 14, and agrees that,

subject to the Federal Arbitration Act, judgment may be entered upon the final award in any court of competent jurisdiction and that other courts may award full faith and credit to such judgment in order to enforce such award. The award shall include interest from the date of the award until paid in full, at a rate fixed by the arbitrator and the arbitrator may, in his or her discretion, award pre-judgment interest. With respect to money damages, nothing contained herein shall be construed to permit the arbitrator or any court or any other forum to award punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for punitive or exemplary damages, subject to the exceptions set forth in [Article 11](#).

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

14.7 **Injunctive Relief.** Provided a Party has made a sufficient showing under the rules and standards set forth in the Federal Rules of Civil Procedure and applicable case law, the arbitrator shall have the freedom to invoke, and the Parties agree to abide by, injunctive measures after either Party submits in writing for arbitration claims requiring immediate relief. Additionally, nothing in this [Article 14](#) will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

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

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

## 15. **PRESS RELEASES; USE OF NAMES**

15.1 **Press Releases.** The form and content of any public announcement to be made by one Party regarding this Agreement, or the subject matter contained herein, shall be subject to the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned, or delayed), except as may be required by Applicable Law in which event the Party required to make such announcement shall, to the extent possible, provide to the other Party a written copy of any such required announcement at least \*\*\* prior to disclosure to give the other Party reasonable advance notice and review of any such announcement. Notwithstanding the foregoing, either Party may publicly disclose without violation of this Agreement, such terms of this Agreement as are, on the advice of such Party's counsel, required by the rules and regulations of the SEC or any other applicable entity having regulatory authority over such Party's

securities; provided that such Party shall advise Purchaser of such intended disclosures and requests confidential treatment of certain commercial terms and technical terms hereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, such Party will provide the other Party, a reasonable time prior to filing, with a copy of the Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements applicable to such Party and that govern redaction of information from material agreements that must be publicly filed. The other Party shall provide any such comments as promptly as practicable. The intention of the Parties is to agree upon a single redacted version of the Agreement to be filed with the SEC or any other applicable entity.

15.2 **Use of Names.** Except as otherwise required by law or by the terms of this Agreement or the License Agreement, or as mutually agreed upon by the Parties, neither Party shall make any use of the name of the other Party in any advertising or promotional material, or otherwise, without the prior written consent of the other Party, which consent shall not be unreasonably withheld.

## 16. MISCELLANEOUS

16.1 **Entire Agreement; Amendment.** This Agreement, including the Exhibits hereto, together with the letter agreement dated September 30th, 2016 between VIVUS and Hercules Capital, Inc., and the terms of the License Agreement which are incorporated herein by reference, 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 anything to the contrary in this Section 16.1, no amendment of the definitions of "Financing Entity," "Financing Default," "Qualified Assignee," or "Permitted Assignment" or Sections 14.1, 16.1, 16.6, and 16.8 hereof that effects the rights of any Financing Entity shall be effective without the prior written consent of each Financing Entity.

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 any or all 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; provided that, in the event of a force majeure impacting the Parties' rights and obligations under Section 2.8 and Section 2.11 of this Agreement, VIVUS shall use Commercially Reasonable Efforts to perform its obligations pursuant to Section 2.8 and Section 2.11 of this Agreement, as applicable. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities

or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party.

16.4 **Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 16.4, and shall be deemed to have been given for all purposes when received, if hand-delivered or by means of facsimile or other electronic transmission, or \*\*\* after being sent by a reputable overnight delivery service.

If to VIVUS:	VIVUS, Inc. 351 E. Evelyn Avenue Mountain View, CA 94041 Facsimile: (650) 934-5320 Attention: Chief Financial Officer Email: cfo@vivus.com
With a copy to:	Weil, Gotshal & Manges LLP 767 Fifth Avenue New York, NY 10153 Facsimile: (212) 310-8007 Attention: Michael A. Epstein Email: michael.epstein@weil.com
If to Purchaser:	Metuchen Pharmaceuticals, LLC 11 Commerce Drive, 1st Floor Cranford, NJ 07016 Facsimile: (908) 272-3084 Attention: Greg Ford Email: GFord@kfe-llc.com
With a copy to:	Mist Pharmaceuticals, LLC 11 Commerce Drive, 1st Floor Cranford, NJ 07016 Facsimile: (908) 272-3084 Attention: Keith Rotenberg, President Email: krotenberg@mistpharma.com
With a copy to:	Lowenstein Sandler LLP 65 Livingston Avenue Roseland, New Jersey 07068 Facsimile: (973) 597-2400 Attention: Michael J. Lerner Email: MLerner@lowenstein.com

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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 (including any Financing Entity or Qualified Assignee, as applicable), (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 any other agreement to Articles, Sections, or Exhibits will be construed to refer to Articles, Sections, and Exhibits of or to this Agreement.

