VIVUS INC
Form 10-Q
August 07, 2018
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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, 2018

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	(IRS employer

incorporation or organization) identification number)

900 E. Hamilton Avenue, Suite 550
Campbell, California 95008
(Address of principal executive office) (Zip Code)

(650) 934-5200

(Registrant's telephone number, including area code)

N/A

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

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

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

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

Large accelerated filer	Accelerated filer	Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company Emerging growth company

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

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

At July 31, 2018, 106,227,162 shares of common stock, par value $.001 per share, were outstanding.

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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, 2018	December 31, 2017
ASSETS	Unaudited	
Current assets:		
Cash and cash equivalents	$ 57,181	$ 66,392
Available-for-sale securities	66,361	159,943
Accounts receivable, net	11,071	12,187
Inventories	22,259	17,712
Prepaid expenses and other current assets	6,399	7,178
Total current assets	163,271	263,412
Property and equipment, net	445	542
Intangible and other non-current assets	141,545	1,014
Total assets	$ 305,261	$ 264,968
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 4,345	$ 10,072
Accrued and other liabilities	26,879	21,475
Deferred revenue	1,897	2,075
Current portion of long-term debt	—	5,147
Total current liabilities	33,121	38,769
Long-term debt, net of current portion	295,498	230,536
Deferred revenue, net of current portion	4,243	4,674
Non-current accrued and other liabilities	283	327
Total liabilities	333,145	274,306
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock; $1.00 par value; 5,000 shares authorized; no shares issued and outstanding at June 30, 2018 and December 31, 2017	—	—
Common stock; $.001 par value; 200,000 shares authorized; 106,187 and 105,977 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	106	105

Additional paid-in capital	839,310	834,730
Accumulated other comprehensive loss	(508)	(608)
Accumulated deficit	(866,792)	(843,565)
Total stockholders' deficit	(27,884)	(9,338)
Total liabilities and stockholders' deficit	$ 305,261	$ 264,968

See accompanying notes to unaudited condensed consolidated financial statements.

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VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue:				
Net product revenue	$ 13,250	$ 8,518	$ 22,882	$ 26,138
License and milestone revenue	—	—	—	5,000
Supply revenue	1,042	2,119	2,725	5,931
Royalty revenue	668	590	1,253	1,170
Total revenue	14,960	11,227	26,860	38,239
Operating expenses:				
Cost of goods sold (excluding amortization)	3,286	3,389	5,916	9,375
Amortization of intangible assets	1,273	181	1,364	362
Selling, general and administrative	11,711	11,630	21,779	23,061
Research and development	2,042	1,014	3,445	3,194
Total operating expenses	18,312	16,214	32,504	35,992
(Loss) income from operations	(3,352)	(4,987)	(5,644)	2,247
Interest expense and other expense, net	9,218	8,398	17,567	16,700
Loss before income taxes	(12,570)	(13,385)	(23,211)	(14,453)
Provision for (benefit from) income taxes	4	1	16	(11)
Net loss	$ (12,574)	$ (13,386)	$ (23,227)	$ (14,442)
Basic and diluted net loss per share:	$ (0.12)	$ (0.13)	$ (0.22)	$ (0.14)
Shares used in per share computation:				
Basic and diluted	106,116	105,712	106,065	105,596

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net loss	$ (12,574)	$ (13,386)	$ (23,227)	$ (14,442)
Unrealized gain on securities, net of taxes	576	109	99	234
Translation adjustment	1	—	1	—
Comprehensive loss	$ (11,997)	$ (13,277)	$ (23,127)	$ (14,208)

See accompanying notes to unaudited condensed consolidated financial statements.

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VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2018	2017
Operating activities:		
Net loss	$ (23,227)	$ (14,442)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	1,495	501
Amortization of debt issuance costs and discounts	10,706	9,973
Amortization of discount or premium on available-for-sale securities	616	442
Share-based compensation expense	1,974	1,468
Changes in assets and liabilities:		
Accounts receivable	1,116	1,037
Inventories	(2,785)	558
Prepaid expenses and other assets	779	2,912
Accounts payable	(5,727)	(323)
Accrued and other liabilities	(2,469)	4,783
Deferred revenue	(609)	(18,197)
Net cash used for operating activities	(18,131)	(11,288)
Investing activities:		
Property and equipment purchases	(34)	(21)
Acquisition of PANCREAZE license	(135,000)	—
Purchases of available-for-sale securities	(7,604)	(20,915)
Proceeds from maturity of available-for-sale securities	40,411	23,120
Proceeds from sales of available-for-sale securities	60,259	7,208
Net cash (used for) provided by investing activities	(41,968)	9,392
Financing activities:		
Net proceeds from debt issuance	107,991	—
Repayments of notes payable	(57,187)	(6,507)
Net proceeds from exercise of common stock options	60	—
Sale of common stock through employee stock purchase plan	24	26
Net cash provided by (used for) financing activities	50,888	(6,481)
Net decrease in cash and cash equivalents	(9,211)	(8,377)
Cash and cash equivalents:		
Beginning of year	66,392	84,783
End of period	$ 57,181	$ 76,406

See accompanying notes to unaudited condensed consolidated financial statements.

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VIVUS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2018

1. BUSINESS AND SIGNIFICANT ACCOUNTING POLICIES

VIVUS is a specialty pharmaceutical company with three approved therapies and one product candidate in active clinical development. Qsymia® (phentermine and topiramate extended release) is approved by the U.S. Food and Drug Administration, or FDA, for chronic weight management. STENDRA® (avanafil) is approved by FDA for erectile dysfunction, or ED, and by the European Commission, or EC, under the trade name SPEDRA, for the treatment of ED in the EU. 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. The Company commercializes Qsymia and PANCREAZE in the U.S. through a smalls 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. VI-0106 (tacrolimus) is in active clinical development and is being studied in patients with pulmonary arterial hypertension, or PAH.

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

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. Management has evaluated all events and transactions that occurred after June 30, 2018 through the date these unaudited condensed consolidated financial statements were filed. There were no events or transactions during this period that require recognition or disclosure in these unaudited condensed consolidated financial statements. The December 31, 2017 condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP.

The unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017 as filed on March 14, 2018 with the Securities and Exchange Commission, or SEC, and as amended by the Form 10-K/A filed on April 26, 2018 with the 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.

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.

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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, 2017 with the exception of its revenue recognition policy as discussed in Note 2.

Recent Accounting Pronouncement Adopted

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers. This standard is a comprehensive new revenue recognition model that requires revenue to be recognized in a manner to depict the transfer of goods or services to a customer at an amount that reflects the consideration expected to be received in exchange for those goods or services. This new standard supersedes most previously-existing revenue recognition guidance. The Company adopted this standard in January 2018 using the modified retrospective basis. See Note 2.

In August 2016, the FASB issued Accounting Standards Update 2016-15, Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments. The standard clarifies how certain cash receipts and cash payments will be presented and classified in the statement of cash flows. The Company adopted this standard in January 2018, and it had no impact on its consolidated financial statements.

Recent Accounting Pronouncements Not Yet 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 will require lessees to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. For public companies, this standard is effective for annual and interim periods beginning on or after December 15, 2018. Early adoption is permitted, but the Company intends to adopt this guidance effective January 1, 2019 using a modified retrospective transition method. The Company's only significant lease is its operating lease for its corporate headquarters, although it has several smaller leases. The Company is completing its analysis, but expects the adoption of this guidance to have a significant impact on its balance sheets as it will recognize right of use assets and corresponding lease liabilities. The Company expects the overall recognition of expense to be similar to current guidance, though the classification of such expense could be significantly different.

2. REVENUES

On January 1, 2018, the Company adopted Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers, or Topic 606. Topic 606 supersedes the revenue recognition requirements in Topic 605 Revenue Recognition, or Topic 605, and requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services.

The Company adopted Topic 606 as of January 1, 2018 using the modified retrospective transition method applied to those contracts which were not completed as of January 1, 2018. Results for reporting periods beginning on or after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under Topic 605. Due in large part to the change in accounting estimate made by the Company in the first quarter of 2017, revenue amounts as reported for the three and six months ended June 30, 2017 under Topic 605 are approximately the same as they would have been under Topic 606, and the

Company did not have or record a cumulative impact of adopting Topic 606 as of January 1, 2018.

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Revenue Recognition

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) the entity 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.

Change in Accounting Estimate in 2017

The Company ships units of Qsymia through a distribution network that includes certified retail pharmacies. The Company began shipping Qsymia in September 2012 and grants rights to its customers to return unsold product from six months prior to and up to 12 months subsequent to product expiration. This has resulted in a potential return period of from 24 to 36 months depending on the ship date of the product. As the Company had no previous experience in selling Qsymia and given its lengthy return period, the Company was not initially able to reliably estimate expected returns of Qsymia at the time of shipment, which was required by the accounting literature at the time, and therefore recognized revenue when units were dispensed to patients through prescriptions, at which point the product was not subject to return, or when the expiration period had ended.

