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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended June 30, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File Number 001-33389

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3136179**
(State or other jurisdiction of incorporation or organization)	(IRS employer identification number)
900 E. Hamilton Avenue, Suite 550 Campbell, California	**95008**
(Address of principal executive office)	(Zip Code)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock	VVUS	The Nasdaq Global Select Market
Preferred Share Purchase Rights		

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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☒	Non-accelerated filer ☐	Smaller reporting company ☒
			Emerging growth company ☐

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

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

At July 31, 2019, 10,642,713 shares of common stock, par value $.001 per share, were outstanding.

VIVUS, INC.

Quarterly Report on Form 10-Q

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PART I: FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

VIVUS, INC.

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

	June 30, 2019	December 31, 2018
ASSETS	Unaudited	
Current assets:		
Cash and cash equivalents	$ 25,022	$ 30,411
Available-for-sale securities	69,344	80,838
Accounts receivable, net	24,568	25,608
Inventories	30,111	23,132
Prepaid expenses and other current assets	6,970	7,538
Total current assets	156,015	167,527
Fixed assets, net	306	341
Right-of-use assets	1,323	—
Intangible and other non-current assets	127,003	134,279
Total assets	$ 284,647	$ 302,147
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 3,800	$ 8,921
Accrued and other liabilities	34,384	33,044
Deferred revenue	1,205	1,235
Current portion of lease liability	710	—
Current portion of long-term debt	185,384	—
Total current liabilities	225,483	43,200
Long-term debt	107,007	294,446
Deferred revenue, net of current portion	3,738	4,290
Lease liability, net of current portion	894	—
Non-current accrued and other liabilities	—	234
Total liabilities	337,122	342,170
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock; $.001 par value; 5,000 shares authorized; no shares issued and outstanding at June 30, 2019 and December 31, 2018	—	—
Common stock; $.001 par value; 200,000 shares authorized; 10,643 and 10,636 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	11	11
Additional paid-in capital	841,702	840,751
Accumulated other comprehensive income (loss)	201	(270)
Accumulated deficit	(894,389)	(880,515)
Total stockholders' deficit	(52,475)	(40,023)
Total liabilities and stockholders' deficit	$ 284,647	$ 302,147

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue:				
Net product revenue	$ 15,104	$ 13,250	$ 28,601	$ 22,882
Supply revenue	1,780	1,042	3,384	2,725
Royalty revenue	1,506	668	2,551	1,253
Total revenue	18,390	14,960	34,536	26,860
Operating expenses:				
Cost of goods sold (excluding amortization)	4,377	3,286	8,685	5,916
Amortization of intangible assets	3,638	1,273	7,276	1,364
Sales and marketing	4,607	3,521	9,141	7,800
General and administrative	5,463	8,190	10,747	13,979
Research and development	2,352	2,042	4,821	3,445
Total operating expenses	20,437	18,312	40,670	32,504
Loss from operations	(2,047)	(3,352)	(6,134)	(5,644)
Interest expense and other expense, net	3,880	9,218	7,750	17,567
Loss before income taxes	(5,927)	(12,570)	(13,884)	(23,211)
Provision for income taxes	8	4	—	16
Net loss	$ (5,935)	$ (12,574)	$ (13,884)	$ (23,227)
Basic and diluted net loss per share:	$ (0.56)	$ (1.18)	$ (1.31)	$ (2.19)
Shares used in per share computation:				
Basic and diluted	10,640	10,612	10,639	10,607

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss	$ (5,935)	$ (12,574)	$ (13,884)	$ (23,227)
Unrealized gain on securities, net of taxes	222	577	471	100
Translation adjustment	—	1	—	1
Comprehensive loss	$ (5,713)	$ (11,996)	$ (13,413)	$ (23,126)

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(In thousands)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balances, April 1, 2018	10,610	$ 11	$ 835,749	$ (1,085)	$ (854,218)	$ (19,543)
Sale of common stock through employee stock purchase plan	5	—	24	—	—	24
Exercise of common stock options for cash	8	—	60	—	—	60
Vesting of restricted stock units	1	—	—	—	—	—
Share-based compensation expense	—	—	1,049	—	—	1,049
Warrants issued for acquisition of PANCREAZE	—	—	828		—	828
Warrants issued in association with the issuance of debt	—	—	1,695		—	1,695
Net unrealized gain on securities	—	—	—	577	—	577
Net loss	—	—	—	—	(12,574)	(12,574)
Balances, June 30, 2018	10,624	11	839,405	(508)	(866,792)	(27,884)
Balances, April 1, 2019	10,637	$ 11	$ 841,219	$ (21)	$ (888,454)	$ (47,245)
Sale of common stock through employee stock purchase plan	6	—	16	—	—	16
Share-based compensation expense	—	—	467	—	—	467
Net unrealized gain on securities	—	—	—	222	—	222
Net loss	—	—	—	—	(5,935)	(5,935)
Balances, June 30, 2019	10,643	$ 11	$ 841,702	$ 201	$ (894,389)	$ (52,475)
Balances, January 1, 2018	10,603	$ 11	$ 834,824	$ (608)	$ (843,565)	$ (9,338)
Sale of common stock through employee stock purchase plan	5	—	24	—	—	24
Exercise of common stock options for cash	8	—	60	—	—	60
Vesting of restricted stock units	8	—	—	—	—	—
Share-based compensation expense	—	—	1,974	—	—	1,974
Warrants issued for acquisition of PANCREAZE	—	—	828		—	828
Warrants issued in association with the issuance of debt	—	—	1,695		—	1,695
Net unrealized gain on securities	—	—	—	100	—	100
Net loss	—	—	—	—	(23,227)	(23,227)
Balances, June 30, 2018	10,624	11	839,405	(508)	(866,792)	(27,884)
Balances, January 1, 2019	10,636	$ 11	$ 840,751	$ (270)	$ (880,515)	$ (40,023)
Sale of common stock through employee stock purchase plan	6	—	16	—	—	16
Vesting of restricted stock units	1	—	—	—	—	—
Share-based compensation expense	—	—	935	—	—	935
Net unrealized gain on securities	—	—	—	471	—	471
Cumulative effect of accounting change	—	—	—	—	10	10
Net loss	—	—	—	—	(13,884)	(13,884)
Balances, June 30, 2019	10,643	$ 11	$ 841,702	$ 201	$ (894,389)	$ (52,475)

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

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

	Six Months Ended June 30,	
	2019	**2018**
Operating activities:		
Net loss	$ (13,884)	$ (23,227)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	7,350	1,495
Amortization of debt issuance costs and discounts	(2,055)	10,706
Amortization of discount or premium on available-for-sale securities	(208)	616
Share-based compensation expense	935	1,974
Changes in assets and liabilities:		
Accounts receivable	1,040	1,116
Inventories	(7,254)	(2,785)
Prepaid expenses and other assets	775	779
Accounts payable	(5,121)	(5,727)
Accrued and other liabilities	1,563	(2,469)
Deferred revenue	(582)	(609)
Net cash used for operating activities	(17,441)	(18,131)
Investing activities:		
Fixed asset purchases	(39)	(34)
Acquisition of PANCREAZE license	—	(135,000)
Purchases of available-for-sale securities	(16,879)	(7,604)
Proceeds from maturity of available-for-sale securities	28,235	40,411
Proceeds from sales of available-for-sale securities	817	60,259
Net cash provided by (used for) investing activities	12,134	(41,968)
Financing activities:		
Net proceeds from debt issuance	—	107,991
Repayments of notes payable	—	(57,187)
Principal payments of financing leases	(98)	—
Net proceeds from exercise of common stock options	—	60
Sale of common stock through employee stock purchase plan	16	24
Net cash (used for) provided by financing activities	(82)	50,888
Net decrease in cash and cash equivalents	(5,389)	(9,211)
Cash and cash equivalents:		
Beginning of year	30,411	66,392
End of period	$ 25,022	$ 57,181

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2019

1. BUSINESS AND SIGNIFICANT ACCOUNTING POLICIES

VIVUS is a specialty pharmaceutical company with three approved therapies (Qsymia®, PANCREAZE® and STENDRA®/SPEDRA™) and one product candidate in clinical development (VI-0106). Qsymia (phentermine and topiramate extended release) is approved by the U.S. Food and Drug Administration ("FDA") for chronic weight management. In June 2018, the Company acquired the U.S. and Canadian commercial rights for PANCREAZE (pancrelipase), which is indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions. STENDRA (avanafil) is approved by FDA for erectile dysfunction ("ED"), and by the European Commission ("EC") under the trade name SPEDRA, for the treatment of ED. The Company commercializes Qsymia and PANCREAZE in the U.S. through a specialty sales force supported by an internal commercial team. The Company licenses the commercial rights to STENDRA/SPEDRA in the U.S., EU and other countries and to PANCREAZE in Canada on a transitional basis until the Company begins commercializing it on its own, which it expects to do in the third quarter of 2019. VI-0106 (tacrolimus) is in clinical development and is being studied in patients with pulmonary arterial hypertension ("PAH").

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

Liquidity and Ability to Continue as a Going Concern

At June 30, 2019, the Company's accumulated deficit was approximately $894.4 million and its cash, cash equivalents and available-for-sale securities were $94.4 million. As of June 30, 2019, the Company had a total of $292.4 million in debt, $181.4 million of which is due May 2020. In addition, at June 30, 2019, the Company was not in compliance with a covenant in the indenture covering its secured debt due 2024 (the "2024 Notes") related to PANCREAZE net revenues. The Company subsequently received a waiver from the holders of the 2024 Notes (the "consenting noteholders") with respect to any potential event of default or default that may have resulted from such covenant non-compliance. In connection with the waiver, the Company agreed with the consenting noteholders to use good faith efforts to make certain amendments to the 2024 Notes indenture at a future date (collectively, the "noteholder conditions"), including transferring $60.0 million from the existing 2024 Notes trustee controlled account into a new controlled account that can only be accessed upon prior written consent of the 2024 Notes trustee at the direction of the noteholders. If the Company does not satisfy the noteholder conditions, the consenting noteholders may revoke the waiver, which could result in an event of default. See Note 14 for additional information regarding the Company's debt.

The Company does not currently have sufficient cash and/or credit facilities in place to address the debt due May 2020 and is actively pursuing funding, which may come through public or private debt or equity financings, collaborations or other available financing sources. Such funding 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, the Company will not be able to continue its operations at its current level and may be required to relinquish rights to certain of its technologies, product candidates or products that it would otherwise seek to develop on its own. It might also be required to delay, reduce the scope of or eliminate one or more of its commercialization or development programs or obtain funds through collaborations with others that are on unfavorable terms. Even if adequate funds become available, the Company may need to raise additional funds in the near future to finance operations and pursue development and commercial opportunities.

The accompanying unaudited condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company's coming debt maturities as well as its negative cash flow from operations and accumulated deficit raise substantial doubt about its ability to continue as a going concern. The unaudited condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019. Management has evaluated all events and transactions that occurred after June 30, 2019 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 condensed consolidated balance sheet data as of December 31, 2018 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, 2018 as filed on February 26, 2019 with the Securities and Exchange Commission ("SEC"). Certain amounts have been reclassified to conform to current year presentation. 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.

Reverse Stock Split

On September 10, 2018, the Company effected a one-for-10 reverse stock split of its common stock. As a result of the reverse stock split, every 10 shares of the Company's pre-reverse split common stock issued and outstanding was combined and converted into one issued and outstanding share of post-reverse split common stock without any change in the par value of the shares. Accordingly, an amount equal to the par value of the decreased shares resulting from the reverse stock split was reclassified from "Common stock" to "Additional paid-in capital." No fractional shares were issued as a result of the reverse stock split; any fractional shares that would have resulted were rounded up to the nearest whole share. Proportionate voting rights and other rights of stockholders were not affected by the reverse stock split, other than as a result of the rounding up of potential fractional shares. All stock options, warrants and restricted stock units outstanding and common stock reserved for issuance under the Company's equity incentive plans immediately prior to the reverse stock split were adjusted by dividing the number of affected shares of common stock by 10 and, where applicable, multiplying the exercise price by 10. All share and per share amounts related to common stock, stock options, warrants and restricted stock units have been restated for all periods to give retroactive effect to the reverse stock split.

Use of Estimates

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

Significant Accounting Policies

There have been no changes to the Company's significant accounting policies since the Company's Annual Report on Form 10-K for the year ended December 31, 2018 with the exception of accounting for leases. See Note 12.

Recent Accounting Pronouncement Adopted

In February 2016, the FASB issued Accounting Standards Update 2016-02, *Leases* (Topic 842), which modifies the accounting by lessees for all leases with a term greater than 12 months. This standard requires lessees

to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. The Company adopted this standard on January 1, 2019 using the modified retrospective transition method, and as a result did not adjust comparative periods. The Company has one large operating lease for its corporate headquarters and several smaller leases, including financing leases for its automobile fleet and copiers. See Note 12.

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued Accounting Standards Update 2016-13, *Measurement of Credit Losses on Financial Instruments*, which requires credit losses on most financial assets measured at amortized cost and certain other instruments to be measured using an expected credit loss model, referred to as the current expected credit loss (CECL) model. Under this model, entities will estimate credit losses over the entire contractual term of the instrument. This standard is effective for fiscal years beginning after December 15, 2019 and early adoption is permitted. The Company is evaluating the potential impact of this standard, but does not expect it to have a material impact on its consolidated financial statements.

In August 2018, the FASB issued Accounting Standards Update 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which adds disclosure requirements to Topic 820 for the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This standard is effective for fiscal years beginning after December 31, 2019 and early adoption is permitted. The Company is evaluating the provisions of this guidance, but currently does not expect it to have a material impact on its consolidated financial statements.

2. REVENUES

For all revenue transactions, the Company evaluates its contracts with its customers to determine revenue recognition using the following five-step model:

1) The Company identifies the contract(s) with a customer
2) The Company identifies the performance obligations in the contract
3) The Company determines the transaction price
4) The Company allocates the transaction price to the identified performance obligations
5) The Company recognizes revenue when (or as) it satisfies a performance obligation

Product Revenue

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

Other product revenue allowances include a reserve for estimated product returns, certain prompt pay discounts and allowances offered to the Company's customers, program rebates and chargebacks. These product revenue allowances are recognized as a reduction of revenue at the date at which the related revenue is recognized. The Company also offers discount programs to patients. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates or chargebacks. The Company reviews the adequacy of product revenue allowances on a quarterly basis. Amounts accrued for product revenue allowances are adjusted when trends or significant events indicate that adjustment is appropriate and to reflect actual experience. See Note 9 for product reserve balances.

Supply Revenue

The Company produces STENDRA/SPEDRA through a contract manufacturing partner and then sells it to the Company's commercialization partners. The Company is the primary responsible party in the commercial supply

arrangements and bears significant risk in the fulfillment of the obligations, including risks associated with manufacturing, regulatory compliance and quality assurance, as well as inventory, financial and credit loss. As such, the Company recognizes supply revenue on a gross basis as the principal party in the arrangements. The Company recognizes supply revenue at the time of shipment and, in the unusual case where the product does not meet contractually-specified product dating criteria at the time of shipment to the partner, the Company records a reserve for estimated product returns. There are no such reserves as of June 30, 2019.

License and Milestone Revenue

License and milestone revenues related to arrangements, usually license and/or supply agreements, entered into by the Company are recognized by following the five-step process outlined above. The allocation and timing of recognition of such revenue will be determined by that process and the amounts recognized and the timing of that recognition may not exactly follow the wording of the agreement as the amount allocated following the accounting analysis of the agreement may differ and the timing of recognition of a significant performance obligation may predate the contractual date.

Royalty Revenue

The Company relies on data provided by its collaboration partner in determining its contractually-based royalty revenue. Such data includes accounting estimates and reports for various discounts and allowances, including product returns. The Company records royalty revenues based on the best data available and makes any adjustments to such revenues as such information becomes available.

Revenue by Source and Geography

Revenue disaggregated by revenue source and by geographic region was as follows (in thousands):

	Three Months Ended June 30,					
	2019			2018		
	U.S.	ROW	Total	U.S.	ROW	Total
Qsymia—Net product revenue	$ 9,994	$ —	$ 9,994	$ 11,134	$ —	$ 11,134
PANCREAZE - Net product revenue	5,110	—	5,110	2,116	—	2,116
PANCREAZE - Royalty revenue	—	987	987	—	74	74
STENDRA/SPEDRA—Supply revenue	—	1,780	1,780	525	517	1,042
STENDRA/SPEDRA—Royalty revenue	—	519	519	—	594	594
Total revenue	$ 15,104	$ 3,286 (1)	$ 18,390	$ 13,775	$ 1,185 (2)	$ 14,960

	Six Months Ended June 30,					
	2019			2018		
	U.S.	ROW	Total	U.S.	ROW	Total
Qsymia—Net product revenue	$ 18,417	$ —	$ 18,417	$ 20,766	$ —	$ 20,766
PANCREAZE - Net product revenue	10,184	—	10,184	2,116	—	2,116
PANCREAZE - Royalty revenue	—	1,557	1,557	—	74	74
STENDRA/SPEDRA—Supply revenue	—	3,384	3,384	1,071	1,654	2,725
STENDRA/SPEDRA—Royalty revenue	—	994	994	—	1,179	1,179
Total revenue	$ 28,601	$ 5,935 (3)	$ 34,536	$ 23,953	$ 2,907 (4)	$ 26,860

(1) $2.3 million of which was attributable to Germany and $1.0 million of which was attributable to Canada.

(2) $1.1 million of which was attributable to Germany.

(3) $4.3 million of which was attributable to Germany and $1.6 million of which was attributable to Canada.

(4) $2.8 million of which was attributable to Germany.

Revenue and cost of goods sold by source was as follows (in thousands):

	Three Months Ended June 30,							
	2019				2018			
	Qsymia	PANCREAZE	STENDRA/ SPEDRA	Total	Qsymia	PANCREAZE	STENDRA/ SPEDRA	Total
Net product revenue	$ 9,994	$ 5,110	$ —	$ 15,104	$ 11,134	$ 2,116	$ —	$ 13,250
Supply revenue	—	—	1,780	1,780	—	—	1,042	1,042
Royalty revenue	—	987	519	1,506	—	74	594	668
Total revenue	$ 9,994	$ 6,097	$ 2,299	$ 18,390	$ 11,134	$ 2,190	$ 1,636	$ 14,960
Cost of goods sold (excluding amortization)	$ 942	$ 1,770	$ 1,665	$ 4,377	$ 1,652	$ 567	$ 1,067	$ 3,286
Amortization of intangible assets	$ 91	$ 3,547	$ —	$ 3,638	$ 90	1,183	$ —	$ 1,273

	Six Months Ended June 30,							
	2019				2018			
	Qsymia	PANCREAZE	STENDRA/ SPEDRA	Total	Qsymia	PANCREAZE	STENDRA/ SPEDRA	Total
Net product revenue	$ 18,417	$ 10,184	$ —	$ 28,601	$ 20,766	$ 2,116	$ —	$ 22,882
Supply revenue	—	—	3,384	3,384	—	—	2,725	2,725
Royalty revenue	—	1,557	994	2,551	—	74	1,179	1,253
Total revenue	$ 18,417	$ 11,741	$ 4,378	$ 34,536	$ 20,766	$ 2,190	$ 3,904	$ 26,860
Cost of goods sold (excluding amortization)	$ 2,324	$ 3,231	$ 3,130	$ 8,685	$ 2,695	$ 568	$ 2,653	$ 5,916
Amortization of intangible assets	$ 182	$ 7,094	$ —	$ 7,276	$ 181	1,183	$ —	$ 1,364

3. SHARE-BASED COMPENSATION

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Cost of goods sold	$ 13	$ 18	$ 27	$ 30
Selling and marketing	70	87	140	174
General and administrative	335	868	664	1,613
Research and development	49	76	104	157
Total share-based compensation expense	$ 467	$ 1,049	$ 935	$ 1,974
Share-based compensation expense capitalized as part of the cost of inventory	$ 14	$ -	$ 14	$ 1

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

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

	As of June 30, 2019			
Cash and cash equivalents and available-for-sale securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and money market funds	$ 25,022	$ —	$ —	$ 25,022
U.S. Treasury securities	27,862	75	(19)	27,918
Corporate debt securities	41,282	163	(19)	41,426
Total	94,166	238	(38)	94,366
Less amounts classified as cash and cash equivalents	(25,022)	—	—	(25,022)
Total available-for-sale securities	$ 69,144	$ 238	$ (38)	$ 69,344

	As of December 31, 2018			
Cash and cash equivalents and available-for-sale securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and money market funds	$ 30,411	$ —	$ —	$ 30,411
U.S. Treasury securities	42,261	34	(111)	42,184
Corporate debt securities	38,848	9	(203)	38,654
Total	111,520	43	(314)	111,249
Less amounts classified as cash and cash equivalents	(30,411)	—	—	(30,411)
Total available-for-sale securities	$ 81,109	$ 43	$ (314)	$ 80,838

As of June 30, 2019, the Company's available-for-sale securities had original contractual maturities up to 57 months. However, the Company may sell these securities prior to their stated maturities in response to changes in the availability of and the yield on alternative investments as well as liquidity requirements. As these securities are readily marketable and are viewed by the Company as available to support current operations, securities with maturities beyond 12 months are classified as current assets. Due to their short-term maturities, the Company believes that the fair value of its bank deposits, accounts payable and accrued expenses approximate their carrying value.

Fair Value Measurements

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

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

The following table represents the fair value hierarchy for our cash, cash equivalents and available-for-sale securities by major security type (in thousands):

	As of June 30, 2019			
	Level 1	Level 2	Level 3	Total
Cash and money market funds	$ 25,022	$ —	$ —	$ 25,022
U.S. Treasury securities	27,918	—	—	27,918
Corporate debt securities	—	41,426	—	41,426
Total	$ 52,940	$ 41,426	$ —	$ 94,366

	As of December 31, 2018			
	Level 1	Level 2	Level 3	Total
Cash and money market funds	$ 30,411	$ —	$ —	$ 30,411
U.S. Treasury securities	42,184	—	—	42,184
Corporate debt securities	—	38,654	—	38,654
Total	$ 72,595	$ 38,654	$ —	$ 111,249

5. ACCOUNTS RECEIVABLE

Accounts receivable consist of the following (in thousands):

	Balance as of	
	June 30, 2019	December 31, 2018
Qsymia	$ 15,408	$ 13,987
PANCREAZE	6,703	10,213
STENDRA/SPEDRA	2,728	1,560
	24,839	25,760
Allowance for cash discounts	(271)	(152)
Net	$ 24,568	$ 25,608

6. INVENTORIES

Inventories consist of the following (in thousands):

	Balance as of	
	June 30, 2019	December 31, 2018
Raw materials	$ 24,089	$ 17,813
Work-in-process	323	1,719
Finished goods	5,699	3,600
Inventories, net	$ 30,111	$ 23,132

Raw materials inventories consist primarily of the active pharmaceutical ingredients ("API") for Qsymia and STENDRA/SPEDRA. Work-in-process and finished goods inventory consist of Qsymia, STENDRA/SPEDRA and PANCREAZE inventory. Inventories are stated at the lower of cost or net realizable value. Cost is determined using the first in, first out method for all inventories, which are valued using a weighted-average cost method calculated for each production batch. The Company periodically evaluates the carrying value of inventory on hand for potential excess amounts over demand using the same lower of cost or net realizable value approach as that used to value the inventory.

7. PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	Balance as of	
	June 30, 2019	December 31, 2018
Prepaid sales and marketing expenses	$ 1,942	$ 1,525
Prepaid insurance	567	1,451
Taxes receivable	2,302	779
Other prepaid expenses and assets	2,159	3,783
Total	$ 6,970	$ 7,538

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

8. INTANGIBLE AND OTHER NON-CURRENT ASSETS

Intangible and other non-current assets consist of the following (in thousands):

	June 30, 2019			December 31, 2018		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
PANCREAZE license (1)	$ 141,895	$ (15,372)	$ 126,523	$ 141,895	$ (8,277)	$ 133,618
Janssen patents (2)	3,050	(2,778)	272	3,050	(2,597)	453
Other non-current assets	208	—	208	208	—	208
Total	$ 145,153	$ (18,150)	$ 127,003	$ 145,153	$ (10,874)	$ 134,279

(1) In June 2018, the Company acquired the rights to license PANCREAZE in the U.S. and Canada, as described further in Note 13. The rights are being amortized over their estimated useful life of 10 years using the straight-line method.

(2) In September 2014, the Company acquired certain patents relating to Qsymia from Janssen Pharmaceuticals, approximately $3.1 million of which was recorded as an intangible asset. The patents are being amortized over their estimated useful life of 5.5 years using the straight-line method.

Other non-current assets primarily consist of real estate deposits. Amortization of intangible assets was $3.6 million and $1.3 million for the three months ended June 30, 2019 and 2018, respectively, and $7.3 million and $1.4 million for the six months ended June 30, 2019 and 2018, respectively. Future expected amortization expenses for intangible assets as of June 30, 2019 are as follows (in thousands):

2019 (rest of year)	$ 7,276
2020	14,280
2021	14,190
2022	14,189
2023	14,190
Thereafter	62,670
Total	$ 126,795

9. ACCRUED AND OTHER LIABILITIES

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

	Balance as of	
	June 30, 2019	December 31, 2018
Reserve for product returns (see Note 2)	$ 15,150	$ 14,878
Product-related accruals (see Note 2)	7,360	8,272
Accrued manufacturing costs	5,268	4,313
Accrued interest on debt (see Note 14)	638	—
Accrued employee compensation and benefits	2,135	2,591
Other accrued liabilities	3,833	2,990
Total	$ 34,384	$ 33,044

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

10. NON-CURRENT ACCRUED AND OTHER LIABILITIES

Non-current accrued and other liabilities at December 31, 2018 were comprised of deferred rent. See Note 12.

11. DEFERRED REVENUE

Deferred revenue relates to a prepayment for future royalties on sales of SPEDRA. In the three and six months ended June 30, 2019, the Company recorded $0.3 million and $0.6 million, respectively, of revenues which had been deferred as of December 31, 2018. In the three and six months ended June 30, 2018, the Company recorded $0.3 million and $0.6 million, respectively, of revenues which had been deferred as of December 31, 2017. These amounts were applied against the prepayment for future royalties.

12. LEASES

The Company adopted Accounting Standards Update 2016-02, Leases (Topic 842) on January 1, 2019 using the modified retrospective transition method, and as a result did not adjust comparative periods. The Company has a large operating lease for its corporate headquarters and several smaller leases, including financing leases for its automobile fleet and copiers. At the time of adoption, the Company recorded the following amounts (in thousands):

	Right-of-Use Asset	Current Portion of Lease Liability	Lease Liability, Net of Current Portion	Current Portion of Deferred Rent	Deferred Rent, Net of Current Portion	Accumulated Deficit
Operating leases	$ 1,201	$ 512	$ 1,017	$ (94)	$ (234)	$ —
Financing leases	329	131	188	—	—	10
Total	$ 1,530	$ 643	$ 1,205	$ (94)	$ (234)	$ 10

The Company's leases have remaining lease terms of from less than 1 year up to 2.3 years, some of which include options to extend the leases for up to 2 years.

The components of lease expense were as follows (in thousands):

	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Operating lease cost	$ 130	$ 261
Finance lease cost:		
Amortization of right-of-use assets	$ 51	$ 104
Interest on lease liabilities	2	5
Total finance lease cost	$ 53	$ 109

Supplemental balance sheet information related to leases was as follows:

	Balance as of June 30, 2019
Right-of-use assets:	
Operating leases	$ 996
Financing leases	327
Total right-of-use assets	$ 1,323
Current portion of lease liability:	
Operating leases	$ 543
Financing leases	167
Total current portion of lease liability	$ 710
Lease liability, net of current portion	
Operating leases	$ 738
Financing leases	156
Total lease liability, net of current portion	$ 894

The weighted average remaining lease term as of June 30, 2019 was 2.2 years for operating leases and 1.9 years for financing leases. The weighted average discount rate as of June 30, 2019 was 7.8% for operating leases and 2.8% for financing leases.

Future payments of lease liabilities are as follows:

	Operating Leases	Finance Leases
2019 (rest of year)	$ 310	$ 92
2020	610	172
2021	482	72
Total lease payments	1,402	336
Less imputed interest	(121)	(13)
Total	$ 1,281	$ 323

13. LICENSE, COMMERCIALIZATION AND SUPPLY AGREEMENTS

MTPC

In January 2001, the Company entered into an exclusive development, license and clinical trial and commercial supply agreement with Tanabe Seiyaku Co., Ltd., now Mitsubishi Tanabe Pharma Corporation ("MTPC"), for the development and commercialization of avanafil. Under the terms of the agreement, MTPC agreed to grant an exclusive license to the Company for products containing avanafil outside of Japan, North Korea, South Korea, China, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Vietnam and the Philippines. The Company agreed to grant MTPC an exclusive, royalty free license within those countries for oral products that we develop containing avanafil. The MTPC agreement contains a number of milestone payments to be made by us based on various triggering events. The term of the MTPC agreement is based on a country by country and on a product by product basis. In August 2012, the Company entered into an amendment to the agreement with MTPC that permitted the Company to manufacture the API and tablets for STENDRA/SPEDRA by itself or through third parties. In 2015, the Company transferred the manufacturing of the API and tablets for STENDRA/SPEDRA to Sanofi. The Company maintains royalty obligations to MTPC which have been passed through to our commercialization partners.

Menarini

In July 2013, the Company entered into a license and commercialization agreement (the "Menarini License Agreement") and a supply agreement (the "Menarini Supply Agreement") with the Menarini Group through its subsidiary Berlin Chemie AG ("Menarini"). Under the terms of the Menarini License Agreement, Menarini received an exclusive license to commercialize and promote SPEDRA for the treatment of ED in over 40 countries, including the EU Member States, plus Australia and New Zealand. Additionally, the Company transferred to Menarini ownership of the marketing authorization for SPEDRA in the EU for the treatment of ED, which was granted by the EC in June 2013. Under the Menarini License Agreement, the Company has and is entitled to receive milestone payments based on certain net sales targets, plus royalties on SPEDRA sales. Under the terms of the Menarini Supply Agreement, the Company supplied Menarini with SPEDRA drug product until December 31, 2018. Menarini also has the right to manufacture SPEDRA independently, provided that it continues to satisfy certain minimum purchase obligations to the Company. Following the expiration of the Menarini Supply Agreement, Menarini would be responsible for its own supply of SPEDRA. Either party may terminate the Menarini Supply Agreement for the other party's uncured material breach or bankruptcy, or upon the termination of the Menarini License Agreement.

In May 2019, the Company entered into Amendment No. 1 to the License and Commercialization Agreement and Commercial Supply Agreement with Menarini effective as of January 1, 2019, pursuant to which certain amendments were made to the Menarini License Agreement and the Menarini Supply Agreement, which include: (i) under the Menarini License Agreement, Menarini's exclusive license to commercialize and promote the Company's drug avanafil for the treatment of erectile dysfunction will be limited to over 40 European countries and will no longer include Australia and New Zealand; (ii) under the Menarini License Agreement, the timing requirements of the product launches by Menarini have been adjusted; (iii) under the Menarini License Agreement, the milestone payments have been adjusted to reflect the removal of Australia and New Zealand and will continue to be non-refundable and non-creditable, with one exception added for certain costs and expenses incurred by Menarini for development work related to an avanafil development opportunity in the Menarini territory ("Menarini Development"); (iv) under the Menarini License Agreement, the royalties on avanafil sales payable by Menarini to the Company will be adjusted to allow Menarini to recoup certain Menarini Development costs and expenses but only as to sales of the Menarini Development product unless the Menarini Development product is commercialized by the Company or its sublicensees outside the Menarini territory; (v) under the Menarini Supply Agreement, the minimum purchase obligations for Menarini will be modified and extended, including the ability of Menarini to satisfy its minimum purchase obligations with the purchase of avanafil active pharmaceutical ingredient ("API") and the addition of minimum purchase obligations for the calendar years for the extended term; and (vi) under the Menarini Supply Agreement, the term will be extended to December 31, 2023, unless otherwise agreed by the parties in writing. The Company and Menarini intend to enter into standalone agreements relating to Australia and New Zealand, including a license with royalties and milestone payments and a supply agreement.

Sanofi

In December 2013, the Company entered into a license and commercialization agreement (the "Sanofi License Agreement") with Sanofi. Under the terms of the Sanofi License Agreement, Sanofi received an exclusive license to commercialize and promote avanafil for therapeutic use in humans in Africa, the Middle East—Turkey and Commonwealth of Independent States, including Russia (the "Sanofi Territory"). On March 23, 2017, the Company and Sanofi entered into the Termination, Rights Reversion and Transition Services Agreement (the "Transition Agreement") effective February 28, 2017. Under the Transition Agreement, effective upon the thirtieth (30th) day following February 28, 2017, the Sanofi License Agreement terminated for all countries in the Sanofi Territory. In addition, under the Transition Agreement, Sanofi provides the Company with certain transition services in support of ongoing regulatory approval efforts while the Company seeks to obtain a new commercial partner or partners for the Sanofi Territory. The Company pays certain transition service fees to Sanofi as part of the Transition Agreement.

In July 2013, the Company 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 Member States, Latin America and other territories. In December 2018, the Company entered into an amendment to the Commercial Supply Agreement with Sanofi Chimie, pursuant to which certain amendments were made to the Commercial Supply Agreement, which include: (i) beginning January 1, 2019, Sanofi Chimie will manufacture and supply API for avanafil on an exclusive basis in all countries where the Company has the right to sell avanafil; (ii) beginning January 1, 2019, the yearly minimum quantities of API that the Company must purchase from Sanofi Chimie will be adjusted, as well as adjustments to the associated pricing and payment terms; and (iii) with the initial five year term of the Commercial Supply Agreement expiring on December 31, 2018, the Company and Sanofi Chimie have agreed to extend the term of the Commercial Supply Agreement until December 31, 2023 unless either party makes a timely election to terminate the agreement and that thereafter the Commercial Supply Agreement will auto-renew for successive one year terms unless either party makes a timely election not to renew.

In November 2013, the Company 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 Member States, Latin America and other territories. The Company has minimum annual purchase commitments under these agreements for at least the initial five-year term. In May 2019, the Company entered into Amendment N°1 to the Manufacturing and Supply Agreement with Sanofi Winthrop Industrie effective as of March 18, 2019, pursuant to which certain amendments were made to the Manufacturing and Supply Agreement, which include: (i) Sanofi Winthrop Industrie will manufacture and supply the tablets for the Company's drug avanafil on an exclusive basis in all countries where the Company or its sublicensees and/or Menarini have the right to sell avanafil; (ii) the yearly minimum quantities of tablets that the Company must purchase from Sanofi Winthrop Industrie and the price of such tablets will be adjusted; and (iii) with the initial term of the Manufacturing and Supply Agreement expiring on January 16, 2021, the Company and Sanofi Winthrop Industrie have agreed to extend the term of the Manufacturing and Supply Agreement until December 31, 2023 unless either party makes a timely election to terminate the agreement and that thereafter the Manufacturing and Supply Agreement will auto-renew for successive one year terms unless either party makes a timely election not to renew.

Metuchen

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

Metuchen will obtain STENDRA exclusively from the Company for a mutually agreed term pursuant to the Metuchen Supply Agreement. Metuchen may elect to transfer the control of the supply chain for STENDRA for the Metuchen 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 Metuchen Supply Agreement, if Metuchen fails to purchase an agreed minimum purchase amount of STENDRA from the Company, it will reimburse the Company for the shortfall as it relates to the Company's out of pocket costs to acquire the API needed to manufacture the agreed upon minimum purchase amount of STENDRA. Upon the termination of the Metuchen Supply Agreement (other than by Metuchen for the Company's uncured material breach or upon completion of the transfer of the control of the supply chain), Metuchen's agreed minimum purchase amount of STENDRA from the Company shall accelerate for the entire then current initial term or renewal term, as applicable. The initial term under the Metuchen Supply Agreement will be for a period of five years, with automatic renewal for successive two-year periods unless either party provides a termination notice to the other party at least two years in advance of the expiration of the then current term.

Alvogen

In September 2017, the Company entered into a license and commercialization agreement (the "Alvogen License Agreement") and a commercial supply agreement (the "Alvogen Supply Agreement") with Alvogen Malta Operations (ROW) Ltd ("Alvogen"). Under the terms of the Alvogen License Agreement, Alvogen will be solely responsible for obtaining and maintaining regulatory approvals for all sales and marketing activities for Qsymia in South Korea. The Company received an upfront payment of $2.5 million in September 2017, which was recorded in license and milestone revenue in the third quarter of 2017, and is eligible to receive additional payments upon Alvogen achieving marketing authorization, commercial launch and reaching a sales milestone. Additionally, the Company will receive a royalty on Alvogen's Qsymia net sales in South Korea. Under the Alvogen Supply Agreement, the Company will supply product to Alvogen on an exclusive basis.

PANCREAZE

In June 2018, the Company closed on an Asset Purchase Agreement (the "PANCREAZE Purchase Agreement") with Janssen Pharmaceuticals, Inc. ("Janssen") pursuant to which the Company acquired the rights to PANCREAZE and PANCREASE MT in the U.S. and Canada and certain existing inventory for a purchase price of $135.0 million in cash.

The Company also acquired all of the outstanding shares of Willow Biopharma Inc. ("Willow"). Willow had no significant assets at the time of acquisition. The Company issued fully-exercisable warrants to the former owners of Willow, including John Amos, M. Scott Oehrlein and Kenneth Suh, the Company's current Chief Executive Officer, Chief Operations Officer and President, respectively, for the purchase of 357,000 shares of the Company's common stock at an exercise price of $3.70 per share and agreed to assume certain of Willow's liabilities. The amounts paid to the former owners were accounted for as a fee for the acquisition of PANCREAZE.

As all the PANCREAZE assets acquired were a part of one product line, the PANCREAZE Purchase Agreement was accounted for as an asset acquisition, with an intangible asset of $141.9 million for the PANCREAZE license recorded on the consolidated balance sheet, which was comprised of the purchase price of $135.0 million, the fair value of the warrants issued of $0.8 million, the value of liabilities assumed of $0.4 million, the value of the Willow liabilities assumed of $1.5 million and accruals for estimated destruction of future unsalable inventory of $6.3 million, less the net value of PANCREAZE inventory acquired of $2.1 million. The fair value of the warrants issued was recorded in additional paid-in capital and was estimated using the Black-Scholes option pricing model, using a term of 7.0 years, an estimated volatility of 61.6%, a risk-free interest rate of 2.91% and an expected dividend yield of 0%. The intangible asset is being amortized over an expected useful life of 10 years, which corresponds with the expiration of certain significant patent rights related to PANCREAZE.

In connection with the PANCREAZE Purchase Agreement, the Company and Janssen also entered into transition services agreements pursuant to which Janssen and a Canadian affiliate of Janssen will provide certain transition services to the Company in the U.S. and Canada as the Company transitions to full control over the PANCREAZE supply chain. The Company and Johnson & Johnson Health Care Systems Inc., a New Jersey corporation and an affiliate of Janssen, also entered into a Long-Term Collaboration Agreement pursuant to which they will cooperate in the reporting and certification of pricing and sales data and the payment of rebates and discounts under certain governmental programs.

