

VIVUS INC
Form 10-Q
May 07, 2012
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For The Quarterly Period Ended March 31, 2012

OR

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

For the transition period from to

Commission File Number 001-33389

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

94-3136179

(IRS employer
identification number)

1172 Castro Street

Mountain View, California

(Address of principal executive office)

94040

(Zip Code)

(650) 934-5200

(Registrant's telephone number, including area code)

N/A

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

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

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

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

Large accelerated filer ☒

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

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

At April 27, 2012, 99,700,943 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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	March 31, 2012 (unaudited)	December 31, 2011*
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 200,682	\$ 39,554
Available-for-sale securities	132,715	107,282
Inventories	2,897	3,107
Prepaid expenses and other assets	2,124	1,793
Total current assets	338,418	151,736
Property and equipment, net	298	320
Total assets	\$ 338,716	\$ 152,056
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,805	\$ 2,940
Accrued research and clinical expenses	1,145	1,425
Accrued employee compensation and benefits	2,593	3,693
Other accrued liabilities	3,172	1,274
Current liabilities of discontinued operations	1,339	1,640
Total current liabilities	13,054	10,972
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; \$1.00 par value; 5,000 shares authorized; no shares issued and outstanding		
Common stock; \$.001 par value; 200,000 shares authorized; 99,701 and 88,975 shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively	100	89
Additional paid-in capital	690,612	487,235
Accumulated other comprehensive (loss) income	(7)	25
Accumulated deficit	(365,043)	(346,265)
Total stockholders' equity	325,662	141,084
Total liabilities and stockholders' equity	\$ 338,716	\$ 152,056

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* Derived from audited consolidated financial statements filed in the Company's 2011 Annual Report on Form 10-K.

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 MARCH 31	
	2012	2011
Operating expenses:		
Research and development	\$ 6,134	\$ 4,480
General and administrative	12,638	5,428
Total operating expenses	18,772	9,908
Loss from operations	(18,772)	(9,908)
Interest and other income (expense):		
Interest and other income, net	18	43
Interest expense	(1)	(1)
Total interest and other income (expense)	17	42
Loss from continuing operations before income taxes	(18,755)	(9,866)
Provision for income taxes	(7)	(1)
Loss from continuing operations	(18,762)	(9,867)
Discontinued operations:		
(Loss) income from discontinued operations, net of tax	(16)	14
Net loss	\$ (18,778)	\$ (9,853)
Basic and diluted net loss per share:		
Continuing operations	\$ (0.20)	\$ (0.12)
Discontinued operations	0.00	0.00
Net loss per share	\$ (0.20)	\$ (0.12)
Shares used in per share computation:		
Basic and diluted	92,267	81,819

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	THREE MONTHS ENDED MARCH 31	
	2012	2011
Net loss	\$ (18,778)	\$ (9,853)

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Other comprehensive (loss) income:

Unrealized (loss) gain on securities, net of taxes		(32)		25
Comprehensive loss	\$	(18,810)	\$	(9,828)

See accompanying notes to unaudited condensed consolidated financial statements.

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VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31	
	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss from continuing operations	\$ (18,762)	\$ (9,867)
Adjustments to reconcile net loss to net cash used for operating activities from continuing operations:		
Depreciation	22	33
Share-based compensation expense	2,718	2,120
Changes in assets and liabilities:		
Inventories	210	
Prepaid expenses and other assets	(331)	(38)
Accounts payable	1,864	(808)
Accrued research and clinical expenses	(280)	(432)
Accrued employee compensation and benefits	(1,100)	(469)
Other accrued liabilities	1,898	(488)
Net cash used for operating activities from continuing operations	(13,761)	(9,949)
Net cash used for operating activities from discontinued operations	(316)	(367)
Net cash used for operating activities	(14,077)	(10,316)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of available-for-sale securities	(48,763)	(30,826)
Proceeds from maturity of available-for-sale securities	14,262	33,720
Proceeds from sale of available-for-sale securities	9,036	
Net cash (used for) provided by investing activities	(25,465)	2,894
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from exercise of common stock options	8,665	1,540
Net proceeds from issuance of common stock	192,005	
Net cash provided by financing activities	200,670	1,540
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	161,128	(5,882)
CASH AND CASH EQUIVALENTS:		
Beginning of period	39,554	37,216
End of period	\$ 200,682	\$ 31,334

See accompanying notes to unaudited condensed consolidated financial statements.