Beginning in the first quarter of 2017, with 48 months of returns experience, the Company believed that it had sufficient data and experience from selling Qsymia to reliably estimate expected returns. Therefore, beginning in the first quarter of 2017, under the then relevant accounting literature, the Company began recognizing revenue from the

sales of Qsymia upon shipment and recording a reserve for expected returns at the time of shipment.

In accordance with this change in accounting estimate, in the first quarter of 2017 the Company recognized a one-time adjustment relating to products that had been previously shipped, consisting of $17.9 million of gross revenues, adjusted for an expected returns reserve of $5.7 million and estimated gross-to-net charges of $4.9 million, for a net impact of $7.3 million in revenues. The Company also recorded increased cost of goods sold of $0.6 million and marketing expense of $0.7 million associated with the change in accounting estimate. The increase in net product revenue resulted in a decrease in net loss of $6.0 million or $0.06 per share for the six months ended June 30, 2017.

Supply Revenue:

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

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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, 2018.

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,					
	2018			2017		
	U.S.	ROW	Total	U.S.	ROW	Total
Qsymia—Net product revenue	$ 11,134	$ —	$ 11,134	$ 8,518	$ —	$ 8,518
PANCREAZE - Net product revenue	2,116	—	2,116	—	—	—
PANCREAZE - Royalty revenue	—	74	74	—	—	—
STENDRA/SPEDRA—Supply revenue	525	517	1,042	—	2,119	2,119
STENDRA/SPEDRA—Royalty revenue	—	594	594	—	590	590
Total revenue	$ 13,775	$ 1,185 (1)	$ 14,960	$ 8,518	$ 2,709 (2)	$ 11,227

	Six Months Ended June 30,					
	2018			2017		
	U.S.	ROW	Total	U.S.	ROW	Total
Qsymia—Net product revenue	$ 20,766	$ —	$ 20,766	$ 26,138	$ —	$ 26,138
PANCREAZE - Net product revenue	2,116	—	2,116	—	—	—
PANCREAZE - Royalty revenue	—	74	74	—	—	—
STENDRA/SPEDRA—License revenue	—	—	—	5,000	—	5,000
STENDRA/SPEDRA—Supply revenue	1,071	1,654	2,725	3,775	2,156	5,931
STENDRA/SPEDRA—Royalty revenue	—	1,179	1,179	—	1,170	1,170
Total revenue	$ 23,953	$ 2,907 (3)	$ 26,860	$ 34,913	$ 3,326 (4)	$ 38,239

(1) $1.1 million of which was attributable to Germany.
(2) $2.7 million of which was attributable to Germany.
(3) $2.8 million of which was attributable to Germany.
(4) $3.3 million of which was attributable to Germany.

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

	Three Months Ended June 30,						
	2018				2017		
	Qsymia	PANCREAZE	STENDRA/ SPEDRA	Total	Qsymia	STENDRA/ SPEDRA	Total
Net product revenue	$ 11,134	$ 2,116	$ —	$ 13,250	$ 8,518	$ —	$ 8,518
Supply revenue	—	—	1,042	1,042	—	2,119	2,119
Royalty revenue	—	74	594	668	—	590	590
Total revenue	$ 11,134	$ 2,190	$ 1,636	$ 14,960	$ 8,518	$ 2,709	$ 11,227
Cost of goods sold (excluding amortization)	$ 1,652	$ 567	$ 1,067	$ 3,286	$ 1,400	$ 1,989	$ 3,389
Amortization of intangible assets	$ 90	$ 1,183	$ —	$ 1,273	$ 181	$ —	$ 181

	Six Months Ended June 30,						
	2018				2017		
	Qsymia	PANCREAZE	STENDRA/ SPEDRA	Total	Qsymia	STENDRA/ SPEDRA	Total
Net product revenue	$ 20,766	$ 2,116	$ —	$ 22,882	$ 26,138	$ —	$ 26,138
License	—	—	—	—	—	5,000	5,000
Supply revenue	—	—	2,725	2,725	—	5,931	5,931
Royalty revenue	—	74	1,179	1,253	—	1,170	1,170
Total revenue	$ 20,766	$ 2,190	$ 3,904	$ 26,860	$ 26,138	$ 12,101	$ 38,239
Cost of goods sold (excluding amortization)	$ 2,695	$ 568	$ 2,653	$ 5,916	$ 3,884	$ 5,491	$ 9,375
Amortization of intangible assets	$ 181	$ 1,183	$ —	$ 1,364	$ 362	$ —	$ 362

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,

	2018	2017	2018	2017
Cost of goods sold	$ 18	$ 14	$ 30	$ 27
Selling, general and administrative	955	640	1,787	1,269
Research and development	76	87	157	172
Total share-based compensation expense	$ 1,049	$ 741	$ 1,974	$ 1,468

Share-based compensation costs capitalized as part of the cost of inventory were $0 and $1,000 for the three months ended June 30, 2018 and 2017, respectively, and $1,000 and $5,000 for the six months ended June 30, 2018 and 2017, respectively.

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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, 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	$ 57,181	$ —	$ —	$ 57,181
U.S. Treasury securities	14,513	—	(172)	14,341
Corporate debt securities	52,357	9	(346)	52,020
Total	124,051	9	(518)	123,542
Less amounts classified as cash and cash equivalents	(57,181)	—	—	(57,181)
Total available-for-sale securities	$ 66,870	$ 9	$ (518)	$ 66,361

	As of December 31, 2017			
Cash and cash equivalents and available-for-sale securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and money market funds	$ 66,392	$ —	$ —	$ 66,392
U.S. Treasury securities	21,070	1	(139)	20,932
Corporate debt securities	139,481	16	(486)	139,011
Total	226,943	17	(625)	226,335
Less amounts classified as cash and cash equivalents	(66,392)	—	—	(66,392)
Total available-for-sale securities	$ 160,551	$ 17	$ (625)	$ 159,943

As of June 30, 2018, 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.

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

	As of June 30, 2018			
	Level 1	Level 2	Level 3	Total
Cash and money market funds	$ 57,181	$ —	$ —	$ 57,181
U.S. Treasury securities	14,341	—	—	14,341
Corporate debt securities	—	52,020	—	52,020
Total	$ 71,522	$ 52,020	$ —	$ 123,542

	As of December 31, 2017			
	Level 1	Level 2	Level 3	Total
Cash and money market funds	$ 66,392	$ —	$ —	$ 66,392
U.S. Treasury securities	20,932	—	—	20,932
Corporate debt securities	—	139,011	—	139,011
Total	$ 87,324	$ 139,011	$ —	$ 226,335

5. ACCOUNTS RECEIVABLE

Accounts receivable consist of the following (in thousands):

	Balance as of	
	June 30, 2018	December 31, 2017

Qsymia	$ 10,050	$ 10,400
STENDRA/SPEDRA	637	1,982
PANCREAZE	571	—
	11,258	12,382
Qsymia allowance for cash discounts	(187)	(195)
Net	$ 11,071	$ 12,187

6. INVENTORIES

Inventories consist of the following (in thousands):

	Balance as of June 30, 2018	December 31, 2017
Raw materials	$ 16,801	$ 13,663
Work-in-process	761	2,264
Finished goods	4,697	1,785
Inventories	$ 22,259	$ 17,712

Raw materials inventories consist primarily of the active pharmaceutical ingredients, or API, for Qsymia and STENDRA/SPEDRA. Work-in-process and finished goods inventory consist of Qsymia and STENDRA/SPEDRA and, at June 30, 2018, also included 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.

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7. PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	Balance as of	
	June 30, 2018	December 31, 2017
Prepaid sales and marketing expenses	$ 1,633	$ 1,538
Taxes receivable	2,016	1,222
Prepaid insurance	466	1,124
Other prepaid expenses and assets	2,284	3,294
Total	$ 6,399	$ 7,178

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

8. INTANGIBLE AND OTHER NON-CURRENT ASSETS

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

	June 30, 2018			December 31, 2017		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
PANCREAZE license (1)	$ 141,895	$ (1,183)	$ 140,712	$ —	$ —	$ —
Janssen patents (2)	3,050	(2,416)	634	3,050	(2,235)	815
Other non-current assets	199	—	199	199	—	199
Total	$ 145,144	$ (3,599)	$ 141,545	$ 3,249	$ (2,235)	$ 1,014

(1) In June 2018, the Company acquired the rights to license PANCREAZE in the U.S. and Canada, as described further in Note 12. 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 $1.3 million and $1.4 million for the three and six months ended June 30, 2018, respectively. Future expected amortization expenses for intangible assets as of June 30, 2018 are as follows (in thousands):

2018 (remainder)	$ 7,276

2019	14,552
2020	14,280
2021	14,190
2022	14,190
Thereafter	76,858
Total	$ 141,346

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9. ACCRUED AND OTHER LIABILITIES

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

	Balance as of June 30, 2018	December 31, 2017
Accrued employee compensation and benefits	$ 2,432	$ 3,642
Reserve for product returns (see Note 2)	7,650	7,854
Product-related accruals (see Note 2)	5,489	5,751
Accrued interest on debt (see Note 13)	729	410
Accrued manufacturing costs	6,720	1,238
Other accrued liabilities	3,859	2,580
Total	$ 26,879	$ 21,475

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 June 30, 2018 and December 31, 2017 were primarily comprised of deferred rent and security deposits.