In conjunction with the PANCREAZE Purchase Agreement, Janssen assigned to the Company the Amended and Restated Know-How License and Supply Agreement (the "Nordmark Supply Agreement") effective as of November 7, 2017 by and between Nordmark Arzneimittel GmbH & Co. KG ("Nordmark") and Janssen. In order to extend the term of the Nordmark Supply Agreement and ensure a stable and predictable price of the Product, the Company entered into the First Amendment to the Supply Agreement on June 26, 2019 (the "Amended Nordmark Supply Agreement"). Under the Amended Nordmark Supply Agreement: (i) the Company shall purchase certain minimum order quantities at the applicable supply prices for the calendar years under the Amended Nordmark Supply Agreement; (ii) in exchange for Nordmark's obligations under the Amended Nordmark Supply Agreement, the Company shall pay an annual fee to Nordmark; (iii) Nordmark and the Company have agreed to undertake joint efforts to develop new formulations of PANCREAZE; (iv) the term of the Amended Nordmark Supply Agreement begins on June 26, 2019 and will continue through December 31, 2029, unless earlier terminated and may be renewed for additional five year periods unless earlier terminated; and (v) Nordmark shall have the option to terminate the Amended Nordmark Supply Agreement upon certain circumstances related to the launch date in the United States if the Company assigns any or all of its rights under the Amended Nordmark Supply Agreement to certain parties and/or enters into a transaction or series of transactions resulting in a Change of Control, as defined in the Amended Nordmark Supply Agreement.

14. LONG-TERM DEBT AND COMMITMENTS

The Company's indebtedness consists of the following (in thousands):

	Balance as of	
	June 30, 2019	December 31, 2018
Convertible senior notes due 2020	$ 181,426	$ 181,426
Unamortized discount and debt issuance costs	3,958	6,358
Convertible senior notes due 2020, net	185,384	187,784
Senior secured notes due 2024	110,000	110,000
Unamortized premium and debt issuance costs, net	(2,993)	(3,338)
Senior secured notes due 2024, net	107,007	106,662
Total debt	292,391	294,446
Less current portion	185,384	—
Total long-term debt	$ 107,007	$ 294,446

Convertible Senior Notes Due 2020

In May 2013, the Company closed offerings of $250.0 million in 4.5% Convertible Senior Notes due May 2020 (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. Total net proceeds from the Convertible Notes were approximately $241.8 million. The Convertible Notes are convertible at a conversion rate of $148.58 per share 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. In June 2018, the Company repurchased $60.0 million of face value of the Convertible Notes for $51.0 million in cash plus accrued but unpaid interest using funds received from the issuance of the Company's Senior Secured Notes Due 2024. The gain was accounted for as a debt modification with the gain applied to the modified debt. In October 2018, the Company repurchased $8.6 million of face value of the Convertible Notes for $7.1 million in cash plus accrued but unpaid interest. The gain on this repurchase of $1.4 million was accounted for as an extinguishment of debt and recorded on the statement of operations as a gain on extinguishment of debt.

Senior Secured Notes Due 2024

In June 2018, the Company entered into an indenture (the "Indenture") with U.S. Bank National Association as trustee and collateral agent regarding the purchase agreement entered into with affiliates of Athyrium Capital Management (collectively, the "Purchasers") for the issuance and sale of (i) $110.0 million of 10.375% senior secured notes due 2024 (the "2024 Notes"), (ii) up to an additional $10.0 million of 10.375% senior secured notes due 2024 to be issued subsequently at the Company's option within 12 months of the issue date of the 2024 Notes, subject to certain conditions, and (iii) a warrant for 330,000 shares issued concurrently with the issuance of the 2024 Notes. The 2024 Notes were issued at a purchase price equal to 99% of the principal amount and contain customary representations, warranties, covenants, conditions and indemnities.

The Company used the net proceeds from the issuance of the 2024 Notes to pay (i) certain fees, costs and expenses relating to the issuance and sale of the 2024 Notes, (ii) to finance a portion of the acquisition of PANCREAZE and (iii) to repurchase $60.0 million of the Company's outstanding Convertible Notes from the Purchasers or their affiliates for a purchase price of $51.0 million (plus accrued but unpaid interest to the repurchase date). The fair value of the warrant issued was estimated using the Black-Scholes option pricing model, using a term of 6.0 years, an estimated volatility of 62.7%, a risk-free interest rate of 2.83% and an expected dividend yield of 0%. The Indenture has an effective interest rate of 11.3% and includes customary covenants and events of default, including covenants that, among other things, restrict the incurrence of future indebtedness, the granting of liens, the making of investments, distributions or dividends, and the Company's ability to merge, consolidate or sell assets, in each case subject to certain exceptions. In addition, the Indenture includes certain financial maintenance covenants related to minimum cash balances and minimum quarterly net revenues related to PANCREAZE.

As of June 30, 2019, the Company was not in compliance with a covenant in the indenture governing its 2024 Notes related to PANCREAZE net revenues. The Company subsequently received a waiver from the consenting noteholders with respect to any potential event of default or default that may have resulted from such covenant non-compliance. In connection with the waiver, the Company agreed to the noteholder conditions, including transferring $60.0 million from the existing 2024 Notes trustee controlled account into a new controlled account that can only be accessed upon prior written consent of the 2024 Notes trustee at the direction of the noteholders. If the Company does not satisfy the noteholder conditions, the consenting noteholders may revoke the waiver, which could result in an event of default.

Future estimated payments, including interest, on all of the Company's indebtedness as of June 30, 2019 are as follows (in thousands):

2019 (rest of year)	$ 9,788
2020	197,374
2021	36,131
2022	41,299
2023	37,789
Thereafter	17,611
	$ 339,992

Cardiovascular Outcomes Trial

As a condition of FDA granting approval to commercialize Qsymia in the U.S., the Company agreed to complete certain post-marketing requirements. One requirement was to perform a cardiovascular outcomes trial ("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 in dialogue with FDA to determine a pathway to provide FDA with information to support the safety of Qsymia in a more cost-effective manner. To date, the Company has not incurred expenses related to the CVOT.

15. NET LOSS PER SHARE

The Company computes basic net 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 $200 per share, and thus no impact on diluted net income per share. Further, when there is a net loss, potentially dilutive common equivalent shares are not included in the calculation of net loss per share since their inclusion would be anti-dilutive.

As the Company recognized a net loss for each of the three- and six-month periods ended June 30, 2019 and 2018, all potential common equivalent shares were excluded for these periods as they were anti-dilutive. Awards and options which were not included in the computation of diluted net loss per share because the effect would be anti-dilutive were 2,900,000 and 1,490,000, respectively, for the three months ended June 30, 2019 and 2018 and 2,844,000 and 1,926,000, respectively, for the six months ended June 30, 2019 and 2018.

16. INCOME TAXES

For the three and six months ended June 30, 2019, the Company recorded a provision for income taxes of $8,000 and $0, respectively. For the three and six months ended June 30, 2018, the Company recorded a provision for income taxes of $4,000 and $16,000, respectively. The provision for income taxes for each of the periods was primarily comprised of state taxes during the period.

The Company periodically evaluates the realizability of its net deferred tax assets based on all available evidence, both positive and negative. The realization of net deferred tax assets is dependent on the Company's ability to generate sufficient future taxable income during periods prior to the expiration of tax attributes to fully utilize these assets. The Company weighed both positive and negative evidence and determined that there is a continued need for a full valuation allowance on its deferred tax assets in the United States as of June 30, 2019. Should the Company determine that it would be able to realize its remaining deferred tax assets in the foreseeable future, an adjustment to its remaining deferred tax assets would cause a material increase to income in the period such determination is made.

As of June 30, 2019, the Company's unrecognized tax benefits were related to federal and California research and development credits which result in an unrecognized tax benefit balance of $98,000. The Company does not expect to have any other significant changes to unrecognized tax benefits through the end of the fiscal year. Because of the Company's history of tax losses, certain tax years remain open to tax audit. The Company's policy is to recognize interest and penalties related to uncertain tax positions (if any) as a component of the income tax provision.

On December 22, 2017, the Tax Cuts and Jobs Act was signed into law. Among other changes is an interest expense deduction limitation effective January 1, 2018. For the periods ending June 30, 2019 and 2018, the Company estimated $8.3 million and $7.0 million, respectively, of non-deductible accrued interest expense in the forecasted taxable income calculation.

On January 1, 2019, the Company adopted Accounting Standards Update 2016-02, *Leases* (Topic 842). See Note 12. The Company has evaluated the income tax effect from the adoption of this standard and has determined that there is no material impact to the tax provision.

The Tax Cuts and Jobs Act also establishes new tax provisions including, but not limited to, (1) creating a new provision designed to tax global intangible low-tax income ("GILTI"); (2) generally eliminating U.S. federal taxes on dividends from foreign subsidiaries; (3) eliminating the corporate alternative minimum tax; (4) creating the base erosion anti-abuse tax; (5) establishing a deduction for foreign derived intangible income; (6) repealing domestic production activity deduction; and (7) establishing new limitations on deductible interest expense and certain executive compensation. The Tax Cuts and Jobs Act has not resulted in a significant impact on the Company's financial statements.

For the periods ending June 30, 2019 and 2018, the Company estimated $500 and $0, respectively, of GILTI inclusion in the taxable income calculation. Due to the Company's limited foreign activity at this time, this did not have a material impact to the tax provision.

17. LEGAL MATTERS

The Company is not aware of any 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 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," "plan," "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:

Risks and uncertainties related to Qsymia® (phentermine and topiramate extended release):

- our, or our current or potential partners', ability to successfully commercialize Qsymia including risks and uncertainties related to expansion to 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 sell through the Qsymia retail pharmacy network;
- the impact of promotional programs for Qsymia on our net product revenue and net income (loss) in future periods;
- our ability to ensure that the entire supply chain for Qsymia timely, efficiently and consistently delivers Qsymia to our customers and partners;
- our ability to accurately forecast Qsymia demand;
- our, or our current or potential partners', ability to successfully seek and gain approval for Qsymia in territories outside the U.S.;
- 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 ("FDA");
- the response from FDA to any data and/or information relating to post-approval clinical studies required for Qsymia;
- our ability to work with FDA to significantly reduce or remove the requirements of the clinical post-approval cardiovascular outcomes trial ("CVOT");
- the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy ("REMS") requirements;
- the impact of any possible future requirement to provide further analysis of previously submitted clinical trial data;
- our dialog with the European Medicines Agency ("EMA") or certain member states on a decentralized basis relating to the resubmission of an application for the grant of a marketing authorization, the timing and scope of such resubmission, the assessment by European health authorities of the application for marketing authorization, and ultimately the decision of such European health authorities whether to grant marketing authorization for Qsymia in the EU;

Risks and uncertainties related to PANCREAZE (pancrelipase):

- our ability to maintain the relationship with the sole manufacturer for PANCREAZE;
- our ability to accurately forecast PANCREAZE demand;
- our ability to maintain a satisfactory level of PANCREAZE inventory;
- risks and uncertainties related to the timing, strategy, tactics and success of the marketing and sales of PANCREAZE;
- our ability to successfully maintain and increase market share against current competing products and potential competitors that may develop alternative formulations of the drug;

- the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand;

Risks and uncertainties related to STENDRA® (avanafil) or SPEDRA™ (avanafil):

- our ability to manage the supply chain for STENDRA/SPEDRA for our current or potential commercial collaborators;
- risks and uncertainties related to the timing, strategy, tactics and success of the launches and commercialization of STENDRA/SPEDRA by our current or potential collaborators;
- 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 partner;
- Sanofi Chimie's ability to manufacture the avanafil active pharmaceutical ingredient and Sanofi Winthrop Industrie's ability to manufacture avanafil tablets;
- the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand;

Risks and uncertainties related to our business:

- our liquidity and capital resources;
- our history of losses and variable quarterly results;
- the volatility and liquidity of the financial markets;
- our expected future revenues, operations and expenditures;
- our ability to effectively manage expenses;
- risks related to our ability to protect our intellectual property and litigation in which we are involved or may become involved;
- uncertainties of government or third-party payor reimbursement;
- our reliance on sole-source suppliers, third parties and our collaborative partners;
- our ability to successfully develop or acquire a proprietary formulation of tacrolimus;
- our ability to identify and acquire cash flow generating assets and opportunities;
- risks related to the failure to obtain or retain federal or state-controlled substances registrations and noncompliance with Drug Enforcement Administration ("DEA") or state controlled substances regulations;
- 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 current and future investigational drug candidates or approved products;
- the timing of initiation and completion of clinical trials and submissions to U.S. and foreign authorities;
- compliance with post-marketing regulatory standards, post-marketing obligations or pharmacovigilance rules is not maintained;
- our ability to execute on our business strategy to enhance long-term stockholder value;
- our ability to address our outstanding balance of $181.4 million of the 4.5% Convertible Senior Notes due in May 2020 (the "Convertible Notes");
- our ability to successfully integrate recent changes to our Board of Directors and the senior management team; and
- other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission (the "SEC") including those set forth in this filing as "Part II. Item 1A. Risk Factors."

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

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the three and six months ended June 30, 2019 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, 2018, as filed with the SEC on February 26, 2019 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.

Reverse Stock Split

On September 10, 2018, we effected a one-for-10 reverse stock split of our common stock. As a result of the reverse stock split, every 10 shares of our pre-reverse split common stock issued and outstanding was combined and converted into one issued and outstanding share of post-reverse split common stock without any change in the par value of the shares. Accordingly, an amount equal to the par value of the decreased shares resulting from the reverse stock split was reclassified from "Common stock" to "Additional paid-in capital." No fractional shares were issued as a result of the reverse stock split; any fractional shares that would have resulted were rounded up to the nearest whole share. Proportionate voting rights and other rights of stockholders were not affected by the reverse stock split, other than as a result of the rounding up of potential fractional shares. All stock options, warrants and restricted stock units outstanding and common stock reserved for issuance under our equity incentive plans immediately prior to the reverse stock split were adjusted by dividing the number of affected shares of common stock by 10 and, where applicable, multiplying the exercise price by 10. All share and per share amounts related to common stock, stock options, warrants and restricted stock units have been restated for all periods to give retroactive effect to the reverse stock split.

OVERVIEW

VIVUS is a specialty pharmaceutical company with three approved therapies and one product candidate in clinical development. Qsymia® (phentermine and topiramate extended release) is approved by FDA for chronic weight management. In June 2018, we acquired the U.S. and Canadian commercial rights for PANCREAZE® (pancrelipase), which is indicated for the treatment of exocrine pancreatic insufficiency ("EPI") due to cystic fibrosis or other conditions. STENDRA® (avanafil) is approved by FDA for erectile dysfunction ("ED") and by the EC under the trade name SPEDRA, for the treatment of ED in the EU. VI-0106 (tacrolimus) is in clinical development and is being studied in patients with pulmonary arterial hypertension ("PAH").

Business Strategy

Early in 2018, we announced that we would focus our strategy on building a portfolio of cash flow generating assets to leverage our expertise in commercializing specialty pharmaceutical assets. In June 2018, we completed the first acquisition under this strategy as we acquired all product rights for PANCREAZE® (pancrelipase) in the United States and PANCREASE® MT in Canada for $135.0 million in cash from Janssen Pharmaceuticals. PANCREAZE is a prescription medicine used to treat people who cannot digest food normally because their pancreas does not make enough enzymes due to cystic fibrosis or other conditions. We believe we can support PANCREAZE in the U.S. market by leveraging our existing commercial infrastructure and 10 additional sales representatives in the U.S. and up to two additional sales representatives in Canada focused on gastro-intestinal and cystic fibrosis physicians. We expect to build a small commercial presence in Canada to support PANCREASE MT, the trade name for pancrelipase in Canada.

In April 2018, we announced the acquisition of Willow Biopharma Inc. ("Willow"). With this acquisition, we announced the addition of three new members to our senior leadership team. John Amos was named our new Chief Executive Officer and a member of the VIVUS Board of Directors. Kenneth Suh continued as President and Chief Executive Officer of Willow until being named President of VIVUS in August 2018. M. Scott Oehrlein was named to the newly created position of Chief Operations Officer of VIVUS. These three individuals have a strong track record of building successful cash flow positive businesses organically and through product acquisition. In combination with the other current members of the senior leadership team, we believe that we are well positioned to continue to successfully execute on our business strategy.

In April 2018, we entered into a note purchase agreement (the "Note Purchase Agreement") with affiliates of Athyrium Capital Management ("Athyrium") for the issuance and sale of up to $110.0 million of 10.375% senior secured notes due 2024 to be issued substantially concurrently with the consummation of the PANCREAZE acquisition. The Note Purchase Agreement also allows up to an additional $10.0 million of 10.375% senior secured notes due 2024 to be issued at our option within 12 months of the initial issue date, subject to certain conditions. Notes in the amount of $110.0 million were issued in June 2018. Concurrent with the issuance of the initial notes, we issued warrants to purchase 0.3 million shares of our common stock to the note holders. Additionally, concurrent with the issuance of the senior secured notes, we repurchased Convertible Notes held by Athyrium, with a face value of $60.0 million, at a discount to par plus accrued interest. In October 2018, we settled a purchase of approximately $8.6 million outstanding principal amount of our Convertible Notes for approximately $7.1 million plus accrued interest. We continue our evaluation of alternatives for addressing our remaining $181.4 million of Convertible Notes. See the Liquidity and Capital Resources section below for a further discussion.

Commercial Products

Qsymia

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

We commercialize Qsymia in the U.S. through a specialty sales force who promote Qsymia to physicians. Our sales efforts are focused on maintaining a commercial presence with high volume prescribers of anti-obesity products. Our marketing efforts have focused on rolling out unique programs to encourage targeted prescribers to gain more experience with Qsymia with their obese or overweight patient population. We continue to invest in digital media in order to amplify our messaging to information-seeking consumers. The digital messaging encourages those consumers most likely to take action to speak with their physicians about obesity treatment options. We believe our enhanced digital strategies deliver clear and compelling communications to potential patients. We utilize a patient savings plan to further drive Qsymia brand preference at the point of prescription and to encourage long-term use of the brand.

In September 2017, we entered into a license and commercialization agreement (the "Alvogen License Agreement") and a commercial supply agreement (the "Alvogen Supply Agreement") with Alvogen Malta Operations (ROW) Ltd ("Alvogen"). Under the terms of the Alvogen License Agreement, Alvogen will be solely responsible for obtaining and maintaining regulatory approvals for all sales and marketing activities for Qsymia in South Korea. We received an upfront payment of $2.5 million in September 2017 and are eligible to receive additional payments upon Alvogen achieving marketing authorization, commercial launch and reaching a sales milestone. Additionally, we will receive a royalty on Alvogen's Qsymia net sales in South Korea. Under the Alvogen Supply Agreement, we will supply product to Alvogen on an exclusive basis.

PANCREAZE

Since its approval, PANCREAZE has been commercialized by Janssen. In June 2018, we acquired the commercial rights to PANCREAZE and PANCREASE MT in the U.S. and Canada. In connection with the acquisition of PANCREAZE, we and Janssen also entered into transition services agreements pursuant to which Janssen and a Canadian affiliate of Janssen will provide certain transition services to us in the U.S. and Canada as we transition to full control over the PANCREAZE supply chain, beginning in the first quarter of 2019. In the first quarter of 2019, we relaunched PANCREAZE by leveraging our existing commercial infrastructure and expanding it to include 10 additional contract sales representatives in the U.S. and up to two sales representatives in Canada focused on gastro-intestinal and cystic fibrosis physicians. We expect to transition to direct sales in Canada in the third quarter of 2019.

Approved in 2010, PANCREAZE is a pancreatic enzyme preparation consisting of pancrelipase, an extract derived from porcine pancreatic glands, as well as other enzyme classes, including porcine-derived lipases, proteases and amylases. PANCREAZE is specifically indicated for the treatment of exocrine pancreatic insufficiency ("EPI"). EPI is a condition that results from a deficiency in the production and/or secretion of pancreatic enzymes. It is

associated with cystic fibrosis, chronic pancreatitis, pancreatic cancer and other conditions, and affects approximately 85 percent of cystic fibrosis patients. There is no cure for EPI and pancreatic enzyme replacement therapy is the primary treatment for the condition.

STENDRA/SPEDRA

STENDRA is an oral phosphodiesterase type 5 ("PDE5") inhibitor that we have licensed from Mitsubishi Tanabe Pharma Corporation ("MTPC"). FDA approved STENDRA in April 2012 for the treatment of ED in the United States. In June 2013, the EC adopted a decision granting marketing authorization for SPEDRA, the approved trade name for avanafil in the EU, for the treatment of ED in the EU.

The Menarini Group, through its subsidiary Berlin Chemie AG ("Menarini"), is our exclusive licensee for the commercialization and promotion of SPEDRA for the treatment of ED in over 40 countries, including the EU Member States. In addition, Menarini licensed rights directly from MTPC to commercialize avanafil in certain Asian territories. We receive royalties from Menarini based on SPEDRA net sales and are entitled to receive future milestone payments based on certain net sales targets. Menarini will also reimburse us for payments made to cover various obligations to MTPC during the term of the Menarini License Agreement. Menarini obtains SPEDRA exclusively from us.

Metuchen Pharmaceuticals LLC ("Metuchen") is our exclusive licensee for the development, commercialization and promotion of STENDRA in the United States, Canada, South America and India. Metuchen reimburses us for payments made to cover royalty and milestone obligations to MTPC, but otherwise owes us no future royalties. Metuchen obtains STENDRA exclusively from us.

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

Product Development Pipeline and Life Cycle Management

VI-0106 - Pulmonary Arterial Hypertension

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

The current medical therapies for PAH involve endothelin receptor antagonists, PDE5 inhibitors, prostacyclin analogues, selective prostaglandin I2 receptor agonists, and soluble guanate cyclase stimulators, which aim to reduce symptoms and improve quality of life. All currently approved products treat the symptoms of PAH, but do not address the underlying disease. We believe that tacrolimus can be used to enhance bone morphogenetic protein receptor type 2 ("BMPR2") signaling, which is reduced in PAH patients, and may therefore address a fundamental cause of PAH.

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

On January 6, 2017, we acquired the exclusive, worldwide rights for the development and commercialization of BMPR2 activators for the treatment of PAH and related vascular diseases from Selten Pharma, Inc. ("Selten"). Selten assigned to us its license to a group of patents owned by the Board of Trustees of the Leland Stanford Junior University ("Stanford") which cover uses of tacrolimus and ascomycin to treat PAH. We paid Selten an upfront payment of $1.0 million, and we will pay additional milestone payments based on global development status and future sales milestones, as well as tiered royalty payments on future sales of these compounds. The total

potential milestone payments are $39.0 million to Selten. We have assumed full responsibility for the development and commercialization of the licensed compounds for the treatment of PAH and related vascular diseases.

In October 2017, we held a pre-IND meeting with FDA for VI-0106, our proprietary formulation of tacrolimus for the treatment of PAH. FDA addressed our questions related to preclinical, nonclinical and clinical data and the planned design of clinical trials of tacrolimus in class III and IV PAH patients, and clarified the requirements needed to file an IND to initiate a clinical trial in this indication. As discussed with FDA, we currently intend to design and conduct clinical trials that could qualify for Fast Track and/or Breakthrough Therapy designation.

Tacrolimus for the treatment of PAH has received Orphan Drug Designation from FDA in the U.S. and the EU on the basis of a scientific opinion adopted by the Committee for Orphan Medicinal Products of the European Medicines Agency in the EU. We are focusing on the development of a proprietary oral formulation of tacrolimus to be used in a clinical development program and, if approved, for commercial use. We anticipate filing an IND with FDA and completing the development of our proprietary formulation of tacrolimus in 2019. We are currently seeking alternatives for financing the development of tacrolimus.

Qsymia for Additional Indications

We are currently considering further development of Qsymia for the treatment of various diseases, including obstructive sleep apnea and nonalcoholic steatohepatitis ("NASH"). We expect no future development until we have concluded our discussions with FDA regarding our CVOT for Qsymia.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the 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 for the year ended December 31, 2018 as filed with the SEC on February 26, 2019. There have been no changes to our significant accounting policies since our Annual Report on Form 10-K for the year ended December 31, 2018 with the exception of accounting for leases as follows.

In February 2016, the FASB issued Accounting Standards Update 2016-02, *Leases* which modifies the accounting by lessees for all leases with a term greater than 12 months. This standard requires lessees to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. We adopted this standard on January 1, 2019. Our only significant lease is our operating lease for our corporate headquarters, although we have several smaller leases, including financing leases for our automobile fleet and copiers. At the time of adoption, we recorded the following amounts (in thousands):

	Right-of-Use Asset	Current Portion of Lease Liability	Lease Liability, Net of Current Portion	Current Portion of Deferred Rent	Deferred Rent, Net of Current Portion	Accumulated Deficit
Operating leases	$ 1,201	$ 512	$ 1,017	$ (94)	$ (234)	$ —
Financing leases	329	131	188	—	—	10
Total	$ 1,530	$ 643	$ 1,205	$ (94)	$ (234)	$ 10

RESULTS OF OPERATIONS

Revenues

(in thousands, except for percentages)	Three Months Ended June 30, 2019	2018	Increase/ (Decrease)	Six Months Ended June 30, 2019	2018	Increase/ (Decrease)
Qsymia—Net product revenue	$ 9,994	$ 11,134	(10)%	$ 18,417	$ 20,766	(11)%
PANCREAZE - Net product revenue	5,110	2,116	141 %	10,184	2,116	381 %
Supply revenue	1,780	1,042	71 %	3,384	2,725	24 %
STENDRA/SPEDRA royalty revenue	519	594	(13)%	994	1,179	(16)%
PANCREAZE royalty revenue	987	74	1,234 %	1,557	74	2,004 %
Total revenue	$ 18,390	$ 14,960	23 %	$ 34,536	$ 26,860	29 %

Net product revenue

Shipments and prescriptions for net product revenue consisted of the following:

(in thousands, except for percentages)	Three Months Ended June 30, 2019	2018	Increase/ (Decrease)	Six Months Ended June 30, 2019	2018	Increase/ (Decrease)
Qsymia units shipped to wholesalers	87	94	(7)%	162	176	(8)%
Qsymia prescriptions dispensed	86	96	(10)%	168	173	(3)%
PANCREAZE units shipped	27	7	286 %	52	7	643 %

The decrease in Qsymia net product revenue is due primarily to decreases in script volumes and supply chain management by wholesalers. We anticipate scripts and shipments in the second half of 2019 to be consistent with or greater than the first half of 2019 as a result of our implementation of the direct-to-patient distribution model and other marketing efforts. PANCREAZE net product revenue was negatively impacted in the first quarter of 2019 by higher wholesaler fees as we took over supply chain management and additional gross-to-net reductions related to promotional strategies, including the issuance of discount coupons. We anticipate that future PANCREAZE product revenue will fluctuate from period to period based on our wholesalers' management of the supply chain and the impact of our relaunch efforts. Also, we anticipate that future PANCREAZE net product revenue will continue to be negatively impacted by potential future promotional strategies, including coupon programs.

License and milestone revenue

License and milestone revenues are dependent on the timing of entering into new collaborations and the timing of our collaborators meeting or being reasonably certain of meeting certain milestone events. As a result, our license and milestone revenue will fluctuate materially between periods.

Supply revenue

The decrease in supply revenue in 2019 as compared to 2018 is due to the timing of orders from our commercialization partners. We supply STENDRA/SPEDRA to our collaborations partners on a cost-plus basis. The variations in supply revenue are a result of the timing of orders placed by our partners and may or may not reflect end user demand for STENDRA/SPEDRA. The timing of purchases by our commercialization partners will be affected by, among other items, their minimum purchase commitments, end user demand, and distributor inventory levels. As a result, supply revenue has and will continue to fluctuate materially between reporting periods.

Royalty revenue

We record royalty revenue related to Canadian sales of PANCREASE MT and sales of STENDRA/SPEDRA based on reports provided by our partners. Once we take over operations for Canadian sales for PANCREASE MT, including ownership of the Canadian inventory, we expect that net sales of PANCREASE MT will be recorded as net product revenue with costs recorded as cost of goods sold. We expect this transition to occur in the third quarter of 2019. We expect STENDRA/SPEDRA royalty revenue in 2019 to remain relatively consistent with current levels.

Cost of goods sold

	Three Months Ended June 30,															
	2019								2018							
(In thousands, except percentages)	Qsymia		PANCREAZE		STENDRA/ SPEDRA		Total		Qsymia		PANCREAZE		STENDRA/ SPEDRA		Total	
Net product revenue	$ 9,994		$ 5,110		$ —		$15,104		$11,134		$2,116		$ —		$13,250	
Supply revenue	—		—		1,780		1,780		—		—		1,042		1,042	
Total product and supply revenue	9,994	100%	$ 5,110	100%	$1,780	100%	$16,884	100%	$11,134	100%	$2,116	100%	$1,042	100%	$14,292	100%
Cost of goods sold (excluding amortization)	942	9%	$ 1,770	35%	$1,665	94%	$ 4,377	26%	$ 1,652	15%	$ 567	27%	$1,067	102%	$ 3,286	23%
Amortization of intangible assets	91	1%	3,547	69%	—	0%	3,638	22%	90	1%	1,183	56%	—	0%	$ 1,273	9%
Total cost of goods sold	1,033	10%	$ 5,317	104%	$1,665	94%	$ 8,015	47%	$ 1,742	16%	$1,750	83%	$1,067	102%	$ 4,559	32%
	$ 8,961	90%	$ (207)	-4%	$ 115	6%	$ 8,869	53%	$ 9,392	84%	$ 366	17%	$ (25)	-2%	$ 9,733	68%

	Six Months Ended June 30,															
	2019								2018							
(In thousands, except percentages)	Qsymia		PANCREAZE		STENDRA/ SPEDRA		Total		Qsymia		PANCREAZE		STENDRA/ SPEDRA		Total	
Net product revenue	$18,417		$10,184		$ —		$28,601		$20,766		$2,116		$ —		$22,882	
Supply revenue	—		—		3,384		3,384		—		—		2,725		2,725	
Total product and supply revenue	$18,417	100%	$10,184	100%	$3,384	100%	$31,985	100%	$20,766	100%	$2,116	100%	$2,725	100%	$25,607	100%
Cost of goods sold (excluding amortization)	$ 2,324	13%	$ 3,231	32%	$3,130	92%	$ 8,685	27%	$ 2,695	13%	$ 568	27%	$2,653	97%	$ 5,916	23%
Amortization of intangible assets	$ 182	1%	$ 7,094	70%	$ —	0%	$ 7,276	23%	$ 181	1%	1,183	56%	$ —	0%	$ 1,364	5%
Total cost of goods sold	$ 2,506	14%	$10,325	101%	$3,130	92%	$15,961	50%	$ 2,876	14%	$1,751	83%	$2,653	97%	$ 7,280	28%
	$15,911	86%	$ (141)	-1%	$ 254	8%	$16,024	50%	$17,890	86%	$ 365	17%	$ 72	3%	$18,327	72%

Cost of goods sold for Qsymia includes the inventory costs of API, third party contract manufacturing and packaging and distribution costs, royalties, cargo insurance, freight, shipping, handling and storage costs, and overhead costs of the employees involved with production. Cost of goods sold for PANCREAZE includes third party contract manufacturing costs, amortization of the PANCREAZE license, service fees, royalties, insurance, and overhead costs. Cost of goods sold for STENDRA/SPEDRA shipped to our commercialization partners includes the inventory costs of API and tableting. Fluctuations in the cost of goods sold as a percentage of net product and supply revenue over the periods was primary due to the sales mix among Qsymia, STENDRA/SPEDRA and PANCREAZE.

Selling, general and administrative expense

	Three Months Ended June 30,		Increase/	Six Months Ended June 30,		Increase/
(In thousands, except percentages)	2019	2018	(Decrease)	2019	2018	(Decrease)
Selling and marketing	$ 4,607	$ 3,521	31 %	$ 9,141	$ 7,800	17 %
General and administrative	5,463	8,190	(33)%	10,747	13,979	(23)%
Total selling, general and administrative expenses	$ 10,070	$ 11,711	(14)%	$ 19,888	$ 21,779	(9)%

The increase in selling and marketing expenses for the three and six months ended June 30, 2019, compared to the same periods in 2018, was due primarily to commercialization efforts for PANCREAZE, including additions to our sales force and promotional activities as we relaunched PANCREAZE in the first quarter of 2019. Selling and marketing expenses are expected to remain stable in future quarters.

The decrease in general and administrative expenses in the three and six months ended June 30, 2019 compared to the same periods in 2018 was primarily due to costs in 2018 associated with the PANCREAZE acquisition. General and administrative expenses could fluctuate significantly on a quarterly basis due to the timing of activities within our business strategy efforts.

Research and development expense

Drug Indication/Description	Three Months Ended June 30, 2019	2018	Increase/ (Decrease)	Six Months Ended June 30, 2019	2018	Increase/ (Decrease)
(In thousands, except percentages)						
Qsymia	$ 748	$ 308	143 %	$ 1,441	$ 328	339 %
STENDRA	42	38	11 %	83	86	(3)%
PANCREAZE	553	96	476 %	1,195	96	1,145 %
VI-0106	40	805	(95)%	65	1,366	(95)%
Share-based compensation	49	76	(36)%	104	157	(34)%
Overhead costs*	920	719	28 %	1,933	1,412	37 %
Total research and development expenses	$ 2,352	$ 2,042	15 %	$ 4,821	$ 3,445	40 %

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

The increase in total research and development expenses in the three and six months ended June 30, 2019 as compared to the same periods in 2018 was primarily due to higher spending for our Qsymia adolescent safety and efficacy study (OB-403) as we enrolled our first patients across multiple sites and started monitoring visits. Additionally, we have increased spending related to post marketing requirements assumed as part of the acquisition of PANCREAZE in June 2018. Our spending to develop tacrolimus for the treatment of PAH experienced a temporary decrease due to the timing of development activities. We expect research and development expenses to continue to remain stable over the remaining months in 2019 for OB-403 as we enroll more patients and increase the number of sites as well as work on the PANCREAZE post-marketing requirements.

Interest expense and other expense, net

Interest expense and other expense, net for the three and six months ended June 30, 2019 was $3.9 million and $7.8 million, respectively, compared to $9.2 million and $17.6 million for the three and six months ended June 30, 2018, respectively. The decrease in 2019 is due to the paydown of debt in 2018 and the loss of its associated discounts, partially offset by the additional debt issued in June 2018. Interest expense and other expense, net consists primarily of interest expense and the amortization of issuance costs from our convertible notes and senior secured notes and the amortization of the debt discount on the convertible notes. Other expense and income were not significant. We expect interest and other expense (income) for the remainder of 2019 to remain consistent. We expect to make annual interest payments of $19.6 million in 2019 on our convertible and senior secured notes.

Provision for (benefit from) income taxes

For the three and six months ended June 30, 2019, we recorded a provision for income taxes of $8,000 and $0, respectively, compared to a provision for income taxes of $4,000 and $16,000, respectively, for the three and six months ended June 30, 2018. The provision and benefit for income taxes for both of the periods is primarily comprised of state taxes during the period.

We periodically evaluate the realizability of our net deferred tax assets based on all available evidence, both positive and negative. The realization of net deferred tax assets is dependent on our ability to generate sufficient future taxable income during periods prior to the expiration of tax attributes to fully utilize these assets. We weighed both positive and negative evidence and determined that there is a continued need for a full valuation allowance on our deferred tax assets in the U.S. as of June 30, 2019. Should there be a change in our ability to recover our deferred tax assets, we would recognize a benefit to our tax provision in the period in which we determine that it is more likely than not that we will recover its deferred tax assets.

LIQUIDITY AND CAPITAL RESOURCES

Cash. Cash, cash equivalents and available-for-sale securities totaled $94.4 million at June 30, 2019, as compared to $111.2 million at December 31, 2018. The decrease was primarily due to net cash used for operating activities and debt servicing during the period.

We invest our excess cash balances in money market, U.S. government securities and corporate debt securities in accordance with our investment policy. Our investment policy has the primary investment objectives of preservation of principal; however, there may be times when certain of the securities in our portfolio will fall below

the credit ratings required in the policy. If those securities are downgraded or impaired, we would experience realized or unrealized losses in the value of our portfolio, which would have an adverse effect on our results of operations, liquidity and financial condition. From time to time, the Company may also invest its cash to retire or purchase its outstanding debt. Investment securities are exposed to various risks, such as interest rate, market and credit. Due to the level of risk associated with certain investment securities and the level of uncertainty related to changes in the value of investment securities, it is possible that changes in these risk factors in the near term could have an adverse material impact on our results of operations or stockholders' equity.

Accounts Receivable. We extend credit to our customers for product sales resulting in accounts receivable. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written off against the allowance for doubtful accounts. Allowances for doubtful accounts are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. Historically, we have had no significant uncollectable accounts receivable. We offer cash discounts to our customers, generally 2% of the sales price as an incentive for prompt payment.

Accounts receivable (net of allowance for cash discounts) at June 30, 2019, was $24.6 million, as compared to $25.6 million at December 31, 2018. Currently, we have not recorded any reserves related to the collectability of accounts receivable.

Summary Cash Flows

	Six Months Ended June 30,	
	2019	2018
	(in thousands)	
Cash provided by (used for):		
Operating activities	$ (17,441)	$ (18,131)
Investing activities	12,134	(41,968)
Financing activities	(82)	50,888

Operating Activities. For the six months ended June 30, 2019, cash used for operating activities resulted from our net loss as adjusted for non-cash items, in addition to the increase in inventories and decreases in accounts payable and deferred revenue, partially offset by decreases in accounts receivable and prepaid expenses and an increase in accrued liabilities. For the six months ended June 30, 2018, cash used for operating activities resulted from our net loss as adjusted for non-cash items, including the decrease in deferred revenue, in addition to an increase in inventories and a decrease in accounts payable.

Investing Activities. Cash provided by investing activities for the six months ended June 30, 2019 resulted primarily from the net maturities of our investment securities. Cash used for investing activities for the six months ended June 30, 2018 resulted from the acquisition of the PANCREAZE license, partially offset by net proceeds from sales and maturities of our investment securities.

Financing Activities. Cash used by financing activities for the six months ended June 30, 2019 related to principal payments on financing leases, partially offset by proceeds from our employee stock purchase plan. Cash provided by financing activities for the six months ended June 30, 2018 resulted from the net proceeds of $108.0 million from the issuance of our Senior Secured Notes due 2024, partially offset by the use of $51.0 million to repurchase $60.0 million of our Convertible Notes and $6.2 million of our Senior Secured Notes due 2018.

At June 30, 2019, our accumulated deficit was approximately $894.4 million and our cash, cash equivalents and available-for-sale securities were $94.4 million. As of June 30, 2019, we had a total of $292.4 million in debt, $181.4 million of which is due May 2020. In addition, at June 30, 2019, we were not in compliance with a covenant in the indenture covering our secured debt due 2024 (the "2024 Notes") related to PANCREAZE net revenues. We subsequently received a waiver from the holders of the 2024 Notes (the "consenting noteholders") with respect to any potential event of default or default that may have resulted from such covenant non-compliance. In connection with the waiver, we agreed with the consenting noteholders to use good faith efforts to make certain amendments to the 2024 Notes indenture at a future date (collectively, the "noteholder conditions"), including transferring $60.0 million from the existing 2024 Notes trustee controlled account into a new controlled account that can only be accessed upon prior written consent of the 2024 Notes trustee at the direction of the noteholders. If we do not satisfy the noteholder conditions, the consenting noteholders may revoke the waiver, which could result in an event of default.