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VIVUS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2012

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles 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 United States generally accepted accounting principles 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 quarter ended March 31, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. Management has evaluated all events and transactions that occurred after March 31, 2012 through the date these condensed consolidated financial statements were filed. There were no events or transactions during this period which require recognition or disclosure in these condensed consolidated financial statements. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America. 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, 2011, as filed on February 28, 2012 with the Securities and Exchange Commission, or SEC. The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

2. DISCONTINUED OPERATIONS

On October 1, 2010, the Company entered into a definitive Asset Purchase Agreement with Meda AB, or Meda, to sell certain rights and assets related to MUSE, transurethral alprostadil, for the treatment of erectile dysfunction, or the MUSE Transaction. Meda had been the Company's European distributor of MUSE since 2002. The assets sold in the MUSE Transaction include the U.S. and foreign MUSE patents, existing inventory, and the manufacturing facility located in Lakewood, New Jersey. The Company retained all of the liabilities associated with the pre-closing operations and products of the MUSE business and the accounts receivable for pre-closing MUSE sales. The transaction closed on November 5, 2010. Prior to the closing of the MUSE Transaction, the Company terminated all of the rights to MUSE and avanafil held by

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Deerfield Management Company, L.P. and affiliates and by Crown Bank, N. A. as collateral to the Company's notes payable. Under the terms of the MUSE Transaction, the Company received an upfront payment of \$22 million upon the closing and is eligible to receive an additional \$1.5 million based on future sales of MUSE, provided that certain sales milestones are reached. Meda is now responsible for the manufacturing, selling and marketing of MUSE. Meda also assumed all post-closing expenses and liabilities associated with MUSE. The Company has agreed not to develop, manufacture or sell any transurethral erectile dysfunction drugs for a period of three years following the closing of the MUSE Transaction.

The sale of the MUSE product and certain related assets has been reported as discontinued operations in the condensed consolidated statements of operations for all periods presented, since (i) the MUSE product and related assets have identifiable cash flows that are largely independent of the cash flows of other groups of assets and liabilities, (ii) the Company does not have any significant continuing involvement with the product after the close of the transaction, and (iii) the cash milestone payment to be received upon achievement of certain sales levels is considered an indirect cash flow. There are no assets related to the MUSE operations for the periods presented. The liabilities related to the MUSE operations are reported as liabilities of discontinued operations in the condensed consolidated balance sheets for all periods presented. The extinguishment of the largest liability of the discontinued operations, accrued product returns, will be settled in accordance with the returns policy and by cash payments made to former customers for the return of expired MUSE product sold by VIVUS. The return window for expired MUSE product will end in 2013.

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The following table summarizes the liabilities of discontinued operations in the condensed consolidated balance sheets (in thousands):

	March 31, 2012 (unaudited)	December 31, 2011
Accounts payable	\$ 5	\$ 17
Accrued product returns	1,334	1,623
Total current liabilities of discontinued operations	\$ 1,339	\$ 1,640

The following table presents summarized results of operations for the discontinued operations presented in the condensed consolidated statements of operations (in thousands)(unaudited):

	For the Three Months Ended March 31, 2012	March 31, 2011
Income (loss) before provision for income taxes	\$ (16)	\$ 14
Net income (loss) from discontinued operations	\$ (16)	\$ 14

3. SHARE-BASED COMPENSATION

The Company accounts for share-based compensation arrangements in accordance with FASB ASC topic 718, *Compensation Stock Compensation*, or ASC 718, and ASC 505-50, *Equity Equity Based Payments to Non-Employees*.

Total share-based compensation expense, related to all of the Company's share-based awards, recognized for the three months ended March 31, 2012 and 2011 was comprised as follows (in thousands, except per share data)(unaudited):

	Three Months Ended March 31 2012	2011
Research and development	\$ 726	\$ 538
General and administrative	1,992	1,582
Share-based compensation expense	\$ 2,718	\$ 2,120

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

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The fair value and the amortized cost of cash, cash equivalents, and available-for-sale securities by major security type at March 31, 2012 and December 31, 2011 are presented in the tables that follow:

As of March 31, 2012 (in thousands)(unaudited):

	Amortized Cost		Estimated Fair Value		Gross Unrealized Gains		Gross Unrealized Losses
Cash and cash equivalents							
Cash and money market funds	\$	200,682	\$	200,682	\$		\$
Total cash and cash equivalents	\$	200,682	\$	200,682	\$		\$

	Amortized Cost		Estimated Fair Value		Gross Unrealized Gains		Gross Unrealized Losses
Available-for-sale securities							
U.S. Treasury securities	\$	132,722	\$	132,715	\$	3	\$ (10)
Total available-for-sale securities	\$	132,722	\$	132,715	\$	3	\$ (10)

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As of December 31, 2011 (in thousands):

	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
Cash and cash equivalents				
Cash and money market funds	\$ 38,547	\$ 38,547	\$	\$
U.S. Treasury securities	1,007	1,007	\$	\$
Total cash and cash equivalents	\$ 39,554	\$ 39,554	\$	\$

	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
Available-for-sale securities				
U.S. Treasury securities	\$ 107,257	\$ 107,282	\$ 27	\$ (2)
Total available-for-sale securities	\$ 107,257	\$ 107,282	\$ 27	\$ (2)

The Company's available-for-sale securities mature within one year.