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, 2018, the Company recorded $0.3 million and $0.6 million, respectively, of revenues which had been deferred as of December 31, 2017.

12. 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, or 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 by itself or through third parties. In 2015, the Company transferred the manufacturing of the API and tablets for STENDRA 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, or the Menarini License Agreement, and a supply agreement, or the Menarini Supply Agreement, with the Menarini Group through its subsidiary Berlin Chemie AG, or 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,

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including the EU, 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 will supply 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 will 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.

Sanofi

In December 2013, the Company entered into a license and commercialization agreement, or 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, or the Sanofi Territory. 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, Latin America and other territories. 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, Latin America and other territories. The Company has minimum annual purchase commitments under these agreements for at least the initial five-year term.

On March 23, 2017, the Company and Sanofi entered into the Termination, Rights Reversion and Transition Services Agreement, or the Transition Agreement, effective February 28, 2017. Under the Transition Agreement, effective upon the thirtieth (30th) day following February 28, 2017, the 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.

Metuchen

On September 30, 2016, the Company entered into a license and commercialization agreement, or the Metuchen License Agreement, and a commercial supply agreement, or the Metuchen Supply Agreement, with Metuchen Pharmaceuticals LLC, or Metuchen. Under the terms of the Metuchen License Agreement, Metuchen received an exclusive license to develop, commercialize and promote STENDRA in the United States, Canada, South America and India, or the Metuchen Territory, effective October 1, 2016. The Company and Metuchen have agreed not to develop, commercialize, or in-license any other product that operates as a PDE-5 inhibitor in the Metuchen Territory for a limited time period, subject to certain exceptions. The Metuchen License Agreement will terminate upon the expiration of the last-to-expire payment obligations under the Metuchen License Agreement; upon expiration of the term of the Metuchen License Agreement, the exclusive license granted under the Metuchen License Agreement shall become fully paid-up, royalty-free, perpetual and irrevocable as to the Company but not certain trademark royalties due to 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 certain raw materials needed to manufacture STENDRA. Upon the termination of the Metuchen Supply Agreement (other than by Metuchen for the Company's uncured material breach or upon completion of the transfer of the control of the supply chain), Metuchen's agreed minimum purchase amount of STENDRA from the Company shall accelerate for the entire then current initial term or renewal term, as applicable. The initial term under the Metuchen Supply Agreement will be for a period of five years, with automatic renewal for successive two-year periods unless either

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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, or the Alvogen License Agreement, and a commercial supply agreement, or the Alvogen Supply Agreement, with Alvogen Malta Operations (ROW) Ltd, or 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.

PANCREAZE

In June 2018, the Company closed on an Asset Purchase Agreement, or the PANCREAZE Purchase Agreement, with Janssen Pharmaceuticals, Inc., or Janssen, pursuant to which the Company acquired the rights to PANCREAZE and PANCREASE MT in the U.S. and Canada for a purchase price of $135,000,000 in cash. As part of the PANCREAZE Purchase Agreement, the Company also acquired certain existing inventory from Janssen. Related to the acquisition, the Company also acquired all of the outstanding shares of Willow Biopharma Inc., or Willow. Willow had no significant assets at the time of acquisition. The Company issued fully-exercisable warrants to the former owners of Willow for the purchase of 3,570,000 shares of the Company's common stock at an exercise price of $0.37 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 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 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.

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13. LONG-TERM DEBT AND COMMITMENTS

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

	Balance as of June 30, 2018	December 31, 2017
Senior secured notes due 2018	$ —	$ 6,187
Unamortized discount and debt issuance costs	—	(7)
Senior secured notes due 2018, net	—	6,180
Convertible senior notes due 2020	190,000	250,000
Unamortized discount and debt issuance costs	(838)	(20,497)
Convertible senior notes due 2020, net	189,162	229,503
Senior secured notes due 2024	110,000	—
Unamortized premium and debt issuance costs, net	(3,664)	—
Senior secured notes due 2024, net	106,336	—
Total debt	295,498	235,683
Less current portion	—	5,147
Total long-term debt	$ 295,498	$ 230,536

Senior Secured Notes Due 2024

In June 2018, the Company entered into an indenture, or 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) $110,000,000 of 10.375% senior secured notes due 2024, or the Notes, (ii) up to an additional $10,000,000 of 10.375% senior secured notes due 2024 to be issued subsequently at the Company's option within 12 months of the Notes issue date, subject to certain conditions, and (iii) a warrant for 3,300,000 shares issued concurrently with the issuance of the Notes. The Notes were issued at a purchase price equal to 99% of the principal amount. The Notes contain customary representations, warranties, covenants, conditions and indemnities.

The Company used the net proceeds from the issuance of the Notes to pay (i) certain fees, costs and expenses relating to the issuance and sale of the Notes, (ii) to finance a portion of the PANCREAZE Asset Acquisition, (iii) to repurchase $60.0 million of the Company's outstanding Convertible Notes due 2020 from the Purchasers or their affiliates for a purchase price of $51.0 million (plus accrued but unpaid interest to the repurchase date) and (iv) for general corporate purposes. 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.

Future estimated payments on all of the Company's indebtedness as of June 30, 2018 are as follows (in thousands):

2018 (remainder)	$ 10,710
2019	19,963
2020	206,163
2021	36,131
2022	41,299
Thereafter	55,400
	$ 369,666

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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, or CVOT, on Qsymia. The cost of a CVOT is estimated to be between $180 million and $220 million incurred over a period of approximately five years. The Company is working with FDA to significantly reduce or remove the requirements of the CVOT. To date, the Company has not incurred expenses related to the CVOT.

14. NET INCOME (LOSS) PER SHARE

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

As the Company recognized a net loss for each of the three-month periods ended June 30, 2018 and 2017, 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 14,902,000 and 13,992,000, respectively, for the three months ended June 30, 2018 and 2017 and 19,261,000 and 13,301,000, respectively, for the six months ended June 30, 2018 and 2017.

15. INCOME TAXES

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. For the three and six months ended June 30, 2017, the Company recorded a provision of $1,000 and a benefit of $11,000, respectively. The benefit and provision for income taxes for each of the periods was primarily comprised of state taxes during the period.

The Company periodically evaluates the realizability of its net deferred tax assets based on all available evidence, both positive and negative. The realization of net deferred tax assets is dependent on the Company's ability to generate

sufficient future taxable income during periods prior to the expiration of tax attributes to fully utilize these assets. The Company weighed both positive and negative evidence and determined that there is a continued need for a full valuation allowance on its deferred tax assets in the United States as of June 30, 2018. 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, 2018, 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 $133,000. 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.

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16. 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.

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

This Management's Discussion and Analysis of Financial 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 negativ 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):

- the timing of initiation and completion of the post-approval clinical studies required as part of the approval of Qsymia by the U.S. Food and Drug Administration, or FDA;
- the response from 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, or CVOT;
- the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy, or REMS, requirements;
- our ability to sell through the Qsymia retail pharmacy network;
- whether the Qsymia retail pharmacy network will simplify and reduce the prescribing burden for physicians, improve access and reduce waiting times for patients seeking to initiate therapy with Qsymia;
    - that we may be required to provide further analysis of previously submitted clinical trial data;
- our dialog with the European Medicines Agency, or EMA, relating to the U.S.-based CVOT for Qsymia, and the resubmission of an application for the grant of a marketing authorization to the EMA, the timing of such resubmission, if any, the results of any required CVOT, the assessment by the EMA of the application for marketing authorization, and their agreement with the data from any required CVOT;
- our, or our current or potential partners', ability to successfully seek and gain approval for Qsymia in territories outside the U.S.;
- our, or our current or potential partners', ability to successfully commercialize Qsymia including risks and uncertainties related to expansion to retail distribution, the broadening of payor reimbursement, the expansion of Qsymia's primary care presence, and the outcomes of our discussions with pharmaceutical companies and our strategic and franchise-specific pathways for Qsymia;
- our ability to ensure that the entire supply chain for Qsymia efficiently and consistently delivers Qsymia to our customers and partners;
- our ability to accurately forecast Qsymia demand;
- the impact of promotional programs for Qsymia on our net product revenue and net income (loss) in future periods;

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;

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- our ability to successfully maintain market share against potential competitors that may develop alternative formulations of the drug; and
- 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 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;
- Sanofi Chimie's ability to manufacture 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 history of losses and variable quarterly results;
- 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, or 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 develop a proprietary formulation and to demonstrate through clinical testing the quality, safety, and efficacy of our current and future investigational drug candidates;
- 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;
- the volatility and liquidity of the financial markets;
- our liquidity and capital resources;
- our expected future revenues, operations and expenditures;
- our ability to execute on our business strategy to enhance long-term stockholder value;
- our ability to address or potentially reduce our outstanding balance of the $190 million of convertible notes due in 2020;
- 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, or the SEC, including those set forth in this filing as "Item 1A. Risk Factors."