We do not currently have sufficient cash and/or credit facilities in place to address the debt due May 2020 and thus are actively pursuing funding, which may come through public or private debt or equity financings, collaborations or other available financing sources. Such funding 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 will not be able to continue our operations at our current level and may be required to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop on our own. We might also 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. Even if adequate funds become available, we may need to raise additional funds in the near future to finance operations and pursue development and commercial opportunities.

Our unaudited condensed consolidated financial statements have been prepared assuming that we will continue as a going concern. Our coming debt maturities as well as our negative cash flow from operations and accumulated deficit raise substantial doubt about our ability to continue as a going concern. Our unaudited condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Off-Balance Sheet Arrangements

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

Commitments and Contingencies

We indemnify our officers and directors for certain events or occurrences pursuant to indemnification agreements, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, stockholder suits and tax matters and as such, we are unable to estimate the potential exposure related to these indemnification agreements. We have not recognized any liabilities relating to these agreements as of June 30, 2019.

Contractual Obligations

During the six months ended June 30, 2019, 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, 2018, filed with the SEC on February 26, 2019, other than the fulfillment of existing obligations in the ordinary course of business.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market and Interest Rate Risk

In the normal course of business, our financial position is subject to a variety of risks, including market risk associated with interest rate movements and foreign currency exchange risk. Our cash, cash equivalents and available-for-sale securities as of June 30, 2019, consisted primarily of money market funds, U.S. Treasury securities and corporate debt securities. Our cash is invested in accordance with an investment policy approved by our Board of Directors that specifies the categories (money market funds, U.S. Treasury securities and debt securities of U.S. government agencies, corporate bonds, asset-backed securities, and other securities), allocations, and ratings of securities we may consider for investment. Currently, we have focused on investing in U.S. Treasuries until market conditions improve.

Our market risk associated with interest rate movements is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable debt securities. The primary objective of our investment activities is to preserve principal. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment may decline. A hypothetical 100 basis point increase in interest rates would reduce the fair value of our available-for-sale securities at June 30, 2019, by approximately $0.4 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 (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

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

ITEM 1A. RISK FACTORS

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

Risks Relating to our Business

Our success will depend on our ability and that of our current or future collaborators to effectively and profitably commercialize Qsymia®, PANCREAZE and STENDRA/SPEDRA.

Our success will depend on our ability and that of our current or future collaborators to effectively and profitably commercialize Qsymia, PANCREAZE and STENDRA/SPEDRA, which will include our ability to:

- expand the use of Qsymia through targeted patient and physician education;
- obtain marketing authorization by the EC for Qsymia in the EU;
- manage our alliances with MTPC, Menarini and Metuchen to help ensure the commercial success of avanafil and the efficiency of our supply chain with Sanofi;
- manage costs;
- improve third-party payor coverage, lower out-of-pocket costs to patients with discount programs, and obtain coverage for obesity under Medicare Part D;
- create market demand for Qsymia through patient and physician education, marketing and sales activities;
- achieve market acceptance and generate product sales;
- comply with the post-marketing requirements established by FDA, including Qsymia's Risk Evaluation and Mitigation Strategy ("REMS") any future changes to the REMS, and any other requirements established by FDA in the future;
- efficiently conduct the post-marketing studies required by FDA;
- effectively and efficiently manage our sales force and commercial team for the promotion of Qsymia and PANCREAZE;
- effectively increase the level of revenue for PANCREAZE;
- successfully assume the supply chain and commercial responsibilities for PANCREAZE;
- maintain a good relationship with the manufacturer of PANCREAZE;
- ensure a sufficient level of PANCREAZE inventory;
- ensure that the active pharmaceutical ingredients ("APIs") for Qsymia and STENDRA/SPEDRA and the finished products are manufactured in sufficient quantities and in compliance with requirements of

FDA and DEA and similar foreign regulatory agencies and with an acceptable quality and pricing level in order to meet commercial demand;

- ensure that the entire supply chain for Qsymia and STENDRA/SPEDRA, from APIs to finished products, efficiently and consistently delivers Qsymia and STENDRA/SPEDRA to customers;
- comply with other healthcare regulatory requirements;
- comply with state and federal controlled substances requirements; and
- maintain and defend our patents, if challenged.

If we are unable to successfully produce and commercialize Qsymia, PANCREAZE and/or STENDRA/SPEDRA, 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 have a new management team which may cause disruption in our business, which disruption could have a materially adverse effect on our results of operations.

In 2018, former executives of Willow Biopharma Inc. joined our management team, including John Amos as our new Chief Executive Officer, M. Scott Oehrlein as our new Chief Operations Officer and Kenneth Suh as our new President. If we are unable to successfully retain and integrate the new management team, our business could be harmed.

We may not be able to successfully develop, launch and commercialize VI-0106 or any other potential future development programs.

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

- successfully develop a proprietary formulation of tacrolimus as a precursor to the clinical development process;
- effectively conduct phase 2 and phase 3 clinical testing on tacrolimus, which could be delayed by slow patient enrollment, long treatment time required to demonstrate effectiveness, disruption of operations at clinical trial sites, adverse medical events or side effects in treated patients, failure of patients taking the placebo to continue to participate in the clinical trials, and insufficient clinical trial data to support effectiveness of VI-0106;
- obtain regulatory approval and market authorization for tacrolimus in the U.S., EU and other territories;
- develop, validate and maintain a commercially viable manufacturing process that is compliant with current Good Manufacturing Practices ("cGMP");
- establish and effectively manage a supply chain for tacrolimus and future development programs to ensure that the API and the finished products are manufactured in sufficient quantities and in compliance with regulatory requirements and with acceptable quality and pricing in order to meet commercial demand;
- effectively determine and manage the appropriate commercialization strategy;
- manage costs;
- achieve market acceptance by patients, the medical community and third-party payors and generate product sales;
- effectively compete with other therapies;
- maintain a continued acceptable safety profile for tacrolimus following approval;

- comply with healthcare regulatory requirements; and
- maintain and defend our patents, if challenged.

If we are unable to successfully develop, produce, launch and commercialize tacrolimus, our ability to generate product sales will be severely limited, which will have a material adverse impact on our business, financial condition, and results of operations.

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

In 2018, we initiated a new business strategy. 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 Qsymia and STENDRA/SPEDRA in their respective licensed territories.

We rely on our collaboration partners, including Alvogen, Menarini and Metuchen, to successfully commercialize Qsymia and STENDRA/SPEDRA in their respective territories, including obtaining any necessary approvals and we cannot assure you that they will be successful. Our dependence on our collaborative arrangements for the commercialization of Qsymia and STENDRA/SPEDRA, including our license agreements with Alvogen, MTPC, Menarini and Metuchen, subject us to a number of risks, including the following:

- we may not be able to control the commercialization of our drug products in the relevant territories, including the amount, timing and quality of resources that our collaborators may devote to our drug products;
- our collaborators may experience financial, regulatory or operational difficulties, which may impair their ability to commercialize our drug products and fulfill their contractual obligations, including satisfying their minimum purchase requirements;
- our collaborators may be required under the laws of the relevant territories to disclose our confidential information or may fail to protect our confidential information;
- as a requirement of the collaborative arrangement, we may be required to relinquish important rights with respect to our drug products, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to satisfactorily complete its commercialization or other obligations under any collaborative arrangement;
- legal disputes or disagreements may occur with one or more of our collaborators or between our collaborators and our suppliers or former collaborators;
- a collaborator could independently move forward with a competing investigational drug candidate developed either independently or in collaboration with others, including with one of our competitors; and

- a collaborator could terminate the collaborative arrangement, which could negatively impact the continued commercialization of our drug products. For example, in September 2016, Auxilium terminated its agreement with us to commercialize STENDRA in the U.S. and Canada and, in March 2017, Sanofi terminated its agreement with us to commercialize STENDRA/SPEDRA in Africa, the Middle East, Turkey, and the CIS, including Russia.

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

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

There have been substantial changes to the Internal Revenue Code, some of which could have an adverse effect on our business.

The Tax Cuts and Jobs Act made substantial changes to the Internal Revenue Code, effective January 1, 2018, some of which could have an adverse effect on our business. In addition to reducing the top corporate income tax rate, changes that could impact our business in the future include (i) eliminating the ability to utilize net operating losses ("NOLs") to reduce income in prior tax years and limiting the utilization of NOLs generated after December 31, 2017 to 80% of future taxable income, which could affect the timing of our ability to utilize NOLs, and (ii) limiting the amount of business interest expenses that can be deducted to 30% of earnings before interest, taxes, depreciation and amortization.

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

We have royalty and milestone-bearing license and commercialization agreements for STENDRA/SPEDRA with Menarini and, prior to October 1, 2016, with Auxilium. Also, on an interim basis, we have agreements with affiliates of Janssen for the commercialization of PANCREASE MT in Canada. In determining our royalty revenue from such agreements, we rely on our collaboration partners to provide accounting estimates and reports for various discounts and allowances, including product returns. As a result of fluctuations in inventory, allowances and buying patterns, actual sales and product returns of STENDRA/SPEDRA in particular reporting periods may be affected, resulting in the need for our commercialization partners to adjust or restate their accounting estimates set forth in the reports provided to us. Such adjustments or restatements may materially and negatively affect our financial position and results of operations. Beginning October 1, 2016, we ceased earning royalty revenue from U.S. sales as a result of the termination of our license and commercialization agreement with Auxilium. Our new license agreement with Metuchen is royalty-free as to us.

If we are unable to enter into agreements with collaborators for the territories that are not covered by our existing commercialization agreements, our ability to commercialize Qsymia and STENDRA/SPEDRA 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 Qsymia and STENDRA/SPEDRA in territories that are not covered by our current commercial collaboration agreements. For example, Qsymia is currently licensed for sale only in the U.S. and we have a commercialization agreement to market Qsymia in South Korea. STENDRA/SPEDRA is currently not marketed in Africa, the Middle East, Turkey, the CIS, Mexico and Central America. We may be unable to enter into agreements with third parties for Qsymia or STENDRA/SPEDRA for these territories on favorable terms or at all, which could delay, impair, or preclude our ability to commercialize Qsymia and STENDRA/SPEDRA 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, or our partners, must obtain separate regulatory approvals. Approval by FDA in the U.S. does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. For example, while our drug STENDRA/SPEDRA has been approved in both the U.S. and the EU, our drug Qsymia has been approved in the U.S. but 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 Qsymia would not have been indicated. We intend to seek approval for Qsymia in the EU and also 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, having relied in large part on third parties to lead any such interactions, and the approval procedures vary among countries and can involve additional clinical 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 Alvogen, Menarini, Metuchen, Janssen and any potential future collaborators in certain territories, intend to market Qsymia and STENDRA/SPEDRA outside the U.S., which will subject us to risks related to conducting business internationally.

We, through Alvogen, Menarini, Metuchen and any potential future collaborators in certain territories, intend to manufacture, market, and distribute Qsymia and STENDRA/SPEDRA outside the U.S. Also, on an interim basis, we have agreements with affiliates of Janssen for the commercialization of PANCREASE MT in Canada. 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, in 2015, we recorded inventory impairment and commitment fees totaling $29.5 million, primarily to write off excess inventory related to Qsymia.

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

Our write-down for excess and obsolete inventory is subjective and requires forecasting of the future market demand for our products. Forecasting demand for Qsymia, a drug in the obesity market in which there had been no new FDA-approved medications in over a decade prior to 2012, and for which reimbursement from third-party payors had previously been non-existent, has been difficult. PANCREAZE has a short shelf life and forecasting both the amounts and the timing of demand for PANCREAZE is difficult. Forecasting demand for STENDRA/SPEDRA, a drug that is new to a crowded and competitive market and has limited sales history, is also difficult. We will continue to evaluate our inventories on a periodic basis. The value of our inventories could be impacted if actual sales differ significantly from our estimates of future demand, if any significant unanticipated changes in future product demand or market conditions occur or if our collaborators fail to satisfy their minimum purchase obligations. 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, including requirements of the Qsymia REMS program, could compromise the commercialization of this product.

We rely on Cardinal Health 105, Inc. (“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, including compliance with relevant state and federal laws.

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 (“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 maintain or enter into agreements with suppliers or our suppliers fail to supply us with the APIs for our products, bulk products or finished products or if we rely on single-source suppliers, we may experience delays in commercializing our products.

We purchase all supplies related to PANCREAZE from a single manufacturer. 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 maintaining or entering into supply agreements on reasonable terms or at all or that we or our suppliers will be able to obtain or maintain the necessary regulatory approvals or state and federal controlled substances registrations for current or potential future suppliers in a timely manner or at all.

We anticipate that we will continue to rely on single-source suppliers for PANCREAZE, phentermine and topiramate for the foreseeable future. Any production shortfall on the part of our suppliers that impairs the supply of phentermine, topiramate or PANCREAZE 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 or PANCREAZE, 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 or our suppliers will be able to obtain or maintain the necessary regulatory approvals or registrations for these suppliers in a timely manner or at all.

Sanofi Chimie manufactures and supplies the API for avanafil on an exclusive basis in the U.S. and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. Sanofi Winthrop Industrie manufactures and supplies the avanafil tablets on an exclusive basis in the U.S. and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. 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 from Sanofi Chimie or tablets from Sanofi Winthrop Industrie or if our collaborators fail to satisfy their minimum purchase obligations, 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, PANCREAZE 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, PANCREAZE 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 acquired the rights to PANCREAZE from Janssen. 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, Janssen 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 and increase market acceptance and generate revenues will be subject to a variety of risks, many of which are out of our control.

Qsymia, PANCREAZE and STENDRA/SPEDRA may not gain or increase 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 obtain marketing authorization by the EC for Qsymia in the EU;
- contraindications for Qsymia and STENDRA/SPEDRA;
- our ability to increase market acceptance for and use of PANCREAZE;
- competition and timing of market introduction of competitive drugs;
- quality, safety and efficacy in the approved setting;
- prevalence and severity of any side effects, including those of the components of our drugs;
- emergence of previously unknown side effects, including those of the generic components of our drugs;
- results of any post-approval studies;
- potential or perceived advantages or disadvantages over alternative treatments, including generics;
- the relative convenience and ease of administration and dosing schedule;
- the convenience and ease of purchasing the drug, as perceived by potential patients;
- strength of sales, marketing and distribution support;
- price, both in absolute terms and relative to alternative treatments;
- the effectiveness of our or our current or any future collaborators' sales and marketing strategies;
- the effect of current and future healthcare laws;
- availability of coverage and reimbursement from government and other third-party payors;
- the level of mandatory discounts required under federal and state healthcare programs and the volume of sales subject to those discounts;
- recommendations for prescribing physicians to complete certain educational programs for prescribing drugs;
- the willingness of patients to pay out-of-pocket in the absence of government or third-party coverage; and
- product labeling, product insert, or new REMS or post-market safety study or trial requirements of FDA or other regulatory authorities.

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

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

Upon receiving approval to market Qsymia, FDA required that we perform additional studies of Qsymia including a cardiovascular outcome trial ("CVOT"). We estimate the cost of a CVOT as currently designed to be between $180.0 million and $220.0 million incurred over a period of approximately five years. We have held several

meetings with FDA to discuss alternative strategies for obtaining cardiovascular ("CV") outcomes data that would be substantially more feasible and that ensure timely collection of data to better inform on the CV safety of Qsymia. In September 2013, we submitted a request to the EMA for Scientific Advice, a procedure similar to the U.S. Special Protocol Assessment process, regarding use of a pre-specified interim analysis from the CVOT to assess the long-term treatment effect of Qsymia on the incidence of major adverse 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 Qsymia 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. We worked with cardiovascular and epidemiology experts in exploring alternate solutions to demonstrate the long-term cardiovascular safety of Qsymia. After reviewing a summary of Phase 3 data relevant to CV risk and post-marketing safety data, the cardiology experts noted that they believe there was an absence of an overt CV risk signal and indicated that they did not believe a randomized placebo-controlled CVOT would provide additional information regarding the CV risk of Qsymia. The epidemiology experts maintained that a well-conducted retrospective observational study could provide data to further inform on potential CV risk. We worked with the expert group to develop a protocol and conduct a retrospective observational study. We have submitted information from this study to FDA in support of a currently pending supplemental New Drug Application ("sNDA") seeking changes to the Qsymia label. Although we and consulted experts believe there is no overt signal for CV risk to justify the CVOT, we are committed to working with FDA to reach a resolution that provides FDA with additional CV safety data. There is no assurance, however, that FDA will accept any measures short of those specified in the CVOT to satisfy this requirement.

As for the EU, even if FDA were to determine that a CVOT is no longer necessary, there would be no assurance that the EMA would reach the same conclusion. There can be no assurance that we will be successful in obtaining FDA or EMA agreement that we have demonstrated the long-term cardiovascular safety of Qsymia. Furthermore, there can be no assurance that FDA or EMA will not request or require us to provide additional information or undertake additional preclinical studies and clinical trials or retrospective observational studies.

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

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

We outsource many key functions of our business and therefore rely on a substantial number of consultants, and we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our regulatory obligations, 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 or other development activities for Qsymia, PANCREAZE and STENDRA, obtain regulatory approval for our future investigational drug candidates, successfully commercialize our approved drugs or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on commercially reasonable terms, or at all.

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

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

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

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

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

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

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

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

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

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

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

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

Competition in the pharmaceutical and medical products industries is intense and is characterized by costly and extensive research efforts and rapid technological progress. We are aware of several pharmaceutical companies also actively engaged in the development of therapies for the treatment of obesity and erectile dysfunction. Many of these companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. Some of the drugs that may compete with Qsymia may not have a REMS requirement and the accompanying complexities such a requirement presents. Our competitors may

develop technologies and products that are more effective than those we are currently marketing or researching and developing. Such developments could render Qsymia and STENDRA less competitive or possibly obsolete.

Qsymia for the treatment of chronic weight management competes with several approved anti-obesity drugs including, Belviq® (lorcaserin), marketed by Eisai Inc., Eisai Co., Ltd.'s U.S. subsidiary; Xenical® (orlistat), marketed by Roche; alli®, the over-the-counter version of orlistat, marketed by GlaxoSmithKline; Contrave® (naltrexone/bupropion), Nalpropion Pharmaceuticals, Inc.'s anti-obesity compound; and Saxenda® (liraglutide), an anti-obesity compound marketed by Novo Nordisk A/S. Agents that have been approved for type 2 diabetes that have demonstrated weight loss in clinical studies may also compete with Qsymia. These include Farxiga™ (dapagliflozin) from AstraZeneca and Bristol-Myers Squibb, an SGLT2 inhibitor; Jardiance® (empagliflozin) from Boehringer Ingelheim, an SGLT2 inhibitor; Victoza® (liraglutide) from Novo Nordisk A/S, a GLP-1 receptor agonist; Invokana® (canaglifozin) from Johnson & Johnson's Janssen Pharmaceuticals, an SGLT2 inhibitor and Glyxambi® (empagliflozin/linagliptin) from Boehringer Ingelheim and Eli Lilly, an SGLT2 inhibitor and DPP-4 inhibitor combination product. Also, EnteroMedics® Inc. markets the Maestro Rechargeable System for certain obese adults, the first weight loss treatment device that targets the nerve pathway between the brain and the stomach that controls feelings of hunger and fullness.

There are also several other investigational drug candidates in Phase 2 clinical trials for the treatment of obesity. There are also a number of generic pharmaceutical drugs that are prescribed for obesity, predominantly phentermine. Phentermine is sold at much lower prices than we charge for Qsymia. The availability of branded prescription drugs, generic drugs and over-the-counter drugs could limit the demand for, and the price we are able to charge for, Qsymia.

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

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

Qsymia may also face challenges and competition from newly developed generic products. Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, newly approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act stimulates competition by providing incentives to generic pharmaceutical manufacturers to introduce non-infringing forms of patented pharmaceutical products and to challenge patents on branded pharmaceutical products. We received two notifications under paragraph IV of the Hatch-Waxman Act challenging certain of our Qsymia patents, and we filed suit against both challengers. In June 2017, we entered into a settlement agreement with Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as "Actavis," and in August 2017, we entered into a settlement agreement with Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc., collectively referred to as "DRL." The settlement agreement with Actavis will permit Actavis to begin selling a generic version of Qsymia on December 1, 2024, or earlier under certain circumstances. The settlement agreement with DRL will permit DRL to begin selling a generic version of Qsymia on June 1, 2025, or earlier under certain circumstances. It is possible that one or more additional companies may file an Abbreviated New Drug Application ("ANDA") and could receive FDA approval to market a generic version of Qsymia before the entry dates specified in our settlement agreements with Actavis and DRL. If a generic version of Qsymia is launched, this will harm our business. Generic manufacturers pursuing ANDA approval are not required to conduct costly and time-consuming clinical trials to establish the safety and efficacy of their products; rather, they are permitted to rely on FDA's finding that the innovator's product is safe and effective. Additionally, generic drug companies generally do not expend significant sums on sales and marketing activities, instead relying on physicians or payors to substitute the generic form of a drug for the branded form. Thus, generic manufacturers can sell their

products at prices much lower than those charged by the innovative pharmaceutical or biotechnology companies who have incurred substantial expenses associated with the research and development of the drug product and who must spend significant sums marketing a new drug.

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

PANCREAZE for the treatment of pancreatic insufficiency competes with Creon®, marketed by AbbVie, Inc., Zenpep®, marketed by Allergan Inc., Pertzye®, marketed by Digestive Care, Inc., and Ultresa™, marketed by Aptalis Phama US, Inc.

STENDRA for the treatment of ED competes with PDE5 inhibitors in the form of oral medications including Viagra® (sildenafil citrate), marketed by Pfizer, Inc.; Cialis® (tadalafil), marketed by Eli Lilly and Company; Levitra® (vardenafil), co-marketed by GlaxoSmithKline plc and Schering-Plough Corporation in the U.S.; and STAXYN® (vardenafil in an oral disintegrating tablet ("ODT")), co-promoted by GlaxoSmithKline plc and Merck & Co., Inc. Additionally, generic formulations of sildenafil citrate and tadalafil are currently available on the market and, on January 3, 2017, we granted Hetero a license to manufacture and commercialize the generic version of STENDRA described in its ANDA filing in the United States as of the date that is the later of (a) October 29, 2024, which is 180 days prior to the expiration of the last to expire of the patents-in-suit, or (b) the date that Hetero obtains final approval from FDA of the Hetero ANDA.

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. On September 30, 2016, we entered into a license and commercialization agreement and a commercial supply agreement with Metuchen. Under the terms of the agreements, Metuchen received an exclusive license to develop, commercialize and promote STENDRA in the United States, Canada, South America and India (the "Territory") effective October 1, 2016. Additionally, on January 6, 2017, we entered into a Patent Assignment Agreement with Selten, whereby we received exclusive, worldwide rights for the development and commercialization of tacrolimus for the treatment of PAH and related vascular diseases. Also, on June 8, 2018, we closed on the acquisition of PANCREAZE from Janssen, pursuant to

which we acquired the rights to PANCREAZE and PANCREASE MT in the U.S. and Canada. Further potential transactions we may consider include a variety of different business arrangements, including strategic partnerships, joint ventures, spin-offs, restructurings, divestitures, business combinations and investments. In addition, another entity may pursue us as an acquisition target. Any such transactions may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges, require additional expertise or disrupt our management or business, any of which could harm our operations and financial results.

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

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

As part of our growth strategy, we may acquire, in-license, develop and/or market additional products and investigational drug candidates. Most recently, on June 8, 2018, we closed on the acquisition of PANCREAZE from Janssen, pursuant to which we acquired the rights to PANCREAZE and PANCREASE MT in the U.S. and Canada. Also, on January 6, 2017, we entered into a Patent Assignment Agreement with Selten, whereby we received exclusive, worldwide rights for the development and commercialization of tacrolimus for the treatment of PAH and related vascular diseases. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical investigational drug candidates and products.

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

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

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

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

regulatory authorities. All investigational drug candidates are prone to certain failures that are relatively common in the field of drug development, including the possibility that an investigational drug candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot be certain that any drugs that we develop or approved products that we may acquire will be commercialized profitably or achieve market acceptance.

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

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

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

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

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

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

For PANCREAZE, Nordmark is our sole source of clinical and commercial supplies. Nordmark has significant experience in manufacturing; however, there is no assurance that they will continue to be successful in supplying PANCREAZE in the future or if we will be able to continue our relationship with Nordmark on favorable terms to us for any future formulations and quantities.

For avanafil, Sanofi Chimie manufactures and supplies 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. Sanofi Winthrop Industrie manufactures and supplies the avanafil tablets for STENDRA and SPEDRA on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. Sanofi is responsible for all aspects of manufacture, including obtaining the starting materials for the production of API. If Sanofi is unable to manufacture the API or tablets in sufficient quantities to meet projected demand, future sales could be adversely affected, which in turn could have a detrimental impact on our financial results, our license, commercialization, and supply agreements with our collaboration partners, and our ability to enter into a collaboration agreement for the commercialization in other territories.

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

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

We seek to maintain the confidential nature of our confidential information through contractual provisions in our agreements with third parties, including our agreements with clinical research organizations ("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. Additionally, we intend to launch the VIVUS Healthcare Platform in 2019, which will provide current and potential customers with an integrated online approach to weight management.

The collection and use of personal health data and other personal data in the EU is governed by the General Data Protection Regulation ("GDPR") which became applicable on May 25, 2018, replacing the EU Data Protection Directive, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting and substantial fines and other administrative penalties. Compliance with the GDPR may be onerous and increase our cost of doing business. For more information concerning the data protection requirements in the EU and the EU Member States and the rules governing the transfer of personal data to the U.S., please refer to the section title "Government Regulation - Fraud and Abuse and Privacy and Data Security Laws and Regulations."

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, patients 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 healthcare Anti-Kickback Statute, 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. Liability under the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Statute 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. Moreover, the anti-kickback statute is subject to evolving interpretation and there are no safe harbors for many common practices, including patient or product support programs, educational and research grants, or charitable donations. 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 imposes civil penalties against individuals and entities for, among other things, 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. Actions under the False Claims Act may be brought by the U.S. Attorney General or as a qui tam action by a private individual in the name of the 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. More recently, federal enforcement agencies are and have been investigating certain pharmaceutical companies' product and patient assistance programs, including manufacturer reimbursement support services, relationships with specialty pharmacies, and grants to independent charitable foundations. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties per false or fraudulent claim or statement. Because of the potential for large monetary exposure, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts. 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;
- The federal Health Insurance Portability and Accountability Act of 1996, as amended by HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- 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. The GDPR, for example, is an EU-wide regulation that imposes restrictions on the processing (e.g.,

collection, use, disclosure) of personal data and that also imposes strict restrictions on the transfer of personal data out of the EU to the U.S. In addition, most healthcare providers who prescribe our products and from whom we obtain patient health information are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 and by the Health Information Technology for Economic and Clinical Health Act ("HITECH") which are collectively referred to as "HIPAA." We are not a HIPAA-covered entity and we do not operate as a business associate to any covered entities. Therefore, the HIPAA privacy and security requirements do not apply to us (other than potentially with respect to providing certain employee benefits). However, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting and/or conspiring to commit a violation of HIPAA. We are unable to predict whether our actions could be subject to prosecution in the event of an impermissible disclosure of health information to us. The legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing amount of focus on privacy and data security issues with the potential to affect our business. These privacy and data security laws and regulations could increase our cost of doing business, and failure to comply with these laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business;

- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the payor. Some state laws also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to certain healthcare providers in the states. Other states prohibit providing meals to prescribers or other marketing-related activities and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Some states require the posting of information relating to clinical studies and their outcomes. Some states and cities require identification or licensing of sales representatives. Some states restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Other states and cities require identification or licensing of state representatives. In addition, some states 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 of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services ("CMS") within the U.S. Department of Health and Human Services information related payments and other transfers of value, directly or indirectly, to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and
- the federal Foreign Corrupt Practices Act of 1977 and other similar anti-bribery laws in other jurisdictions prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, candidates for foreign political office, or public 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. and foreign 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.

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal healthcare laws, including the federal healthcare Anti-Kickback Statute. 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, imprisonment, damages, fines, exclusion from government-funded healthcare programs, like Medicare and Medicaid (i.e., loss of coverage for products), and the curtailment or restructuring of our operations including by entering into a Corporate Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General. Any penalties, damages, fines, curtailment or restructuring of our operations, or associated adverse publicity, could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws and regulations, the risks cannot be entirely eliminated. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy data, security and fraud laws and regulations may prove costly.

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

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

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

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

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

FDA, and third-country authorities, including the competent authorities of the EU Member States, have the authority to impose significant restrictions, including REMS requirements, on approved products through regulations on advertising, promotional and distribution activities. After approval, if products are marketed in contradiction with FDA laws and regulations, FDA may issue warning letters that require specific remedial measures to be taken, as well as an immediate cessation of the impermissible conduct, resulting in adverse publicity. FDA may also require that all future promotional materials receive prior agency review and approval before use. Certain states have also adopted regulations and reporting requirements surrounding the promotion of pharmaceuticals. Qsymia, PANCREAZE and STENDRA are subject to these regulations. Failure by us or any of our collaborators 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 or limit our ability to commercialize our drugs.

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

In addition, Qsymia is a controlled substance and subject to DEA and state regulations relating to manufacturing, storage, record keeping, reporting, distribution and prescription procedures and requirements related to necessary DEA registrations and state licenses. The DEA periodically inspects facilities for compliance with its rules and regulations. Failure to comply with current and future regulations of the DEA, relevant state authorities or any comparable international requirements could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, fines, injunctions, or civil or criminal penalties, and could result in, among other things, additional operating costs to us or delays in distribution of Qsymia and could have an adverse effect on our business and financial condition.

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 cGMP. These regulations govern quality control of the manufacturing processes and documentation policies and procedures, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of our third-party contractors must be inspected

routinely for compliance. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulation occurs independent of such an inspection or audit, we or FDA may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the issuance of a warning letter, temporary or permanent suspension of a clinical trial or commercial sales, recalls, market withdrawals, seizures, or the temporary or permanent closure of a facility. Any such remedial measures would be imposed upon us or third parties with whom we contract until satisfactory cGMP compliance is achieved. FDA could also impose civil penalties. We must also comply with similar regulatory requirements of foreign regulatory agencies.

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

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

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

We participate in the Medicaid Drug Rebate program, established by the Omnibus Budget Reconciliation Act of 1990 and amended by the Veterans Health Care Act of 1992 as well as subsequent legislation. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug, which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. Our failure to comply with these price reporting and rebate payment options could negatively impact our financial results.

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 at 100 percent 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 $2.8 billion in 2019 and thereafter, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law.

CMS issued final regulations that became effective on April 1, 2016 to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. Moreover, certain legislative changes to and regulatory changes under the Affordable Care Act have occurred in the 115th United States Congress and under the

Trump Administration. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the individual mandate, beginning in 2019. Additional legislative changes to and regulatory changes under the Affordable Care Act remain possible. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time consuming, and could have a material adverse effect on our results of operations.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B 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 Affordable Care Act expanded the 340B program to include additional types of covered entities: certain free standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The 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 Health Resources and Services Administration ("HRSA"), which administers the 340B program, issued a final 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, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under the new regulation. Implementation of this final rule and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. HRSA also is implementing a 340B ceiling price reporting requirement during the first quarter of 2019 pursuant to which we are required to report the 340B ceiling prices for our covered outpatient drugs to HRSA on a quarterly basis. 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 340B ceiling price at which we are required to offer our products to certain covered entities, and we may be required to issue refunds to covered entities.

We are liable for errors associated with our submission of pricing data. Civil monetary penalties can be applied if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. 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 significant civil monetary penalties 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 significant civil monetary penalty 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.

CMS and the Office of the Inspector General have pursued manufacturers that were alleged to have failed 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 $181,071 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. 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 files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It is 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 include measures that 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, and proposals that would do so. Further, federal budgetary concerns could result in the implementation of significant federal spending cuts, including cuts in Medicare and other health related spending in the near-term. For example, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2027. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue.

In March 2010, the President signed 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.
- 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 at 100 percent of the average manufacturer price.
- Effective in January 2011, pharmaceutical companies were required to provide a 50 percent discount on branded prescription drugs dispensed to beneficiaries during their Medicare Part D coverage gap period or "donut hole," which is a coverage gap that currently exists in the Medicare Part D prescription drug program. The BBA increased such manufacturer point-of-sale discounts to 70% effective as of January 1, 2019. 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 an annual, nondeductible, branded prescription drug fee to the federal government, which is apportioned among pharmaceutical manufacturers according to their market share in certain government healthcare programs, although this fee does not apply to sales of certain products approved exclusively for orphan indications. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $2.8 billion in 2019 and thereafter, 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 revenue.

CMS issued final regulations that became effective on April 1, 2016 to implement the changes to the Medicaid Drug Rebate Program under the Affordable Care Act.

There can be no assurance that future healthcare legislation or other changes in the administration or interpretation of government healthcare or third-party reimbursement programs will not have a material adverse effect on us. Healthcare reform is also under consideration in other countries where we intend to market Qsymia. Some of the provisions of the Affordable Care Act have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act and to alter the implementation of the Affordable Care Act and related laws. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the individual mandate, beginning in 2019. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved.

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

approved drugs and investigational drug candidates or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our approved drugs and investigational drug candidates and our business will be harmed. Congress has enacted healthcare reform and may enact further reform, which could adversely affect the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business.

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

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

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 ("CSO"), CROs, safety monitoring company and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, accidents, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our investigational drug candidate development programs and drug manufacturing operations. For example, the loss of clinical trial data from completed or ongoing clinical trials for our investigational drug candidates could result in delays in our regulatory approval efforts with FDA, the EC, or the competent authorities of the EU Member States, and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our investigational drug candidates, or commercialization of our approved drugs, could be delayed. If we are unable to restore our information systems in the event of a systems failure, our communications, daily operations and the ability to develop our investigational drug candidates and approved drug commercialization efforts would be severely affected.

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

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

Brexit may harm our ability to market our products, to do business, increase our costs and negatively affect our stock price.

Worldwide economic conditions remain uncertain due to various developments including the decision by the United Kingdom to initiate the formal procedure of withdrawal from the EU (often referred to as "Brexit"), current economic challenges in Asia and other disruptions to global and regional economies and markets.

Brexit has created significant uncertainty about the future relationship between the United Kingdom and the EU, including with respect to the laws and regulations that will apply as the United Kingdom determines which EU laws to replace or replicate in the event of a withdrawal. From a regulatory perspective, the United Kingdom's withdrawal from the EU could give rise to significant complexity and risks. In addition, the exact terms of the United Kingdom's withdrawal and the laws and regulations that will apply after the United Kingdom withdraws from the EU may affect manufacturing sites that hold an EU manufacturing authorization issued by the United Kingdom competent authorities.

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. For example, we have limited patent coverage for PANCREAZE, which would not protect us should others develop alternative formulations of the drug. These companies would then be able to develop, manufacture and sell products that compete directly with our products. In that case, our revenues and operating results could decline.

Other entities may also challenge the validity or enforceability of our patents and patent applications in litigation or administrative proceedings. The sponsor of a generic application seeking to rely on one of our approved drug products as the reference listed drug must make one of several certifications regarding each listed patent. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is a challenge to the patent; it is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product. Once FDA accepts for filing a generic application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the reference listed drug ("RLD") NDA holder and patent owner that the application with patent challenge has been submitted, and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner file suit against the generic applicant for patent infringement within 45 days of receiving the Paragraph IV notice, FDA is prohibited from approving the generic application for a period of 30 months from the date of receipt of the notice. If the RLD has new chemical entity exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the 30-month stay does not begin until five years after the RLD approval. FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation. If a competitor or a generic pharmaceutical provider successfully challenges our patents, the protection provided by these patents could be reduced or eliminated and our ability to commercialize any approved drugs would be at risk. In addition, if a competitor or generic manufacturer were to receive approval to sell a generic or follow-on version of one of our products, our approved product would become subject to increased competition and our revenues for that product would be adversely affected.

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

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

We may receive additional notices of ANDA filings submitted by generic drug companies asserting that generic forms of our approved therapies would not infringe on our issued patents. As a result of these potential filings, we may commence additional litigation to defend our patent rights, which would result in additional litigation costs and, depending on the outcome of the litigation, might result in competition from lower cost generic or follow-on products earlier than anticipated.

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

We received certain Paragraph IV certification notices and have entered into settlement agreements with those who have submitted those notices. The settlement agreement with Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as "Actavis," will permit Actavis to begin selling a generic version of Qsymia on December 1, 2024, or earlier under certain circumstances. The settlement with Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc., collectively referred to as "DRL," will permit DRL to begin selling a generic version of Qsymia on June 1, 2025, or earlier under certain circumstances. It is possible that one or more additional companies may file an ANDA and could receive FDA approval to market a generic version of Qsymia before the entry dates specified in our settlement agreements with Actavis and DRL, including if it is determined that the generic product does not infringe our patents, or that our patents are invalid or unenforceable. Although we intend to vigorously enforce our intellectual property rights relating to Qsymia, in the event there is a future ANDA filer, there can be no assurance that we will prevail in a future defense of our patent rights. If a generic version of Qsymia or any of our other approved therapies is introduced, these therapies 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 will require additional capital for our debt servicing requirements and future operating plans, and we may not be able to secure the requisite additional funding on acceptable terms, or at all, which would not allow us to continue our operations at current levels and may force us to delay, reduce or eliminate commercialization or development efforts.

We anticipate that we will require additional funding prior to May 2020 to service our existing debt, fund operations and pursue development and commercial opportunities. Our future capital requirements will depend upon numerous factors, including:

- our ability to expand the use of Qsymia and PANCREAZE;

- the costs associated with the integration of PANCREAZE operations;
- the costs to commercialize PANCREAZE;
- our ability to obtain marketing authorization by the EC for Qsymia in the EU and other territories;
- our ability to manage costs;
- the cost required to maintain the REMS program for Qsymia;
- the cost, timing and outcome of the post-approval clinical studies FDA has required us to perform as part of the approval for Qsymia;
- our ability, along with our collaboration partners, to successfully produce and commercialize STENDRA/SPEDRA;
- our ability to successfully commercialize STENDRA/SPEDRA 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 costs associated with obtaining, developing and marketing any new development assets;
- the scope, timing, costs and results of pre-clinical, clinical and retrospective observational studies and trials;
- the cost of access to electronic records and databases that allow for retrospective observational studies;
- patient recruitment and enrollment in future clinical trials;
- the costs involved in seeking regulatory approvals for future drug candidates;
- the costs involved in filing and pursuing patent applications, defending and enforcing patent claims;
- the establishment of collaborations, sublicenses and strategic alliances and the related costs, including milestone payments;
- the cost of manufacturing and commercialization activities and arrangements;
- the level of resources devoted to our future sales and marketing capabilities;
- the cost, timing and outcome of litigation, if any;
- the impact of healthcare reform, if any, imposed by the federal government; and
- the activities of competitors.

Future capital requirements will also depend on the extent to which we acquire or invest in additional businesses, products and technologies. On January 6, 2017, we entered into a Patent Assignment Agreement with Selten whereby we received exclusive, worldwide rights for the development and commercialization of BMPR2 activators for the treatment of PAH and related vascular diseases. We paid Selten an upfront payment of $1.0 million, and we will pay additional milestone payments based on global development status and future sales milestones, as well as tiered royalty payments on future sales of these compounds. The total potential milestone payments are $39.6 million.