In the ordinary course of business, the Company may sell securities at a loss for a number of reasons, including, but not limited to: (i) changes in the investment environment; (ii) expectation that the fair value could deteriorate further; (iii) desire to reduce exposure to an issuer or an industry; (iv) changes in credit quality; or (v) changes in expected cash flow.

Fair Value Measurements

The following fair value hierarchy tables present information about the Company's assets (cash and cash equivalents and available-for-sale securities) measured at fair value on a recurring basis as of March 31, 2012 (in thousands)(unaudited):

	Balance at March 31, 2012	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Cash and cash equivalents:				
Cash and money market funds	\$ 200,682	\$ 200,682	\$	\$
Total cash and cash equivalents	\$ 200,682	\$ 200,682	\$	\$

	Balance at March 31, 2012	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Available-for-sale securities:				
U.S. Treasury securities	\$ 132,715	\$ 132,715	\$	\$
Total available-for-sale securities	\$ 132,715	\$ 132,715	\$	\$

Reported as:

Cash and cash equivalents	\$ 200,682
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Available-for-sale securities		132,715
Total	\$	333,397

The Company's valuation techniques used to measure the fair value of money market funds were derived from quoted market prices as active markets for these instruments exist. Investments in marketable securities are held by a custodian who obtains investment prices from a third party pricing provider that uses standard inputs derived from or corroborated by observable market data to models that vary by asset class. There were no assets or liabilities where Level 3 valuation techniques were used and there were no assets and liabilities measured at fair value on a non-recurring basis.

5. INVENTORIES

Inventory balances consist of (in thousands):

	March 31, 2012 (unaudited)		December 31, 2011	
Raw materials	\$	2,897	\$	3,107

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The raw materials balance at March 31, 2012 and December 31, 2011 consists of the active pharmaceutical ingredients for development of our investigational drug candidate, Qnexa®, which we intend to market, if approved, under a different name.

The Company has made and anticipates in future periods that it will scale-up and make commercial quantities of certain of its product candidates prior to the date it anticipates that such products will receive final Food and Drug Administration, or FDA, approval in the U.S. or European Medicines Agency approval in the European Union (i.e., pre-launch inventories). Pre-launch inventories are included on the condensed consolidated balance sheets once the product under review has attained a stage in the development process of having been subject to a Phase 3 clinical trial or its equivalent, or if a regulatory filing has been made for licensure for marketing the product and the product has a well characterized manufacturing process. Periodic stability testing is performed on the raw materials inventory. An impairment analysis of the raw materials inventory was performed as of March 31, 2012 and the Company believes that the raw materials inventory is not impaired as of that date.

6. AGREEMENTS

In 2001, VIVUS entered into a Development, Licensing and Supply Agreement with Tanabe for the development of avanafil, an oral phosphodiesterase type 5, or PDE5, inhibitor investigational drug candidate for the treatment of erectile dysfunction. In October 2007, Tanabe and Mitsubishi Pharma Corporation completed their merger and announced their name change to Mitsubishi Tanabe Pharma Corporation, or MTPC. Under the terms of the 2001 Development, Licensing and Supply Agreement with Tanabe, the Company paid a \$2 million license fee obligation to Tanabe in the year ended December 31, 2006. No payments were made under this agreement with MTPC in the year ended December 31, 2008; however, the Company paid MTPC \$4 million in January 2009 following the enrollment in December 2008 of the first patient in the first Phase 3 clinical study and in August 2011, VIVUS paid MTPC a \$4 million milestone related to the filing of a New Drug Application, or NDA, to the FDA for avanafil in June 2011. The Company expects to make other substantial payments to MTPC in accordance with its agreement with MTPC as the Company continues to develop and, if approved for sale, commercialize avanafil for the oral treatment of male sexual dysfunction. Such potential future milestone payments total \$11 million in the aggregate and include payments upon: the obtainment of the first regulatory approval in the U.S. and any major European country; and achievement of \$250 million or more in calendar year sales. In April 2012, the FDA approved the NDA for avanafil. Accordingly, the Company now owes MTPC, in accordance with its agreement with MTPC, a \$3 million milestone payment, which it intends to pay in May 2012.