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

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All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the three and six months ended June 30, 2018 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, 2017, as filed with the SEC on March 14, 2018 and as amended by the Form 10-K/A filed with the SEC on April 26, 2018, and other disclosures (including the disclosures under "Part II. Item 1A. Risk Factors") included in this Quarterly Report on Form 10-Q. Our unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles and are presented in U.S. dollars.

OVERVIEW

VIVUS is a specialty pharmaceutical company with three approved therapies and one product candidate in active clinical development. Qsymia® (phentermine and topiramate extended release) is approved by FDA for chronic weight management. STENDRA® (avanafil) is approved by FDA for erectile dysfunction, or ED, and by the EC under the trade name SPEDRA, for the treatment of ED in the EU. 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, or EPI, due to cystic fibrosis or other conditions. VI-0106 (tacrolimus) is in active clinical development and is being studied in patients with pulmonary arterial hypertension, or 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 pharma 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 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 U.S. field sales force and internal commercial infrastructure. We expect to build a small commercial presence in Canada to support PANCREASE MT, the trade name for pancrelipase in Canada.

Another key strategy for 2018 was the recruitment and hiring of a permanent full-time CEO. In April 2018, we announced the acquisition of Willow Biopharma Inc., or Willow. With this acquisition, we announced the addition of three new members to our senior leadership team. John Amos has been 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 has been 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 through product acquisition. In combination with the current members of the senior leadership team, we believe that we are well positioned to continue to successfully execute on our 2018 business plan.

In April 2018, we entered into a note purchase agreement, or the Note Purchase Agreement, with affiliates of Athyrium Capital Management for the issuance and sale of up to $110 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 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 million were issued in June 2018. Concurrent with the issuance of the initial notes, we issued warrants to purchase 3.3 million shares of our common stock to the note holders. Additionally, concurrent with the issuance of the senior secured notes, we repurchased Convertible Notes due 2020 held by Athyrium, with a face value of $60 million, at a discount to par plus accrued interest. We continue our evaluation of alternatives for addressing our remaining $190 million of convertible notes due in May 2020.

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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 previously approved drugs, phentermine and topiramate. Although the exact mechanism of action is unknown, Qsymia is believed to suppress appetite and increase satiety, or the feeling of being full, the two main mechanisms that impact eating behavior.

We commercialize Qsymia in the U.S. through a small 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, or the Alvogen License Agreement, and a commercial supply agreement, or the Alvogen Supply Agreement, with Alvogen Malta Operations (ROW) Ltd, or 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.

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 the Company transitions to full control over the PANCREAZE supply chain. Once that transition occurs, we intend to commercialize PANCREAZE in the U.S. and Canada by leveraging our existing U.S. field sales force and internal commercial infrastructure.

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, or 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 and chronic pancreatitis, 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, or PDE5, inhibitor that we have licensed from Mitsubishi Tanabe Pharma Corporation, or MTPC. FDA approved STENDRA in April 2012 for the treatment of ED in the United States. In June 2013, the EC adopted a decision granting marketing authorization for SPEDRA, the approved trade name for avanafil in the EU, for the treatment of ED in the EU.

The Menarini Group, through its subsidiary Berlin Chemie AG, or Menarini, is our exclusive licensee for the commercialization and promotion of SPEDRA for the treatment of ED in over 40 countries, including the EU, Australia and New Zealand. In addition, Menarini licensed rights directly from MTPC to commercialize avanafil in

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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, or 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 for territories in which we do not currently have a commercial collaboration, including Africa, the Middle East, Turkey, the CIS, including Russia, Mexico and Central America.

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 reduced bone morphogenetic protein receptor type 2, or BMPR2, signaling that is prevalent in PAH patients and may therefore address a fundamental cause of PAH.

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

On January 6, 2017, we 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., or Selten. Selten assigned to us its license to a group of patents owned by the Board of Trustees of the Leland Stanford Junior University, or Stanford, which cover uses of tacrolimus and ascomycin to treat PAH. 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 United States and 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 for commercial use. We anticipate filing

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an IND with FDA and completing the development of our proprietary formulation of tacrolimus in 2018. 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, or 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, or our Annual Report, as filed with the SEC on March 14, 2018. There has been one significant change in our critical accounting policies during the six months ended June 30, 2018, as outlined below:

Revenue Recognition

For all revenue transactions, we evaluate our contracts with our customers to determine revenue recognition using the following five-step model:

1)We identify the contract(s) with a customer

2)We identify the performance obligations in the contract

3)We determine the transaction price

4)We allocate the transaction price to the identified performance obligations

5)We recognize revenue when (or as) the entity satisfies a performance obligation

Product Revenue:

Product revenue is recognized at the time of shipment at which time we have satisfied our performance obligation. Product revenue is recognized net of consideration paid to our 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 our 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. We also offer discount programs to patients. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates or chargebacks. We review the adequacy of product revenue allowances on a quarterly basis. Amounts accrued for product revenue allowances are adjusted when trends or significant events indicate that adjustment is appropriate and to reflect actual experience. See Note 9 for product reserve balances.

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Change in Accounting Estimate in 2017

We ship units of Qsymia through a distribution network that includes certified retail pharmacies. We began shipping Qsymia in September 2012 and grant rights to our customers to return unsold product from six months prior to and up to 12 months subsequent to product expiration. This has resulted in a potential return period of from 24 to 36 months depending on the ship date of the product. As we had no previous experience in selling Qsymia and given the lengthy return period, we were not initially able to reliably estimate expected returns of Qsymia at the time of shipment, which was required by the accounting literature at the time, and therefore recognized revenue when units were dispensed to patients through prescriptions, at which point the product was not subject to return, or when the expiration period had ended.

Beginning in the first quarter of 2017, with 48 months of returns experience, we believed that we had sufficient data and experience from selling Qsymia to reliably estimate expected returns. Therefore, beginning in the first quarter of 2017, under the then relevant accounting literature, we began recognizing revenue from the sales of Qsymia upon shipment and recording a reserve for expected returns at the time of shipment.

In accordance with this change in accounting estimate, in the first quarter of 2017 we recognized a one-time adjustment relating to products that had been previously shipped, consisting of $17.9 million of gross revenues, adjusted for an expected returns reserve of $5.7 million and estimated gross-to-net charges of $4.9 million, for a net impact of $7.3 million in revenues. We also recorded increased cost of goods sold of $0.6 million and marketing expense of $0.7 million associated with the change in accounting estimate. The increase in net product revenue resulted in a decrease in net loss of $6.0 million or $0.06 per share in the first six months of 2017.

Supply Revenue:

We produce STENDRA or SPEDRA through a contract manufacturing partner and then sell it to our commercialization partners. We are the primary responsible party in the commercial supply arrangements and bear 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, we recognize supply revenue on a gross basis as the principal party in the arrangements. We recognize 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, we record a reserve for estimated product returns. There are no such reserves as of June 30, 2018.

License and Milestone Revenue

License and milestone revenues related to arrangements, usually license and/or supply agreements, entered into by us 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

We rely on data provided by our collaboration partners in determining our contractually-based royalty revenue. Such data includes accounting estimates and reports for various discounts and allowances, including product returns. We record royalty revenues based on the best data available and make any adjustments to such revenues as such information becomes available.