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

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

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

As of June 30, 2019, we have $181.4 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 1,683,000 shares of our common stock under certain circumstances prior to maturity at a conversion rate of 6.73038 shares per $1,000 principal amount of Convertible Notes, which represents a conversion price of approximately $148.58 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.

In April 2018, we entered into an agreement for a new $120.0 million senior secured note (the "Athyrium Notes") with Athyrium Capital Management, LP ("Athyrium"). $110.0 million of the Athyrium Notes were drawn down in June 2018, with the remaining $10.0 million available for drawing upon meeting certain conditions. Payments on the Athyrium Notes bear interest at 10.375% and are interest-only for the first 36 months; thereafter the notes will be repaid in 36 equal monthly payments. Concurrently, we repurchased Convertible Notes held by Athyrium, with a face value of $60.0 million, for $51.0 million. In October 2018, we settled a purchase of approximately $8.6 million outstanding principal amount of our Convertible Notes for approximately $7.1 million plus accrued interest. We continue our evaluation of alternatives for addressing our remaining $181.4 million of Convertible Notes.

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

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

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

At June 30, 2019, we had $94.4 million in cash, cash equivalents and available-for-sale securities. While at June 30, 2019, our excess cash balances were invested in money market, U.S. Treasury securities and corporate debt securities, our investment policy as approved by our Board of Directors, also provides for investments in debt securities of U.S. government agencies, corporate debt securities and asset-backed securities. Our investment policy has the primary investment objectives of preservation of principal. However, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy. These factors could impact the liquidity or valuation of our available-for-sale securities, all of which were invested in U.S. Treasury securities or corporate debt securities as of June 30, 2019. If those securities are downgraded or impaired we would experience losses in the value of our portfolio which would have an adverse effect on our results of operations, liquidity and financial condition. An investment in money market mutual funds is not insured or guaranteed by the Federal Deposit Insurance Corporation or any other government agency. Although money market mutual funds seek to preserve the value of the investment at $1 per share, it is possible to lose money by investing in money market mutual funds.

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

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

For example, on March 27, 2014, Mary Jane and Thomas Jasin, who purport to be purchasers of VIVUS common stock, filed an Amended Complaint in Santa Clara County Superior Court alleging securities fraud against us and three of our former officers and directors. In that complaint, captioned Jasin v. VIVUS, Inc., Case No. 114 cv 261427, plaintiffs asserted claims under California's securities and consumer protection securities statutes. Plaintiffs alleged generally that defendants misrepresented the prospects for our success, including with respect to the launch of Qsymia, while purportedly selling VIVUS stock for personal profit. Plaintiffs alleged losses of "at least" $2.8 million, and sought damages and other relief. On July 18, 2014, the same plaintiffs filed a complaint in the United States District Court for the Northern District of California, captioned Jasin v. VIVUS, Inc., Case No. 5:14 cv 03263. The Jasins' federal complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, based on facts substantially similar to those alleged in their state court action. On September 15, 2014, pursuant to an agreement between the parties, plaintiffs voluntarily dismissed their state court action with prejudice. Defendants moved to dismiss the federal action and moved to dismiss again after plaintiffs amended their complaint to include additional factual allegations and to add seven new claims under California law. The court granted the latter motion on June 18, 2015, dismissing the seven California claims with prejudice and dismissing the two federal claims with leave to amend. Plaintiffs filed a Second Amended Complaint on August 17, 2015. Defendants moved to dismiss that complaint as well. On April 19, 2016, the court granted defendants' motion to dismiss with prejudice and entered judgment in favor of defendants. Plaintiffs filed a notice of appeal to the Ninth Circuit Court of Appeals on May 18, 2016. The Ninth Circuit issued a decision on January 16, 2018, affirming the district court's dismissal of the action. The deadline for Plaintiffs to seek rehearing in the Ninth Circuit and to file a petition for certiorari in the Supreme Court has now expired and the matter is concluded.

We have an accumulated deficit of $894.4 million as of June 30, 2019, and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of $894.4 million for the period from our inception through June 30, 2019, 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, 2018, we had approximately $630.7 million and $273.6 million of net operating loss ("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 ("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 our formation, due to the significant complexity and cost associated with the study. We have completed studies through December 31, 2016 and concluded no adjustments were required. If we have experienced a change of control at any time since our formation, our NOL carryforwards and tax credits may not be available, or their utilization could be subject to an annual limitation under Section 382. A full valuation allowance has been provided against our NOL carryforwards, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Accordingly, there would be no impact on the consolidated balance sheet or statement of operations.

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

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

Risks Relating to an Investment in our Common Stock

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

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

- our ability to meet the expectations of investors related to the production and commercialization of Qsymia, PANCREAZE 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 Qsymia in the EU;
- the costs, timing and outcome of post-approval clinical studies which FDA has required us to perform as part of the approval for Qsymia and STENDRA;
- the cost required to maintain the REMS program for Qsymia;
- results within the clinical trial programs for Qsymia and STENDRA or other results or decisions affecting the development of our investigational drug candidates;
- announcements of technological innovations or new products by us or our competitors;
- approval of, or announcements of, other anti-obesity compounds in development;
- publication of generic drug combination weight loss data by outside individuals or companies;
- actual or anticipated fluctuations in our financial results;
- our ability to obtain needed financing;
- sales by insiders or major stockholders;
- economic conditions in the U.S. and abroad;
- the volatility and liquidity of the financial markets;
- comments by or changes in assessments of us or financial estimates by security analysts;
- negative reports by the media or industry analysts on various aspects of our products, our performance and our future operations;
- the status of the CVOT and our related discussions with FDA;
- adverse regulatory actions or decisions;
- any loss of key management;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- discussions about us or our stock price by the financial and scientific press and in online investor communities;
- trading activity by highly technical investors utilizing sophisticated algorithms and high frequency trading;
- investment activities employed by short sellers of our common stock;
- developments or disputes concerning patents or other proprietary rights;
- reports of prescription data by us or from independent third parties for our products;
- licensing, product, patent or securities litigation; and
- public concern as to the safety or efficacy of our drugs or future investigational drug candidates developed by us.

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

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

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

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

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

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

On November 8, 2016, our Board of Directors adopted an amendment and restatement of our Preferred Stock Rights Plan, which was originally adopted on March 26, 2007. As amended and restated, the Preferred Stock Rights Plan is designed to protect stockholder value by mitigating the likelihood of an "ownership change" that would result in significant limitations to our ability to use our NOLs 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 submitted the plan to a vote at the 2017 annual meeting of stockholders, and stockholders ratified the plan at the 2017 annual meeting of stockholders. 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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

VIVUS, INC.
INDEX TO EXHIBITS

EXHIBIT NUMBER	DESCRIPTION
3.1[(1)]	Restated Certificate of Incorporation of the Registrant, as amended and restated through September 10, 2018.
3.2[(2)]	Amended and Restated Bylaws of the Registrant, as further amended.
3.3[(3)]	Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Registrant.
4.1[(4)]	Specimen Common Stock Certificate of the Registrant.
4.2[(5)]	Amended and Restated Preferred Stock Rights Agreement dated as of November 9, 2016, between the Registrant and Computershare Trust Company, N.A.
4.3[(6)]	Indenture dated as of May 21, 2013, by and between the Registrant and Deutsche Bank Trust Company Americas, as trustee.
4.4[(7)]	Form of 4.50% Convertible Senior Note due May 1, 2020 (included in Exhibit 4.3).
4.5[(8)]	Warrant to Purchase Shares of Common Stock issued to Torreya Capital, LLC dated February 23, 2018.
4.6[(9)]	Indenture, dated as of June 8, 2018, among the Registrant, the other guarantors from time to time party thereto and U.S. Bank National Association, as trustee and collateral agent.
4.7[(10)]	Form of 2024 Note (included in Exhibit 4.6).
4.8[(11)]	Form of Athyrium Warrant, dated as of June 8, 2018.

4.9[12]#	Form of Warrant to be issued by the Registrant to certain shareholders of Willow Biopharma Inc.
4.10[13]	First Supplemental Indenture, dated as of October 11, 2018, among the Registrant, as issuer and U.S. Bank National Association, as trustee and collateral agent.
10.1*	Amendment No. 5 to Collateral Agreement dated as of June 5, 2019 between the Registrant and U.S. Bank National Association, as trustee and collateral agent.
10.2*††	Amendment Nº1 to the Manufacturing and Supply Agreement dated May 22, 2019 between the Registrant and Sanofi Winthrop Industrie.
10.3*††	Amendment No. 1 to License and Commercialization Agreement and Commercial Supply Agreement dated May 21, 2019 between the Registrant and the Menarini Group through its subsidiary Berlin-Chemie AG.
10.4*††	Amended and Restated Know-How License and Supply Agreement dated November 3, 2017 between Janssen Pharmaceuticals, Inc. and Nordmark Arzneimittel GmbH & Co. KG.
10.5*††	First Amendment to the Amended and Restated Know-How License and Supply Agreement dated June 26, 2019 between the Registrant and Nordmark Arzneimittel GmbH & Co. KG.
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
32+	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, 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.

†† Portions of this exhibit have been omitted pursuant to Item 601 of Regulation S-K.

* Filed herewith.

+ Furnished herewith.

# Indicates management contract or compensatory plan or arrangement.

(1) Incorporated by reference to Exhibit 3.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on September 10, 2018 (File No. 001-33389).

(2) Incorporated by reference to Exhibit 3.2 filed with the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 7, 2018 (File No. 001-33389).

(3) 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 (File No. 001-33389).

(4) 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 (File No.: 000-23490).

(5) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on November 9, 2016 (File No. 001-33389).

(6) 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 (File No. 001-33389).

(7) 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 (File No. 001-33389).

(8) Incorporated by reference to Exhibit 4.5 filed with the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 8, 2018 (File No. 001-33389).

(9) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on June 11, 2018 (File No. 001-33389).

(10) Incorporated by reference to Exhibit 4.2 filed with the Registrant's Current Report on Form 8-K filed with the SEC on June 11, 2018 (File No. 001-33389).

(11) Incorporated by reference to Exhibit 4.3 filed with the Registrant's Current Report on Form 8-K filed with the SEC on June 11, 2018 (File No. 001-33389).

(12) Incorporated by reference to Exhibit 4.9 filed with the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 7, 2018 (File No. 001-33389).

(13) Incorporated by reference to Exhibit 4.3 filed with the Registrant's Current Report on Form 8-K filed with the SEC on October 17, 2018 (File No. 001-33389).

SIGNATURES

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

Date: August 6, 2019

VIVUS, Inc.

/s/ John P. Amos
John P. Amos
Chief Executive Officer

/s/ Mark K. Oki
Mark K. Oki
Senior Vice President, Chief Financial Officer and Chief Accounting Officer

Exhibit 10.1

Execution Version

AMENDMENT NO. 5 TO COLLATERAL AGREEMENT

This AMENDMENT NO. 5 TO COLLATERAL AGREEMENT, dated as of June 5, 2019 (this "**Amendment**"), is entered into by and between VIVUS, Inc., a Delaware corporation ("**Issuer**"), U.S. Bank National Association, as Trustee ("**Trustee**") and U.S. Bank National Association, as Collateral Agent ("**Collateral Agent**").

WHEREAS, the Issuer, Trustee and Collateral Agent are parties to that certain Collateral Agreement, dated as of June 8, 2018 (as amended by that Amendment No. 1 to Collateral Agreement dated as of July 6, 2018, that Amendment No. 2 to Collateral Agreement dated as of October 11, 2018, that Amendment No. 3 to Collateral Agreement dated as of December 7, 2018 and that Amendment No. 4 to Collateral Agreement dated as of March 20, 2019, the "Collateral Agreement"); and

WHEREAS, the parties thereto desire to amend the Collateral Agreement pursuant to Section 8.21 thereof on the terms set forth in this Amendment.

NOW, THEREFORE, in consideration of the foregoing premises, the mutual covenants and agreements hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged and accepted, the parties hereto, intending to be legally bound, hereby agree as follows:

1. Amendments to Collateral Agreement.

    a. Amendment to Schedule 4.13. Schedule 4.13 of the Collateral Agreement is hereby amended by deleting it and replacing it in its entirety with the form attached hereto as Exhibit A.

2. Miscellaneous.

    a. Ratification of Collateral Agreement. Except as expressly amended and modified by this Amendment, the Collateral Agreement, including the exhibits and schedules thereto, is and shall remain unchanged and in full force and effect in accordance with its terms.

    b. Other Miscellaneous Terms. The provisions of Sections 8.15, 8.16 and 8.20 of the Collateral Agreement shall apply *mutatis mutandis* to this Amendment.

[*Signature pages follow*]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment as of the date first written above.

VIVUS, INC.

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

[SIGNATURE PAGE TO AMENDMENT NO. 5 TO COLLATERAL AGREEMENT]

U.S. BANK NATIONAL ASSOCIATION,
as Trustee

By: /s/ Alison D.B. Nadeau
Name:Alison D.B. Nadeau
Title:Vice President

U.S. BANK NATIONAL ASSOCIATION,
as Collateral Agent

By: /s/ Alison D.B. Nadeau
Name:Alison D.B. Nadeau
Title:Vice President

[SIGNATURE PAGE TO AMENDMENT NO. 5 TO COLLATERAL AGREEMENT]

EXHIBIT A

Schedule 4.13

Certain Post-Closing Obligations

1. The Issuer shall, no later than July 31, 2018, (a) enter into an Account Control Agreement in form and substance satisfactory to the Majority Holders with respect to each of the accounts disclosed in Section 9 of the Issuer's Perfection Certificate delivered on or prior to the Effective Date or (b) move any such account to another financial institution approved by the Majority Holders and ensure that such replacement bank account is subject to the "**control**" (as defined in Article 9 of the UCC) of the Collateral Agent pursuant to an Account Control Agreement in form and substance satisfactory to the Majority Holders.

2. To the extent obtainable using commercially reasonable efforts, no later than sixty (60) calendar days following the Effective Date, the Issuer shall execute and deliver bailee agreements to be entered into among the Issuer, the Collateral Agent and each of the following warehouseman, bailees, agents or processors referred to in the Issuer's Perfection Certificate delivered on or prior to the Effective Date: (a) Catalent; (b) Cardinal; (c) Sanofi; and (d) Nordmark.

3. The Issuer shall, no later than July 31, 2019, cause Vivus Pharmaceuticals Limited (f/k/a Willow Biopharma Inc.) to (i) open a Canadian Dollar denominated deposit account (a sub-account of Wells Fargo Bank, National Association's master account with Royal Bank of Canada) and a Canadian Dollar denominated deposit account at Wells Fargo Bank, National Association's Cayman Islands Branch (together, the "New Accounts") and (ii) enter into (a) an Account Control Agreement with respect to the New Accounts and any and all other deposit accounts, securities accounts and commodity accounts with the Collateral Agent and the applicable bank, securities intermediary or commodity intermediary with which such account or accounts are held and (b) all other related agreements, documents and instruments, including any pledge agreement from Vivus Pharmaceuticals Limited in favor of the Collateral Agent with respect to any such accounts (including the New Accounts).

4. The Issuer shall, no later than October 30, 2019, dissolve or otherwise terminate, or cause the dissolution or termination of, the following Restricted Subsidiaries of the Issuer, and provide evidence thereof to the Collateral Agent: (a) VIVUS UK LIMITED, a private limited company organized and existing under the laws of the United Kingdom, (b) VIVUS LIMITED, organized and existing under the laws of Bermuda, (c) VIVUS International, L.P., organized and existing under the laws of Bermuda, (d) VIVUS INTERNATIONAL LIMITED, organized and existing under the laws of Ireland and (e) VIVUS REAL ESTATE LLC, a limited liability company organized and existing under the laws of the State of New Jersey.

[****] = Certain confidential information contained in this document has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

AMENDMENT N°1 to the
MANUFACTURING AND SUPPLY AGREEMENT
Effective as of September 1st, 2013

THIS AMENDMENT is effective as of the 18th day of March, 2019 (the "Amendment Effective Date")

BETWEEN

VIVUS, Inc., a corporation incorporated under the laws of the State of Delaware USA, having its registered office at 900 E. Hamilton Avenue, Suite 550 Campbell, CA 95008, USA;

Hereinafter referred to as "VIVUS" and as the "**Purchaser**";

AND

SANOFI WINTHROP INDUSTRIE, a company organized and existing under the laws of France, having its principal offices at 20 avenue Raymond Aron, 92165 Antony Cedex, France, acting for itself and on behalf of its Affiliates as hereinafter defined;

Hereinafter collectively referred to as "**SWI**"

VIVUS and SWI are hereinafter individually referred to as "**Party**" and collectively referred to as the "**Parties.**"

WHEREAS the Parties entered into that certain MANUFACTURING AND SUPPLY AGREEMENT effective as of September 1, 2013, (the "**Agreement**"**);**

WHEREAS the Parties now desire to make certain amendments to the terms and conditions of the Agreement, as reflected below in this amendment No. 1 (the "**Amendment**"**)** effective on the Amendment Effective Date;

WHEREAS all capitalized terms used in this Amendment shall be as defined in the Agreement unless otherwise defined herein; and

WHEREAS the Parties expressly acknowledge and agree that (a) except as expressly provided in this Amendment, all provisions of the Agreement, which are not expressly modified by the terms set forth in this Amendment shall remain valid and unchanged and apply to the Amendment, (b) this Amendment is an integral part of the Agreement, and (c) other than this Amendment, no other binding alteration, amendment, change or addition to the Agreement exists as of the Amendment Effective Date.

NOW THEREFORE THE PARTIES AGREE TO AMEND THE AGREEMENT AS FOLLOWS:

1. Amendment of Section 1— "Exclusive Territory" and "Semi-Exclusive Territory"

The definition of "Semi-Exclusive Territory" shall be deleted in its entirety, and the definition of "Exclusive Territory" shall be replaced in its entirety with the following:

"Exclusive Territory" shall mean all countries in the Purchaser Territory.

2. Amendment of Section 2 - SUPPLY OF PRODUCTS

Section 2.1 shall be replaced in its entirety with the following:

2.1 Supply of Product.

(a) *Supply and Purchase of Product*. Except as may otherwise be provided in this Section 2.1, SWI undertakes to supply and cause to be delivered, and Purchaser undertakes to purchase exclusively from SWI, Purchaser's total needs of Product for commercial supply in the Exclusive Territory. Purchaser agrees to purchase the Product from SWI, pursuant to Purchase Orders submitted to SWI by Purchaser, from time to time in accordance with Section 2.3.

(b) *Minimum Quantities*. During the Term and for the duration of this Agreement, Purchaser hereby agrees to purchase a minimum of [****] final blend Batches of Product annually **("Minimum Yearly Quantity")**. Such Minimum Yearly Quantity shall not be subject to any reduction whatsoever; provided, however, that SWI agrees and acknowledges that any prior Minimum Yearly Quantity from the Effective Date of the Agreement through to December 31, 2018 are hereby waived and forgiven in full.

(c)SWI acknowledges and agrees that Purchaser or its sub-licensees may sell any saleable tablets that Purchaser, or its sub-licensees, produce in connection with the validation of drug product manufacturing sites; provided, however, that such validation quantities are not to exceed [****] batches in total of each dosage. The Parties hereto agree that the total estimated annual yield is [****].

The Parties expressly acknowledge and agree that, as of the Amendment Effective Date Section 2 of the Agreement is amended so that to remove any obligation related to Semi-Exclusive Territory.

Section 2.4 Prescribed Yield of the Agreement shall be replaced in its entirety as follows:

2.4 Prescribed Yield

(a) *Generally*. As of the Amendment Effective Date, the Parties acknowledge and agree that the Prescribed Yield for tableted Product shall be [****] percent ([****]%) of the projected Product obtained for the yield of each batch. Prescribed Yield is calculated as follows:

(annual mean amount of Compound in the useable yield in bulk tablets)

(annual mean amount of dispensed Compound to the Compound + mannitol milling step)

At the time of this Amendment, the [****] percent ([****]%) prescribed yield was calculated as follows:

(mean [****] of Compound contained in a bulk tablet lot)

([****] of Compound dispensed to the milling step)x 100 = [****]%

The Parties further acknowledged and agree that this percentage represents Product yield to date as of the Amendment Effective Date, and reflects the percentage of actual yield in tablets vs. the

total amount of Compound input into each batch of Finished Product and its calculated theoretical tablet yield.

During the [****] period following the Amendment Effective Date, SWI agrees to perform optimization studies as mutually agreed upon (including SWI quoted and agreed upon expenses being funded by Purchaser) with the goal of reducing the overage of Compound added at the milling steps in order to increase the Prescribed Yield. Purchaser agrees to [****]. At the end of this [****] period, any process changes would be evaluated by the Parties and implemented, if feasible, based on the regulatory and cGMP requirements identified for such change. Once actions are implemented, a new Prescribed Yield will be established based on the tablet yields experienced over such [****] period. If such attempts to reduce the overage are unsuccessful, SWI will not be penalized beyond shortfall payment vs the Prescribed Yield.

(b) *Shortfalls*. To the extent that the total yield of all Batches of Product in the aggregate fall below the Prescribed Yield for the relevant Calendar Year and such event is not directly attributable to any information or improper materials supplied by Purchaser or any other acts or omissions by Purchaser (a **"Yield Shortfall"),** SWI shall [****].

(c) *Excess*. Once the studies are implemented to reduce the Compound overage and increase yield, a new Prescribed Yield is established, and to the extent that the total yield of all Batches of Product in the aggregate exceed [****]% for the relevant Calendar Year (a **"Yield Excess"),** the Parties shall [****] of the Compound resulting from such Yield Excess. Notwithstanding the above, the [****] for Yield Excess will not commence until [****] percent ([****]%).'

3. Amendment of Section 9 - TERM; TERMINATION

Pursuant to Section 9.1 of the Agreement, the initial term of the Agreement expires on January [16], 2021, which represents five (5) years after the date of the first commercial sale. The Parties wish to extend the initial term of the Agreement to December 31, 2023.

Therefore, Section 9.1 shall be replaced in its entirety with the following:

'9.1 Term. This Agreement shall become effective as of September 1, 2013 and unless terminated as provided herein, shall remain in full force and effect until December 31st, 2023 (the **"Term").**

Either Party shall be entitled to terminate the Agreement subject to [****] prior written notice to the other Party, it being specified, however, that the [****] prior notice period cannot be effective before December 31, 2021. Thereafter, the Agreement shall be automatically renewed for successive one (1) year terms, unless either Party provides notice of their desire to not renew for a subsequent one (1) year term at least [****] in advance of the end of the then current term.'

4. Amendment of Section 16.6 - ASSIGNMENT

Section 16.6 shall be replaced in its entirety by the following provision:

'**16.6 Assignment**. Neither Party may subcontract, assign, extend or transfer any of its rights and obligations under this Agreement without the express and prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; except that:

(i) VIVUS may transfer or assign its rights and obligations under this Agreement, in whole or in part, to its Affiliates, in whole to a single Commercialization Partner, or a third party in connection with a sale, sublicense, transfer or assignment of (a) rights relating to the manufacture or the Product, or (b) all or substantially all of its assets or (c) the business relating to the Product; and

(j) SWI may transfer or assign its rights and obligations under this Agreement (a) to its Affiliate; or (b) in connection with a sale, sublicense, transfer or assignment of all or substantially all of the assets or rights relating to the manufacture of the Product.

No assignment or transfer of this Agreement or of any rights hereunder shall relieve the assigning Party of any of its obligations and liabilities hereunder, unless the assignee undertakes in writing to, and can reasonably, assume such obligations and liabilities.

Any assignment or attempted assignment in violation of the terms of this Section 16.6 shall be null, void and of no legal effect.'

5. Addition of Section 8.5 REGULATORY SUPPORT

Section 8.5, as reflected below, shall be added to the Agreement:

'8.5 Regulatory Support. SWI agrees to support Purchaser, its sub-licensees and commercial partners with the applicable manufacturing documentation necessary to meet regulatory requirements in the Territory. At the time of signature of this amendment, the cost of this support will equal [****] Euros [****], [****]. This cost will be indexed with [****] outlined in Exhibit B. The Parties will review this support as needed and will adjust as necessary and as mutually agreed upon in order to support the then current business, including, if deemed necessary, a reduction or termination of such regulatory support services. This cost will be billed [****].'

6. Amendment to EXHIBIT B

EXHIBIT B of the Agreement shall be deleted in its entirety and replaced with the following:

'EXHIBIT B
Price

The Price for each dosage form of the Product is as follows:

		10 batch Minimum	30 batch Minimum
	Dosage	**2018 Price per 1000 tablets**	**2018 Price per 1000 tablets**
Avanafil tablets	[****]	[****]	[****]
Avanafil tablets	[****]	[****]	[****]
Avanafil tablets	[****]	[****]	[****]

As from January 1, 2019, and thereafter on a [****] basis, the purchase price defined above shall be reviewed and amended according to the latest available [****]

In witness whereof, the Parties have executed this Amendment to the Agreement as of the Amendment Effective Date, by their authorized officers, who by signing confirm their authority and intention to bind the Party they represent. This Amendment is so executed in the English language in two (2) counterparts, each of which shall be deemed to be an original.

SANOFI WINTHROP INDUSTRIE

Date: 28/03/2019

By: /s/ Andrea Ruggeri

Name: Andrea Ruggeri
Title: Head of Pharma Core and Global Established Products Sites

VIVUS, Inc.

Date: 22 May 2019

By: /s/ John L. Slebir

Name: John L. Slebir
Title: SVP, General Counsel

[****] = Certain confidential information contained in this document has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

AMENDMENT NO. 1 TO LICENSE AND COMMERCIALIZATION AGREEMENT AND COMMERCIAL SUPPLY AGREEMENT

THIS AMENDMENT NO. 1 TO LICENSE AND COMMERCIALIZATION AGREEMENT AND COMMERCIAL SUPPLY AGREEMENT (the "**Amendment**") is effective as of the 1st day of January, 2019 (the "**Amendment Effective Date**") by and between **VIVUS, INC.**, a Delaware corporation with its principal place of business at 900 E. Hamilton Avenue, Suite 550, Campbell, CA 95008, United States ("**VIVUS**"), and **BERLIN-CHEMIE AG**, a German public limited company having a place of business at Glienicker Weg 125 – 127, 12489 Berlin, Germany ("**Menarini**"). VIVUS and Menarini are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

The Parties have entered into (a) that certain License and Commercialization Agreement, having an execution date of July 5, 2013 (the "**License Agreement**") and (b) that certain Commercial Supply Agreement, having an effective date of July 5, 2013 (the "**Supply Agreement**").

The Parties now desire to amend the License Agreement and Supply Agreement as set forth below.

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

1. The countries of Australia and New Zealand shall be excluded from the definition of Menarini Territory (the "**Excluded Territories**"). For the avoidance of doubt, this amendment to the License Agreement also changes the definition of "**Purchaser Territory**" in the Supply Agreement and any and all references to the Excluded Territories shall be deleted accordingly.

2. Section 4.3(e) of the License Agreement is hereby deleted in its entirety and replaced by the following:

   (e) **Other Development**. As between the Parties, except for the responsibilities assigned to Menarini pursuant and Sections 4.1, 4.2(b), 4.3(b), and 4.9 or as agreed by the Parties below, VIVUS shall have the sole right to conduct any further Development work (including clinical trials) on the Product, at its sole discretion but with the aim of preserving the Product profile and the commercial viability of the Product in the Menarini Territory. VIVUS shall be responsible for all of its costs in connection with any further Development activities that it conducts, unless otherwise mutually agreed by the Parties. Notwithstanding the above, the Parties hereby agree that an oral dispersible formulation of the Product (the "**ODF**") may be developed for sale and use by Menarini in the Menarini Territory, by VIVUS in the VIVUS Territory, and by Menarini or its Affiliates or sublicensees (the "**Menarini Group**") in the countries that the Menarini Group has the right to Commercialize the Product. The Parties further agree that: (i) Menarini shall lead and direct the ODF Development, with assistance from VIVUS as reasonably requested by Menarini from time to time; (ii) the ODF shall be a Joint Invention; (iii) Menarini shall be responsible for all of the costs in connection with the ODF

Development subject to the royalty reduction set forth in Section 7.5(d); and (iv) VIVUS, with reasonable and necessary support by Menarini, shall be solely responsible for obtaining Regulatory Approval of the ODF for sale and use in the VIVUS Territory. Notwithstanding the above and for the sake of clarity, the Parties agree that Menarini shall have the right but not the obligation to perform such ODF Development and Menarini shall be entitled to suspend and/or stop such ODF Development at any time and for whatsoever reason. In such case, Menarini shall promptly inform VIVUS in writing of its decision to suspend or stop the ODF Development and VIVUS shall not be entitled to receive any fee or other payment, compensation, indemnity, damages for loss of profit, expenses or the like as a consequence of Menarini's decision; provided that Menarini shall be solely responsible for any third party costs incurred by VIVUS at Menarini's request as part of the ODF Development, including orders of API or Product.

3. Section 4.6(a) of the License Agreement is hereby deleted in its entirety and replaced by the following:

(a) **Product Launch**. Subject to Section 4.6(b), Menarini shall (i) commence a Product Launch in each Major Country in the Menarini Territory no later than [****] after grant of the Product Marketing Authorization by the European Commission; (ii) use [****] to commence a Product Launch in each of the other European Union countries in the Menarini Territory that are not a Major Country within [****] after grant of the Product Marketing Authorization by the European Commission; and (iii) commence a Product Launch in each other non-European Union country in the Menarini Territory as agreed separately by the Parties in writing; provided that Menarini shall have a period of [****] from the date of this Amendment to commence a Product Launch in Montenegro, Macedonia and Kosovo, and should Menarini fail to commence the Product Launch within such period in such countries VIVUS shall be entitled to terminate the Agreement on a country by country basis; provided, however that Menarini accepts and acknowledges that MTPC has the right as set forth in Section 6.1 of the MTPC Agreement to request a reversion of the license on a country by country basis in such countries for the failure to commence a Product Launch within [****] from the earliest first sale in the United States or Major European Country (France, Germany, Italy, Spain and United Kingdom). For the sake of clarity, it is agreed between the Parties that the Product Launch shall be fulfilled as of the first placing on the market of any form, formulation, dosage strength, or packaging configuration of the Product by Menarini in accordance with the definition of Product Launch set forth in Section 1.54.

4. Section 4.8(a) of the License Agreement is hereby deleted in its entirety and replaced by the following:

(a) Menarini shall be responsible, at its sole expense, for preparing and producing the Promotional Materials. VIVUS will review and approve English translations of the Promotional Materials developed by at the central level (excluding local translation and adaptation of such Promotional Materials) within and no later than [****] from the receipt of the Promotional Materials from Menarini. In the absence of comments or approval within the [****] period by VIVUS, Menarini's central level proposal

for Promotional Material in question shall be considered accepted and approved by VIVUS. VIVUS shall not refuse approval of Promotional Material unreasonably; provided that Menarini acknowledges that VIVUS is obligated to obtain approval from MTPC of all Promotional Materials. In any event, Menarini shall ensure that all Promotional Materials used by it, its Affiliates, and its sublicensees are consistent with applicable Regulatory Approval(s) in the Menarini Territory and otherwise comply with Applicable Law. To the extent that VIVUS disagrees with Promotional messages or tactics proposed by Menarini for Product in the Menarini Territory, it may raise such issues with Menarini for discussion and resolution, with escalation to the JSC, if necessary.

5. Section 4.8(d) of the License Agreement shall be added as follows:

(d) To the extent permitted by Applicable Law and is customary for such materials in the United Kingdom, Italy, France, Germany, Spain, Austria, Switzerland, Sweden, Finland, Denmark, Norway, Iceland, the Netherlands and to the extent feasible depending upon the status of the relevant MAA, all Promotional Materials shall include the following statement: *"Licensed by Vivus Inc. and Mitsubishi Tanabe Pharma Corporation"*. Menarini shall provide VIVUS with copies of the above mentioned materials as soon as reasonably practicable after such Promotional Materials are first used. For the sake of clarity, such statement shall not be applicable to any and all Promotional Materials already produced by Menarini; provided, that Menarini will use Commercially Reasonable Efforts to have MTPC's name removed from any Promotional Materials at an appropriate time (e.g., reprinting and label amendment) in all countries in the Menarini Territory other than those noted above.

6. Section 5.1(b) of the License Agreement is hereby deleted in its entirety and replaced by the following:

(b) **Other Approvals**. Menarini shall be the legal and beneficial owner of all Other Approvals. Regulatory Materials relating to the Other Approvals shall be filed by, and in the name of, Menarini, or by Menarini's designee reasonably acceptable to VIVUS, unless otherwise mutually agreed in writing by the Parties.

7. Section 7.2 of the License Agreement is hereby deleted in its entirety and replaced by the following:

7.2 **Regulatory Milestone Payment**. Menarini shall make each of the payments indicated below to VIVUS within [****] after the achievement of the corresponding milestone event.

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

*For the avoidance of doubt, this second milestone would be in addition to the first milestone, since the first milestone applies regardless of whether the Label Expansion Filing is filed or approved. The Parties shall work together to include the Time of Onset Claim in the SmPC. VIVUS shall have [****] from approval of the MAA by the European Commission to seek modification of the SmPC in one or more Label Expansion Filings; provided, however, that such deadline shall automatically be extended to [****] after approval of the MAA by the European Commission if modification of the SmPC is delayed as a result of the action or inaction of Menarini.

Each milestone payment in this Section 7.2 shall be paid only once. The maximum total amount of payment to VIVUS pursuant to this Section 7.2 shall be €[****]. Each such payment shall be made in Euros by wire transfer of immediately available funds into an account designated by VIVUS. Except as set forth in Section 7.5(c), each such payment is nonrefundable and noncreditable against any other payments due hereunder.

8.Section 7.4 of the License Agreement is hereby deleted and replaced in its entirety by the following:

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

Aggregate Net Sales in a Calendar Year	***Payment***
€[****]	€[****]
€[****]	€[****]
€[****]	€[****]

It is expressly agreed between the Parties that the Net Sales made by Menarini in the Excluded Territories shall not be taken into consideration in the calculation of such Aggregate Net Sales. Each sales milestone payment in this Section 7.4 shall be paid only once. The maximum total amount of payment to VIVUS pursuant to this Section 7.4 shall be €[****]. Menarini shall notify and pay to VIVUS the amounts set forth in this Section

7.4 together with the delivery of the quarterly report pursuant to Section 7.8 for the calendar quarter in which the applicable event was achieved. For clarity, in the event more than one (1) of the aggregate Net Sales thresholds in achieved in a calendar year, Menarini shall owe each of the corresponding payments. Each such payment shall be made in Euros by wire transfer of immediately available funds into an account designated by VIVUS. Each such payment is nonrefundable and noncreditable against any other payments due hereunder.

9. Section 7.5 of the License Agreement is hereby deleted and replaced in its entirety by the following:

7.5 **Royalty to VIVUS**.

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

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

(c) During the Royalty Term, on a calendar quarter basis, Menarini shall pay to VIVUS a royalty equal to [****] percent ([****]%) of Net Sales of ODF Products; provided, however, that such royalty shall be reduced to [****] percent ([****]%) of the first $[****] of Net Sales of ODF Products in the Menarini Territory (the "**ODF Reduced Royalty**") until such time that the aggregate ODF Reduced Royalty paid to VIVUS exceeds the lesser of (i) [****] percent ([****]%) of the reasonable and necessary Third Party costs and expenses incurred in the ODF Development or (ii) €[****] (the "**ODF Reduced Royalty Cap**"); provided further, however, that the Parties agree to implement a similar royalty reduction on royalties payable to VIVUS under Section 7.5(a) to the extent VIVUS, or its sublicensee, obtains Regulatory Approval of the ODF Product in the VIVUS Territory and the ODF Reduced Royalty Cap has yet to be achieved. The Parties further agree that, as of January 1, 2021, the ODF Reduced Royalty shall be adjusted to apply on a calendar year basis and equal [****] percent ([****]%) of the first $[****] of Net Sales of ODF Products in the Menarini Territory; provided further, however, that the Parties agree to implement a similar royalty reduction on royalties payable to VIVUS under Section 7.5(a) to the extent VIVUS, or its sublicensee, obtains Regulatory Approval of the ODF Product in the VIVUS Territory and the ODF Reduced Royalty Cap has yet to be achieved. To the extent the ODF Reduced Royalty Cap has yet to be achieved as of the end of the Royalty Term and VIVUS, or its sublicensee, is commercializing the ODF Product in the VIVUS Territory at that time, VIVUS agrees to [****]. For the sake of clarity, Menarini acknowledges and agrees that (i) the ODF Reduced Royalty Cap shall be achieved one time only regardless of which

royalty it is applied against and (ii) the ODF Reduced Royalty shall not in any circumstance apply to royalties owed under Section 7.6.

10. Section 8.5 of the License Agreement is hereby deleted and replaced in its entirety by the following:

8.5 **Patent Marking**. Menarini shall, and require its Affiliates and sublicensees, to mark Products sold by it hereunder with appropriate patent numbers or indicia to the extent required by Applicable Law and/or customary within each country of the Menarini Territory here Product is sold.

11. For the sake of clarity, the Parties agree that the "**Effective Date**" of the License Agreement occurred on July 5, 2013.

12. The Parties to discuss in good faith the possible transfer of the Avanafil Global Safety Database from VIVUS to Menarini.

13. A definition of "API" is hereby added to the Supply Agreement as follows: "**API**" means the Product's active pharmaceutical ingredient.

14. The definition of "Minimum Purchase Obligation" and Exhibit C thereto of the Supply Agreement are hereby deleted and replaced in their entirety by the following:

"**Minimum Purchase Obligation**" means the greater of (a) such quantities of Product or API, subject to Section 2.4, described in Exhibit C and (b) [****] percent ([****]%) of Purchaser's, or Purchaser's designee's, worldwide requirements of Product or API, subject to Section 2.4.

EXHIBIT C

Minimum Purchase Obligations

Calendar Year	Minimum Purchase Obligation
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]

[****]	[****]
[****]	[****]
[****]	[****]

Notwithstanding the above, the Parties agree that Menarini shall be entitled to sell the finished Product manufactured by Menarini at its Von Heyden manufacturing facility from API supplied by VIVUS to Menarini for purposes of process validation; provided that the quantities of API supplied by VIVUS to Menarini for such process validation shall not be credited against Menarini's Minimum Purchase Obligations (the "**Tablet Validation Product**"). Furthermore, the Parties agree that Menarini shall be entitled to sell the finished Product manufactured with the API manufactured by Menarini at its Lusochimica manufacturing facility; provided that the quantities of API manufactured by Menarini for such process validation shall not be credited against Menarini's Minimum Purchase Obligations (the "**API Validation Product**"). Menarini further agrees (i) to pay royalties pursuant to Article 7 on any Product sold pursuant to this paragraph and (ii) that the Tablet Validation Products and API Validation Products are not to exceed [****] batches in total of each dosage with an estimated total yield of [****] tablets, [****] tablets, and [****] tablets.