The term of the MTPC agreement is based on a country-by-country and on a product-by-product basis. The term shall continue until the later of (i) 10 years after the date of the first sale for a particular product, or (ii) the expiration of the last-to-expire patents within the MTPC patents covering such product in such country. In the event that the Company's product is deemed to be (i) insufficiently effective or insufficiently safe relative to other PDE5 inhibitor compounds based on published information, or (ii) not economically feasible to develop due to unforeseen regulatory hurdles or costs as measured by standards common in the pharmaceutical industry for this type of product, the Company has the right to terminate the agreement with MTPC with respect to such product.

On October 16, 2001, the Company entered into an assignment agreement, or the Assignment Agreement, with Thomas Najarian, M.D. for a combination of pharmaceutical agents for the treatment of obesity and other disorders, or the Combination Therapy, that has since been the focus of our investigational drug candidate development program for Qnexa for the treatment of obesity, obstructive sleep apnea and diabetes. The Combination Therapy and all related patent applications, or the Patents, were transferred to the Company with worldwide rights to develop and commercialize the Combination Therapy and exploit the Patents. Pursuant to the Assignment Agreement, the Company has paid a total of \$220,000 to Dr. Najarian through March 31, 2012 and has issued him options to purchase 40,000 shares of our common stock. The Company is obligated under the terms of the Assignment Agreement to make a milestone payment of \$1 million and issue an option to purchase 20,000 shares of VIVUS common stock to Dr. Najarian upon marketing approval by the FDA of a product for the treatment of obesity that is based upon the Combination Therapy and Patents. The Assignment Agreement will require the Company to pay royalties on worldwide net sales of a

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product for the treatment of obesity that is based upon the Combination Therapy and Patents until the last-to-expire of the assigned Patents. To the extent that the Company decides not to commercially exploit the Patents, the Assignment Agreement will terminate and the Combination Therapy and Patents will be assigned back to Dr. Najarian. In 2006, Dr. Najarian joined the Company as a part-time employee and currently serves as a Principal Scientist.

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7. COMMITMENTS AND CONTINGENCIES

Lease Commitments

In November 2006, the Company entered into a 30-month lease for its corporate headquarters located in Mountain View, California, or Lease. On December 16, 2008, November 12, 2009, December 3, 2010 and February 14, 2012, we entered into a first, second, third and fourth amendment, respectively, to this Lease. Under the fourth amendment to the Lease, the average base rent for the current premises is set at \$2.50 per square foot or \$45,015 per month. The fourth amendment also extended the lease term for the current premises for a period of twelve months commencing August 1, 2012 and terminating July 31, 2013 and provided us one additional option to extend the term of the Lease of the current premises for one year from the expiration of the Lease. In addition, the fourth amendment included a new lease on an additional 4,914 square feet of office space located at 1174 Castro Street, Mountain View, California, or the Expansion Space, which is adjacent to the Company's corporate headquarters. The average base rent for the Expansion Space is approximately \$2.75 per square foot or \$13,513 per month. The new lease for the Expansion Space has a term of 60 months commencing on March 15, 2012, with an option to extend the term for one year from the expiration of the new lease.

Future minimum lease payments under operating leases at March 31, 2012 were as follows (in thousands)(unaudited):

2012 (remainder)	\$	924
2013		736
2014		249
2015		255
2016		215
2017		65
	\$	2,444

Other Agreements

Commitments under other agreements at March 31, 2012 were as follows (in thousands)(unaudited):

Clinical consultants and clinical research organizations	\$	4,654
General and administrative services agreements		12,011
Leland F. Wilson's employment agreement		1,579
Research consultants and other contractors		6,308
MTPC (avanafil product testing and finished goods)		7,336
Total	\$	31,888

On December 19, 2007, the Compensation Committee of the Board of Directors of the Company approved an employment agreement, or the Employment Agreement, with Leland F. Wilson, the Company's President and Chief Executive Officer. The Employment Agreement includes salary, incentive compensation, retirement benefits and length of employment, among other items, as agreed to with Mr. Wilson. The

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Employment Agreement had an initial term of two years commencing on the effective date, June 1, 2007, or the Effective Date. On January 23, 2009, the Compensation Committee approved an amendment to the Employment Agreement, or the Amendment, which amends the Employment Agreement. Pursuant to the Amendment, the initial term of the Employment Agreement was increased from two to three years commencing on June 1, 2007 and other relevant dates were also extended to reflect the three-year initial term. On January 21, 2011, the Compensation Committee approved the second amendment to Mr. Wilson's Employment Agreement. Pursuant to the second amendment, the initial term of the Employment Agreement is increased to four years commencing on June 1, 2007. As neither party provided notice of termination, the Employment Agreement was automatically extended for an additional one-year term commencing on June 1, 2011. On January 27, 2012, the Compensation Committee approved the third amendment to the Employment Agreement which increased the initial term of the Employment Agreement from four (4) to five (5) years commencing on June 1, 2007.