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RESULTS OF OPERATIONS

Revenues

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands, except for percentages)	2018	2017	Increase/ (Decrease)		2018	2017	Increase/ (Decrease)	
Qsymia—Net product revenue	$ 11,134	$ 8,518	31	%	$ 20,766	$ 26,138	(21)	%
PANCREAZE - Net product revenue	2,116	—	N/A		2,116	—	N/A	
License and milestone revenue	—	—	N/A		—	5,000	(100)	%
Supply revenue	1,042	2,119	(51)	%	2,725	5,931	(54)	%
Royalty revenue	668	590	13	%	1,253	1,170	7	%
Total revenue	$ 14,960	$ 11,227	33	%	$ 26,860	$ 38,239	(30)	%

Net product revenue

PANCREAZE net product revenue for the three and six months ended June 30, 2018 includes 22 days of revenue. Qsymia net product revenue for the six months ended June 30, 2017 includes a one-time adjustment of $7.3 million related to shipments, which had previously been deferred due to our change to the “sell-in” revenue recognition methodology. Shipments and prescriptions for Qsymia revenue consisted of the following:

	Three Months Ended June 30,		Increase/ (Decrease)		Six Months Ended June 30,		Increase/ (Decrease)	
(in thousands, except for percentages)	2018	2017			2018	2017		
Qsymia units shipped to wholesalers	94	83	13	%	176	173	2	%
Qsymia prescriptions dispensed	96	105	(9)	%	173	207	(16)	%

Net product revenue for PANCREAZE for the three and six months ended June 30, 2018 related to the shipment of 7,000 units. We anticipate a continuation of the volatility in the timing of Qsymia sales. Overall, we expect Qsymia net product revenue in 2018 to decrease from 2017 levels due to market conditions.

License and milestone revenue

License and milestone revenue for the six months ended June 30, 2017 consisted of a one-time $5.0 million payment received for a license to certain clinical and non-clinical data related to phentermine. License and milestone revenues are dependent on the timing of entering into new collaborations and the timing of our collaborators meeting certain milestone events. As a result, our license and milestone revenue will fluctuate materially between periods.

Supply revenue

The decrease in supply revenue in 2018 as compared to 2017 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 will be recorded as net product revenue with costs recorded as cost of goods sold. We expect royalty revenue in 2018 to remain relatively constant from 2017 levels.

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Cost of goods sold

	Three Months Ended June 30, 2018								2017							
nds, except percentages)	Qsymia		PANCREAZE		STENDRA/ SPEDRA		Total		Qsymia		STENDRA/ SPEDRA		Total	
ct revenue	$ 11,134		$ 2,116		$ —		$ 13,250		$ 8,518		$ —		$ 8,51	
venue	—		—		1,042		1,042		—		2,119		2,11	
duct and supply revenue	11,134	100%	$ 2,116	100%	$ 1,042	100%	$ 14,292	100%	$ 8,518	100%	$ 2,119	100%	$ 10,6	
oods sold (excluding ion)	1,652	15%	$ 567	27%	$ 1,067	102%	$ 3,286	23%	$ 1,400	16%	$ 1,989	94%	$ 3,38	
tion of intangible assets	90	1%	1,183	56%	—	0%	1,273	9%	181	2%	—	0%	$ 181	
of goods sold	1,742	16%	$ 1,750	83%	$ 1,067	102%	$ 4,559	32%	$ 1,581	19%	$ 1,989	94%	$ 3,57	
	$ 9,392	84%	$ 366	17%	$ (25)	-2%	$ 9,733	68%	$ 6,937	81%	$ 130	6%	$ 7,06	

	Six Months Ended June 30, 2018								2017							
	Qsymia		PANCREAZE		STENDRA/ SPEDRA		Total		Qsymia		STENDRA/ SPEDRA		Total	
ct revenue	$ 20,766		$ 2,116		$ —		$ 22,882		$ 26,138		$ —		$ 26,1	
venue	—		—		2,725		2,725		—		5,931		5,93	
duct and supply revenue	$ 20,766	100%	$ 2,116	100%	$ 2,725	100%	$ 25,607	100%	$ 26,138	100%	$ 5,931	100%	$ 32,0	
oods sold (excluding ion)	$ 2,695	13%	$ 568	27%	$ 2,653	97%	$ 5,916	23%	$ 3,884	15%	$ 5,491	93%	$ 9,37	
tion of intangible assets	$ 181	1%	$ 1,183	56%	$ —	0%	$ 1,364	5%	$ 362	1%	$ —	0%	$ 362	
of goods sold	$ 2,876	14%	$ 1,751	83%	$ 2,653	97%	$ 7,280	28%	$ 4,246	16%	$ 5,491	93%	$ 9,73	
	$ 17,890	86%	$ 365	17%	$ 72	3%	$ 18,327	72%	$ 21,892	84%	$ 440	7%	$ 22,3	

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,				Six Months Ended June 30,			
(In thousands, except percentages)	2018	2017	Increase/ (Decrease)		2018	2017	Increase/ (Decrease)	
Selling and marketing	$ 3,521	$ 5,398	(35)	%	$ 7,800	$ 10,858	(28)	%
General and administrative	8,190	6,232	31	%	13,979	12,203	15	%
	$ 11,711	$ 11,630	1	%	$ 21,779	$ 23,061	(6)	%

Total selling, general and
administrative expenses

The decrease in selling and marketing expenses for the three and six months ended June 30, 2018, compared to the same periods in 2018, was due primarily to lower employee costs as a result of the reduction of the size of our sales force in 2017, partially offset by increased spending for marketing programs. Selling and marketing expenses are expected to stay flat in the remainder of 2018 as compared to the first quarter of 2018.

The increase in general and administrative expenses in the three and six months ended June 30, 2018 compared to the same periods in 2017 was primarily due to approximately $2.0 million in one-time expenses related to the PANCREAZE acquisition and the addition of our new executive officers. General and administrative expenses could fluctuate significantly on a quarterly basis due to the timing of activities within our business strategy review.

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Research and development expense

Drug Indication/Description (In thousands, except percentages)	Three Months Ended June 30, 2018	2017	Increase/ (Decrease)	Six Months Ended June 30, 2018	2017	Increase/ (Decrease)
Qsymia	$ 308	$ —	N/A	$ 328	$ —	N/A
STENDRA	38	99	(62) %	86	101	(15) %
PANCREAZE	96	—	N/A	96	—	N/A
VI-0106	805	200	303 %	1,366	1,385	(1) %
Share-based compensation	76	87	(13) %	157	172	(9) %
Overhead costs*	719	628	14 %	1,412	1,536	(8) %
Total research and development expenses	$ 2,042	$ 1,014	101 %	$ 3,445	$ 3,194	8 %

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

The increase in total research and development expenses in the three and six months ended June 30, 2018 as compared to the same periods in 2017 was primarily due to increased spending for the development of VI-0106, partially offset in the six-month period as the spending in 2017 included the license fees paid to Selten. We expect our research and development expenses to increase over the second half of 2018 as we continue our efforts related to our post-marketing requirements for Qsymia, specifically an adolescent safety and efficacy trial, and increase development activities for VI-0106 for the treatment of PAH.

Interest expense and other expense, net

Interest expense and other expense, net for the three and six months ended June 30, 2018 was $9.2 million and $17.6 million, respectively, compared to $8.4 million and $16.7 million for the three and six months ended June 30, 2017, respectively. The increase in 2018 is due to the impact of 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 2018 to increase from the levels in the first half due to the interest expense related to the additional debt issued in June 2018.

Provision for (benefit from) income taxes

For the three and six months ended June 30, 2018, we recorded a provision for income taxes of $4,000 and $16,000, respectively, compared to $1,000 and a benefit of $11,000 for the three and six months ended June 30, 2018, respectively. 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, 2018.

LIQUIDITY AND CAPITAL RESOURCES

Cash. Cash, cash equivalents and available-for-sale securities totaled $123.5 million at June 30, 2018, as compared to $226.3 million at December 31, 2017. The decrease was primarily due to net cash used for the acquisition of the PANCREAZE license, operating activities and debt repayments during the period, partially offset by cash received from the issuance of the new debt.

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

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

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

Accounts receivable (net of allowance for cash discounts) at June 30, 2018, was $11.1 million, as compared to $12.2 million at December 31, 2017. Currently, we do not have any significant concerns related to accounts receivable or collections.

Summary Cash Flows

	Six Months Ended June 30,	
	2018	2017
	(in thousands)	
Cash provided by (used for):		
Operating activities	$ (18,131)	$ (11,288)
Investing activities	(41,968)	9,392
Financing activities	50,888	(6,481)

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

Investing Activities. 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. Cash provided by investing activities for the six months ended June 30, 2017 primarily related to the purchases and maturities of investment securities.

Financing Activities. 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 repayments of $51.0 million of our Convertible Notes and $6.2 million of our Senior Secured Notes due 2018. Cash used for financing activities for the six months ended June 30, 2017 primarily related to our repayments of $6.5 million under the Senior Secured Notes due 2018.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs at least for the next twelve months. However, we anticipate that we may require additional funding to evaluate commercial opportunities, which could come in the form of an asset acquisition, such as our acquisition of PANCREAZE, a license, a co-development agreement, a merger or acquisition or other form, create a pathway for centralized approval of the marketing authorization application for Qsiva in the EU, conduct

post-approval clinical studies for Qsymia, conduct non-clinical and clinical research and development work to support regulatory submissions and applications for our current and future investigational drug candidates, finance the costs involved in filing and prosecuting patent applications and enforcing or defending our patent claims, if any, to fund operating expenses and manufacture quantities of our investigational drug candidates and to make payments under our existing license agreements and supply agreements.