15. Section 2.4 of the Supply Agreement is hereby deleted and replaced in its entirety by the following:

2.4 **Minimum Purchase Requirements**. Purchaser shall be required to either (a) purchase no less than the [****] from VIVUS in accordance with the terms of this Agreement or (b) [****]; provided, however, that Purchaser may fulfill its obligations under subsection (a) above by electing [****] (the "**API Purchase Option**"). Menarini shall reimburse VIVUS, in cash, for any payment or penalty that VIVUS may incur from the New Third Party Manufacturer and/or any other relevant Third Party manufacturer as a result of Purchaser's failure to purchase the Minimum Purchase Obligation or Purchaser's decision to exercise the API Purchase Option; provided that such payment or penalty shall be reasonably documented and justified by VIVUS as to the amount of such payment or penalty. VIVUS acknowledges and agrees that to the extent Menarini or VIVUS' other sublicensees have purchased a minimum of [****] final blend batches of bulk Product in any calendar year that Purchaser shall not be obligated to reimburse VIVUS any amounts relating to Purchaser's election to fulfill its Minimum Purchase Obligation under subsection (a) above for the same calendar year through the purchase of API rather than bulk Product. The Parties agree that with respect to the API purchased by Menarini pursuant to the API Purchase Option: (a) such API shall be stored at a facility owned and operated by the New Third Party Manufacturer and/or any other relevant Third Party manufacturer according to good manufacturing practices and (b) the ownership and risk of loss shall pass to Menarini as of the date of the invoice from VIVUS for such API Purchase Option; such invoice shall be issued not earlier than the end of each Calendar Year.

16. A Section 2.12 shall be inserted into the Supply Agreement as follows: 2.12

Manufacturing Yield.

(a) The Parties agree that the annual target yield of the manufacturing process for the Product (the "**Product Target Yield**") shall be no lower than [****] percent ([****]%). In the event that the actual annual yield (the "**Actual Yield**") falls below the Product Target Yield, then VIVUS shall [****]; provided that in no event shall the VIVUS markup be reduced below [****] percent ([****]%). For example, if the Actual Yield in calendar year 2018 totals [****] percent ([****]%), then the VIVUS markup of [****] percent ([****]%) would be reduced for calendar year 2019 to [****] percent ([****]%). For purposes of this Amendment, the Parties acknowledge and agree that Actual Yield is calculated as follows: (annual mean amount of API in the useable yield in bulk tablets / (annual mean amount of dispensed API to the API+mannitol milling step). At the time of this Amendment, the [****] percent ([****]%) Actual Yield was calculated as follows: (mean [****] API in bulk tablet lots / [****] API dispensed to the milling step) x 100 = [****]%. The Parties further acknowledge and agree that this calculation represents the percentage of Actual Yield in tablets vs. the total amount of API input into each batch of bulk tablets and its calculated theoretical tablet yield.

(b) During the [****] period following the Amendment Effective Date, VIVUS agrees to perform optimization studies as mutually agreed upon with the New Third Party Manufacturer with the goal of reducing the overage of API added at the milling steps in order to increase the Actual Yield. At the end of this [****] period, any process changes would be evaluated by VIVUS and the New Third Party Manufacturer and implemented, if feasible, based on the regulatory and GMP requirements identified for such change. If such attempts to reduce the overage are unsuccessful, VIVUS will not be penalized beyond the reduction of the markup as set forth above.

17. Section 3.1 of the Supply Agreement is hereby deleted and replaced in its entirety by the following:

3.1 **Prices for Product and API.** Purchaser shall pay to VIVUS the Price for the units of Product or quantity of API supplied to Purchaser pursuant to this Agreement. Purchaser shall be solely responsible for determining the price at which it will sell the Product. The Parties acknowledge and agree that the current costs for Product and API from VIVUS' current New Third Party Manufacturer, which shall be used to calculate Manufacturing Cost, are as follows:

(a)API:

(i)for [****] batches or [****] or less, €[****] per [****];

(ii) for [****] batches to [****] batches or [****], €[****] per [****]; and

(iii) for [****] batches or more or [****], €[****] per [****].

(b)Products:

(i) for [****] to [****] batches, per 1,000 tablets: [****]/€[****], [****]/€[****], and [****]/€[****]; and

(ii) for [****] or more batches, per 1,000 tablets: [****]/€[****], [****]/€[****], and [****]/€[****].

Notwithstanding the above, the Parties acknowledge and agree that these costs remain subject to [****] and such other increases that are specified under the Agreement.

18. Section 9.1 of the Supply Agreement is hereby deleted and replaced in its entirety by the following:

9.1 **Term.** The term of this Agreement (the "**Term**") will commence on the Effective Date and will continue, unless otherwise agreed by the Parties in writing, until December 31st, 2023.

19. Section 9.5 of the Supply Agreement is hereby deleted and replaced in its entirety by the following:

9.5 **Effects of Termination**. Upon expiration or termination of this Agreement, VIVUS shall manufacture and supply, and Purchaser shall purchase from VIVUS (a) any and all quantities of Product or API ordered by Purchaser pursuant to this Agreement prior to the date on which such notice is given, for the applicable Price ("**Ordered Product**"), and (b) any and all materials held by VIVUS or MTPC (or any other Third Party manufacturer of Product) for exclusive use in the manufacture of Compound, API or bulk Product based on binding part of the Forecasts provided by Purchaser, for an amount equal to the [****] with respect to such materials ("**Required Materials**"). Termination or expiration of this Agreement will not relieve any outstanding obligations due hereunder prior to the termination or expiration, including, without limitation, Purchaser's Minimum Purchase Obligations hereunder; provided, however, that following a termination pursuant to Section 9.2 or Section 9.3 VIVUS shall not be obligated to supply Product or API and shall have the right to receive [****].

20. Section 9.6 of the Supply Agreement is hereby deleted and replaced in its entirety by the following:

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 the termination or expiration of this Agreement for any reason: 1 (any relevant definitions), 2.4, 3 (solely in relation to Product sold prior to expiration or termination of this Agreement or in relation to Product or other materials sold pursuant to Section 9.5), 4.2, 4.3, 8.1, 9.5, 9.6, and 10-16.

21. The Parties acknowledge and agree that (a) except as expressly provided in this Amendment, each of the License Agreement and Supply Agreement shall remain unmodified and in full force and effect and (b) other than this Amendment, no other binding alteration, amendment, change or addition to the License Agreement and/or Supply Agreement exists as of the Amendment Effective Date.

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

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

VIVUS, INC.	**Berlin–Chemie Ag**
By: /s/ John L. Slebir	By: /s/ Dr. Reinhard Uppenkamp
Name: John L. Slebir	Name: Dr. Reinhard Uppenkamp
Title: SVP, General Counsel	Title: Chairman of the Board
Date: 21 May 2019	Date:
	By: /s/ Dr. Attilio Sebastio
	Name: Dr. Attilio Sebastio
	Title: CFO
	Date:

Exhibit 10.4

[****] = Certain confidential information contained in this document has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

Execution Version

AMENDED AND RESTATED KNOW-HOW LICENSE AND SUPPLY AGREEMENT

by and between

JANSSEN PHARMACEUTICALS, INC.

And

NORDMARK ARZNEIMITTEL GMBH & CO. KG

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AMENDED AND RESTATED KNOW-HOW LICENSE AND SUPPLY AGREEMENT

This Amended and Restated Know-How License and Supply Agreement ("**Agreement**") is made effective as of the 3rd day of November, 2017 ("**Effective Date**") by and between Janssen Pharmaceuticals, Inc., a corporation formed under the laws of Pennsylvania with offices at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08650 ("**Janssen**"), and Nordmark Arzneimittel GmbH & Co. KG, a company incorporated under the laws of Germany, with offices at Pinnauallee 4, 25436 Uetersen, Germany ("**Nordmark**"). Janssen and Nordmark may each be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Knoll AG, located in Ludwigshafen, Germany ("**Knoll**") and McNeilab, Inc. ("**McNeilab**"), located in Spring House, Pennsylvania 19477, predecessor in interest to Janssen, entered into a Know-How License and Supply Agreement effective July 15, 1987, regarding supply of the pharmaceutical product containing Pancrelipase, as amended by the Amendment to Know-How License and Supply Agreement between Knoll and McNeilab dated July 8, 1988, (collectively, the "**Prior Agreement**");

WHEREAS, in 1975 BASF AG ("**BASF**") acquired Knoll, located in Ludwigshafen, Germany, and Knoll became a wholly owned subsidiary of BASF;

WHEREAS, prior to January 1, 1997, Nordmark Arzneimittel GmbH was a wholly owned subsidiary of Knoll;

WHEREAS, on January 1, 1997, Nordmark Arzneimittel GmbH was liquidated and became Knoll's production site, Uetersen ("**Site Uetersen**");

WHEREAS, prior to [****] and/or [****] and/or [****] had developed know-how related to the [****];

WHEREAS, effective March 1, 2001, Abbott Laboratories acquired Knoll;

WHEREAS, simultaneously to Abbott Laboratories acquiring Knoll, and effective March 1, 2001, Site Uetersen was spun off in a management buy-out as the separate and independent company Nordmark;

WHEREAS, prior to Abbott Laboratories acquiring Knoll, Knoll had requested Janssen's agreement to transfer the Prior Agreement including all its rights and obligations to newly formed Nordmark and did receive written confirmation for such transfer from Janssen on March 21, 2001 ("**Assignment Letter**" as attached in Exhibit A);

WHEREAS, in such [****] and [****] agreed in writing that [****] shall remain entitled [****];

WHEREAS, after [****] but prior to the [****] developed and generated [****];

WHEREAS, after [****] but prior to the [****] developed and introduced [****];

WHEREAS, on [****] and [****] signed an agreement [****] in order to clarify [****] shall be construed to have caused the [****] including, but not limited to, [****]; provided, however, that [****] remains entitled to [****];

WHEREAS, on April 12, 2010, the FDA (as defined below) approved NDA-22523, submitted by Janssen, for the use of PANCREAZE (pancrelipase) Delayed-Release Capsules for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions in the USA (as defined below);

WHEREAS, in such approval, the FDA deferred requirement for development by Janssen of an age appropriate formulation for PANCREAZE (pancrelipase) Delayed-Release Capsules to allow for dosing to the youngest, lowest weight pediatric patients, including infants;

WHEREAS, [****] and [****] entered into a [****] regarding the use of [****] in the development of [****];

WHEREAS, [****] and [****] entered into a [****] regarding services related to the development of [****];

WHEREAS, on March 7, 2014, the FDA approved Janssen's sNDA for Pancreaze 2600 which is an age appropriate formulation for PANCREAZE (pancrelipase) Delayed-Release Capsules to allow for dosing to the youngest, lowest weight pediatric patients, including infants;

WHEREAS, patents and patent applications of Allergan Pharmaceuticals International Ltd, Allergan plc and/or any of their Affiliates (collectively, "**Allergan**") related to Pancrelipase and Products (as defined below) were granted and/or filed to/by Allergan and/or claim a priority date prior to October 1, 2015 in the USA and the rest of the world (the "**Allergan Patents**");

WHEREAS, on October 1, 2015 Allergan and Janssen concluded a certain license agreement (the "**Allergan-Janssen License Agreement**"), according to which Janssen has the right under the Licensed Patents (as such term is defined in the Allergan-Janssen License Agreement) (i) to Manufacture and to have Manufactured Licensed Products (as such term is defined in the Allergan-Janssen License Agreement) outside the USA and Canada solely for importation, use and sale in the USA and Canada, and (ii) to Manufacture, use, offer for sale, import and/or sell Licensed Products (as such term is defined in the Allergan-Janssen License Agreement) in the USA and Canada;

WHEREAS, on October 1, 2015 Allergan and Nordmark concluded a certain cooperation and settlement agreement (the "**CSA**"), pursuant to which [****] and [****] and its Affiliates and any Third Party to which [****] transfer, assign, sell, out-license or otherwise grant fully or partly certain [****], supply [****] and/or import for the benefit of [****], (ii) to generate and supply [****] in the rest of the world such [****],

WHEREAS, the CSA also provides that, until the earlier of the expiration of the last of the Allergan Patents or the termination of the Allergan-Janssen License Agreement, Allergan grants (amongst others) Nordmark and its Affiliates, Legal Successors (as defined below) and Partial Successors (as defined below) a license under the Allergan Patents (i) to sell to [****],

supply to [****] and/or import for the benefit of [****], (ii) to generate and supply [****] in the rest of the world such [****] (together the "**Allergan-Nordmark License**");

WHEREAS, to facilitate Janssen's (i) satisfaction of a FDA imposed post-marketing requirement for a new pediatric dosage formulation under 21 USC § 355(c) of its pancrelipase-containing drug product and subsequent commercialization of such formulation and (ii) subsequent reformulation and commercialization of currently commercialized PANCREAZE® products, Janssen desires to obtain from Nordmark, and Nordmark is willing to grant to Janssen, certain exclusive (as set forth in Section 2.1) rights under the Licensed Know-How (as defined below), and Janssen desires to purchase from Nordmark and Nordmark is willing to sell to Janssen the Contracted Products (as defined below), and the terms and conditions set forth herein;

WHEREAS, Nordmark is in the business of making and selling the Contracted Products, and Janssen would like to purchase the Contracted Products from Nordmark pursuant to the terms of this Agreement; and

WHEREAS, Nordmark and Janssen now desire to enter into this Agreement in order to amend and restate the Prior Agreement as set forth herein and provide for the supply of the Contracted Products pursuant to the terms and conditions set forth herein.

NOW, **THEREFORE**, in consideration of the mutual covenants and agreements contained herein, the Parties agree as follows:

1. DEFINITIONS

As used in this Agreement, the following words and phrases shall have the following meanings:

[****]

"**Acceptance**" has the meaning set forth in Section 8.2.

"**Achievement Date**" has the meaning set forth in Section 6.2.

"**Advanced Product**" means any Product that cumulatively fulfills all of the following conditions:

[****]

"**Advanced Supply Prices**" has the meaning set forth in Section 6.2.

"**Affiliate**" of a Party hereto means any entity that controls or is controlled by such Party, or is under common control with such Party. For purposes of this definition, an entity shall be deemed to control another entity if it owns or controls, directly or indirectly, at least fifty percent (50%) of the voting equity of another entity (or other comparable ownership interest) or has the right to control and direct the management of the entity.

"**Agreement**" has the meaning set forth in the Recitals.

"**Allergan**" has the meaning set forth in the Recitals.

"**Allergan-Janssen License Agreement**" has the meaning set forth in the Recitals.

"**Allergan-Nordmark License**" has the meaning set forth in the Recitals.

"**Allergan Patents**" has the meaning set forth in the Recitals.

"**Annual Maximum Order Quantity**" has the meaning set forth in Section 4.1(c).

"**Annual Minimum Order Quantity**" has the meaning set forth in Section 3.3.

"**Annual Product Review**" has the meaning set forth in Section 9.6.

"**Anti-Corruption Laws**" has the meaning set forth in Section 20.1.

"**API**" means active pharmaceutical ingredient.

"**Apparent Defect**" has the meaning set forth in Section 8.2.1.

"**Assignment Letter**" has the meaning set forth in the Recitals.

"**Bankruptcy Code**" has the meaning set forth in Section 16.5.

"**Base Prices**" has the meaning set forth in Exhibit F.

"**BASF**" has the meaning set forth in the Recitals.

"**Batch**" means a specific quantity of any Contracted Product comprising a number of Units (as defined below) mutually agreed upon between the Parties, and that (i) is intended to have uniform character and comply to Quality (as defined below), and (ii) is Manufactured according to a single Purchase Order (as defined below) during the same cycle of Manufacturing.

"**Bulk Product**" means drug product in the pharmaceutical form of capsules filled with MFT (as defined below) and as set forth in Exhibit C and Exhibit D.

"**Business Day**" means a day other than a Saturday, Sunday or a day on which banks in the USA or Germany are authorized or obligated by Law to close.

"**Calendar Month**" means a financial month based on the J&J Universal Calendar (the "**J&J Universal Calendar**"), a copy of which for the year 2017 is attached as Exhibit K and a copy of which prior to the beginning of each such year for succeeding years shall be provided to Nordmark); *provided*, *however*, that (i) the first Calendar Month under this Agreement shall extend from the Effective Date until the last day of the first Calendar Month of the Term (as defined below) and (ii) the last Calendar Month under this Agreement shall extend from the first day of such Calendar Month until the last day of the Term.

"**Calendar Quarter**" means a financial quarter based on the J&J Universal Calendar (the "**J&J Universal Calendar**"); *provided*, *however*, that (i) the first Calendar Quarter under this

Agreement shall extend from the Effective Date until the last day of the first Calendar Quarter of the Term (as defined below) and (ii) the last Calendar Quarter under this Agreement shall extend from the first day of such Calendar Quarter until the last day of the Term.

"**Calendar Year** " means a calendar year based on the J&J Universal Calendar; *provided*, *however*, that (i) the first Calendar Year under this Agreement shall extend from the Effective Date until the last day of the first Calendar Year of the Term (as defined below) (ii) the last Calendar Year under this Agreement shall extend from the first day of such Calendar Year until the last day of the Term.

"**Certificate of Analysis**" means a document identified as such, signed or released by a Person qualified to sign or release such document in accordance with cGMP (as defined below) and provided by Nordmark to Janssen in respect of the applicable Contracted Product that sets forth the analytical test results for each specified Contracted Product against the applicable Product Specification (as defined below) delivered to Janssen under this Agreement.

"**Certificate of Compliance**" means a document identified as such, signed or released by a Person qualified to sign or release such document in accordance with cGMP and provided by Nordmark to Janssen in respect of the applicable Contracted Product that sets forth the conformity of (i) such Contracted Product with the applicable Marketing Authorization (as defined below) for such Contracted Product as provided for by Janssen to Nordmark according to EU GMP Guide Part I Annex 16; and (ii) of the Manufacture of such Contracted Product with cGMP.

"**Compound**" means Pancrelipase [****].

"**Concerned Party**" has the meaning set forth in Section 22.1.

"**Confidential Information**" means all information, data and/or know-how that relates to any Contracted Product or the technology, marketing strategies or business of the disclosing Party or its Affiliates (whether disclosed prior to or subsequent to the Effective Date, and whether disclosed in writing, electronically, orally, visually or by any other means) and that is disclosed in connection with this Agreement by either Party (or any of its Affiliates), including Janssen Confidential Information and Nordmark Confidential Information (as defined below), as applicable. For clarity, Confidential Information shall include all confidential information protected under Section 6.9 of the Prior Agreement.

"**Contracted Products**" means all Legacy Products and all Advanced Products.

"**Costs**" shall mean:

- costs for (i) [****] and (ii) [****]
- costs of any [****] as follows: costs (i) [****], (ii) [****], (iii) [****], (iv) [****], (v) [****], (vi) [****] and
- costs for [****].

[****]

[****]

"**Covered Matters**" means such matters that may be resolved by an Expert or Expert Panel in the event the Parties are unable to reach a resolution, as explicitly set forth in Sections 4.4, 6.3, 8.2.3, 8.4, 10.1.2, 10.2, 16.6.1, 16.6.4 and 16.6.5 in accordance with a mechanism as set forth in Section 22.

[****]

"**CSA**" has the meaning set forth in the Recitals.

"**Current Good Manufacturing Practices**" or "**cGMP**" means (i) the good manufacturing practices required by the FDA and set forth in the FD&C Act or FDA regulations (including without limitation 21 CFR §§ 210 and 211), in effect at any time during the Term of this Agreement, for the Manufacturing and testing of pharmaceutical materials as applied solely to Contracted Products; and (ii) the corresponding requirements of each applicable Regulatory Authority (as defined below).

"**Defect**" means any deviation of any Contracted Product from Quality and "**Defective**" shall have a corresponding meaning. The Parties expressly agree that the Contracted Product shall not be considered to have a Defect (or to be Defective) for the purposes of this Agreement, if the Contracted Product has been Manufactured and tested in full compliance with Quality.

"**Delivery Date**" means the date that a Contracted Product is made available by Nordmark for pick-up by a common carrier designated by Janssen.

"**DMF**" means the Drug Master File for Compound owned, held and as filed by Nordmark or its Affiliates with (i) the FDA in the USA (US-DMF-7090) and (ii) Health Canada (as defined below) in Canada (DMF 2013-089).

"**Effective Date**" has the meaning set forth in the Recitals. "**EFT**" means electronic funds transfer.

"**Expert**" has the meaning set forth in Section 22.2.

"**Expert Panel**" has the meaning set forth in Section 22.3.

"**Facility**" means Nordmark's facility located at Pinnauallee 4, 25436 Uetersen, Germany and, subject to Janssen's prior written approval, such other facilities used by Nordmark in the Manufacture, packaging and storage of any Contracted Product or Raw Materials (as defined below).

"**FDA**" means the U.S. Food and Drug Administration or any successor entity thereto.

"**FD&C Act**" means the U.S. Federal Food, Drug and Cosmetic Act, as may be amended from time to time.

"**Firm Period**" has the meaning set forth in Section 4.1(a).

"**Force Majeure Event**" has the meaning set forth in Section 18.1.

"**Governing Law**" has the meaning set forth in Section 21.1.

"**Governmental Authority**" means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other instrumentality of any government in the Territory and Germany.

"**Health Canada**" means the Canadian federal government department established pursuant to the *Department of Health Act* (Canada), as amended, or any successor entity thereto.

"**Initial Term**" has the meaning set forth in Section 16.1.

"**Insurance Year**" means the Calendar Year.

"**Insured Incident**" means any damage or indemnification claim made against Nordmark in writing by Janssen or any Third Party for Costs [****].

"**Intellectual Property Rights**" has the meaning set forth in Section 2.4.

"**Intermediate Product**" means MFT and as set forth in Exhibit C and Exhibit D.

"[****] **Release Limit**" has the meaning set forth in Section 8.5.

"**Janssen**" has the meaning set forth in the Recitals.

"**Janssen Confidential Information**" has the meaning set forth in Section 15.2.

[****]

"**Janssen Successors**" has the meaning set forth in the Recitals.

"**Janssen Trademarks**" means the proprietary mark(s) for Contracted Products owned by Janssen or one of its Affiliates set forth in Exhibit L.

"**J&J Universal Calendar**" has the meaning set forth in the definition of Calendar Month.

"**Knoll**" has the meaning set forth in the Recitals.

"**Know-How License**" has the meaning set forth in Section 2.1.

"**Late Delivery**" has the meaning set forth in Section 7.6.

"**Latent Defect**" has the meaning set forth in Section 8.3.

"**Law**" means any and all laws, statutes, regulations, rules, directives, orders, judgments, injunctions, ordinances or other binding requirements of any kind having the effect of law

promulgated by any Governmental Authority within the applicable jurisdiction (including cGMP, any binding Regulatory Authority guidance documents pertaining to manufacturing and quality control practice) and any legal obligation to a Governmental Authority to which either Party is subject (e.g. a corporate integrity agreement or settlement agreement with a Governmental Authority).

"**Lead Time**" means a time period of [****] in advance of any requested Delivery Date, by which a Purchase Order must be placed by Janssen to Nordmark for Nordmark to be obliged to deliver any Contracted Product by such Delivery Date under this Agreement.

"**Legacy Product**" means any Product that is not an Advanced Product that cumulatively fulfills all of the following conditions:

[****]

"**Legacy Supply Prices**" has the meaning set forth in Section 6.1.

"**Legal Successor**" shall mean, with respect to a Party: (a) any Third Party which, always and in each case subject to the terms of Section 23, acquires, is assigned or otherwise receives after the Effective Date all of a Party's right, title and interest to its business related to the Contracted Products, as applicable, worldwide; (b) any Third Party (or group of Third Parties acting in concert) which acquires or otherwise becomes the beneficial owner of all of the equity or voting interests of such Party after the Effective Date; and (c) any entity resulting from such Party consolidating with or merging into another corporation or entity after the Effective Date, or from any other corporation or entity consolidating with or merging into such Party after the Effective Date, in the case of each of (a) through (c) above irrespective whether by law or by contract and irrespective by which kind of transaction or legal form.

[****]

"**Licensed Know-How**" [****].

"**Licensed Know-How Fee**" [****].

"**Manufacture**" means all activities related to the manufacturing of any Contracted Product, or Compound including: manufacturing for clinical use or commercial sale; in-process and finished Contracted Product testing, fill/finish, labeling and packaging; release of any Contracted Product; quality assurance activities related to manufacturing and release of any Contracted Product; ongoing stability tests; and regulatory activities related to any of the foregoing. Each of Manufacturing and Manufactured shall have a corresponding meaning.

"**Marketing Authorization**" means marketing authorization for any Contracted Product owned, held and as filed by Janssen or its Affiliates with (i) the FDA in the USA, and (ii) Health Canada in Canada by Janssen or its Affiliates or the equivalent filings in any other country outside of the USA.

"**Master Batch Record**" means a formal set of instructions for the Manufacturing of each Contracted Product to be Manufactured hereunder.

"**McNeilab**" has the meaning set forth in the Recitals.

"**MFT**" means drug product in the pharmaceutical form of microfilm tablets.

[****]

[****]

"**MSA**" has the meaning set forth in the Recitals.

"**New Nordmark Know-How**" means all proprietary or confidential verbal and written information owned by Nordmark concerning the Contracted Products [****].

"**Non-Binding Period**" has the meaning set forth in Section 4.1(a).

"**Non-Force Majeure Party**" has the meaning set forth in Section 18.1.

"**Nordmark**" has the meaning set forth in the Recitals.

"**Nordmark Confidential Information**" has the meaning set forth in Section 15.1.

"**Nordmark Liability Caps**" means: (i) with respect to Costs for destruction and replacement of Contracted Product, in particular – but not limited to costs for transportation of replacement Contracted Product, the lesser of [****] Euros per Insured Incident and [****] Euros per Insurance Year; (ii) with respect to Costs of a Recall, the lesser of [****] Euros per Insured Incident and [****] Euros per Insurance Year; and (iii) with respect to Costs for claims for personal injury or death, the lesser of [****] Euros per Insured Incident and [****] Euros per Insurance Year; provided, however, that the foregoing shall not limit Nordmark's liability under this Agreement for liabilities arising from (i) fraud, fraudulent misrepresentation or willful misconduct ("Vorsatz") by Nordmark or (ii) Nordmark's internal or external expenses in respect of the Manufacture of replacement Contracted Products (other than with respect to Costs for destruction and transportation as expressly described above).

"**Nordmark Property**" has the meaning set forth in Section 13.6.

"**Nordmark SOPs**" means Nordmark's standard operating procedures.

[****]

"**Pancrelipase**" means the API extracted from porcine pancreas including one or more of protease, amylase and lipase, and can be in the form of, but not limited to pancreatin powder Ph. Eur., pancreatin powder USP, pancrelipase powder according to the according USP monograph and pancreatin pellets (USP and Ph.Eur.).

"**Partial Successor**" shall mean a Third Party which, always and in each case subject to the terms of Section 22, acquires, is assigned or otherwise receives from a Party after the Effective Date all of such Party's right, title and interest to all or certain of the Contracted Products, as

applicable, within a specific geographic territory only, but not worldwide, irrespective whether by law or by contract and irrespective by which kind of transaction or legal form.

"**Party**" and "**Parties**" has the meaning set forth in the Recitals.

"**Person**" means an individual, a limited liability company, a joint venture, a corporation, a partnership, an association, a trust, a division, an unincorporated organization, or an operating group of any of the foregoing or any other entity or organization, whether governmental or otherwise.

"**Pre-March 1, 2001 Pancreatin Know-How**" has the meaning set forth in the Recitals. "**Prior Agreement**" has the meaning set forth in the Recitals.

"**Product**" means finished drug product containing Pancrelipase as API and formulated into MFTs.

"**Product Presentation**" means each of the presentations of any Contracted Product set forth in Exhibit C and Exhibit D, and as may be amended by the Parties from time to time pursuant to Section 27.

"**Product Specifications**" means, with respect to each Contracted Product, the specifications and testing to be performed for such Contracted Product, as set forth in the product specifications referenced in (i) the Marketing Authorizations of the Contracted Products in the Territory (as defined below) as provided to Nordmark by Janssen; and (ii) Appendix VI of the Quality Agreement (as defined below). [****] Release Limits. The Product Specifications may be modified from time to time only by a written agreement of the Parties.

"**Purchase Order**" has the meaning set forth in Section 4.1(b).

"**Quality**" means any Contracted Product (i) in compliance to the applicable Product Specifications (such compliance as set forth in the applicable Certificate of Analysis), (ii) in compliance to the Marketing Authorization for such Contracted Product as provided for by Janssen to Nordmark, and (iii) Manufactured in compliance with cGMP (together (ii) and (iii) compliance as set forth in the Certificate of Compliance).

"**Quality Agreement**" means the agreement between Janssen or its Affiliate and Nordmark with an effective date of November 2, 2015 including any amendments, attachments, appendices and exhibits thereto, entered into to specify the quality assurance requirements and responsibilities of the Parties necessary for the Manufacturing, supply and acceptance of the Contracted Product, as attached hereto and incorporated herein by reference as Exhibit G.

"**Raw Materials**" means the materials and components required to Manufacture and package the Contracted Products for use in the Territory in accordance with the Product Specifications.

"**Recall**" has the meaning set forth in Section 11.2.

"**Referral Notice**" has the meaning set forth in Section 22.1.

"**Referring Party**" has the meaning set forth in Section 22.1.

"**Regulatory Approval**" means the technical, medical and scientific licenses, registrations, authorizations and approvals (including marketing authorizations) of all applicable Regulatory Authorities necessary for the commercial Manufacture, distribution, marketing, promotion, offer for sale, use, import, export and sale of a Contracted Product in a regulatory jurisdiction.

"**Regulatory Authority**" means any Governmental Authority in the Territory and Germany regulating (i) the manufacture, importation, distribution, use and/or sale of or the performance with respect to a Contracted Product or (ii) health, safety or environmental matters generally.

"**Release Executed Batch Record**" means a Batch record that has been complied in accordance with the Master Batch Record, reviewed and approved by the Nordmark quality group.

"**Renewal Term**" has the meaning set forth in Section 16.1.

"**Short Delivery**" has the meaning set forth in Section 7.4.

"**Site Uetersen**" has the meaning set forth in the Recitals.

"**Supply Forecast**" has the meaning set forth in Section 4.1.

"**Supply Prices**" means either Legacy Supply Prices or Advanced Supply Prices, as applicable.

"**Supporting Materials**" has the meaning set forth in Section 22.4.

"**Tax**" or "**Taxes**" means any federal, state, local, foreign, or other tax, fee, levy, assessment, or other governmental charge, including without limitation, income, franchise gross receipts, property, sales, use services, value added, withholding, social security estimated, accumulated earnings, alternative or add-on minimum, transfer, license, privilege, payroll, profits, capital stock, employment, unemployment, excise, severance, stamp, occupancy, customs, or occupation tax, including any interest, additions to tax and penalties in connection therewith.

"**Technology Transfer Assets**" has the meaning set forth in Section 16.6.4.1.

"**Technology Transfer**" has the meaning set forth in Section 16.6.4.1.

"**Term**" has the meaning set forth in Section 16.1.

"**Territory**" means the USA and Canada.

"**Third Party**" means any Person other than Nordmark or Janssen or an Affiliate of Nordmark or Janssen.

"**Unit**" means one individually packaged bottle of one hundred (100) Intermediate Product MFT containing capsules, unless specified otherwise in Legacy Supply Prices or Advanced Supply Prices.

"**USA**" means the United States of America and its territories, possessions and commonwealths.

"**Young Person**" has the meaning set forth in Exhibit I.

2. GRANT OF RIGHTS

2.1 **Know-How License**. Subject to the terms of this Agreement and in particular, but not limited to, subject to the process and mechanism set out in Section 2.3 and the last sentence of this Section 2.1 (i.e. the terms identified "for clarify" hereafter), Nordmark hereby grants Janssen an exclusive, royalty-free, non-transferable (except as permitted under Section 23.1) license to use the Licensed Know-How during the Term within the Territory, solely for the purposes of (i) filing, maintaining, amending, supplementing, or renewing Regulatory Approvals owned by Janssen in the Territory for any Contracted Product, and (ii) marketing and selling any Contracted Product in the Territory (the "**Know-How License**"). For clarity, (a) no license is granted by Nordmark under the Licensed Know-How to Janssen to Manufacture itself or have Manufactured by Third Parties any Contracted Product or any other products, and Janssen shall not use any of the Licensed Know-How to Manufacture itself or have Manufactured by Third Parties any Contracted Product or any other products (except as set forth in Section 16.6.4); (b) Janssen shall not sublicense the Licensed Know-How to any Third Parties without the prior written consent of Nordmark (except as set forth in Section 16.6.4); (c) [****]; (d) the Know-How License does not include any rights or licenses in respect of the marketing, sale or importation of Intermediate Product or Bulk Product in the Territory by Janssen; and (e) the Know-How License shall not restrict Nordmark's right to grant a license under the Licensed Know-How to a Third Party inside or outside the Territory with respect to any product (other than the Contracted Products), including – but not limited to – with respect to [****], for any purpose whatsoever, including – but not limited to – (i) to use the Compound in respect of any product that is not a Contracted Product, and/or (ii) to use the Licensed Know-How for (x) manufacturing, (y) filing, maintaining, amending, supplementing or renewing regulatory approvals for any product that is not a Contracted Product,, (z) marketing and selling any product that is not a Contracted Product (including, but not limited to, medicinal products) whether or not containing the Compound and whether or not in the same or comparable therapeutic area or indication as the Contracted Products.

2.2 **Trademark License**. Janssen grants to Nordmark during the Term a non-exclusive, royalty-free, non-transferable (except as permitted under Section 23.1) license to use Janssen Trademarks for the sole purpose of allowing Nordmark to fulfill its responsibilities under this Agreement during the Term. Nordmark shall only use the Janssen Trademarks as directed by Janssen and in a manner consistent with the quality of products and services previously offered under such Janssen Trademarks. Such license shall not be transferable in whole or in part and shall immediately cease upon the early termination or expiration of this Agreement. Janssen shall be solely responsible for selecting, registering and enforcing Janssen Trademarks used to identify each Contracted Product and, except as set forth herein, shall have sole and exclusive rights in such Janssen Trademarks.

2.3 **Process and Mechanism**. No documents, submissions, written communications or written responses that incorporate or include any Licensed Know-how shall be filed to

any Regulatory Authority by Janssen without the prior written approval of Nordmark, which approval shall not unreasonably be withheld, and decisions will be made by Nordmark in a timely manner. Without limiting the generality of the foregoing, if Nordmark fails to approve or disapprove in writing a request to incorporate or include any Licensed Know-How in any regulatory filing within thirty (30) Business Days of Janssen's request, Nordmark shall be deemed to have approved such request, unless Nordmark reasonably informs Janssen in writing within such thirty (30) Business Day period that (i) more information is necessary, or (ii) more time is needed, to make a decision, in such case the Parties shall determine in good faith a mutually acceptable extension to such thirty (30) Business Day period. No documents, submissions, communications or responses that incorporate or include any Licensed Know-How which in accordance with the first sentence of this Section were filed with any Regulatory Authority by Janssen shall be made available by Janssen directly or indirectly to any other Third Party other than such Regulatory Authority. In the event Janssen requires material assistance from Nordmark with any regulatory filing, Nordmark shall provide such assistance to Janssen under a mutually agreed Statement of Work under the MSA.

2.4 **No Further Rights**. Except as otherwise provided in this Section 2, no right, title, interest or license by Nordmark to Janssen is either granted or implied under any trademark, patent, copyright, trade secrets, know-how and/or any other intellectual property right (collectively, "**Intellectual Property Rights**") by (i) granting the Know-How License under Section 2.1, (ii) providing certain know-how [****], (iii) disclosure by Nordmark in accordance with this Agreement, and/or (iv) selling any Contracted Product to Janssen.

2.5 **Acknowledgement Regarding Ownership**. Janssen acknowledges that it is not the owner of the Licensed Know-How or Nordmark's Intellectual Property Rights. Nordmark shall own the Licensed Know-How and all of its Intellectual Property Rights regarding all deliverables created and/or Contracted Products Manufactured by Nordmark in connection with the performance of Nordmark under this Agreement.

3. SUPPLY AND PURCHASE OBLIGATIONS

3.1 **Agreement to Purchase and Supply**. Subject to the terms and conditions of this Agreement, Janssen shall purchase from Nordmark, and Nordmark shall Manufacture and deliver to Janssen, any Contracted Products in accordance with Sections 3.3 and 4 of this Agreement. Such Contracted Product shall be sold by Janssen only in the Territory. Each Contracted Product sold hereunder shall conform to the Product Specification for such Contracted Product. [****].

3.2 **Exclusivity of Supply**. Janssen shall purchase all of its requirements of Contracted Products from Nordmark and shall not move the Manufacture of any Contracted Product to a Janssen facility or a Third Party facility without agreement in writing by Nordmark.

3.3 **Minimum Order Quantity.** The annual (per Calendar Year) minimum order quantity of Contracted Products is equivalent to not less than [****] Batches (Batch size [****]) of Intermediate Product (the "**Annual Minimum Order Quantity**"). Janssen shall purchase

not less than the Annual Minimum Order Quantity per Calendar Year. For clarity, the Annual Minimum Order Quantity may be met by purchasing individual Batches that are comprised solely of Legacy Products, solely of Advanced Products or combinations of both Legacy Products and Advanced Products. If, prior to the conclusion of any Calendar Year, [****]. If the Purchase Orders do not reach at least [****] of the Annual Minimum Order Quantity in each of [****], such shortfall shall be considered a material breach and Nordmark may terminate the Agreement with [****] written notice (without prejudice to Nordmark's right to claim the aforementioned compensation for the shortfall); provided, however, that if a failure of Janssen to place Purchase Orders for amounts of Contracted Products equal to at least [****] of the Annual Minimum Order Quantity is the result of a Force Majeure Event, or the Parties otherwise agree in writing not to count a failure of Janssen towards the [****] threshold described above, the Parties shall not consider such failure for the purposes of determining Nordmark's rights and remedies set forth in this sentence.

4. FORECASTS AND PURCHASE ORDERS

4.1 **Supply Forecasts**. Prior to the [****], Janssen shall provide Nordmark a written forecast of its anticipated monthly requirements for each Contracted Product for the next succeeding [****] ("**Supply Forecast**"). Each Supply Forecast shall be binding on Janssen in accordance with the following:

(a) Subject to Sections 4.3 and 4.5, Janssen shall be obligated to purchase [****] of the quantity of any Contracted Product forecasted for each of the [****] of each Supply Forecast (the "**Firm Period**"). The quantities of Units of each Contracted Product forecasted for delivery in the [****] of such Supply Forecast (the "**Non-Binding Period**") shall be non-binding.

(b) Subject to the Lead Time, Janssen shall place written Purchase Orders for the quantities of each Contracted Product with Nordmark (each, a "**Purchase Order**") covered in the Firm Period of each Supply Forecast. Each Supply Forecast shall be accompanied by a Purchase Order for the last month of the Firm Period (if not previously delivered), such that each Purchase Order is delivered at least [****] in advance of the Delivery Date specified therein.

(c) In the event that Janssen fails to timely provide a Supply Forecast as provided in this Section 4.1, Nordmark may, in its discretion, rely on [****]. [****]. Janssen shall be bound [****] in accordance with Section 4.1(b), and Nordmark shall be bound, subject to the following sentence, to accept Purchase Orders for the Firm Period in accordance with Section 4.4. The obligation to accept Purchase Orders for the Firm Period is subject to a [****] (the "**Annual Maximum Order Quantity**"). For clarity, the Annual Maximum Order Quantity may be met by purchasing individual Batches that are comprised solely of Legacy Products, solely of Advanced Products or combinations of both Legacy

Products and Advanced Products. In case of higher quantities, Nordmark and Janssen will agree on a prolonged Lead Time.