16.6 **Assignment.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that (a) 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, (b) Purchaser may assign this Agreement and any of Purchaser’s rights or obligations hereunder as collateral to any Financing Entity pursuant to one or more Financing Documents without the consent of VIVUS or any other Person, (c) neither the consent of VIVUS nor any other Person shall be required for the assignment of this Agreement and all of Purchaser’s rights, obligations and liabilities hereunder (including any and all liabilities that accrued prior to such assignment, but excluding liabilities under Sections 4.4 and 10.2 hereof) to any Financing Entity upon the occurrence of a Financing Default, provided that at least five (5) Business Days prior to any transfer or assignment of this Agreement in accordance with the terms of this clause (c), such Financing Entity provides VIVUS with a general description of the Financing Entity’s business and operations or equivalent documentation, and (d) neither the consent of VIVUS nor any other Person shall be required for the assignment of this Agreement and all of Purchaser’s rights, obligations and liabilities hereunder by Purchaser (with the consent of the Financing Entity, provided that the Purchaser and the Financing Entity jointly provide timely notice to VIVUS of such consent) or any Financing Entity upon the occurrence of a Financing Default to any Qualified Assignee that is a successor to or assignee of all or substantially all of the assets or business of Purchaser to which this Agreement pertains; provided that any assignment to a Financing Entity or a Qualified Assignee in connection with a Financing Default must also include an agreement, in writing, signed by such Financing Entity or Qualified Assignee, as applicable, to assume performance of all of Purchaser’s rights and obligations, and assume all of Purchaser’s outstanding liabilities (including any and all liabilities that accrued prior to such assignment, but excluding liabilities under Sections 4.4 and 10.2 hereof), provided that in the case of clauses (c) and (d) above, with respect to any liabilities accrued by Purchaser (including Purchaser’s liabilities under Sections 4.4 and 10.2 hereof),

such Financing Entity and/or Qualified Assignee, as applicable, shall, at VIVUS' request and expense (which shall be limited to such Financing Entity's or Qualified Assignee's, as applicable, reasonable out-of-pocket-expenses), cooperate and provide reasonable assistance to VIVUS (including the providing, subject to a customary confidentiality agreement, of any relevant information to VIVUS in such Person's possession) in connection with, and to support, VIVUS' efforts to seek recovery for any Losses under Purchaser's insurance policy), thereunder (any of the foregoing assignments, a "**Permitted Assignment**"). Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16.6 shall be null, void and of no legal effect.

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

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 (i) the Parties and, to the extent provided in Sections 10.1 and 10.3, the Indemnified Parties and (ii) any Financing Entity solely with respect to Sections 14.1, 16.1, 16.6, and this Section 16.8 (and the Parties hereto acknowledge and agree that each Financing Entity (including Hercules Capital, Inc.) is an express third-party beneficiary of such Sections 14.1, 16.1, 16.6, and this Section 16.8). 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' sole and exclusive option, either by VIVUS directly or by any Affiliate or Third Party that VIVUS causes to satisfy, meet or fulfill such obligation, in whole or in part. Any obligation of Purchaser under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at Purchaser's sole and exclusive option, either by Purchaser directly or by any Affiliate of Purchaser or Third Party that Purchaser causes to satisfy, meet or fulfill such obligation, in whole or in part. Each of the Parties guarantees the performance of all actions, agreements and obligations to be performed by any Affiliates of such Party or a Third Party under the terms and conditions of this Agreement, and shall cause its Affiliates or such Third Party to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

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

*[Signature page follows]*

**Metuchen Pharmaceuticals LLC**

By: /s/ J. Gregory Ford  
Name: J. Gregory Ford  
Title: CEO  
Date: 9/30/2016

**Vivus, Inc.**

By: /s/ Seth H. Z. Fischer  
Name: Seth H. Z. Fischer  
Title: CEO  
Date: 9/30/2016

**Acknowledged and Agreed:**

**Hercules Capital, Inc.**

By: /s/ Melanie Grace  
Name: Melanie Grace  
Title: GC/CCO  
Date: 9/30/2016

*[Signature Page to Commercial Supply Agreement]*

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EXHIBIT A

Table 1 Specifications for Commercial Bulk Avanafil Tablets

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**EXHIBIT B**  
**Current Manufacturing Cost**

For Product manufactured by Sanofi, the Manufacturing Cost shall be as follows, subject to an annual Sanofi price increase, currency exchange rate fluctuation and yield loss adjustment if significant:

<u>Dosage forms</u>	<u>Current Manufacturing Cost</u> (per tablet)
50mg tablet	US\$***/tablet
100mg tablet	US\$***/tablet
200mg tablet	US\$***/tablet

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EXHIBIT C  
Minimum Purchase Obligations\*

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\* For purposes of this Agreement, “\*\*\*” will be calculated as the number \*\*\* or \*\*\* the number of \*\*\*. Thus, for example, \*\*\* is \*\*\*, and \*\*\* equals \*\*\*.

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**EXHIBIT D**

**Current Inventory**

50 mg dosage strength – \*\*\* tablets;

100 mg dosage strength – \*\*\* tablets; and

200 mg dosage strength – \*\*\* tablets.

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## CERTIFICATION

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

1. I have reviewed this quarterly report on Form 10-Q of VIVUS, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

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

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## CERTIFICATION

I, Mark K. Oki, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VIVUS, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

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

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

I, Seth H. Z. Fischer, Chief Executive Officer of VIVUS, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended September 30, 2016, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: November 9, 2016

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

I, Mark K. Oki, Chief Financial Officer and Chief Accounting Officer of VIVUS, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended September 30, 2016, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: November 9, 2016

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

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