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

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rights to certain of our technologies, product candidates or products that we would otherwise seek to develop on our own.

Off-Balance Sheet Arrangements

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

Commitments and Contingencies

We indemnify our officers and directors for certain events or occurrences pursuant to indemnification agreements, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, stockholder suits and tax matters and as such, we are unable to estimate the potential exposure related to these indemnification agreements. We have not recognized any liabilities relating to these agreements as of June 30, 2018.

Contractual Obligations

During the six months ended June 30, 2018, 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, 2017, filed with the SEC on March 14, 2018, and as amended by the Form 10-K/A filed on April 26, 2018 with the SEC, other than the fulfillment of existing obligations in the ordinary course of business and minimum future purchase requirements related to PANCREAZE.

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, 2018, 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, 2018, by approximately $0.3 million. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

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

ITEM 4. CONTROLS AND PROCEDURES

(a.) Evaluation of disclosure controls and procedures. We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the timelines

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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.

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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 Qsiva™ in the EU;
- manage our alliances with MTPC, Menarini and Metuchen to help ensure the commercial success of avanafil;
- 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, or REMS, any future changes to the REMS, and any other requirements established by FDA in the future;
- efficiently conduct the post-marketing studies required by FDA;
- comply with other healthcare regulatory requirements;
- comply with state and federal controlled substances requirements;
- maintain and defend our patents, if challenged;
- ensure that the active pharmaceutical ingredients, or APIs, for Qsymia and STENDRA/SPEDRA and the finished products are manufactured in sufficient quantities and in compliance with requirements of FDA and 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;
- effectively and efficiently manage our sales force and commercial team for the promotion of Qsymia and PANCREAZE;

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- effectively increase the level of revenue for PANCREAZE;
- successfully assume the commercial responsibilities for PANCREAZE;
- maintain a good relationship with the manufacturer of PANCREAZE; and
- ensure a sufficient level of PANCREAZE inventory.

If we are unable to successfully commercialize Qsymia, PANCREAZE and 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 who has joined us 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 tacrolimus or any other potential future development programs.

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

- successfully develop a proprietary formulation of tacrolimus as a precursor to the clinical development process;
- effectively conduct phase 2 and phase 3 clinical testing on tacrolimus, which could be delayed by slow patient enrollment, long treatment time required to demonstrate effectiveness, disruption of operations at clinical trial sites, adverse medical events or side effects in treated patients, failure of patients taking the placebo to continue to participate in the clinical trials, and insufficient clinical trial data to support effectiveness of tacrolimus;
- obtain regulatory approval and market authorization for tacrolimus in the U.S., EU and other territories;
- develop, validate and maintain a commercially viable manufacturing process that is compliant with cGMP;
- establish and effectively manage a supply chain for tacrolimus 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.

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

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

In 2016, we initiated a business strategy review with an outside advisor. These changes, and the potential for additional changes to our management, organizational structure and strategic business plan, may cause speculation and uncertainty regarding our future business strategy and direction. These changes may cause or result in:

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

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

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

We rely on our collaboration partners, including Alvogen, MTPC, 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;
- our collaborators may be required under the laws of the relevant territories to disclose our confidential information or may fail to protect our confidential information;
- as a requirement of the collaborative arrangement, we may be required to relinquish important rights with respect to our drug products, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator’s business strategy may adversely affect a collaborator’s willingness or ability to satisfactorily complete its commercialization or other obligations under any collaborative arrangement;
- legal disputes or disagreements may occur with one or more of our collaborators;
- a collaborator could independently move forward with a competing investigational drug candidate developed either independently or in collaboration with others, including with one of our competitors; and
- a collaborator could terminate the collaborative arrangement, which could negatively impact the continued commercialization of our drug products. For example, in September 2016, Auxilium terminated its agreement with us to commercialize STENDRA in the U.S. and Canada and, in March

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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, 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, or 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. For example, in April 2015, we were informed by Endo, upon their purchase of Auxilium, that Endo had revised its accounting estimate for STENDRA return reserve related to sales made in 2014. Under the terms of our license and commercialization agreement, adjustments to the return reserve can be deducted from reported net revenue. As a result, in the year ended December 31, 2015, we recorded an adjustment of $1.2 million to reduce our royalty revenue on net sales of STENDRA. The reduction in royalty revenue resulted in an increase to net loss of $1.2 million, or $0.01 per share, for the year ended December 31, 2015. Such adjustments or restatements may materially and negatively affect our financial position and results of operations. Beginning October 1, 2016, we ceased earning royalty revenue from U.S. sales as a result of the termination of our license and commercialization agreement with Auxilium. Our new license agreement with Metuchen is royalty-free as to us.

If we are unable to enter into agreements with collaborators for the territories that are not covered by our existing commercialization agreements, our ability to commercialize STENDRA/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 STENDRA/SPEDRA in territories that are not covered by our current commercial

collaboration agreements, such as Africa, the Middle East, Turkey, the CIS, Mexico and Central America. We may be unable to enter into agreements with third parties for STENDRA/SPEDRA for these territories on favorable terms or at all, which could delay, impair, or preclude our ability to commercialize STENDRA/SPEDRA in these territories.

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

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

We, together with Alvogen, Menarini, Metuchen and any potential future collaborators in certain territories, intend to market Qsymia, PANCREAZE 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.

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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. Forecasting demand for STENDRA/SPEDRA, a drug that is new to a crowded and competitive market and has limited sales history, is also difficult. We will continue to evaluate our inventories on a periodic basis. The value of our inventories could be impacted if actual sales differ significantly from our estimates of future demand or if any significant unanticipated changes in future product demand or market conditions occur. Any of these events, or a combination thereof, could result in additional inventory write-downs in future periods, which could be material.

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

We rely on Cardinal Health 105, Inc., or Cardinal Health, a third-party distribution and supply-chain management company, to warehouse Qsymia and distribute it to the certified home delivery pharmacies and wholesalers that then distribute Qsymia directly to patients and certified retail pharmacies. Cardinal Health provides billing, collection and returns services. Cardinal Health is our exclusive supplier of distribution logistics services, and accordingly we depend on Cardinal Health to satisfactorily perform its obligations under our agreement with them, 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, or HCP, data. In addition, we have contracted with third-party data warehouses to store this patient and HCP data and report it to us. We rely on this third-party data in order to recognize revenue and comply with the REMS requirements for Qsymia, such as data analysis. This distribution and data collection network requires significant coordination with our sales and marketing, finance, regulatory and medical affairs teams, in light of the REMS requirements applicable to Qsymia.

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

unable to effectively manage the distribution and data collection process, sales of Qsymia could be severely compromised and our business, financial condition and results of operations would be harmed.

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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 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 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 on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. We have entered into supply agreements with Menarini and Metuchen under which we are obligated to supply them with avanafil tablets. If we are unable to maintain a reliable supply of avanafil API or tablets from Sanofi Chimie and/or Sanofi Winthrop Industrie, we may be unable to satisfy our obligations under these supply agreements in a timely manner or at all, and we may, as a result, be in breach of one or both of these agreements.

We have in-licensed all or a portion of the rights to Qsymia, 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 licensed 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.

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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 find the right partner for expanded Qsymia commercial promotion to a broader primary care physician audience;
- our ability to obtain marketing authorization by the EC for Qsiva in the EU;
- 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.

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

Upon receiving approval to market Qsymia, FDA required that we perform additional studies of Qsymia including a cardiovascular outcome trial, or CVOT. We estimate the cost of a CVOT as currently designed to be between $180 million and $220 million incurred over a period of approximately five years. We have held several meetings with FDA to discuss alternative strategies for obtaining cardiovascular, or CV, outcomes data that would be substantially more feasible and that ensure timely collection of data to better inform on the CV safety of Qsymia. 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 Qsiva for treatment of obesity in accordance with the EU centralized marketing authorization procedure. We received feedback in 2014 from the EMA and the various competent authorities of the EU Member States. 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. 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 may not be able to remain listed on The Nasdaq Stock Market.

On October 4, 2017, we received a letter from The Nasdaq Stock Market, or Nasdaq, indicating that, based upon the closing bid price of our common stock for the preceding 30 consecutive business days, we no longer meet the continued listing requirement of maintaining a minimum bid price of $1 per share, as set forth in Nasdaq Listing Rule 5450(a)(1). On April 3, 2018, we received a letter from Nasdaq indicating that we did not regain compliance within

the compliance period. On May 17, 2018, we received a letter from Nasdaq informing us that the Nasdaq Hearings Panel had granted our request for continued listing subject to the condition that, on or before October 1, 2018, we must have effected a reverse stock split and evidenced a closing bid price of $1.00 or more for a minimum of ten prior consecutive trading days. If we do not succeed in doing so, Nasdaq could delist our common stock. If Nasdaq delists our common stock, the delisting could adversely affect the market liquidity of our common stock and the price of our common stock.