4.2 **Purchase Orders**. Each Purchase Order shall specify, subject to the Annual Maximum Order Quantity, the quantities of Units of each Contracted Product to be delivered, and, subject to the Lead Time, the proposed Delivery Date and the delivery location(s) for such quantities of Units of each Contracted Product. Subject to Sections 4.3 and 4.5, such Purchase Orders, including quantities of each Contracted Products, shall be consistent with the quantities set forth in the Firm Period of the applicable Supply Forecast and otherwise in compliance with the terms set forth in this Section 4.

4.3 **Intermediate Product Variation**. It is agreed upon between the Parties that (i) always full Intermediate Product Batches ([****]) are used in one (1) production campaign and (ii) due to the fact that in relation to the Manufacture all Contracted Products ([****]) are filled by mass according to the individual lipolytic activities of the respective Intermediate Product ([****]) Batch, as a consequence the resulting number of Units per such Intermediate Product Batch ([****]) may vary by [****]. Furthermore the Parties agree that (i) in case the number of Units are lower than indicated in the respective Purchase Order, and provided that such number of Units is not more than [****] than the number indicated in the applicable Purchase Order, such lower number of Units will not be considered as a Short Delivery and Janssen will only pay the Supply Price for such lower number of Units to Nordmark, and (ii) in case the number of Units are higher than indicated in the respective Purchase Order, and provided such number of Units is not more than [****] than the number indicated in the applicable Purchase Order, Nordmark will be allowed to ship such higher number of Units, and Janssen will pay the Supply Price for such higher number of Units to Nordmark. In the event, the number of Units is greater than [****] than the number indicated in the applicable Purchase Order, Nordmark shall prior to shipping such excess Units, notify Janssen of the amount of such excess Units, and Janssen shall in its sole discretion approve or reject shipment of such excess Units.

4.4 **Purchase Order Confirmation and Rejection**. Nordmark, in writing, shall confirm, reject or otherwise respond to Janssen within [****] in accordance with the terms of this Agreement. In the event Nordmark is unable to fulfill a Purchase Order consistent with the quantities set forth in the Firm Period of the applicable Supply Forecast or within the Delivery Date proposed by Janssen, Nordmark shall notify Janssen immediately, but in any event no later than within [****]. Nordmark shall not reject any Purchase Order that is consistent with the applicable Supply Forecast provided in accordance with Section 4.1. For clarity, Nordmark is not obligated to accept or agree to the Delivery Date proposed by Janssen in the Purchase Order that does not reflect the Lead Time or exceeds the Annual Maximum Order Quantity, provided that Nordmark shall use commercially reasonable efforts to meet such Delivery Date in each case. For the avoidance of doubt, nothing in this Section 4.4 shall limit the liability of Nordmark under Section 7.5 of this Agreement with respect to its failure to supply the quantities of Contracted Products specified in the Firm Period of the Supply Forecast. Unless otherwise mutually agreed in writing by the Parties and subject to Sections 4.3 and 4.5, Nordmark shall supply and deliver such quantities of Contracted Product to Janssen as set forth in each confirmed

Purchase Order no later than [****] after the Delivery Date specified therein; provided, however, that in the event of corrective actions agreed between the Parties (i) Nordmark is not obligated to supply and deliver no later than [****] after the Delivery Date specified in the Purchase Order, and (ii) the Parties will agree in good faith a new Delivery Date. In case the Parties do not reach agreement, each Party may refer the matter to the Expert or Expert Panel pursuant to Section 22. A Purchase Order that has been confirmed by Nordmark may not be cancelled by Janssen without the prior written consent of Nordmark.

4.5 **Exemption Clause**. It is agreed upon between the Parties that (i) in case that in a production campaign of Intermediate Product [****] Batches where no Intermediate Product [****] Batch is suitable for the Manufacture of the [****] Legacy Products, or (ii) in case that in a production campaign of Intermediate Product [****] Batches where no Intermediate Product [****] dry Batch is suitable for the Manufacture of the [****] Advanced Products, Nordmark will not be obliged to deliver any such [****] Legacy Product or [****] Advanced Product on the Delivery Date as specified in the Purchase Order and any delivery after the Delivery Date specified in the Purchase Order shall not be considered a Late Delivery. Nordmark will inform Janssen [****] prior to any Bulk Product production campaign whether there will be fractions of such Intermediate Product [****] or Intermediate Product [****] Batches intended but unfit for the use in the Manufacture of the according [****] Legacy Bulk Products and/or [****] Advanced Bulk Product. Janssen agrees that Nordmark will be entitled to use the remaining quantity of any such Intermediate Product [****] or Intermediate Product [****] Batch for any other Legacy Product or Advanced Product at Janssen's discretion with respect to which of the Contracted Products the remaining quantity is used, unless Janssen informs Nordmark in writing at least [****] prior to the production campaign of the according Bulk Products that it chooses to compensate Nordmark for unused Intermediate Product [****] or Intermediate [****] dry material instead of converting it to any Contracted Product. In that case Nordmark will discharge such unused Intermediate Product [****] or Intermediate Product [****] material. Notwithstanding the foregoing, Janssen shall be entitled to require Nordmark to produce new Intermediate Product [****] in a quantity sufficient to Manufacture the [****] Legacy Bulk Products and/or [****] Advanced Bulk Products designated in the applicable Purchase Order using the commercially reasonable quickest possible way (but in any event no later than [****] from Nordmark notifying Janssen of the Intermediate Product [****] shortfall).

4.6 **Efforts to Supply**. From time to time, Janssen may submit Purchase Orders for any Contracted Product in excess of the number of Units specified for the same Calendar Month of the Firm Period in the most recent Supply Forecast. Nordmark shall use all commercially reasonable efforts to Manufacture such excess Units. In the event that Nordmark is unable to Manufacture such excess Units by the Delivery Date specified in the applicable Purchase Order, Nordmark shall provide Janssen with the best available Delivery Date for the excess Units. A failure by Nordmark to provide such excess Units shall not be deemed a breach by Nordmark of this Agreement or a failure to supply.

4.7 **Changes to Pending Purchase Orders**. Janssen may increase or decrease the number of Units that it intends to purchase of a particular Contracted Product using the Intermediate

Product [****] in a pending Purchase Order, provided that, any such increase or decrease is offset by a corresponding increase or decrease in a different Contracted Product using the Intermediate Product [****] such that Janssen is still using up the entire quantity of the Intermediate Product [****] Batch it was obligated to purchase under the original Purchase Order and such request to increase or decrease the amount of Units is provided to Nordmark no later than [****] Business Days prior to the Delivery Date for such Units; provided, that, Nordmark shall consider in good faith decreasing such notice period at the request of Janssen and shall use commercially reasonable efforts to fulfill Janssen's request to the extent Janssen is unable to provide notice to Nordmark within such notice period. Nordmark shall consider in good faith, but shall have no obligation to agree to, any other changes to pending Purchase Orders requested by Janssen.

4.8 **Order Cancellation**.

4.8.1 **Raw Materials**. Janssen acknowledges and agrees that, in order for Nordmark to meet its obligation to supply Contracted Products under this Agreement, Nordmark must order Raw Materials in accordance with defined lead times and any minimum order quantities imposed by Third Party vendors. Nordmark shall be entitled to order, and shall maintain, quantities of Raw Materials required to Manufacture those Contracted Products forecasted by Janssen for up to the first [****] of the Supply Forecast so that Nordmark shall be able to comply with Delivery Dates for all Purchase Orders and anticipated orders of any Contracted Product; provided, however, that in relation to certain Raw Materials set forth in Exhibit M, Nordmark shall be entitled to order, and shall maintain, quantities of these Raw Materials according to the minimum order quantities as also set forth in Exhibit M. Nordmark shall be responsible for, and shall administer on a daily basis, the procurement of the Raw Materials in accordance with the terms herein. Except as permitted by the Quality Agreement, Nordmark shall not initiate any changes or make any substitutions to the Raw Materials or to the Third Party vendors of the Raw Materials. Nordmark's responsibilities in connection with the purchasing and procurement of Raw Materials from the Third Party vendors in accordance with the terms of this Agreement shall include: ordering, purchasing, transportation, reception, inspection, release and storage of Raw Materials. For clarity, according to the Quality Agreement, Janssen shall be solely responsible for the qualification and monitoring of the following suppliers: (i) the glass bottles [****], and (ii) the closures [****].

4.8.2 **Reimbursement for Unused Raw Materials**. To the extent Nordmark has purchased Raw Materials in accordance with Section 4.8.1, but subsequent to such purchase and prior to the conversion of any Raw Materials into any Contracted Product, Janssen either cancels a Purchase Order or does not issue a Purchase Order in accordance with the Firm Period of a Supply Forecast or informs Nordmark that it no longer desires to have Nordmark use such Raw Materials in any Contracted Product, Nordmark shall first use good faith efforts to utilize such Raw Materials in other of Nordmark's or its customers' products or return such Raw Materials to applicable Third Party vendors and receive a credit for such purchase. If Nordmark is unable to utilize the Raw Materials in some

other aspect of its business and the Third Party vendor refuses to accept such Raw Materials and provides Nordmark with a credit, then Nordmark shall invoice Janssen for the cost of such Raw Materials within [****] days of Janssen cancelling a Purchase Order or not issuing a Purchase Order in accordance with the Firm Period of a Supply Forecast or informing Nordmark that it no longer desires to have Nordmark use such Raw Materials in any Contracted Product and Janssen [****]. After receipt of payment for such Raw Materials, Nordmark shall destroy such Raw Materials, as directed by Janssen. Janssen shall reimburse Nordmark for all reasonable and documented costs and expenses relating to the destruction of such Raw Materials.

4.9 **Forms**. Subject to Section 4.2, in ordering or delivering any Contracted Product, each Party may use its respective standard form of Purchase Order, provided that nothing in those forms shall be construed to modify or amend the terms and conditions of this Agreement. In the event of any conflict between the terms and conditions of any such form and the terms and conditions of this Agreement, the terms and conditions of this Agreement shall control.

5. PERMITS; DMF(S) AND CGMP; COMPLIANCE

5.1 **Manufacturing Permits**. As of the Effective Date, Nordmark shall be responsible for obtaining, at its expense, any licenses or permits and any regulatory and government approvals, necessary to Manufacture each Contracted Product, including all licenses and permits required for the operation of Nordmark's facilities. Janssen shall be solely responsible for satisfying the FDA Establishment Fee in the USA and comparable fees in Canada as the holder of the Marketing Authorizations in the Territory.

5.2 **Regulatory Approvals, DMF**. Nordmark, at its sole cost and expense, shall file and shall maintain a valid DMF during the Term, all in accordance with applicable Law. Nordmark shall provide Janssen with an access letter or right of reference letter entitling Janssen to make continuing reference to the DMF in connection with any regulatory filings made with respect to any Contracted Product with a Regulatory Authority by Janssen. For clarity, the filing, maintenance and associated costs thereof in respect of any other drug master files referenced in any Janssen or Marketing Authorizations of a Third Party shall not be the responsibility of Nordmark.

5.3 **Compliance**. Upon Janssen's request, Nordmark shall provide a Certificate of Analysis and a Certificate of Compliance with any shipment of any Contracted Product delivered hereunder. All quantities of any Contracted Product delivered to Janssen under this Agreement shall be Manufactured in accordance with cGMP and conform to the Product Specification for such Contracted Product.

5.4 **Environmental, Safety and Industrial Hygiene**. With respect to all environmental, safety and industrial hygiene matters related to Nordmark's activities provided for Janssen, Nordmark shall, at its expense (i) comply with all applicable Law, (ii) inform Janssen promptly of any significant adverse event (e.g., fires, explosions, accidental discharges), and (iii) implement any corrective action which may be commercially

reasonably requested by Janssen within the time frame agreed between the Parties (but in any event within a commercially reasonable period of time).

6. SUPPLY COST AND PAYMENT

6.1 **Legacy Product Supply Price**. In consideration of the supply of any Legacy Product by Nordmark to Janssen under the terms and conditions of this Agreement, Janssen shall pay Nordmark the supply prices set forth in Exhibit E ("**Legacy Supply Prices**").

6.2 **Advanced Product Supply Price**. In consideration of the supply of any Advanced Product by Nordmark to Janssen under the terms and conditions of this Agreement, Janssen shall pay Nordmark the supply prices set forth in Exhibit F ("**Advanced Supply Prices**") plus a [****] ("**Licensed Know-How Fee**") of the then agreed and thus valid [****]; provided, however, that Nordmark agrees to [****] (the "**Achievement Date**"). [****]. Unless otherwise mutually agreed to by the Parties in writing, the Licensed Know-How Fee [****].

6.3 **Supply Price Adjustment**. The Supply Prices under this Agreement shall be reviewed annually by the Parties beginning [****] prior to the end of each Calendar Year. In connection with such pricing reviews, Nordmark shall produce documentation as to the changes if any, in (i) the costs of [****] and (ii) changes to the [****]. The Parties shall cooperate to determine whether such changes affect Nordmark's costs of Manufacturing each Contracted Product and, if such changes are determined to affect such costs the Supply Price shall be increased or decreased, as applicable to reflect such cost changes by an amount mutually agreed upon by the Parties. The Parties agree that the proposed Supply Price increase shall not exceed [****] of the then current Supply Price unless Nordmark's cost increase (including documented cost increases for Raw Materials) exceeds [****]. Such Supply Price increases shall be applicable to any and all Purchase Orders with a Delivery Date on or after January 1st of the Calendar Year for which such Supply Price increase was mutually agreed upon by the Parties. In case the Parties do not reach mutual agreement before January 1st of such Calendar Year, each Party may refer the matter to the Expert or Expert Panel pursuant to Section 22. The decision of the Expert or Expert Panel on the Supply Price increases shall be binding, and the Supply Price increase determined by the Expert or Expert Panel pursuant to Section 22 shall be applicable to any and all Purchase Orders with the Delivery Date on or after January 1st of the Calendar Year following the reference to the Expert or Expert Panel (if the matter was referred to the Expert or Expert Panel before January 1st of such Calendar Year) or the concerned Calendar Year (if the matter was referred after January 1st).

6.4 **Cost Improvements**. During the Term of this Agreement the Parties shall work together to develop reasonable and implementable cost reduction projects related to the Manufacture of any Contracted Product. The Parties shall allocate any resulting cost savings between themselves, in pro rata proportion to the financial investment made by each Party to recognize such cost improvements.

6.5 **Invoicing**. Nordmark shall invoice Janssen for Contracted Product on the Delivery Date. Each invoice shall be payable by Janssen within [****] after receipt of such invoice,

except for amounts disputed in good faith in accordance with Section 6.6. Any undisputed payment due under this Agreement not received within [****] after receipt of such invoice shall, at Nordmark's option, bear interest at the lesser of (i) the maximum rate permitted by Governing Law, or (ii) [****]. Janssen may reject any invoice, if such invoice is sent to Janssen more than [****]; and shall not be obligated to pay any amounts, including any pass-through expenses or Taxes that otherwise would have been reimbursable in accordance with this Agreement.

6.6 **Payment Disputes**. If Janssen in good faith believes that some portion of the amount invoiced by Nordmark was in error, Janssen shall pay all undisputed amounts when due and shall notify Nordmark in writing of its dispute within thirty (30) days of receipt of the invoice, specifying in reasonable detail the nature of the dispute and identifying the portion of the invoice that is disputed. The Parties shall in good faith work together to promptly resolve such dispute. Once such dispute is resolved, if additional payment is required by Janssen, Nordmark shall issue Janssen a new invoice including if applicable any interest according to Section 6.5 to be paid by Janssen in accordance with Section 6.5 above.

6.7 **Payment Terms**. All amounts due under this Agreement shall be made by EFT of [****] to an account designated in writing by Nordmark.

6.8 **Withholding Tax**. Janssen shall make all payments to Nordmark under this Agreement [****]. Any Tax required to be withheld on amounts payable by Janssen under this Agreement shall be [****]. Any such Tax required to be withheld shall be an expense of and borne by [****]. If any such Tax is assessed against and paid by [****]. The Parties shall cooperate with respect to all documentation required by any taxing authority or reasonably requested by [****].

6.9 **Default in Payment Obligations**. In addition to all other remedies available to Nordmark in the event of a Janssen default, or if Janssen fails to make payments as required hereunder (with the exception of those payments involving a good faith disputed amount) [****], Nordmark may refuse all further Purchase Orders until Janssen's account is paid in full.

7. DELIVERY OF CONTRACTED PRODUCT

7.1 **Delivery Terms**. Any Contracted Product shall be delivered to Janssen, or to a location designated by Janssen in the Purchase Order, [****], by a common carrier designated by Janssen in the Purchase Order, [****]. Nordmark reserves the right to load and ship any Contracted Product during normal business hours and per a mutually agreed upon shipment schedule.

7.2 **Shipment**. Nordmark shall pack all Contracted Products ordered hereunder in a manner agreed upon by both Parties that is suitable for shipment, sufficient to enable the Contracted Products to withstand the effects of shipping, including handling during loading and unloading, and in compliance with applicable shipment guidelines as outlined in the Quality Agreement.

7.3 **Wooden Pallets**. This clause applies to all Contracted Products and/or materials shipped to Janssen or authorized locations on wooden pallets. Wooden pallets shall be made from wood that is certified to be free of 2, 4, 6-tribromophenol (TBP) and any other form of phenol-based fungicide treatment, and shall comply with the International Standards for Phytosanitary Measures Publication No. 15, 2009 Revision (ISPM 15) for heat treatment only. While ISPM 15 currently provides for the use of Methyl Bromide (MB), the use of pallets fumigated with Methyl Bromide is also prohibited. All wooden pallets shall properly display that they meet the requirements with a specified mark as shown in ISPM 15 Annex II. Failure to meet this requirement may lead to rejection of Contracted Product shipments at Nordmark's expense.

7.4 **Quantity Check**. Janssen shall be responsible for ensuring that the Contracted Products are subjected to a quantity check following their arrival at Janssen (or at the location designated by Janssen in the Purchase Order) and all Contracted Products shall be deemed to have been delivered in the correct quantity (i.e. no Short Delivery), unless within thirty (30) days of their arrival at Janssen or at the location designated by Janssen in the Purchase Order, Janssen has given notice in writing to Nordmark of the existence of a shortage of the number of Units as indicated in the Purchase Order (after taking into account [****] pursuant to Section 4.3) being found upon receipt of the respective Contracted Products ("**Short Delivery**"), giving details of the Short Delivery in question.

7.5 **Short Delivery**. In the event that Janssen notifies Nordmark in writing with reference to this Section 7.5 of a Short Delivery and if Janssen's claim is confirmed, Janssen shall be entitled to require Nordmark to deliver those quantities required to make up the Short Delivery using the commercially reasonable quickest possible way (but in any event no later than [****] at Janssen or at the location designated by Janssen in the Purchase Order from the date of the receipt of the written Short Delivery notice) at Nordmark's cost and risk. The aforementioned rights and remedies are the sole and exclusive rights and remedies of Janssen in case of Short Delivery and all other rights and remedies are expressly excluded, unless Nordmark acted in gross negligence or willful misconduct. Notwithstanding the foregoing, if more than [****] Short Deliveries occur within a certain [****] period, then Janssen's rights and remedies in respect of any Short Delivery thereafter within such [****] period shall not be limited by this Section 7.5 and such [****] or more Short Deliveries occurring in the same [****] period may collectively be considered a material breach of this Agreement and, provided that Nordmark acted culpably, Janssen shall have the right to seek damages for any such Short Delivery not cured by Nordmark pursuant to this Section 7.5; provided, however, that (i) if Janssen has not notified Nordmark of such breach in writing at the latest by the end of the [****] period following the occurrence of the [****] Short Delivery, or (ii) in the event a Short Delivery is the result of a Force Majeure Event or the Parties otherwise agree in writing to not count a Short Delivery towards the [****] Short Delivery threshold described above, the Parties shall not consider such Short Delivery for the purposes of determining Janssen's rights and remedies set forth in this sentence.

7.6 **Late Delivery**. Nordmark shall notify Janssen in writing with reference to this Section 7.6 of any delivery that will occur later than [****] after the Delivery Date specified in the applicable Purchase Order ("**Late Delivery**"). Janssen shall also notify Nordmark in

writing with reference to this Section 7.6 of any delivery that actually occurs later than [****] after the Delivery Date specified in the applicable Purchase Order. Janssen shall be entitled to require Nordmark to deliver those quantities required to make up the Late Delivery using the commercially reasonable quickest possible way (but in any event no later than [****] at Janssen or at the location designated by Janssen in the Purchase Order from the date of the receipt of the written Late Delivery notice) at Nordmark's cost and risk. For any Late Delivery occurring more than [****] after the Delivery Date specified in the applicable Purchase Order, Janssen shall receive a discount of [****] on the then current Supply Prices. The aforementioned rights and remedies are the sole and exclusive rights and remedies of Janssen in case of Late Delivery and all other rights and remedies are expressly excluded, unless Nordmark acted in gross negligence or willful misconduct. Notwithstanding the foregoing, if more than [****] Late Deliveries occur within a certain [****], then Janssen's rights and remedies in respect of any Late Delivery thereafter within such [****] period shall not be limited by this Section 7.6 and such [****] or more Late Deliveries occurring in the same [****] period may collectively be considered a material breach of this Agreement and, provided that Nordmark acted culpably, Janssen shall have the right to seek damages for any such Late Delivery not cured by Nordmark pursuant to this Section 7.6; provided, however, that (i) if Janssen has not notified Nordmark of such breach in writing at the latest by the end of the [****] period following the occurrence of the [****] Late Delivery, or (ii) in the event a Late Delivery is the result of a Force Majeure Event or the Parties otherwise agree in writing to not count a Late Delivery towards the [****] Late Delivery threshold described above, the Parties shall not consider such Late Delivery for the purposes of determining Janssen's rights and remedies set forth in this sentence. For the avoidance of doubt, the Parties expressly agree that if the Parties have agreed on corrective actions as set forth in Section 4.4 and Nordmark has not delivered within [****] after the Delivery Date specified in the respective purchase order, this shall not be deemed a Late Delivery.

8. QUALITY AGREEMENT; NON-CONFORMING CONTRACTED PRODUCTS; DEFECTS

8.1 **Quality Agreement**. The Parties have entered into a Quality Agreement regarding the production by Nordmark of Contracted Products, which is attached hereto and incorporated herein as Exhibit G. In the event of any conflict or inconsistency between any term in this Agreement related to quality assurance matters and any term of the Quality Agreement, the terms of the Quality Agreement shall control.

8.2 **Product Conformity**. Within [****] from receipt of the Release Executed Batch Record (if requested by Janssen), the Certificate of Analysis and the Certificate of Compliance by Janssen from Nordmark, Janssen shall (i) inspect, test and determine whether any Contracted Product conforms to Quality, and (ii) inspect the relevant accompanying documentation (under the Quality Agreement) which (if requested by Janssen) may include the Release Executed Batch Record. Janssen shall notify Nordmark in writing without undue delay of its acceptance of such Contracted Product conforming to Quality ("**Acceptance**").

8.2.1 If Janssen fails to notify Nordmark within the applicable time period that any shipment of Contracted Product does not conform to Quality (i.e. does have a Defect), then such Contracted Product shall be deemed to have been delivered free from any Defect which is detectable by any test or inspections to be performed by Janssen in accordance with the Quality Agreement ("**Apparent Defect**") and Acceptance shall be deemed to have occurred on the [****] after the Delivery Date and Janssen shall have waived its rights (i) to revoke Acceptance and (ii) regarding any Apparent Defects.

8.2.2 If Janssen believes any shipment of Contracted Product does not conform to Quality (i.e. does have a Defect), it shall notify Nordmark by e-mail and provide a detailed explanation of the non-conformity. Upon receipt of such notice, Nordmark shall investigate such alleged non-conformity, and (i) if Nordmark agrees such Contracted Product is non-conforming, deliver to Janssen a corrective action plan within [****] after receipt of Janssen's written notice of non-conformity, or such additional time as is reasonably agreed to by Janssen if such investigation or plan requires data from sources other than Janssen or Nordmark, or (ii) if Nordmark disagrees with Janssen's determination that the shipment of Contracted Product is non-conforming, Nordmark shall so notify Janssen by e-mail within the [****] period.

8.2.3 If the Parties dispute whether a shipment of Contracted Product is conforming or non-conforming to Quality, the shipment of Contracted Product shall be submitted to the Expert or Expert Panel pursuant to Section 22 for evaluation and the determination by the Expert or Expert Panel of conformity or nonconformity to Quality, and the cause thereof if nonconforming to Quality, shall be binding upon the Parties. The incorrect Party shall bear the costs of such Expert or Expert Panel, absent manifest error. The fees and expenses of the Expert or Expert Panel incurred in making such determination as well as all additional associated costs shall be paid as follows:

8.2.3.1 In the event the allegedly non-conforming Contracted Product is determined to be conforming to Quality, all such fees and expenses for the Expert or Expert Panel, including freight and disposition costs, shall be paid by Janssen.

8.2.3.2 In the event such independent Expert or Expert Panel determines the tested Contracted Product to be non-conforming to Quality and determines further such non-conformance was caused by Nordmark or Nordmark's suppliers (with the exception of the suppliers identified in Section 4.8.1 (last sentence)) (i) all such fees and expenses for the Expert or Expert Panel, including reimbursement of freight and disposition costs, shall be paid by Nordmark; and (ii) the Parties shall jointly investigate the cause of such failure and shall reasonably cooperate in order to resolve the issue(s) underlying such failure as described in the Quality Agreement.

8.2.3.3 In the event the tested Contracted Product is determined by such independent Expert or Expert Panel to be non-conforming, but such Expert or Expert Panel is not able to determine the cause of such non-conformance, all such fees and expenses for the Expert or Expert Panel, including freight and disposition costs, shall be borne equally by the Parties.

8.2.3.4 In the event such independent Expert or Expert Panel determines the tested Contracted Product to be non-conforming and determines further that such non-conformance was caused by Janssen or any of Janssen's suppliers or contractors, or was otherwise caused after the Delivery Date of the relevant Contracted Product, all such fees and expenses for the Expert or Expert Panel, including freight and disposition costs, shall be borne by Janssen.

8.3 **Latent Defect**. If, within [****] after Janssen's Acceptance of any Contracted Product, Janssen discovers a Defect which is not detectable by any tests or inspections to be performed by Janssen in accordance with the Quality Agreement (in each case, a "**Latent Defect**") such as, without limitation, a contaminant in such Contracted Product that existed in the Contracted Product on or before Janssen's Acceptance of such Contracted Product, Janssen shall, promptly upon discovery thereof, notify Nordmark in writing with reference to this Section 8.3 of any such Latent Defect, and Janssen shall have the right to reject such Contracted Product under the procedures regarding rejection set forth in Section 8.2 above. For clarity, a contaminant, which is detectable by any tests or inspections to be performed by Janssen in accordance with the Quality Agreement, shall be deemed an Apparent Defect. If Janssen fails to notify Nordmark within the applicable time period about a Latent Defect, then Contracted Product shall be deemed to have been delivered free from any Latent Defect and Janssen shall have waived any and all rights regarding any Latent Defects.

8.4 **Remedies for Non-Conforming Contracted Product**. In the event Nordmark or the Expert or Expert Panel determines that the Contracted Products are non-conforming (i.e. have a Defect), Nordmark shall produce replacement Contracted Product for such Contracted Product that contains a Defect by a date mutually agreed to by the Parties, but in any event no later than [****] from the date Nordmark, the Expert or the Expert Panel determine that the Contracted Products have a Defect; provided, that, Janssen shall have the right to request that Nordmark commence production of such replacement Contracted Product prior to a determination by the Expert or the Expert Panel that the Contracted Product is Defective; provided, further, that Janssen shall be solely responsible for the costs of such replacement Contracted Product (including the Manufacturing cost) to the extent the Expert or the Expert Panel determines that such Contracted Product is not Defective. Nordmark shall incur the costs of the Manufacturing of the replacement Contracted Product, if it was determined in accordance with Section 8.2.3.2 that the non-conformance to Quality was caused by Nordmark or Nordmark's suppliers (with the exception of the suppliers identified in Section 4.8.1 (last sentence)). If the cause for non-conforming cannot be determined in accordance with Section 8.2.3.3, the cost of the Manufacturing of the replacement Contracted Product, shall be born equally by the

Parties. In the event that it was determined that the non-conformity was caused by Janssen or any of Janssen's suppliers or contractors, or was otherwise caused after the delivery date of the relevant Contracted Product, in accordance with Section 8.2.3.4, Janssen shall incur the cost of the Manufacturing of the replacement Contracted Product. Acceptance of any part of a Batch of Contracted Product shall not bind Janssen to accept any Contracted Product that contains a Defect simultaneously provided by Nordmark, nor deprive Janssen of the right to reject any previous or future nonconforming Contracted Product. The aforementioned rights and remedies are the sole and exclusive rights and remedies of Janssen in case of an Apparent Defect and all other rights and remedies are expressly excluded, unless Nordmark acted in gross negligence or willful misconduct. For clarity: The aforementioned exclusion of other rights and remedies does not apply to Latent Defects. Notwithstanding the foregoing, if more than [****] Apparent Defects occur within a certain [****] period, then Janssen's rights and remedies in respect of any Apparent Defect thereafter within such [****] period shall not be limited by this Section 8.4 and such [****] or more Apparent Defects occurring in the same [****] period may collectively be considered a material breach of this Agreement and, provided that Nordmark acted culpably, Janssen shall have the right to seek damages for any such Apparent Defect not cured by Nordmark pursuant to this Section 8.4; provided, however, that (i) if Janssen has not notified Nordmark of such breach in writing at the latest by the end of the [****] period following the occurrence of the [****] Apparent Defect, or (ii) in the event an Apparent Defect is the result of a Force Majeure Event or the Parties otherwise agree in writing to not count an Apparent Defect towards the [****] Apparent Defect threshold described above, the Parties shall not consider such Apparent Defect for the purposes of determining Janssen's rights and remedies set forth in this sentence.

8.5 **Product Assay Release Limits**. All Contracted Products Manufactured by Nordmark for Janssen shall meet the applicable [****] release specifications for lipolytic activity ("[****] **Release Limit**") as set forth in the Product Presentations in Exhibit C and Exhibit D. Any Contracted Product that does not meet the [****] Release Limits shall be deemed to be Defective. Nordmark shall notify Janssen in writing with reference to this Section 8.5 of any such Contracted Product that does not meet the [****] Release Limits. Nordmark shall bear all of the Manufacturing costs associated with all Contracted Products that do not meet the applicable [****] Release Limit, including the cost of replacing or replenishing any Raw Materials used in such Contracted Product's Manufacture. If requested by Janssen, Nordmark shall produce replacement Contracted Product that meets the [****] Release Limit within a date mutually agreed to by the Parties, the cost (according to the applicable Supply Prices) of which shall be borne by Janssen. All other rights and remedies of Janssen in case of Contracted Products, which do not meet the [****] Release Limit, are expressly excluded, unless in case of gross negligence or willful misconduct by Nordmark. Notwithstanding the foregoing, if more than [****] failures to meet the [****] Release Limit occur within a certain [****] period, then Janssen's rights and remedies in respect of any Contracted Product that does not meet the [****] Release Limit thereafter within such [****] period shall not be limited by this Section 8.5 and such [****] or more failures to meet the [****] Release Limit occurring in the same [****] period may collectively be considered a material breach of this Agreement and, provided that Nordmark acted culpably, Janssen shall have the right to seek damages for any such failure not cured by Nordmark pursuant to this

Section 8.5; provided, however, that (i) if Janssen has not notified Nordmark of such breach in writing at the latest by the end of the [****] period following the occurrence of the [****] failure to meet the [****] Release Limit, or (ii) in the event a failure of a Contracted Product to meet the [****] Release Limit is the result of a Force Majeure Event or the Parties otherwise agree in writing to not count such failure towards the [****] failures to meet the [****] Release Limit threshold described above, the Parties shall not consider such failure for the purposes of determining Janssen's rights and remedies set forth in this sentence.

8.6 [****]. Janssen, at its discretion, may from time to time request [****]. Any requested changes to the [****] shall be made in writing, and shall not apply to any [****] to be supplied in connection with any [****]. Nordmark shall promptly notify Janssen of any [****]. For clarity, the Parties expressly agree that [****]. Janssen shall reimburse to Nordmark the [****]. If requested by Janssen, Nordmark shall [****].

9. INSPECTIONS AND AUDITS

9.1 **Manufacturing**. Nordmark shall Manufacture all Contracted Product in accordance with the applicable Product Specifications, the Quality Agreement, cGMP and any Law applicable to the Manufacturing of Contracted Product in the location where such Contracted Product is Manufactured. With prior written notice thereof, Janssen shall have the right to be present at Nordmark's facilities during Manufacturing.

9.2 **cGMP Audits**. Janssen shall have the right to audit Nordmark's facilities as described in the Quality Agreement. All information disclosed or reviewed in such inspections shall be maintained as Confidential Information in accordance with Section 15.

9.3 **Environmental, Health and Safety Audit**. In addition to the cGMP audit, Nordmark shall allow Janssen or its representative to perform one Environmental, Health and Safety audit which may take place in person or electronically every [****] years, except that if Nordmark fails such audit or material issues are discovered Nordmark shall be required to undergo such audits more frequently until all material issues are resolved. If such audit is conducted in person, Nordmark shall allow a maximum of [****] representatives from Janssen to have access for a maximum of [****] upon prior written notice, which shall include an agenda for the inspection, at a time mutually agreed upon by the Parties and during normal business hours to inspect relevant health and safety records under applicable Law relating to the health, safety, and employment of Young Persons. For the avoidance of doubt, Janssen understands that it shall not be given access to the Confidential Information of other clients of Nordmark. At all times that Janssen or its representative is on site, Janssen or its representative shall comply with Nordmark's reasonable visitor's policies.

9.4 **Testing**. Nordmark shall test, or cause to be tested by Third Party testing facilities (audited by Nordmark prior to use, in accordance with the Product Specifications) each Batch of Contracted Product Manufactured pursuant to this Agreement before delivery to Janssen. A Certificate of Analysis for each Batch of Contracted Product delivered to Janssen shall set forth the items tested by Nordmark, specifications, and test results. As

required by the FDA and any other applicable Regulatory Authority, Janssen shall be responsible for final release of each Batch of any Contracted Product.

9.5 **Stability Testing**. [****], Nordmark shall perform all stability testing required to be performed on any Contracted Product. Such testing shall be performed in accordance with the procedures set out in the Nordmark SOPs for the stability testing and each Contracted Product specific stability protocol. Such stability protocol shall contain a listing of the analytical testing and corresponding Product Specifications, to be performed on the Contracted Product in connection with the stability testing program under 21 CFR § 166 or alternatively by a previously approved protocol. All stability protocols have to be approved by Janssen, unless otherwise advised by Janssen.

9.6 **Quality Review**. [****] Nordmark shall review the quality of the Contracted Products as set forth in the Quality Agreement once annually ("**Annual Product Review**"). Nordmark shall provide Janssen a copy of the results of the Annual Product Review and recommendations, if any.

9.7 **Canadian Biologic Review**. [****] Nordmark shall be responsible for preparing and delivering to Janssen no later than [****] of each Calendar Year, the Yearly Biologic Product Report required by Health Canada to be submitted by all manufacturers of all Schedule D (Biologic) drugs in accordance with the *Guidance for Sponsors: Lot Release Program for Schedule D (Biologics) Drugs*. The review period will be analogue to the review period of the Annual Product Review.

10. PRODUCT CHANGES

10.1 **Changes in Manufacturing**.

10.1.1 **Changes to Master Batch Records and Product Specifications**. Nordmark shall inform Janssen within [****] of the result of any regulatory development or changes to any Contracted Product-specific Nordmark SOPs that may materially affect the Manufacture of such Contracted Product. In accordance with requirements in the Quality Agreement, Nordmark shall notify Janssen of and obtain written approval from Janssen for changes to Contracted Product-specific Master Batch Records and Product Specifications prior to the Manufacture of subsequent Batches of such Contracted Product.

10.1.2 **Product-Specific Changes**. If facility, equipment, process, system or specification changes are required of Nordmark as a result of requirements set forth by the FDA or any other Regulatory Authority, and such regulatory changes apply solely to the Manufacturing and supply of the Contracted Products, the Parties shall review such requirements and agree in writing to such regulatory changes, including reasonable costs thereof. Unless otherwise mutually agreed to in writing, Janssen shall bear [****] of the costs (i) [****]. In the event any facility, equipment, process, system or specification changes are required of Nordmark as a result of requirements set forth by the FDA or any other Regulatory Authority, and such regulatory changes apply both to the

Manufacturing and supply of the Contracted Products and the products of other Nordmark customers, the Parties agree to negotiate in good faith a reasonable allocation of the costs (if any) associated with such changes. If the Parties cannot agree on how to allocate the costs of any other changes, this matter shall be referred to the Expert or Expert Panel pursuant to Section 22, and the Expert or Expert Panel shall finally determine the allocation of costs. For clarity, Nordmark is under no obligation to implement any changes unless there is agreement between the Parties regarding the costs.

10.1.3 **Nordmark Initiated Changes**: If facility, equipment or system changes are required of Nordmark as a result of Nordmark's business decision and such changes apply to the Manufacture and supply of the Contracted Products, then Nordmark shall provide Janssen with appropriate advance written notice of the intended change in order to facilitate the required notification and/or approval of any Regulatory Authority. Unless otherwise mutually agreed to in writing, [****] of the costs of any Nordmark initiated changes.

10.2 **Equipment Expenses**. If Nordmark is required to obtain specialized equipment in order to Manufacture Contracted Product for Janssen, the allocation of cost and ownership of such equipment shall be mutually agreed upon by the Parties in writing. Unless otherwise mutually agreed to in writing, [****] of the costs of any Janssen initiated requirements to obtain specialized equipment. If the Parties cannot agree on an allocation of the cost of any specialized equipment, this matter shall be referred to the Expert or Expert Panel pursuant to Section 22, and the Expert or Expert Panel shall finally determine the allocation of costs. For clarity, Nordmark is under no obligation to obtain or implement any specialized equipment unless there is agreement between the Parties regarding the costs.

11. PRODUCT COMPLAINTS, ADVERSE EVENTS AND RECALLS

11.1 **Customer Complaints and Adverse Events**. Janssen, as required by cGMP, shall maintain all customer complaint and adverse event files. Any such complaints received by Nordmark shall be forwarded to Janssen. Janssen shall be responsible for the review of the complaint or adverse event to determine the need for an investigation or the need to report to the FDA or any other applicable Regulatory Authority as required by cGMP. Janssen shall send to Nordmark all Contracted Product complaints received by Janssen which require investigation (and shall provide to Nordmark all Contracted Product which is the subject of such complaints). Nordmark shall conduct an evaluation for each Contracted Product complaint and further investigate those complaints pursuant to Nordmark SOPs. Nordmark shall report findings and follow-up of each investigation to Janssen within [****]. Janssen shall make these complaint files available to Nordmark in the event they are required during an FDA inspection.

11.2 **Recalls**. In the event Janssen shall be required to recall any Contracted Product because such Contracted Product may violate Laws or the Product Specifications, or in the event that Janssen elects to institute a voluntary recall (each, a "**Recall**"), Janssen shall be responsible for coordinating such Recall. Janssen promptly shall notify Nordmark if any

Contracted Product is the subject of a Recall and provide Nordmark with a copy of all documents relating to such Recall. Nordmark shall cooperate with Janssen in connection with any Recall.