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

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

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

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

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

Once an applicant receives authorization to market a medicinal product in an EU Member State, through any application route, the applicant is required to engage in pricing discussions and negotiations with a separate pricing authority in that country. The legislators, policymakers and healthcare insurance funds in the EU Member States continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the

attention being paid to healthcare cost containment and other austerity measures in the EU. Certain of these changes could impose limitations on the prices pharmaceutical companies are able to charge for their products. The amounts of reimbursement available from governmental agencies or third-party payors for these products may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products. Furthermore, an increasing number of EU Member States and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in the price of medicinal products in some

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

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

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

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

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

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

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

Damages awarded in a product liability action could be substantial and could have a negative impact on our financial condition. Whether or not we were ultimately successful in product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources, and might result in adverse publicity, all of which would impair our business. In addition, product liability claims could result in an FDA investigation of the safety or efficacy of our product, our third-party manufacturing processes and facilities, or our marketing programs. An FDA

investigation could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension or withdrawal of approval.

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

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

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

There are also surgical approaches to treat severe obesity that are becoming increasingly accepted. Two of the most well established surgical procedures are gastric bypass surgery and adjustable gastric banding, or lap bands. In February 2011, FDA approved the use of a lap band in patients with a BMI of 30 (reduced from 35) with comorbidities. The lowering of the BMI requirement will make more obese patients eligible for 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, the Company entered into a settlement agreement with Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as Actavis, and in August 2017, the Company 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 with DRL will permit DRL to begin selling a generic version of Qsymia on June 1, 2025, or earlier

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under certain circumstances. It is possible that one or more additional companies may file an Abbreviated New Drug Application, or 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., UltresaTM, marketed by Aptalis Phama US, Inc., Pertzye®, marketed by Digestive Care, Inc., and Zenpep®, marketed by Allergan 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, or ODT), co-promoted by GlaxoSmithKline plc and Merck & Co., Inc.

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

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

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

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

From time to time, we consider strategic transactions, such as out-licensing or in-licensing of compounds or technologies, acquisitions of companies and asset purchases. 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

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United States, Canada, South America and India, or the Territory, effective October 1, 2016. Additionally, on January 6, 2017, we entered into a Patent Assignment Agreement with Selten, whereby we received exclusive, worldwide rights for the development and commercialization of tacrolimus for the treatment of PAH and related vascular diseases. Also, on June 8, 2018, we closed on the PANCREAZE Purchase Agreement with 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 PANCREAZE Purchase Agreement with Janssen, pursuant to which the Company 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

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· inability to retain key employees of any acquired businesses.

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

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

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

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

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

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

For example, Catalent Pharma Solutions, LLC, or Catalent, is our sole source of clinical and commercial supplies for Qsymia. While Catalent has significant experience in commercial scale manufacturing, there is no assurance that

Catalent will be successful in continuing to supply Qsymia at current levels or increasing the scale of the Qsymia manufacturing process, should the market demand for Qsymia expand beyond the level supportable by the current validated manufacturing process. Such a failure by Catalent to meet current demand or to further scale up the commercial manufacturing process for Qsymia could have a material adverse impact on our ability to realize

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commercial success with Qsymia in the U.S. market, and have a material adverse impact on our plan, market price of our common stock and financial condition.

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

The collection and use of personal health data and other personal data in the EU is governed by the provisions of the Data Protection Directive as implemented into national laws by the EU Member States. This Directive imposes restrictions on the processing (e.g., collection, use, disclosure) of personal data, including a number of requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals prior to processing their personal data, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict restrictions on the transfer of personal data out of the EU to the United States. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the EU Member States may result in fines and other administrative penalties. The General Data Protection Regulation, or GDPR, an EU-wide regulation that will be fully enforceable by May 25, 2018, will introduce new data protection requirements in the EU and substantial fines for violations of the data protection rules. The GDPR will increase our responsibility and liability in relation to EU personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules. This may be onerous and increase our cost of doing business.

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

Our arrangements with third-party payors, 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

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and regulations, and privacy and data security laws and regulations, that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback 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. 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. 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. 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 the Health Information Technology for Economic and Clinical Health Act, or 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. In addition, most healthcare providers who prescribe our products and from whom we obtain patient health information are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 and by the Health Information Technology for Economic and Clinical Health Act, or HITECH, which are collectively referred to as HIPAA. We are not a HIPAA-covered entity and we do not operate as a business associate to any covered entities. Therefore, the HIPAA privacy and security requirements do not apply to us (other than potentially with respect to providing certain employee benefits). However, we could be subject to criminal penalties if

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we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting and/or conspiring to commit a violation of HIPAA. We are unable to predict whether our actions could be subject to prosecution in the event of an impermissible disclosure of health information to us. The legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing amount of focus on privacy and data security issues with the potential to affect our business. These privacy and data security laws and regulations could increase our cost of doing business, and failure to comply with these laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business;

- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the payor. Some state laws also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to certain health care providers in the states. Other states prohibit providing meals to prescribers or other marketing-related activities. 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, California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes of conduct. Foreign governments often have similar regulations, which we also will be subject to in those countries where we market and sell products;
- the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain pharmaceutical manufacturers to engage in extensive tracking of payments and other transfers of value to physicians and teaching hospitals, and to submit such data to Centers for Medicare and Medicaid Services within the U.S. Department of Health and Human Services, or CMS, which will then make all of this data publicly available on the CMS website. Pharmaceutical manufacturers with products for which payment is available under Medicare, Medicaid or the State Children’s Health Insurance Program must submit a report to CMS on or before the 90th day of each calendar year disclosing reportable payments made in the previous calendar year; and
- the federal Foreign Corrupt Practices Act of 1977 and other similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the SEC. A determination that our operations or activities are not, or were not, in compliance with United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

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

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

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

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

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

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

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

criminal sanctions.

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

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

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

We obtain the necessary raw materials and components for the manufacture of Qsymia and STENDRA as well as certain services, such as analytical testing packaging and labeling, from third parties. In particular, we rely on Catalent to supply Qsymia capsules and Packaging Coordinators, Inc., or PCI, for Qsymia packaging services. We rely on Sanofi Chimie and Sanofi Winthrop to supply avanafil API and tablets. We and these suppliers and service providers are required to follow cGMP requirements and are subject to routine and unannounced inspections by FDA and by state and foreign regulatory agencies for compliance with cGMP requirements and other applicable

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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 for innovator drugs at 100% of the average manufacturer price. In addition, the Affordable Care Act and subsequent legislation changed the definition of average manufacturer price. Finally, the Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $4.1 billion in 2018, 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 drug pricing program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community

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

The Affordable Care Act expanded the 340B program to include additional entity types: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The Affordable Care Act also obligates the Secretary of the U.S. Department of Health and Human Services, or HHS, to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The Health Resources and Services Administration, or HRSA, the agency that administers the 340B program, recently updated the agreement with participating manufacturers. The Affordable Care Act also obligates the Secretary of HHS to create regulations and processes to improve the integrity of the 340B program. On January 5, 2017, HRSA issued a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The effective date of the regulation has been delayed until July 1, 2018. Implementation of this final rule and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

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

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false average manufacturer price or best price information to the government, we may be liable for civil monetary penalties in the amount of $181,071 per item of false information. Our failure to submit monthly/quarterly average manufacturer price and best price data on a timely basis could result in a civil monetary penalty of $18,107 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs.

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

If we misstate Non-FAMPs or FCPs, we must restate these figures. Additionally, pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject us to penalties of $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

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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, or NADAC, 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 proposals include measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide. Further, federal budgetary concerns could result in the implementation of significant federal spending cuts, including cuts in Medicare and other health related spending in the near-term. For example, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue.

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

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

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innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price.

- Effective in January 2011, pharmaceutical companies must provide a 50% discount on branded prescription drugs dispensed to beneficiaries within the Medicare Part D coverage gap or "donut hole," which is a coverage gap that currently exists in the Medicare Part D prescription drug program. We currently do not have coverage under Medicare Part D for our drugs, but this could change in the future.
- Effective in January 2011, the Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $4.1 billion in 2018, 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.

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. 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.

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

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

Furthermore, there can be no assurance that healthcare providers would not actively seek to provide patients with generic versions of the active ingredients in Qsymia in order to treat obesity at a potential lower cost and outside of the REMS requirements.