11.2.1 To the extent that a Recall of any Contracted Product is not directly attributable to a Latent Defect, which was caused by the negligence or willful misconduct of Nordmark, Janssen shall, subject the liability limitations set forth in Section 13.4, be responsible for the expenses (i) of notification of any regulatory bodies or authorities, (ii) for collection (including transportation) of any Contracted Product which is subject of a Recall, (iii) for temporary storage of any Contracted Product which is subject of a Recall, (iv) for removal or disposal of any Contracted Product which is subject of the Recall, (v) for the recalled Contracted Product according to the applicable Supply Prices except for the Licensed Know-How Fee, (vi) for the cost of surplus Raw Materials left over from the Manufacture the recalled Contracted Product that cannot be repurposed by Nordmark or Nordmark elects not to repurpose, and (vii) to reimburse Nordmark for any costs reasonably expended by Nordmark to assist Janssen to effect such Recall.

11.2.2 To the extent that a Recall of any Contracted Product is directly attributable to a Latent Defect, which was caused by the negligence or willful misconduct of Nordmark, Nordmark shall, subject the liability limitations set forth in Sections 13.4, 13.7 and the Nordmark Liability Caps, be responsible (i) for the Costs (a) of notification of any regulatory bodies or authorities, (b) for collection (including transportation) of any Contracted Product which is subject of a Recall, (c) for temporary storage of any Contracted Product which is subject of a Recall, (d) for removal or disposal of any Contracted Product which is subject of the Recall, and (e) of surplus Raw Materials left over from the Manufacture of the recalled Contracted Product that cannot be repurposed by Janssen or Janssen elects not to repurpose, and (ii) to replace all Contracted Products subject to such Recall free of charge according to the provisions set forth in Section 7.5 (Short Delivery).

12. REPRESENTATIONS AND WARRANTIES; DISCLAIMER

12.1 **Mutual Representations**. Each Party hereby represents and warrants to the other Party that (i) the person executing this Agreement is authorized to execute this Agreement; (ii) this Agreement is legal and valid and the obligations binding upon such Party are enforceable by their terms; and (iii) has the right and authority to enter into this Agreement, and its performance of its obligations under this Agreement does not and shall not conflict with or constitute a default under its certificate of incorporation or formation, bylaws or other constitutive document or any of its obligations to any Third Parties. The representations and warranties contained herein are deemed to be material obligations and shall survive any payment by Janssen and any termination or expiration of this Agreement.

12.2 **Nordmark Warranties and Covenants**.

12.2.1 Nordmark represents and warrants that as of Effective Date:

(a) it has obtained and maintained and has complied with any permits, licenses (including but not limited the DMF(s) for Compound in the Territory) and certifications that Nordmark and Nordmark's personnel are required to perform its obligations in accordance with the terms of this Agreement.

(b) it has the necessary facilities, equipment, and personnel with the requisite expertise, experience and skill to Manufacture the Contracted Product in accordance with all regulations and guidelines set forth by the FDA, Health Canada, European Medicines Agency, cGMP, and all applicable German Laws.

(c) it has complied with German Law regarding employment of people under the age of eighteen (18) years. Nordmark has read and understands the Janssen's Policy on the Employment of Young People attached hereto as Exhibit I.

(d) to its actual knowledge and subject to the [****], the Manufacture of Contracted Products in the Facility [****]. For clarity, no further warranty and representation is given by [****] and [****] does not assume any further liability or responsibility regarding [****].

Nordmark hereby represents and warrants in the form of a guaranty ("Garantie") under Section 276 German Civil Code (Bürgerliches Gesetzbuch) to Janssen that the statements set forth in this Section 12.2.1 are true and correct as of the Effective Date.

12.2.2 Nordmark covenants that:

(a) at the time of Nordmark's release, Contracted Product shall be free from Defects and be of merchantable quality and shall not be adulterated or misbranded within the meaning of the FD&C Act when delivered by Nordmark to the common carrier designated by Janssen.

(b) it will obtain and will maintain and comply with any permits, licenses (including but not limited the DMF(s) for Compound in the Territory) and certifications that Nordmark and Nordmark's personnel are required to perform its obligations in accordance with the terms of this Agreement.

(c) it shall have the necessary facilities, equipment, and personnel with the requisite expertise, experience and skill to Manufacture the Contracted Product in accordance with all regulations and guidelines set forth by the FDA, Health Canada, European Medicines Agency, cGMP, and all applicable German Laws.

(d) it shall comply with German Law regarding employment of people under the age of eighteen (18) years. Nordmark has read and understands the Janssen's Policy on the Employment of Young People attached hereto as Exhibit I.

The covenants given by Nordmark in this Section 12.2.2 are not a guaranty ("Garantie") under Section 276 German Civil Code, an independent warranty promise ("selbständiges Garantieversprechen") under Section 311 German Civil Code, or a condition warranty ("Beschaffenheitsgarantie") under Section 443 German Civil Code, but a description or obligation to negligence ("verschuldensabhängige Eigenschaftsbeschreibung oder Verpflichtung") or willful misconduct of Nordmark.

For the avoidance of doubt the Parties expressly agree that in case of a Defect or in case of a Recall the rights and remedies of Janssen under Sections 8.4. (in case of a Defect) and under Section 11.2.2 (in case of a Recall) are the sole and only rights and remedies of Janssen, even if there is a breach of a Nordmark representation and warranty (in particular – but not limited to – a breach of Section 12.2.2 (a), and/or 12.2.2 (c)) unless in the case of gross negligence or willful misconduct by Nordmark; provided, however, this is without prejudice to an indemnification obligation of Nordmark pursuant to Section 13.2.

12.3 **Janssen Warranties and Covenants**.

12.3.1 Janssen represents and warrants as of the Effective Date that:

(a) it has obtained and maintained and has complied with any permits, licenses (including but not limited the Marketing Authorizations for all Contracted Products in the Territory) and certifications that Janssen and Janssen's personnel are required to perform its obligations in accordance with the terms of this Agreement.

(b) to its actual knowledge and subject to the Allergan-Janssen License Agreement, the Manufacturing, import, marketing, distributing, selling and/or offering for sale of Contracted Products in the Territory does not infringe Intellectual Property Rights of Third Parties. For clarity, no further warranty and representation is given by Janssen regarding Intellectual Property Rights of Third Parties and Janssen does not assume any further liability or responsibility regarding Third Party Intellectual Property Rights.

Janssen hereby represents and warrants in the form of a guaranty ("Garantie") under Section 276 German Civil Code (Bürgerliches Gesetzbuch) to Nordmark that the statements set forth in this Section 12.3.1 are true and correct as of the Effective Date.

12.3.2 Janssen covenants that:

(a) during the Term, it shall not Manufacture itself or have Manufactured by Third Parties any Contracted Product or any other Products.

(b) it will obtain and will maintain and comply with any permits, licenses (including but not limited the Marketing Authorizations for all Contracted Products in the Territory) and certifications that Janssen and Janssen's

personnel are required to perform its obligations in accordance with the terms of this Agreement.

(c) upon Nordmark's request, it shall send to Nordmark a written report of its quarterly sales of each Contracted Product in value (US$), in quantity (Units), its stock position (in Units) thereof and about the market development of the Contracted Products compared to the main competitors, within sixty (60) days of such request.

(d) it shall inform Nordmark in case Allergan-Janssen License Agreement is terminated.

The covenants given by Janssen in this Section 12.3.2 are not a guaranty ("Garantie") under Section 276 German Civil Code, an independent warranty promise ("selbständiges Garantieversprechen") under Section 311 German Civil Code, or a condition warranty ("Beschaffenheitsgarantie") under Section 443 German Civil Code, but a description or obligation subject to negligence ("verschuldensabhängige Eigenschaftsbeschreibung oder Verpflichtung") or willful misconduct of Janssen.

13. INDEMNIFICATION; LIMITATION OF LIABILITY

13.1 **Janssen Indemnification**. Subject to Section 13.4, Janssen shall defend, indemnify and hold harmless Nordmark and its Affiliates, and their respective employees, officers, directors and agents, and the successors and permitted assigns thereof, against any and all Third Party liability, claims, demands, damages, losses and expenses in connection with or arising out of (i) Janssen's culpable breach of any representation or obligation under this Agreement, (ii) the negligence or willful misconduct of Janssen in connection with this Agreement, or (iii) if selling and/or offering for sale the Contracted Products in the Territory infringes the Intellectual Property Rights of Third Parties; except, in each case of subclauses (i), (ii) and (iii) above, to the extent such Third Party liability, claims, demands, damages, losses and expenses arise in connection with or out of (x) Nordmark's culpable breach of any representation or obligation under this Agreement or (y) the negligence or willful misconduct of Nordmark in connection with this Agreement.

13.2 **Nordmark Indemnification**. Subject to Sections 13.4 and 13.7, Nordmark shall defend, indemnify and hold harmless Janssen and its Affiliates, and their respective employees, officers, directors and agents, and the successors and permitted assigns thereof, against any and all Third Party liability, claims, demands, damages, losses and expenses, in connection with or arising out of (i) Nordmark's culpable breach of any representation or obligation under this Agreement, (ii) the negligence or willful misconduct of Nordmark or its Affiliates in connection with this Agreement; except, in each case of subclauses (i) and (ii) above, to the extent such Third Party liability, claims, demands, damages, losses and expenses arise in connection with or out of (x) Janssen's culpable breach of any representation or obligation under this Agreement or (y) the negligence or willful misconduct of Janssen in connection with this Agreement.

13.3 **Indemnitee Obligations**. An indemnified Party shall give the indemnifying Party prompt written notice of any matter upon which the indemnified Party intends to base a claim for indemnification under this Section 13; provided, however, that no delay on the part of the indemnified Party in notifying the indemnifying Party shall relieve the indemnifying part of any liability or obligations hereunder except to the extent the indemnifying Party has been materially prejudiced by such delay. The obligation of the indemnifying Party hereunder shall apply only if the indemnified Party permits the indemnifying Party and its attorneys and personnel to handle and control the defense of such claims or suits, including pretrial, trial or settlement, and the indemnified Party fully cooperates and assists in such defense. The indemnified Party shall have the right to assume control of the defense, settlement, negotiations or litigation relating to such claim at its own expense. The indemnifying Party agrees that it shall not settle or compromise any such claim or suit without the prior written consent of the indemnified Party, which consent shall not be unreasonably withheld, delayed or conditioned.

13.4 **Limitation of Liability and Indemnification Obligation**.

13.4.1 NEITHER PARTY TO THIS AGREEMENT SHALL BE LIABLE OR RESPONSIBLE FOR EXEMPLARY, MULTIPLIED OR CONSEQUENTIAL DAMAGES (INCLUDING LOSS OF PROFITS OR LOSS OF OPPORTUNITY), OR LOST PROFITS EVEN IF DESIGNATED DIRECT DAMAGES, WHETHER IN CONTRACT, LAW, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY THEREOF; PROVIDED, FURTHER, HOWEVER, THAT THE FOREGOING SHALL NOT LIMIT A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 13 (INDEMNIFICATION; LIMITATION OF LIABILITY).

13.4.2 IN ADDITION TO SECTION 13.4.1, NORDMARK'S LIABILITY VIS-À-VIS JANSSEN UNDER THIS AGREEMENT OR UNDER GOVERNING LAW FOR WHATEVER REASON, INCLUDING – BUT NOT LIMITED TO – UNDER INDEMNIFICATION OBLIGATIONS OF NORDMARK UNDER SECTION 13 (INDEMNIFICATION; LIMITATION OF LIABILITY), IS LIMITED AS FOLLOWS:

13.4.2.1 IN THE CASE OF LIABILITY VIS-À-VIS JANSSEN (INCLUDING AN INDEMNIFICATION OBLIGATION VIS-À-VIS JANSSEN) IN RESPECT OF AND/OR IN CONNECTION WITH AN INSURED INCIDENT, IN NO EVENT SHALL THE AGGREGATE, CUMULATIVE LIABILITY OF NORDMARK AND ITS AFFILIATES (INCLUDING AN INDEMNIFICATION OBLIGATION VIS-À-VIS JANSSEN) [****] (UNLESS IN CASE OF GROSS NEGLIGENCE; IN WHICH CASE SECTION 13.4.2.2 SHALL APPLY).

13.4.2.2 IN THE CASE OF LIABILITY VIS-À-VIS JANSSEN (INCLUDING AN INDEMNIFICATION OBLIGATION VIS-À-VIS JANSSEN) IN

RESPECT OF AND/OR IN CONNECTION WITH AN INSURED INCIDENT ARISING DUE TO NORDMARK'S GROSS NEGLIGENCE, IN NO EVENT SHALL THE AGGREGATE, CUMULATIVE LIABILITY OF NORDMARK AND ITS AFFILIATES (INCLUDING AN INDEMNIFICATION OBLIGATION VIS-À-VIS JANSSEN) [****].

13.4.2.3 IN THE CASE OF LIABILITY VIS-À-VIS JANSSEN (INCLUDING AN INDEMNIFICATION OBLIGATION VIS-À-VIS JANSSEN), OTHER THAN LIABILITY IN RESPECT OF AND/OR IN CONNECTION WITH AN INSURED INCIDENT (IN WHICH CASE SECTION 13.4.2.1 SHALL APPLY), IN NO EVENT SHALL THE AGGREGATE, CUMULATIVE LIABILITY OF NORDMARK AND ITS AFFILIATES (INCLUDING AN INDEMNIFICATION OBLIGATION VIS-À-VIS JANSSEN) [****] THE DATE ON WHICH SUCH DAMAGES ARE INCURRED BY JANSSEN OR ITS AFFILIATES (UNLESS IN CASE OF GROSS NEGLIGENCE, IN WHICH CASE SECTION 13.4.2.4 SHALL APPLY).

13.4.2.4 IN THE CASE OF LIABILITY VIS-À-VIS JANSSEN (INCLUDING AN INDEMNIFICATION OBLIGATION VIS-À-VIS JANSSEN), OTHER THAN LIABILITY IN RESPECT OF AND/OR IN CONNECTION WITH AN INSURED INCIDENT (IN WHICH CASE SECTION 13.4.2.2 SHALL APPLY), ARISING DUE TO NORDMARK'S GROSS NEGLIGENCE, IN NO EVENT SHALL THE AGGREGATE, CUMULATIVE LIABILITY OF NORDMARK AND ITS AFFILIATES (INCLUDING AN INDEMNIFICATION OBLIGATION VIS-À-VIS JANSSEN) [****] THE DATE ON WHICH SUCH DAMAGES ARE INCURRED BY JANSSEN OR ITS AFFILIATES.

13.4.3 IN ADDITION TO SECTION 13.4.1, JANSSEN'S LIABILITY VIS-À-VIS NORDMARK UNDER THIS AGREEMENT OR UNDER GOVERNING LAW FOR WHATEVER REASON, INCLUDING – BUT NOT LIMITED TO - INDEMNIFICATION OBLIGATIONS OF JANSSEN UNDER SECTION 13 (INDEMNIFICATION; LIMITATION OF LIABILITY), IS LIMITED AS FOLLOWS:

13.4.3.1 IN THE CASE OF LIABILITY VIS-À-VIS NORDMARK (INCLUDING AN INDEMNIFICATION OBLIGATION VIS-À-VIS NORDMARK), IN NO EVENT SHALL THE AGGREGATE, CUMULATIVE LIABILITY OF JANSSEN AND ITS AFFILIATES (INCLUDING AN INDEMNIFICATION OBLIGATION VIS-À-VIS NORDMARK) [****] THE DATE ON WHICH SUCH DAMAGES ARE INCURRED BY NORDMARK OR ITS AFFILIATES (UNLESS IN CASE OF GROSS NEGLIGENCE, IN WHICH CASE SECTION 13.4.3.2 SHALL APPLY).

13.4.3.2 IN THE CASE OF LIABILITY VIS-À-VIS NORDMARK (INCLUDING AN INDEMNIFICATION OBLIGATION VIS-À-VIS NORDMARK) ARISING DUE TO JANSSEN'S GROSS NEGLIGENCE, IN NO EVENT SHALL THE AGGREGATE, CUMULATIVE LIABILITY OF JANSSEN AND ITS AFFILIATES (INCLUDING AN INDEMNIFICATION OBLIGATION VIS-À-VIS NORDMARK) [****] THE DATE ON WHICH SUCH DAMAGES ARE INCURRED BY NORDMARK OR ITS AFFILIATES.

13.4.4 THIS SECTION 13.4 SHALL NOT LIMIT A PARTY'S LIABILITIES ARISING FROM A PARTY'S FRAUD, FRAUDLENT MISREPRESENTATION, WILLFUL MISCONDUCT OR BREACH OF SECTION 15 (CONFIDENTIALITY).

13.5 **Waiver of Subrogation**. Insofar as any liability on the part of an indemnifying Party is excluded or limited by virtue of any provision of this Agreement, such exclusion or limitation is intended to be effective not only as against the indemnified Party but also as against the indemnified Party's insurers such that the indemnified Party's insurers shall have no claim against the indemnifying Party by way of subrogation where the indemnified Party does not itself have such a claim. The indemnified Party shall use commercially reasonable efforts to cause such insurers to waive their rights of subrogation against the indemnifying Party where the indemnified Party does not itself have such claim.

13.6 **Waiver of Recovery**. All Nordmark Raw Materials and Nordmark owned equipment used by Nordmark in the Manufacture of any Contracted Product (collectively, the "Nordmark Property") shall at all times remain the property of Nordmark and Nordmark assumes risk of loss for such Nordmark Property until delivery of such Contracted Product to a common carrier as specified under Section 7.1. Nordmark hereby waives any and all rights of recovery against Janssen and its Affiliates, and against any of their respective directors, officers, employees, agents or representatives, for any loss or damage to Nordmark Property to the extent the loss or damage is covered or could be covered by insurance (whether or not such insurance is described in this Agreement).

13.7 **Limitation of Nordmark Liability in Relation to (I) Importation, Marketing, Promotion and Sale of the Contracted Products, and Filing and Maintenance of the Marketing Authorizations, and (II) Subcontractors and Suppliers**.

13.7.1 Nordmark does not assume any liability or responsibility whatsoever in relation to import into the Territory and the marketing, promotion and selling of the Contracted Products in the Territory and the filing and maintenance of the Marketing Authorizations in the Territory. All these aforementioned activities are the sole liability and responsibility of Janssen, including without limitation, the safety and efficacy of the Contracted Products and that the aforementioned activities do not infringe Intellectual Property Rights of Third Parties; provided, however, that the foregoing shall not limit Nordmark's liability in respect of breaches of its obligations set forth in this Agreement.

13.7.2 Nordmark is not liable or responsible in the event any subcontractor or supplier (including without limitation the suppliers and/or subcontractors set forth in the Quality Agreement) (i) discontinues sale, supply or delivery of any products (in particular – but not limited to – raw materials), (ii) fails to perform, and/or (iii) ceases business operations; provided, however, that the foregoing shall not limit Nordmark's liability for liabilities arising from (x) fraud, fraudulent misrepresentation or willful misconduct by Nordmark, (y) Nordmark's failure to diligently select (unless such selection and/or determination was made by Janssen in writing) and/or audit (to the extent such auditing is assigned to Nordmark under the Quality Agreement) such subcontractor or supplier, or (z) Nordmark's failure to use commercially reasonably efforts to prevent or mitigate such liabilities through the identification and designation of back-up subcontractors and/or suppliers.

14. INSURANCE

14.1 **Insurance**. Each Party shall, at its own expense, maintain in full force and effect reasonable, valid and collectible insurance policies with a reputable insurer, providing sufficient coverage for its liability under the performance of its obligations and associated activities under this Agreement. Written certificates with regard to said insurance policies shall be delivered to any Party upon the other Party's reasonable request.

14.2 **No Limitation**. In no event shall the liability of either Party be limited to that which is recoverable by insurance.

15. CONFIDENTIALITY

15.1 As used herein, "Nordmark Confidential Information" shall include all information given to Janssen by Nordmark, or otherwise acquired by Nordmark, in connection with this Agreement or the Prior Agreement, and all information derived or generated therefrom, including information relating to (i) any of the products or services of Nordmark or its Affiliates (ii) costs, productivity or technological advances, (iii) Licensed Know-How and (iv) this Agreement and any other information disclosed by Nordmark in connection therewith. Nordmark Confidential Information also includes any information given to Janssen by Nordmark with respect to any potential products or services that Nordmark may provide, regardless of whether Nordmark actually provides any such products or services, including any discussions between the Parties with respect thereto and all information derived or generated therefrom.

15.2 As used herein, "Janssen Confidential Information" shall include all information given to Nordmark by Janssen, or otherwise acquired by Janssen, in connection with this Agreement or the Prior Agreement, and all information derived or generated therefrom, including information relating to (i) any of the products of Janssen or its Affiliates (including the Contracted Products), (ii) costs, productivity or technological advances, and (iii) this Agreement, any services and any other information in connection therewith.

15.3 Confidential Information does not include the following information: (i) information that is or was independently developed by the receiving Party without use of or reference to any of the disclosing Party's Confidential Information, (ii) information that is or was received from a Third Party that did not have any confidentiality or other similar obligation or restriction on use with respect to such information; (iii) information that was already in the receiving Party's possession at the time of disclosure, or (iv) information that becomes or was a part of the public domain through no breach of this Agreement by the receiving Party.

15.4 Nordmark, on the one hand, and Janssen, on the other hand, shall not, except as otherwise provided below (i) use or reproduce the Confidential Information of the other Party for any purpose other than as needed fulfill its obligations hereunder, or (ii) disclose the Confidential Information of the disclosing Party to any Third Party, without the prior written approval of the disclosing Party, such approval not to be unreasonably withheld if the disclosing Party intends to disclose Confidential Information of the other Party to its or their existing or potential distributors, investors, licensees, collaborators or acquirors of the business to which this Agreement relates, who have a specific need to know such Confidential Information and who are bound by obligations of confidentiality and restriction on use no less restrictive than those set forth in this Section 15. However, Janssen shall by no means disclose any of the Licensed Know-How to any Third Party.

15.5 Notwithstanding Section 15.4, a Party may disclose Confidential Information of the other Party: (i) to the extent necessary to comply with applicable Law, including the rules or regulations of the U.S. Securities and Exchange Commission or similar Governmental Authority in any country other than the USA or of any stock exchange or listing entity, provided that such first Party provides prior written notice of such disclosure to the other Party if permitted and takes all reasonable actions to avoid or minimize the degree of such disclosure, (ii) as permitted by this Agreement, (iii) as necessary to defend or prosecute any indemnification claim or any litigation or dispute and (iv) to its Affiliates, and to its and their directors, officers, employees, consultants, agents, auditors, and attorneys, or, solely in respect of the disclosure of the terms of this Agreement, to any Third Party, and to its and their directors, officers, employees, consultants, agents, auditors, and attorneys, to which the assignment of this Agreement would not require the prior written consent of Nordmark pursuant to the terms of Section 23.1, in each case who, in such disclosing Party's sole determination, have a specific need to know such Confidential Information and who are bound by obligations of confidentiality and restriction on use no less restrictive than those set forth in this Section 15. For clarity, Janssen may only disclose Confidential Information to any Regulatory Authority subject to the conditions and the process and mechanism in accordance with Section 2.3.

15.6 The receiving Party shall (i) use at least the same degree of care that the receiving Party uses to protect its own proprietary information of a similar nature and value, but no less than reasonable care, to protect and maintain the Confidential Information of the disclosing Party, (ii) restrict disclosure of the disclosing Party's Confidential Information to its employees, consultants, agents and representatives who have a need to know such information and shall advise such persons of the confidentiality of such information and be responsible for any actions of such parties that would be in breach of this Agreement if

done by the receiving Party, and (iii) return or destroy, as requested by disclosing Party, all disclosing Party Confidential Information upon disclosing Party's request, except only as required to perform obligations under or exercise rights granted in this Agreement. For the avoidance of doubt, Nordmark shall be under no obligation to disclose any know-how in respect of the Contracted Products under this Section 15.

15.7 Each Party stipulates and agrees that a breach of any of the provisions of this Section 15 by such Party could have a material and adverse effect upon the other Party and that damages arising from such breach may be difficult or impossible to ascertain. Accordingly, in the event of any breach or threatened breach of any provision of this Section 15 by either Party, the other Party shall be entitled to institute and prosecute proceedings in any court of competent jurisdiction, to enjoin the other Party from such breach or to seek specific performance of this Agreement, without posting a bond. Nothing contained herein shall preclude either Party from pursuing any other remedy for any breach or threatened breach of this Agreement, and all of such remedies shall be cumulative.

15.8 Neither Party shall originate any publicity, news release, or other announcement, written or oral, whether to the public press, the trade, any of the other Party's customers, suppliers or otherwise, relating to this Agreement without the prior written approval of the other Party. Without limiting the foregoing, neither Party shall use any names, trademarks or logos of the other Party (except as permitted by Section 2.2) without the prior written consent of such Party.

16. TERM AND TERMINATION

16.1 **Initial Term**. This Agreement shall begin on the Effective Date and continue through December 31, 2022 ("**Initial Term**"), unless earlier terminated in accordance with Sections 16.2, 16.3, 16.4 or 16.5 of this Agreement. This Agreement shall be renewed automatically for additional [****] periods commencing at the expiration of the Initial Term (each a "**Renewal Term**", together with the Initial Term, the "**Term**") unless either Janssen or Nordmark terminates this Agreement by giving the other Party written notice of its intent to terminate (i) at least [****] (in the case of a termination by Janssen) or at least [****] (in the case of a termination by Nordmark) prior to the expiration of the Initial Term and (ii) [****] prior to the expiration of any Renewal Term.

16.2 **Termination for Breach**.

16.2.1 In the event of any material breach of this Agreement, the non-breaching Party shall have the right to terminate this Agreement in its entirety provided that the non-breaching Party provides notice of such breach to the breaching Party specifying the nature of the alleged breach and such breach has not been cured within [****] after such notice thereof.

16.2.2 Without prejudice to any other rights of termination for material breach contained in this Agreement, the Parties agree as follows:

16.2.2.1 It shall be considered a material breach of Nordmark within the meaning of Section 16.2.1 if Nordmark does not comply with one or several of the following obligations under this Agreement, in particular, without limitation:

- Section 7.5 (Short Delivery) (subject to the remedies set forth therein);
- Section 7.6 (Late Delivery) (subject to the remedies set forth therein);
- Section 8.3 (Latent Defect) (subject to the remedies set forth therein and in Section 8.2 and provided that more than two (2) Latent Defects occur within a certain twelve (12)-month-period);
- Section 8.4 (Remedies for Non-Conforming Contracted Product) (subject to the remedies set forth therein);
- Section 8.5 (Product Assay Release Limits) (subject to the remedies set forth therein);
- Section 12.2.1(d);
- Breach of Section 15 (Confidentiality) in any material respect; and
- Section 22.1 (Assignment; Subcontractors).

16.2.2.2 It shall be considered a material breach of Janssen within the meaning of Section 16.2.1 if Janssen does not comply with one or several of the following obligations under this Agreement, in particular, without limitation:

- Section 2.1 (Know-How License);
- Section 2.3 (Process and Mechanism);
- Section 3.2 (Exclusivity of Supply);
- Section 12.3.1(b);
- Breach of Section 15 (Confidentiality) in any material respect; and
- Section 22.1 (Assignment; Subcontracting).

16.2.3 Notwithstanding any termination of this Agreement as a result of a breach, the terminating Party shall be entitled, in accordance with applicable Governing Law and this Agreement, to exercise any other remedies available to it at Governing Law or in equity.

16.3 **Janssen Termination**. Notwithstanding anything else herein, Janssen may terminate this Agreement at any time and for any reason, upon [****] written notice to Nordmark. Upon receipt of such written notice, Nordmark shall immediately cease any Manufacture of the Contracted Product and not incur further expenses under any outstanding Purchase Order(s).

16.4 **Termination due to Termination or Expiration of the Allergan-Janssen License Agreement or the CSA**.

16.4.1 Nordmark shall provide Janssen written notice within [****] of Nordmark's receipt of any notice of material breach of, or potential termination or expiration of, the Allergan-Nordmark License or the CSA. Janssen shall provide Nordmark written notice within [****] of Janssen's receipt of any notice of material breach of, or potential termination or expiration of, the Allergan-Janssen License Agreement.

16.4.2 Notwithstanding anything else herein, either Party may terminate this Agreement immediately by giving the other Party written notice thereof in the event of termination or expiration of the Allergan-Janssen License Agreement, the Allergan-Nordmark License or the CSA.

16.5 **Termination due to Insolvency**. This Agreement may be terminated immediately by either Party by giving the other Party written notice thereof in the event such other Party makes a general assignment for the benefit of its creditors, acknowledges in writing its inability to meet its obligations as they become due in the general course, or proceedings of a case are commenced in any court of competent jurisdiction by or against such Party seeking (i) such Party's reorganization, liquidation, dissolution, arrangement or winding up, or the composition or readjustment of its debts, (ii) the appointment of a receiver or trustee for or over such Party's property, or (iii) similar relief in respect of such Party under any Law relating to bankruptcy, insolvency, reorganization, winding up or composition or adjustment of debt, and such proceedings shall continue dismissed, or an order with respect to any of the foregoing that is entered and continues unstated, for a period of more than sixty (60) calendar days.

All rights and licenses granted under or pursuant to any section of this Agreement are for purposes of Section 365(n) of Title 11, United States Code or any analogous provisions in any other country or jurisdiction (the "**Bankruptcy Code**") licenses of rights to "intellectual property" as defined in Section 101(56) of the Bankruptcy Code (and any equivalent provisions under the bankruptcy or insolvency laws of any other relevant jurisdiction). The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code.

16.6 **Effects of Termination**.

16.6.1 **Non-cancelable Costs and Expenses**. In the event of the termination or cancellation of this Agreement, except by Janssen as a result of a breach by Nordmark under Section 16.2, Janssen shall (i) [****], and (ii) [****]. In addition, Janssen shall pay the [****]. Upon Janssen's request, Nordmark shall ship such Raw Materials and such Intermediate Products, Bulk Products or Contracted Products to Janssen pursuant to Section 7.1. Nordmark shall invoice Janssen and the Parties shall satisfy such invoices in accordance with Sections 6.5 and 6.6. Each Party may refer any dispute to the Expert or Expert Panel pursuant to Section 22.1 following the date that is thirty (30) days following the non-disputing Party's receipt of written notice of such dispute.

16.6.2 **Sale of Remaining Inventory**. After expiration or termination of this Agreement Janssen shall be entitled to sell remaining stocks of any Contracted Product during a period of six (6) months under the conditions of this Agreement. Notwithstanding the foregoing, Janssen shall have no right to sell remaining stocks of any Contracted products under this Section 16.6.2 if (a) the Agreement is terminated by Nordmark as a result of a material breach by Janssen under Section 16.2, solely in respect of Janssen's obligations hereunder with respect to the maintenance of the Marketing Authorizations; (b) Nordmark chooses to purchase such remaining stock at cost; or (c) Nordmark would reasonably be expected to incur liability vis-à-vis Third Parties as a result of Janssen's exercise of its rights under this Section 16.6.2; provided, however, that in the event such liability is or is reasonably expected to be non-material in nature, (x) Janssen shall be entitled to sell remaining stocks of any Contracted products under this Section 16.6.2 and (y) Janssen shall, subject to the limitations set forth in Section 13.4, indemnify and hold harmless Nordmark from and against any such non-material liability.

16.6.3 **Remedies**. Termination, expiration, cancellation or abandonment of this Agreement through any means or for any reason shall be without prejudice to the rights and remedies of either Party with respect to any antecedent breach of any of the provisions of this Agreement.

16.6.4 **Technology Transfer Option**.

16.6.4.1 If Nordmark decides to fully and finally discontinue its business to which this Agreement relates, and if this business is not assigned or transferred to a Partial or Legal Successor of Nordmark, Janssen shall have the option of electing, by written notice to Nordmark, to purchase from Nordmark – as far as in Nordmark's possession and control and subject to any rights of or agreements with Third Parties – such materials, technology and information related to the Manufacture of the Contracted Products and/or such rights in relation to such materials, technology and information (collectively, the "**Technology Transfer Assets**") in an amount equal to the fair market value of such

Technology Transfer Assets, as mutually agreed by the Parties, each acting in good faith (the "**Technology** Transfer"). For clarity, Nordmark shall promptly notify Janssen in writing in the event Nordmark decides to fully and finally discontinue its business to which this Agreement relates and such business will not be assigned or transferred to a Partial or Legal Successor of Nordmark.

16.6.4.2 Following delivery of such notice pursuant to Section 16.6.4.1, the Parties shall each negotiate in good faith in furtherance of reaching agreement with respect to the fair market value of the Technology Transfer Assets sought to be purchased by Janssen, and related terms and conditions of such purchase, for a period of sixty (60) Business Days from the date of such exercise notice. If within such sixty (60)-Business Day period (or such longer period as may be mutually agreed by the Parties) the Parties are unable to reach an agreement on the fair market value, each Party may refer the matter to the Expert or Expert Panel pursuant to Section 22.1 for evaluation and determination of the fair market value of the Technology Transfer Assets. The determination by the Expert or Expert Panel shall be binding upon the Parties. If neither Party refers the matter to the Expert or Expert Panel, then Nordmark shall be under no obligation to sell to Janssen the Technology Transfer Assets.

16.6.4.3 As soon as the Parties have agreed on, or the Expert or Expert Panel has determined, the fair market value and the Parties have agreed on the related terms and conditions of the purchase of the Technology Transfer Assets, and upon full payment of the then agreed or determined amount by Janssen, Nordmark shall transfer to Janssen or its Affiliate(s) or to a Third Party designated by Janssen or its Affiliate(s) the Technology Transfer Assets. Nordmark shall complete the Technology Transfer as promptly as practicable and shall make scientific and technical staff available as necessary and reasonably useful to assist in Janssen or its Affiliates', or Janssen or its Affiliates' Third Party designee's, efforts. Nordmark shall take such further action and generate such data and documentation as are reasonably necessary to accomplish the foregoing. Each Party shall be solely responsible for all of its costs and expenses incurred in fulfilling its obligations under this Section 16.6.4.

16.6.5 [****]

16.7 **No Partial Termination**. The Parties expressly agree that in case of a right to terminate, the terminating Party may only terminate this Agreement wholly (i.e. related to all Contracted Products), and not partially (i.e. related to only certain of the Contracted Products).

17. REGULATORY

17.1 **Regulatory Approvals**. Janssen is responsible to obtain and maintain Regulatory Approval of Marketing Authorizations for each Contracted Product Manufactured by Nordmark hereunder. Janssen shall advise Nordmark of document requirements in support of Regulatory Authority applications including amendments, applications for further Marketing Authorizations, supplements and maintenance of such. Nordmark shall provide documents and assist Janssen in preparation of submissions to Regulatory Authorities based on work orders agreed upon between the Parties as set forth in the MSA. Prior to submission to the Regulatory Authority, Janssen shall provide Nordmark with a copy of the CMC section for review and comment. A final copy of the CMC section shall be provided by Janssen to Nordmark upon submission to the Regulatory Authority.

17.2 **Regulatory Authority Inspections**. Nordmark shall permit access to Regulatory Authorities to Nordmark's premises. Nordmark shall inform Janssen of any announced regulatory inspection that solely involves any Contracted Product within forty-eight (48) hours of the notification to Nordmark of such inspection related to any Contracted Product. Nordmark shall immediately inform Janssen of any unannounced regulatory inspection that solely involves any Contracted Product. Upon Janssen's request, such notice shall include without limitation the name of the agency, the number and names of inspectors and the scope of audit, related to any Contracted Product. Nordmark shall permit Janssen representatives to be present at the Facility for inspection that directly involves any Contracted Product. Janssen shall participate directly in the inspection at the sole discretion of Nordmark. Nordmark shall inform Janssen of the result of any regulatory inspection which directly affects the Manufacturing of a Contracted Product, including any notice of violation or other similar notice received by Nordmark affecting Manufacturing, the Facility, testing, storage or handling of a Contracted Product. In the event that there are Inspectional Observations (i.e. FDA Form 483) or other similar regulatory communication, specifically related to the Contracted Product, Janssen shall be informed immediately and shall have the opportunity to review and provide Nordmark with comments to Nordmark's draft responses and corrective actions. Janssen shall provide its comments to the draft responses and corrective actions within twenty-four (24) hours or other timeframe as agreed upon by the Parties to meet regulatory commitments. Nordmark shall retain the final authority for the content of the responses to the Regulatory Authority. Nordmark shall forward to Janssen any observations and responses from a routine regulatory inspection by the FDA, Health Canada or the German competent authorities relating to the Facility where the Contracted Products are Manufactured and stored. Nordmark shall also supply Janssen a complete copy of any Form 483, letter or communication issued by the FDA, Health Canada or the German competent authorities which is directly related to the Manufacturing of the Contracted Products. Nordmark reserves the right to appropriately redact any of the foregoing documentation provided to preserve any Third Party Confidential Information.

18. FORCE MAJEURE; DISASTER RECOVERY

18.1 **Force Majeure**. If any Party is affected by any fire, explosion, flood, or other acts of God; war, terrorist acts or civil commotion; national strike, lock-out; or failure of public utilities or common carriers (a "**Force Majeure Event**"), such affected Party shall not be liable in connection with this Agreement to the extent affected by such Force Majeure Event; provided that such Party gives immediate written notice to the other Party (the "**Non-Force Majeure Party**") of the Force Majeure Event and that such affected Party exercises all reasonable efforts to eliminate the effects of the Force Majeure Event on this Agreement as soon as and to the extent practicable. If any Force Majeure Event continues for a period longer than three (3) months, the Non-Force Majeure Party may terminate this Agreement upon written notice to the other Party affected by the Force Majeure Event. This Section 18 does not limit or alter the parties' right to terminate this Agreement as set forth in Section 16 above.

18.2 **Disaster Recovery**. Nordmark and Janssen shall work together to develop a disaster recovery plan for Manufacturing of the Contracted Products, which may include validation of additional manufacturing equipment. The activities required and allocation of costs associated with such plan shall be mutually agreed.

19. NOTICES

To be effective, all notices and other communications hereunder shall be in writing and delivered personally or mailed by Federal Express or another internationally recognized courier service (billed to sender), to the Parties at the following addresses (or to such other address as either Party may designate by notice as provided in this Section 19):

If to Nordmark:

Nordmark Arzneimittel GmbH & Co. KG
Attn.: Managing Director
Pinnauallee 4
25436 Uetersen
Germany

[****]
[****]
info@nordmark-pharma.de

If to Janssen:

Janssen Pharmaceuticals, Inc.
1125 Trenton-Harbourton Road
Titusville, New Jersey 08650
USA

20. FOREIGN CORRUPT PRACTICES ACT

20.1 **Foreign Corrupt Practices Act**. Neither Party shall perform any actions in connection with this Agreement that are prohibited by local and other anti-corruption Laws (collectively "**Anti-Corruption Laws**") that may be applicable to one or both Parties to this Agreement. Without limiting the foregoing, neither Party shall make any payments, or offer or transfer anything of value, to any government official or government employee, to any political Party official or candidate for political office or to any other Third Party related to the Agreement in a manner that would violate Anti-Corruption Laws.

21. GOVERNING LAW AND ARBITRATION

21.1 This agreement shall be governed by, and shall be construed in accordance with the Laws of Germany, excluding any conflict of law provisions (the "Governing Law").

21.2 Any dispute, controversy or claim arising out of or related to this Agreement, or the interpretation, application, breach, termination or validity thereof, including any claim of inducement by fraud or otherwise shall be resolved by arbitration in accordance with Exhibit J attached hereto.

22. EXPEDITED DISPUTE RESOLUTION

22.1 If reference is made to this Section 22.1, each Party (the "Referring Party") may initiate against the other Party (the "Concerned Party") an expedited dispute resolution by an Expert or an Expert Panel (as defined below) solely to resolve a Covered Matter by serving written notice thereof to the Concerned Party (a "Referral Notice").

22.2 In the Referral Notice, the Referring Party shall (i) nominate an independent and impartial expert ("Expert") and (ii) state the Covered Matter that it wishes the Expert or, as the case may be, the Expert Panel (as defined below) to determine as follows, including the specific remedy or determination the Referring Party seeks.

22.3 Upon service of a Referral Notice, the Concerned Party shall have the right to meet and interview the Expert. If the Concerned Party disapproves of the Referring Party's choice of the Expert, it shall within ten (10) Business Days also appoint an independent and impartial expert to serve on an Expert Panel (as defined below). The two (2) so selected experts will be instructed to choose a third independent and impartial expert within ten (10) Business Days of the appointment of the Expert by the Concerned Party (all three experts being the "Expert Panel"), the Expert Panel being constituted and working in accordance with the WIPO Expert Determination Rules effective as the date of the Referral Notice.

22.4 Within thirty (30) calendar days after the giving of a Referral Notice or, if the Concerned Party disagrees with the Referring Party's choice of Expert, within twenty (20) calendar days after constitution of the Expert Panel pursuant to Section 22.3 each Party shall provide to the other Party and to the Expert or, as the case may be, the Expert Panel (i) a written statement setting forth any facts or other information that is relevant or necessary

to the determination of the Covered Matter, as well as the determination that such Party seeks, and (ii) any other supporting documentation or materials that are relevant or necessary to the determination of the Covered Matter ((i) and (ii) collectively, "Supporting Materials"). A Party may amend its Supporting Materials, provided that it submits any amended Supporting Materials to the other Party and to the Expert or, as the case may be, the Expert Panel, within the timeframe set forth in the first sentence of this Section 22.4.

22.5 The Expert or the Expert Panel (which shall decide by majority) shall make its determination on the Covered Matters solely on the basis of the Supporting Materials provided by the Parties pursuant to Section 22.4; an oral hearing shall only take place where absolutely necessary, and as solely determined by the Expert or Expert Panel. The Expert or the Expert Panel shall issue its determination in writing within thirty (30) calendar days of the date of its receipt of the last statement pursuant to Section 22.4 or, if an oral hearing, within thirty (30) calendar days of the oral hearing.

22.6 All matters under this subsection must be conducted, and the Expert or the Expert Panel's determination shall be written in the English language. The Parties will provide (or procure that others provide) the Expert or the Expert Panel with such reasonable assistance and documents as the Expert or the Expert Panel reasonably requires for the purpose of reaching a determination.

22.7 The Expert or the Expert Panel shall act as an expert and not as an arbitral tribunal. The Expert or the Expert Panel shall determine only Covered Matters. The Expert's or the Expert Panel's written determination on the Covered Matters referred to it shall be final and binding on the Parties. Any legal dispute regarding the scope, legal effect or validity of any such determination shall be subject to the arbitration agreement pursuant to Section 21.2, provided that the Parties need not submit to non-binding mediation prior to beginning arbitration proceedings.

22.8 Unless otherwise stated in this Agreement, the Expert's or Expert Panel's fees and any costs properly incurred by it in arriving at its determination (including any fees and costs of any advisers appointed by the Expert or the Expert Panel) shall be borne by the Parties in such proportions as the Expert or Expert Panel shall direct.

23. ASSIGNMENT; SUBCONTRACTING

23.1 **Assignment**. Neither Party may assign its rights or obligations under this Agreement, or the Agreement itself without prior written consent of the other Party (not to be unreasonably withheld); provided, however, that each Party may, without the other Party's consent, (i) assign any or all of its rights and obligations under this Agreement to an Affiliate of such Party, (ii) assign all of its rights and obligations under this Agreement to Legal Successor of such Party, or (iii) assign part of its rights and obligations under this Agreement to a Partial Successor of such Party; provided, further, however, that (x) [****] and (y) Nordmark shall not assign its rights or obligations under this Agreement to any party that is not primarily engaged in the pharmaceutical industry without the prior written consent of Janssen. For clarity, the Parties agree that it will be considered

reasonable for either Party not to consent, or to withhold, condition or delay the consent to a proposed assignment by the other Party to a party which meets one or more of the aforementioned criteria in subclauses (x) and (y). Should the Party being requested to provide consent neither provide nor refuse consent within twenty (20) Business Days of receipt of a request, the Party requesting consent shall notify the other Party of the fact that no reaction has been received. If the Party receiving such notification does not provide or refuse consent within ten (10) Business Days of receipt of that notification, the assignment shall be deemed to have the appropriate consent. In case of dispute concerning the date of receipt, the receipt date of invoice by certified or registered mail shall be decisive. No assignment of this Agreement, or any rights or obligations hereunder, shall release the assigning Party from any of its obligations or liabilities hereunder.

The request for consent, the consent or the refusal of consent, and the notification according to Section 23.1 shall be sent to the other Party by certified or registered mail and by email to the addresses set forth in Section 19.

Any attempt by a Party to assign this Agreement in conflict with the above provision of assignment shall be null and void. Subject to the foregoing, this Agreement shall bind and inure to the benefit of the Parties hereto and their respective Legal Successors or Partial Successors and permitted assigns.

23.2 **Subcontractors**. Nordmark shall not subcontract any of its obligations hereunder to any non-affiliated subcontractor, without the prior written consent of Janssen, provided, however, that any subcontractor specified in the Quality Agreement shall not require written consent.

24. RECORDS RETENTION

Nordmark shall maintain and manage for the duration of the Agreement and thereafter for such period as may be required by applicable Law, all paper or electronic records, files, documents, work papers, receipts and all other information in any form provided by Janssen, its Affiliates or their respective employees or agents or generated by Nordmark or its employees or contractors in connection with its obligations hereunder, in accordance with German Law. Furthermore, if certain records must be retained and maintained for the purposes of compliance with any applicable regulatory requirements (including without limitation all applicable requirements of the FDA and any other Regulatory Authorities, the U.S. Health Insurance Portability and Accountability Act (HIPAA) or other applicable equivalent international requirements), Janssen shall communicate such specific record retention requirements to Nordmark and the Parties shall subsequently discuss and agree on any additional record retention arrangements that are required to ensure compliance with said regulatory requirements (it being understood that Nordmark shall not unreasonably withhold its consent with any retention arrangements that are reasonably proposed by Janssen).

25. ALLIANCES

Notwithstanding anything to the contrary herein, Nordmark understands and acknowledges that Janssen may enter into alliances or distribution arrangements with Third Parties who may engage in joint (with Janssen, its Affiliates or distributors) or unilateral marketing and promoting of the Contracted Products or any combination of products that include the Contracted Products.

26. ENTIRE AGREEMENT

It is the mutual desire and intent of the Parties to provide certainty as to their respective future rights and remedies against each other by defining the extent of their mutual undertakings as provided herein. Accordingly, this Agreement (i) supersedes all previous understandings, agreements and representations between the Parties, written or oral, relating to the performance of services as specified in this Agreement, including the Prior Agreement and the Letter of Understanding (but excluding the MSA and the Quality Agreement) and, (ii) constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and incorporates all representations, warranties, covenants, commitments and understandings on which they have relied in entering into this Agreement, and, except as provided for herein, neither Party makes any covenant or other commitment concerning its future action nor does either Party make any promises, representations, conditions, provisions or terms related thereto.

27. SEVERABILITY

Any term or provision of this Agreement which is invalid or unenforceable in any jurisdiction shall, to the extent the economic benefits conferred by such to both Parties remain substantially unimpaired, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions or affecting the validity or enforceability of any of such terms or provisions in any other jurisdiction.

28. WAIVER AND MODIFICATION OF AGREEMENT

No waiver or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both Parties hereto. The failure of either Party to enforce at any time for any period any provision hereof shall not be construed to be a waiver of such provision or of the right of such Party thereafter to enforce each such provision, nor shall any single or partial exercise of any right or remedy hereunder preclude any other or further exercise thereof or the exercise of any other right or remedy.

29. INTERPRETATION; HEADINGS

Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement: (i) “include”, “includes” and “including” are not limiting and mean include, includes and including, without limitation; (ii) definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms; (iii) references to an agreement, statute, regulation or instrument mean such agreement, statute, regulation or instrument as from time to time amended, modified or supplemented; (iv) references to a Person are also to its successors and permitted assigns; (v) references to an “Section” or “Exhibit” refer to a Section of, or any Exhibit to, this Agreement unless otherwise indicated; (f) the word “will”

shall be construed to have the same meaning and effect as the word "shall"; (vi) the word "any" means "any and all" unless otherwise indicated by context; (vii) the use of any gender shall be applicable to all genders; (viii) the words "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement as an entirety and not to any particular provision; and (ix) all references to days or months will be deemed references to calendar days or months unless otherwise expressly specified. The headings of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. Any reference in this Agreement to a matter or action being subject to the "mutual agreement" or "mutual consultation" of the Parties, or words of similar import, shall not be construed as an agreement that the Parties shall agree to such matter or action. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party on the basis that such Party drafted this Agreement or any portion thereof.

30. RELATIONSHIP OF THE PARTIES

The relationship of the Parties established by this Agreement is that of independent contractors, and nothing contained herein shall be construed to (i) give either Party any right or authority to create or assume any obligation of any kind on behalf of the other or (ii) constitute the Parties as partners, joint ventures, co-owners or otherwise as participants in a joint or common undertaking.

31. SURVIVAL

The provisions of Sections 1 (Definitions), 9.2 (cGMP Audits), 9.3 (Environmental, Health and Safety Audit), 9.6 (Quality Review), 9.7 (Canadian Biologic Review) (provided, that, in each case of Sections 9.3, 9.6 and 9.7, such provisions shall survive for such period ending on the expiration of shelf life of all Contracted Products existing at the time of expiration or termination of this Agreement), 13 (Indemnification; Limitation of Liability), 14 (Insurance), 15 (Confidentiality), 16.6 (Term and Termination), 17.2 (Regulatory Authority Inspections), 19 (Notices), 21 (Governing Law), 23 (Assignment; Subcontracting), 24 (Records Retention) (such provisions shall survive only for such period set forth therein), 26 (Entire Agreement), 27 (Severability), 29 (Interpretation; Headings) and 31 (Survival) hereof shall survive the expiration or termination of this Agreement by any Party for any reason.

[*The remainder of this page has been left intentionally blank.*]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be signed by their duly authorized representatives as of the Effective Date.

Nordmark Arzneimittel GmbH & Co. KG

By: /s/ Dr. J. Tonne

Name: Dr. Jörn Tonne

Title: CEO

Date: 03-November-2017

By: /s/ Dr. J. Lüdemann

Name: Dr. Jan Lüdemann

Title: Vice President Sales

Date: 03-November-2017

[Signature Page to Amended and Restated Know-How License and Supply Agreement]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be signed by their duly authorized representatives as of the Effective Date.

Janssen Pharmaceuticals, Inc.

By: /s/ F. Pease

Name: FLAVIA PEASE

Title: TREASURER

Date: November 2, 2017

[Signature Page to Amended and Restated Know-How License and Supply Agreement]

[****] = Certain confidential information contained in this document has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

Execution Copy

FIRST AMENDMENT

to the

AMENDED AND RESTATED KNOW-HOW LICENSE AND SUPPLY AGREEMENT

(as concluded between Janssen Pharmaceuticals, Inc. and Nordmark Arzneimittel GmbH & Co. KG)

by and between

VIVUS, INC.

and

NORDMARK ARZNEIMITTEL GMBH & CO. KG

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This Amendment (hereinafter referred to as the **"First Amendment")** to the Amended and Restated Know-How License and Supply Agreement (hereinafter referred to as the **"Agreement")** is made effective as of 26 June 2019 **("Effective Date")** by and between VIVUS, Inc., a company organized and existing under the laws of Delaware and having its principle office at 900 E. Hamilton Avenue, Suite 550, Campbell, CA 95008, USA (hereinafter referred to as "Vivus"), and Nordmark Arzneimittel GmbH & Co. KG, a company organized and existing under the laws of Germany, having its principal office at Pinnauallee 4, 25436 Uetersen, Germany (hereinafter referred to as **"Nordmark").**

Vivus and Nordmark hereinafter each referred to as a **"Party"** and collectively referred to as the **"Parties".**

RECITALS

WHEREAS, Janssen Pharmaceuticals, Inc., a corporation formed under the laws of Pennsylvania with offices at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08650, United States **("Janssen"),** and Nordmark entered into the Agreement, effective 3rd November 2017, according to which (i) Nordmark grants to Janssen the Know-How License (as defined in the Agreement) for the purposes of marketing and selling the Contracted Product (as defined in the Agreement) in the Territory (as defined in the Agreement), and (ii) Janssen shall purchase from Nordmark and Nordmark shall Manufacture (as defined in the Agreement) and deliver to Janssen Contracted Products (as defined in the Agreement);

WHEREAS, effective 8th June 2018, Janssen has assigned all of its rights and obligations under the Agreement to Vivus as its Legal Successor (as defined in the Agreement) in accordance with Section 23.1 of the Agreement; and

WHEREAS, because of the assignment from Janssen to Vivus as Janssen's Legal Successor (as defined in the Agreement), the term "Janssen" in the Agreement (as amended by this First Amendment) shall mean "Vivus", except where such references relate to past actions of Janssen that have no bearing on the ongoing contractual relations between Vivus and Nordmark, including, without limitation, in the following provisions of the Agreement (as amended by this First Amendment): the Recitals including any definitions contained therein and the definition of Quality Agreement; and

WHEREAS, Nordmark and Vivus now desire to enter into this First Amendment in order to amend the Agreement as set forth herein and provide for the supply of the Contracted Products pursuant to the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the Parties agree as follows:

1. DEFINITIONS

1.1 Unless explicitly stated otherwise in Section 1.2 below, all terms written in capital letters used in this First Amendment shall have the meaning as defined in the Agreement.

1.2 For the purpose of this First Amendment, the terms set forth hereinafter shall have the following meaning:

1.2.1 **"Agreement"** has the meaning set forth in the Recitals.

1.2.2 **"Assignment Notice"** has the meaning set forth in Section 9.2.

1.2.3 **"Change of Control"** means any event by which a Third Party acquires the majority shareholders' or members' voting rights of Vivus or acquires the right to appoint or remove a majority of the members of the board of directors of Vivus enabling such Third Party to exercise a dominant influence.

1.2.4 **"Effective Date" has the** meaning set forth in the Recitals.

1.2.5 **"First Amendment" has the meaning set forth in the Recitals.**

1.2.6 **"First Amendment Termination Option"** has the meaning set forth in Section 9.1.

1.2.7 **"Option Notice"** has the meaning set forth in Section 9.3.

1.2.8 **"Option Period I" has the meaning** set forth in Section 9.3.

1.2.9 **"Option Period II"** has the meaning set forth in Section 9.3.

1.2.10 **"Vivus"** has the meaning set forth in the Recitals.

2. DEFINITIONS IN THE AGREEMENT

2.1 The Definition of "Partial Successor" in Section 1 of the Agreement shall be amended and restated as follows:

> **"Partial Successor" shall mean a Third Party** which, always and in each case subject to the terms of Section 23, acquires, is assigned or otherwise receives from a Party after the Effective Date all of such Party's right, title and interest to all or certain of the Contracted Products, as applicable, within a specific geographic territory only, but not worldwide, irrespective whether by law or by contract and irrespective by which kind of transaction or legal form. For the avoidance of doubt, the Parties expressly agree that a sublicense in accordance with Section 2.1 (b) of this Agreement does not qualify the Third Party receiving such sublicense rights a Partial Successor.

2.2 The Definition of "Contracted Products" in Section 1 of the Agreement shall be amended and restated as follows:

"Contracted Products" means all Legacy Products and all Advanced Products. [****].

2.3 New definitions shall be added to Section 1 in the Agreement as follows:

"Advanced Product [****]**"** shall have the meaning as set forth in Section 3.3.2.2 (d).

"Difference I" shall have the meaning as set forth in Section 3.3.1.1 (c).

"Difference II" shall have the meaning as set forth in Section 3.3.2.1 (c).

"First Renewal Term" has the meaning set forth in Section 16.1.

"Initial Term" has the meaning set forth in Section 16.1.

"[****]**"** shall mean the [****]**.**

"[****]**"** shall mean the [****]**.**

"[****]**"** shall have the meaning set forth in Section 3.4.

"Minimum Costs I" shall have the meaning as set forth in Section 3.3.1.1 (b).

"Minimum Costs II" shall have the meaning as set forth in Section 3.3.2.1 (b).

"Minimum Order I" shall have the meaning as set forth in Section 3.3.1.1 (a).

"Minimum Order II" shall have the meaning as set forth in Section 3.3.2.1 (a).

"Minimum Costs II Change" shall have the meaning as set forth in Section 3.3.2.1 (b).

"Nordmark R&P Fee" shall have the meaning as set forth in Section 6.2 (a).

"Product Mix" shall mean the following mix of Contracted Products, regardless of whether each Contracted Product is a Legacy Product or an Advanced Product:

Contracted Product	Units
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]

"Reduced Nordmark R&P Fee" shall have the meaning as set forth in Section 6.2 (a).

"Subsequent Renewal Term" has the meaning set forth in Section 16.1.

"Term" has the meaning set forth in Section 16.1.

"Total Costs" shall have the meaning as set forth in Section 3.3.1.1. (e).

3. RIGHT TO GRANT A SUBLICENSE FOR CANADA

Section 2.1 of the Agreement shall be amended and restated as follows:

„Know-How License. Subject to the terms of this Agreement and in particular, but not limited to, subject to the process and mechanism set out in Section 2.3 and the last sentence of this Section 2.1 (i.e. the terms identified „for clarity" hereafter), Nordmark hereby grants Janssen an exclusive, royalty-free, nontransferable (except as permitted under Section 23.1 and under this Section 2.1 (b)) license to use the Licensed Know-How during the Term within the Territory, solely for the purposes of (i) filing, maintaining, amending, supplementing, or renewing Regulatory Approvals owned by Janssen in the Territory for any Contracted Product, and (ii) marketing and selling any Contracted Product in the Territory (the **„Know-How License").**

For clarity,

(a) no license is granted by Nordmark under the Licensed Know-How to Janssen to Manufacture itself or have Manufactured by Third Parties any Contracted Product or any other products, and Janssen shall not use any of the Licensed Know-How to Manufacture itself or have Manufactured by Third Parties any Contracted Product or any other products (except as set forth in Section 16.6.4);

(b) Janssen shall not sublicense the Licensed Know-How to any Third Parties without the prior written consent of Nordmark (except as set forth in Section 16.6.4); provided, however, that Janssen, notwithstanding any provision to the contrary in this Agreement, shall have the right, without Nordmark's consent, to grant a sublicense under the Licensed Know-How in Canada to a Third Party in Canada solely for the purpose of marketing and selling any Contracted Product in Canada, unless such Third Party [****].

(c) [****]**;**

(d) the Know-How License does not include any rights or licenses in respect of the marketing, sale or importation of Intermediate Product or Bulk Product in the Territory by Janssen; and

(e) the Know-How License shall not restrict Nordmark's right to grant a license under the Licensed Know-How to a Third Party inside or outside the Territory with respect to any product (other than the Contracted Products), [****]**."**

4. ADJUSTMENTS OF MINIMUM ORDER QUANTITIES AND SUPPLY PRICES; ADJUSTMENTS OF CORRESPONDING EXHIBITS

4.1 Section 3.3 of the Agreement shall be amended and restated as follows:

„3.3 **Minimum Order Quantities and Minimum Order Sales.**

3.3.1 **Calendar Years 2019 and 2020.**

3.3.1.1 The following shall apply in Calendar Years 2019 and 2020, provided, [****]:

(a) The annual minimum order quantity of Contracted Products in each of Calendar Year 2019 and Calendar Year 2020 is equivalent to not less than [****]. This Minimum Order I corresponds, by way of example, to [****] of the Product Mix.

(b) Janssen guarantees to Nordmark in each of Calendar Year 2019 and Calendar Year 2020 minimum annual sales of Nordmark to Janssen with Contracted Products in the amount of Euro [****] **(„Minimum Costs I").** For the avoidance of doubt, the Parties agree that such Minimum Costs I are fixed for Calendar Year 2019 and Calendar Year 2020 and are not subject to any adjustments.

(c) For Calendar Year 2019 and for Calendar Year 2020, Janssen may, in its sole discretion, decide either to (i) [****], (ii) [****] **(„Difference I").** [****]. In this case Janssen shall pay [****]. For the avoidance of doubt, the Parties expressly agree that in case [****]**.**

(d) Nordmark shall (i) calculate Difference I for Calendar Year 2019 and for Calendar Year 2020, and (ii) provide the corresponding invoices to Janssen by 15th January of the following Calendar Year. [****].

(e) For the purposes of calculating Difference I Total Costs shall include costs for (i) [****], and (ii) [****]. In case Contracted Products are not delivered in time due to reasons within Nordmark's responsibility or reasonable control, such Contracted Products will be considered delivered with respect to the Total Costs.

(f) For the avoidance of doubt, the Parties agree on the following calculation example for Difference I: If (i) Janssen purchases and gets delivered Contracted Products for Euro [****], and (ii) there are destruction costs of Euro [****].

3.3.1.2 The following shall apply in Calendar Year 2019 and Calendar Year 2020, [****]:

The terms below in Section 3.3.2.1 (b) shall apply on a pro rata basis. For clarity, [****] Minimum Costs in 2020 would amount to Euro [****], which would be the sum of Euro [****] ([****]% of Euro [****]) Minimum Costs I and Euro [****] ([****]% of Euro [****]) Minimum Costs II.

3.3.2 **Calendar Year 2021 and all following Calendar Years**

3.3.2.1 The following shall apply [****]**:**

(a) The annual minimum order quantity of Contracted Products in Calendar Year 2021 and any following Calendar Year shall be equivalent to not less than [****] Intermediate Product MFT batches **(„Minimum Order II").** This Minimum Order II corresponds, by way of example, to [****] of the Product Mix.

(b) As of 1st January 2019, Janssen guarantees to Nordmark in Calendar Year 2021 and in any following Calendar Year minimum annual sales of Nordmark to Janssen with Contracted Products in the amount of Euro [****] **(„Minimum Costs II").** Such Minimum Costs II shall be subject to [****] according to [****]. For clarity, in case the [****]. In case the [****], the [****] would further [****]. The difference between the Minimum Costs II as of 1st January 2019 and [****] **(„Minimum Costs II Change")** would in this case be Euro [****]. For clarity: this mechanism leading to the [****] will continue until the [****], regardless of whether the [****] occurs after [****].

(c) For Calendar Year 2021 and in any following Calendar Year, Janssen may, in its sole discretion, decide either to (i) [****] (ii) [****] **(„Difference II").** In case the [****]. In this case Janssen shall pay [****]. For the avoidance of doubt, the Parties expressly agree that in case [****].

(d) Nordmark shall (i) [****], and (ii) provide the corresponding invoices to Janssen by 15th January of the following Calendar Year. [****].

(e) For the purposes of calculating Difference II, Total Costs shall include costs for (i) [****], and (ii) [****]. In case Contracted Products are not delivered in time due to reasons within Nordmark's responsibility or reasonable control, such

Contracted Products will be considered delivered with respect to the Total Costs.

(f) For the avoidance of doubt, the Parties agree on the following calculation example for Difference II: If (i) [****] and (ii) [****].

3.3.2.2 The following shall apply [****]:

(a) The annual minimum order quantity of Contracted Products

in Calendar Year 2021 and any following Calendar Year shall be Minimum Order I.

(b) Janssen guarantees to Nordmark in Calendar Year 2021 and in any following Calendar Year minimum annual sales of Nordmark to Janssen with Contracted Products in the amount of Minimum Costs I.

(c) For Calendar Year 2021 and any following Calendar Year, Janssen may, in its sole discretion, decide either to (i) [****], or to (ii) [****]. For the avoidance of doubt, the Parties expressly agree that in case Janssen chooses option (ii), [****].

(d) Janssen shall pay to Nordmark [****] **(„Advanced Product** [****]**").** This Advanced Product [****] shall be due on the [****]. If [****], the Advanced Product [****] will be calculated on a monthly pro-rata-basis. Nordmark will provide the corresponding invoices to Janssen until the end of each quarter. The according amounts are payable by Janssen to Nordmark in [****]. The Parties expressly agree that the Advanced Product [****] is not payable by Janssen (i) if [****], or (ii) [****]. For the avoidance of doubt, the Parties expressly agree that as of [****].

4.2 A new Section 3.4 shall be added to the Agreement:

„3.4 **Synchronicity of** [****]**.** Vivus shall use commercially reasonable efforts that the [****] is parallel to the [****] and vice versa and that the period between the [****] and the [****] does not exceed a maximum of [****] (the "[****]"). The Parties agree that Nordmark is under no obligation whatsoever to Manufacture and deliver to Janssen the Contracted Products in a different quality (i.e. to Manufacture and deliver both Legacy Products and Advanced Products) for a period exceeding the [****]. For clarity: in this event (i.e. if the [****] is exceeded) Nordmark shall only be obliged to Manufacture and deliver to Janssen the [****]."

4.3 A new Section 3.5 shall be added to the Agreement:

„3.5 **Relaunch of Legacy Products.** The Parties agree to use commercially reasonable efforts to relaunch the Legacy Products, if the Advanced Products lose marketing authorizations in the USA and/or in Canada after the [****] and/or the [****]."

4.4 Section 6.1 of the Agreement shall be amended and restated as follows:

„6.1 **Legacy Product Supply Price.** In consideration of the supply of any Legacy Product by Nordmark to Janssen under the terms and conditions of this Agreement, Janssen shall pay Nordmark as of the 1st January 2019 the supply prices set forth in Exhibit E **(„Legacy Supply Prices")."**

4.5 Section 6.2 of the Agreement shall be amended and restated as follows:

„6.2 **Advanced Product Supply Price.** In consideration of the supply of any Advanced Product by Nordmark to Janssen under the terms and conditions of this Agreement, Janssen shall pay Nordmark as of the [****] the supply prices set forth in Exhibit F **(„Advanced Supply Prices")."**

4.6 A new Section 6.2 (a) shall be added to the Agreement:

„6.2 (a) **„Nordmark R&P Fee.** As of the [****]**,** Janssen will pay Nordmark [****] **a**mounting to Euro [****] **(„Nordmark R&P Fee").** At the [****], the Nordmark R&P Fee will be [****] **(„Reduced Nordmark R&P Fee").** After the [****]**,** the Reduced Nordmark R&P Fee shall be subject to [****] according to Section 6.3 of this Agreement. For clarity, an exemplary Reduced Nordmark R&P Fee in [****] of Euro [****] and a [****]% in [****] would lead to a new Reduced Nordmark R&P Fee in [****] of Euro [****]. The same mechanism shall apply for all subsequent Calendar Years. For further clarity, the mechanism shall also apply in case of [****]. Nordmark shall provide the corresponding invoices for the Nordmark R&P Fee or the Reduced Nordmark R&P Fee, as the case may be, to Janssen until the end of each quarter. The according amounts shall be payable by Janssen to Nordmark [****]. The Parties agree and acknowledge that any development and improvement of the Contracted Products shall be subject to (i) a mutually agreed upon amendment of this Agreement, (ii) a mutually agreed upon scope of work and schedule, and (iii) a purchase order in an amount and form acceptable to Nordmark, provided, that (i), (ii) and (iii) is at the sole discretion of Nordmark following good faith discussions between the Parties. The Parties further agree and acknowledge that the payment of the Nordmark R&P Fee or the Reduced Nordmark R&P Fee, as the case may be, shall not obligate Nordmark to agree to any amendment of this Agreement or to

any subsequent scope of work, schedule or purchase order proposed by Janssen."

4.7 A new Section 6.2 (b) shall be added to the Agreement:

„6.2 (b) **Sum of Minimum Cost II and Nordmark R&P Fee.** In any case, upon the [****], the sum of the Minimum Costs II and the Reduced Nordmark R&P Fee shall be Euro [****]. For clarity: this will also be the case should the [****] occur before [****].

4.8 A new Section 6.3 (a) shall be added to the Agreement:

„6.3 (a) **Supply Price Adjustment for Calendar Year 2018.** For the avoidance of doubt, the Parties expressly agree that the Legacy Supply Prices as set forth in Exhibit E and the Advanced Supply Prices as set forth in Exhibit F shall include the Supply Price Adjustments for Calendar Year 2018 according to Section 6.3 of this Agreement."

4.9 A new Section 6.3 (b) shall be added to the Agreement:

„6.3 (b) **Supply Price Adjustment for Calendar Year 2019 and any following Calendar Year.** For the avoidance of doubt, the Parties expressly agree that the Legacy Supply Prices as set forth in Exhibit E and the Advanced Supply Prices as set forth in Exhibit F will be adjusted according to Section 6.3 of this Agreement."

4.10 Exhibit E of the Agreement shall be replaced by Exhibit E attached to this First Amendment.

4.11 Exhibit F of the Agreement shall be replaced by Exhibit F attached to this First Amendment.

5. ADJUSTMENTS OF PRODUCT RELEASE LIMITS

5.1 Exhibit C of the Agreement shall be replaced by Exhibit C attached to this First Amendment.

5.2 Exhibit D of the Agreement shall be replaced by Exhibit D attached to this First Amendment.

6. TERM AND TERMINATION

6.1 Section 16.1 of the Agreement shall be amended and restated as follows:

„Initial Term. This Agreement shall begin on the Effective Date and continue through 31' December 2029 **(„Initial Term"),** unless earlier terminated in accordance with Sections 16.2, 16.4 or 16.5 of this Agreement. This Agreement shall be renewed automatically for additional five (5) year periods unless earlier terminated in accordance with Sections 16.2, 16.4 or 16.5 of this Agreement as follows: (i) commencing at the expiration of the Initial Term (the **„First Renewal Term")** unless

Janssen terminates this Agreement by giving Nordmark written notice of its intent to terminate at least [****] prior to the expiration of the Initial Term and (ii) commencing at the expiration of the First Renewal Term (each a **„Subsequent Renewal Term",** together with the Initial Term and the First Renewal Term, the **„Term")** unless either Janssen or Nordmark terminates this Agreement by giving the other Party written notice of its intent to terminate at least [****] prior to the expiration of the First Renewal Term or any Subsequent Renewal Term."

6.2 Section 16.2.2.2. of the Agreement shall be amended and restated as follows:

„It shall be considered a material breach of Janssen within the meaning of Section 16.2.1 if Janssen

(a) does not comply with one or several of the following obligations under this Agreement, in particular, without limitation:

- Section 2.1 (Know-How License);
- Section 2.3 (Process and Mechanism);
- Section 3.2 (Exclusivity of Supply);
- Section 12.3.1(b);
- Breach of Section 15 (Confidentiality) in any material respect; and
- Section 22.1 (Assignment; Subcontracting); and/or

(b) does not make payments that are due according to this Agreement, in particular, but without limitation, according to Section 3.3."

2.1 The Parties agree that Section 16.3 of the Agreement shall be deleted, and that this Section shall be left intentionally blank in the Agreement.

7. ASSIGNMENT

Section 23.1 of the Agreement shall be amended and restated as follows:

„Assignment. Neither Party may assign its rights or obligations under this Agreement, or the Agreement itself without prior written consent of the other Party (not to be unreasonably withheld or delayed); provided, however, that

(a) Janssen may assign its rights or obligations under this Agreement relating to Canada only (for clarity: no rights and obligations whatsoever relating to the USA) without Nordmark's consent; and

(b) each Party may, without the other Party's consent, (i) assign any or all its rights and obligations under this Agreement to an Affiliate of such Party, (ii) assign all its rights and obligations under this Agreement to the Legal Successor of

such Party, or (iii) assign part of its rights and obligations under this Agreement to a Partial Successor of such Party;

in case of (a) and/or (b) provided further, however, that

(x) Janssen shall not assign its rights or obligations under this Agreement, whether relating to Canada only or to the USA only or to the USA and Canada, to any party (i) [****], (ii) [****] and/or (iii) [****] without the prior written consent of Nordmark, and

(y) Nordmark shall not assign its rights or obligations under this Agreement to any party that is not primarily engaged in the pharmaceutical industry without the prior written consent of Janssen.

For clarity, the Parties agree that it will be considered reasonable for either Party not to consent, or to withhold, condition or delay the consent to a proposed assignment by the other Party to a party which meets one or more of the aforementioned criteria in subclauses (x) and (y).

Should the Party being requested to provide consent neither provide nor refuse consent within [****] of receipt of a request, the Party requesting consent shall notify the other Party of the fact that no consent or refusal to consent has been received. If the Party receiving such notification does not provide or refuse consent within [****] of receipt of that notification, the assignment shall be deemed to have the appropriate consent. In case of dispute concerning the date of receipt, the receipt date of invoice by certified or registered mail shall be decisive. No assignment of this Agreement, or any rights or obligations hereunder, shall release the assigning Party from any of its obligations or liabilities hereunder.

The request for consent, the consent or the refusal of consent, and the notification according to this Section 23.1 shall be sent to the other Party by certified or registered mail and by email to the addresses set forth in Section 19.

Any attempt by a Party to assign this Agreement in conflict with the above provision of assignment shall be null and void. Subject to the foregoing, this Agreement shall bind and inure to the benefit of the Parties hereto and their respective Legal Successors or Partial Successors and permitted assigns."

8. NOTICES

Section 19 of the Agreement shall be amended and restated as follows:

„To be effective, all notices and other communications hereunder shall be in writing and delivered personally or mailed by Federal Express or another internationally recognized courier service (billed to sender), to the Parties at the following addresses (or to such other address as either Party may designate by notice as provided in this Section 19):

If to Nordmark:

Nordmark Arzneimittel GmbH & Co. KG
Attn.: Managing Director
Pinnauallee 4
25436 Uetersen
Germany

[****]
[****]
info@nordmark-pharma.de

If to Vivus:

VIVUS, Inc.
Attn.: CFO and General Counsel
900 East Hamilton Avenue, Suite 550
Campbell, CA 95008
U.S.A.
oki@vivus.com (with copy to CFO@vivus.com)
Slebir@vivus.com (with copy to generalcounsel@vivus.com)

9. FIRST AMENDMENT TERMINATION OPTION FOR NORDMARK

9.1 **First Amendment Termination Option.** Nordmark shall have the option to terminate this First Amendment with the effects of such termination set forth in Section 9.5 below **(„First Amendment Termination Option")** anytime before the [****], if Vivus (i) assigns any or all of its rights and obligations under the Agreement (as amended by this First Amendment) to a Legal Successor and/or to a Partial Successor in accordance with Section 23.1 of the Agreement (as amended by this First Amendment), and/or (ii) enters into a transaction or series of related transactions resulting in a Change of Control. For clarity, Nordmark's First Amendment Termination Option shall terminate as of the [****] and have no further import or effect.

9.2 **Assignment Notice.** Vivus shall provide written notice to Nordmark of a Change of Control or of its good faith intent following approval of the Vivus Board of Directors to perfect an assignment to a Legal Successor or Partial Successor **(„Assignment Notice").** This Assignment Notice shall be provided to Nordmark without undue delay and shall identify the party acquiring control or the potential Legal Successor or Partial Successor and generally describe the form of the Change of Control or potential assignment.

9.3 **Option Period and Option Notice.** Nordmark shall have a period of [****] **(„Option Period I")** to exercise the First Amendment Termination Option by notifying Vivus in writing **(„Option Notice").** Nordmark shall have the right to exercise the First Amendment Termination Option at any time, i.e. even after the assignment or the Change of Control **(„Option Period H"),** if (i) Vivus does not provide an Assignment Notice to Nordmark, and/or (ii) the actual Change of Control or actual assignment is perfected with a third party, which is not an Affiliate of the third party identified in the Assignment Notice or substantially deviates regarding the

form of the Change of Control or the assignment or in terms of economics from the Assignment Notice.

9.4 **Notices.** The Assignment Notice and the Option Notice shall be sent to the other Party by certified or registered mail and by email to the addresses set forth in Section 19 of the Agreement (as amended by this First Amendment).

9.5 **Effects of Exercising the First Amendment Termination Option.**

9.5.1 If Nordmark exercises the First Amendment Termination Option within Option Period I or, as the case may be, Option Period II, this First Amendment shall terminate; provided, however, that Section 6.1 of this First Amendment (amending Section 16.1 of the Agreement) shall survive such termination with all other provisions of this First Amendment having no further import or effect such that the Agreement, as amended by Section 6.1 of this First Amendment, will become effective again, including, but not limited to, the provisions regarding Supply Prices and the Know-How-Fee in Section 6.2.

9.5.2 If (i) Nordmark does not exercise the First Amendment Termination Option within the Option Period I or, as the case may be, the Option Period II, and (ii) the Change of Control or assignment becomes effective before [****], Vivus shall guarantee to Nordmark Minimum Costs II according to Section 3.3.2.1 of the Agreement (as amended by this First Amendment) and the Nordmark R&P Fee according Section 6.2. (a) of the Agreement (as amended by this First Amendment) shall apply immediately upon the Change of Control or the assignment becomes effective.

10. MISCELLANEOUS

10.1 This First Amendment shall become effective upon the Effective Date.

10.2 Unless explicitly stated otherwise herein, all terms and conditions of the Agreement shall remain unaffected by this First Amendment.

[The remainder of this page has been left intentionally blank.]

IN WITNESS WHEREOF, the Parties have caused this First Amendment to be signed by their duly authorized representatives as of the Effective Date.

Nordmark Arzneimittel GmbH & Co. KG

By: /s/ Dr. J. Tonne

Name: Dr. Jörn Tonne

Title: CEO

Date: 26 – June – 2019

[Signature Page to First Amendment]

IN WITNESS WHEREOF, the Parties have caused this First Amendment to be signed by their duly authorized representatives as of the Effective Date.

Vivus, Inc.

By: /s/ John Amos

Name: John P. Amos

Title: Chief Executive Officer

Date: 6/26/2019

Exhibit 31.1

CERTIFICATION

I, John P. Amos, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2019

By: /s/ John P. Amos
John P. Amos
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Mark K. Oki, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2019

By: /s/ Mark K. Oki
Mark K. Oki
Senior Vice President, Chief Financial Officer and Chief Accounting Officer

Exhibit 32

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

I, John P. Amos, Chief Executive Officer of VIVUS, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended June 30, 2019, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: August 6, 2019

By: /s/ John P. Amos
John P. Amos
Chief Executive Officer

I, Mark K. Oki, Senior Vice President, Chief Financial Officer and Chief Accounting Officer of VIVUS, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended June 30, 2019, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: August 6, 2019

By: /s/ Mark K. Oki
Mark K. Oki
Senior Vice President, Chief Financial Officer and Chief Accounting Officer