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

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

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

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

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

to develop our investigational drug candidates and approved drug commercialization efforts would be severely affected.

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

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

Risks Relating to our Intellectual Property

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

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

In addition, we cannot make assurances as to how much protection, if any, will be provided by our issued patents. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Others may independently develop similar or alternative technologies or design around our patented technologies or products. 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, or RLD, NDA holder and patent owner that the application with patent challenge has been submitted, and provide the factual and legal basis for the applicant’s assertion that the patent is invalid or not infringed. If the NDA holder or patent owner file suit against the generic applicant for patent infringement within 45 days of receiving the Paragraph IV notice, FDA is prohibited from approving the generic application for a period of 30 months from the date of receipt of the notice. If the RLD has

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

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

We have received 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 is introduced, Qsymia would become subject to increased competition and our revenue would be adversely affected.

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

Our commercial success also depends, in part, upon our ability to develop future investigational drug candidates, market and sell approved drugs and conduct our other research, development and commercialization activities without infringing or misappropriating the patents and other proprietary rights of others. There are many patents and patent applications owned by others that could be relevant to our business. For example, there are numerous U.S. and foreign issued patents and pending patent applications owned by others that are related to the therapeutic areas in which we have approved drugs or future investigational drug candidates as well as the therapeutic targets to which these drugs

and candidates are directed. There are also numerous issued patents and patent applications covering chemical compounds or synthetic processes that may be necessary or useful to use in our research, development, manufacturing or commercialization activities. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our approved drugs, future investigational drug candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our approved drugs, investigational drug candidates or

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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.

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Risks Relating to our Financial Position and Need for Financing

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

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

- our ability to expand the use of Qsymia through targeted patient and physician education;
- our ability to obtain marketing authorization by the EC for Qsiva in the EU;
- 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 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 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

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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, 2018, we have $190.0 million in 4.5% Convertible Senior Notes due May 1, 2020, which we refer to as the Convertible Notes. The Convertible Notes are convertible into approximately 16,826,000 shares of our common stock under certain circumstances prior to maturity at a conversion rate of 67.3038 shares per $1,000 principal amount of Convertible Notes, which represents a conversion price of approximately $14.858 per share, subject to adjustment under certain conditions. On October 8, 2015, IEH Biopharma LLC, a subsidiary of Icahn Enterprises L.P., announced that it had received tenders for $170,165,000 of the aggregate principal amount of our Convertible Notes in its previously announced cash tender offer for any and all of the outstanding Convertible Notes. The Convertible Notes are convertible at the option of the holders under certain conditions at any time prior to the close of business on the business day immediately preceding November 1, 2019. Investors in our common stock will be diluted to the extent the Convertible Notes are converted into shares of our common stock, rather than being settled in cash.

In April 2018, we entered into an agreement for a new $120 million senior secured note with Athyrium Capital Management, LP, or Athyrium Notes. $110 million of the Athyrium Notes were drawn down in June 2018, with the remaining $10 million available for drawing upon meeting certain EBITDA thresholds or purchasing our outstanding convertible notes. 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 million, for $51 million. We continue our evaluation of alternatives for addressing our remaining $190.0 million of convertible notes due in May 2020.

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

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

covenants that restrict our operations.

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

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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, 2018, we had $123.5 million in cash, cash equivalents and available-for-sale securities. While at June 30, 2018, 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, 2018. 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

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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 have now expired and the matter is concluded.

We have an accumulated deficit of $866.9 million as of June 30, 2018, and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of $866.9 million for the period from our inception through June 30, 2018, 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, 2017, we had approximately $640.4 million and $276.2 million of net operating loss, or NOL, carryforwards with which to offset our future taxable income for federal and state income tax reporting purposes, respectively. Utilization of our net operating loss and tax credit carryforwards, or tax attributes, may be subject to substantial annual limitations provided by the Internal Revenue Code and similar state provisions to the extent certain ownership changes are deemed to occur. Such an annual limitation could result in the expiration of the tax attributes before utilization. The tax attributes reflected above have not been reduced by any limitations. To the extent it is determined upon completion of the analysis that such limitations do apply, we will adjust the tax attributes accordingly. We face the risk that our ability to use our tax attributes will be substantially restricted if we undergo an "ownership change" as defined in Section 382 of the U.S. Internal Revenue Code, or Section 382. An ownership change under Section 382 would occur if "5-percent shareholders," within the meaning of Section 382, collectively increased their ownership in the Company by more than 50 percentage points over a rolling three-year period. We have not completed a recent study to assess whether any change of control has occurred or whether there have been multiple changes of control since the Company's formation, due to the significant complexity and cost associated with the study. We have completed studies through December 31, 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.

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Risks Relating to an Investment in our Common Stock

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

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

- our ability to meet the expectations of investors related to the commercialization of Qsymia, 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 Qsiva 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;
- 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.

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

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

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

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

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

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

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

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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;

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

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

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

Issuer Purchases of Equity Securities

Period	(a) Total number of shares (or units) purchased	(b) Average price paid per share (or unit)	(c) Total number of shares (or units) purchased as part of publicly announced plans or programs	(d) Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs
April 2018	876	$ 0.42	876	
May 2018	935	$ 0.52	935	
June 2018	876	$ 0.84	876	
Total	2,687	$ 0.59	2,687	2,628

(a) In the second quarter of 2018, restricted stock unit awards held by certain non-employee directors of the Company vested. These restricted stock units were settled by issuing to each non-employee director shares in the amount due to the director upon vesting, less the portion required to satisfy the estimated income tax liability based on the published stock price at the close of market on the settlement date or the next trading day, which the Company issued to the non-employee director in cash.

On April 30, 2018, the Company issued warrants to purchase 3.6 million shares of the Company’s common stock to the shareholders of Willow Biopharma Inc., with an exercise price of $0.37 per share. The warrants are immediately exercisable and will expire seven years after the date of issuance. The Company issued the warrants and will issue the underlying common stock pursuant to the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

On June 8, 2018, the Company issued a warrant to purchase 3.3 million shares of the Company’s common stock to affiliates of Athyrium Capital Management. The warrant has an exercise price of $0.3951 per share, is immediately exercisable and will expire six years after the issuance date. The Company issued the warrant and will issue the underlying common stock pursuant to the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

VIVUS, INC.

INDEX TO EXHIBITS

1. 2. 3.

EXHIBIT NUMBER	DESCRIPTION
2.1*†	Asset Purchase Agreement between the Registrant and Janssen Pharmaceuticals, Inc. dated April 30, 2018.
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2*	Amended and Restated Bylaws of the Registrant, as further amended.
3.3(2)	Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Registrant.
4.1(3)	Specimen Common Stock Certificate of the Registrant.
4.2(4)	Amended and Restated Preferred Stock Rights Agreement dated as of November 9, 2016, between the Registrant and Computershare Trust Company, N.A.
4.3(5)	Indenture dated as of May 21, 2013, by and between the Registrant and Deutsche Bank Trust Company Americas, as trustee.
4.4(6)	Form of 4.50% Convertible Senior Note due May 1, 2020.
4.5(7)	Warrant to Purchase Shares of Common Stock issued to Torreya Capital, LLC dated February 23, 2018.
4.6(8)	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(9)	Form of 2024 Note (included in Exhibit 4.6).
4.8(10)	Form of Athyrium Warrant, dated as of June 8, 2018.
4.9*#	Form of Warrant to be issued by the Registrant to certain shareholders of Willow Biopharma Inc.
10.1(11)	

	Collateral Agreement, 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.
10.2(12)#	2018 Inducement Equity Incentive Plan.
10.3*	Purchase Agreement between the Registrant and affiliates of Athyrium Capital Management dated April 30, 2018.
10.4*#	Form of Agreement under the 2018 Inducement Equity Incentive Plan.
10.5*#	Form of Third Amended and Restated Change of Control and Severance Agreement.
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.

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101 The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, 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.

*Filed herewith.

+Furnished herewith.

†Confidential portions of this exhibit have been redacted and filed separately with the SEC pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

#Indicates management contract or compensatory plan or arrangement.

(1) Incorporated by reference to Exhibit 3.2 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1996, filed with the SEC on March 28, 1997.
(2) Incorporated by reference to Exhibit 3.3 filed with the Registrant's Registration Statement on Form 8-A filed with the SEC on March 28, 2007.
(3) 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.
(4) 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.
(5) 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.
(6) 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.
(7) 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.
(8) 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.
(9) 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.
(10) 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.
(11) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the SEC on June 11, 2018.
(12) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Registration Statement on Form S-8 filed with the SEC on June 1, 2018.

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SIGNATURES

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

Date: August 7, 2018 VIVUS, Inc.

/s/ John Amos
John Amos
Chief Executive Officer

/s/ Mark K. Oki
Mark K. Oki
Chief Financial Officer and Chief Accounting Officer