Indemnifications

In the normal course of business, the Company provides indemnifications of varying scope to certain customers against claims of intellectual property infringement made by third parties arising from the use of its products and to its clinical research organizations and investigator sites against liabilities incurred in connection with any third-party claim arising from the work performed on behalf of the Company, among others. Historically, costs related to these indemnification provisions have not been significant and the Company is unable to estimate the maximum potential impact of these indemnification provisions on its future results of operations.

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On May 15, 2007, the Company closed its transaction with K-V Pharmaceutical Company, or K-V, for the sale of its investigational drug candidate, Evamist. At the time of the sale, Evamist was an investigational drug candidate and was not yet approved by the U. S. Food and Drug Administration, or FDA, for marketing. Pursuant to the terms of the Asset Purchase Agreement for the sale of the Evamist product to K-V, the Company made certain representations and warranties concerning its rights and assets related to Evamist and the Company's authority to enter into and consummate the transaction. The Company also made certain covenants that survive the closing date of the transaction, including a covenant not to operate a business that competes, in the U.S., and its territories and protectorates, with the Evamist product.

Pursuant to the terms of the Asset Purchase Agreement, (see Note 2: Discontinued Operations), the Company entered into with Meda AB, or Meda, to sell certain of the assets related to the MUSE business to Meda, or the MUSE Transaction, the Company agreed to indemnify Meda in connection with the representations and warranties that it made concerning its rights, liabilities and assets related to the MUSE business and its authority to enter into and consummate the MUSE Transaction. The Company also made certain covenants in the Asset Purchase Agreement which survive the closing of the MUSE Transaction, including a three year covenant not to develop, manufacture, promote or commercialize a trans-urethral erectile dysfunction drug.

To the extent permitted under Delaware law, the Company has agreements whereby it indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The indemnification period covers all pertinent events and occurrences during the officer's or director's lifetime. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited; however, the Company maintains director and officer insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

8. INCOME TAXES

The Company makes certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes.

As part of the process of preparing its condensed consolidated financial statements, the Company is required to estimate its income taxes in each of the jurisdictions in which it operates. This process involves the Company estimating its current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included in the Company's condensed consolidated balance sheets.

The Company assesses the likelihood that it will be able to recover its deferred tax assets. The Company considers all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is not more likely than not that the Company will recover its deferred tax assets, the Company will increase its provision for taxes by recording a valuation allowance against the deferred tax assets that the Company estimates will not ultimately be recoverable. As a result of the Company's analysis of all available evidence, both positive and negative, as of March 31, 2012, it was considered more likely than not that the Company's deferred tax assets would not be realized. However, should there be a change in the Company's ability to recover its deferred tax assets, the Company would recognize a benefit to its tax provision in the period in which the Company determines that it is more likely than not that it can recover its deferred tax assets.

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The total gross unrecognized tax benefits as of March 31, 2012 are \$1.2 million and relate to state tax exposures, of which \$160,000 would affect the effective tax rate if recognized. The total unrecognized tax benefits as of March 31, 2012 of \$1.2 million includes approximately \$1.1 million of unrecognized tax benefits that have been netted against the related deferred tax assets.

The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of its provision for income taxes. During the three months ended March 31, 2012, the Company accrued \$2,000 of interest and penalties related to unrecognized tax benefits.

Although the Company files U.S. federal, various state, and foreign tax returns, the Company's only major tax jurisdictions are the U.S., California and New Jersey. The Company's income tax return for the year ended December 31, 2007 is currently under examination by the California Franchise Tax Board. Based on the progress of the audit to date, the Company believes adjustments may be made in earlier years that will reduce tax attributes available to offset tax due in 2007. The Company did not increase its unrecognized tax benefits for the three months ended March 31, 2012.

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The Company's income tax return for the years ended December 31, 2007 and 2008 are currently under examination by the Internal Revenue Service. The Company is awaiting the final report from the IRS and does not expect adverse results. The Company is currently under examination by the State of New Jersey for the years ended December 31, 2007 through 2009. Because the Company used net operating loss carryforwards and other tax attributes to offset its taxable income on its 2007 income tax returns for U.S. Federal and California, such attributes can be adjusted by these taxing authorities until the statute closes on the year in which such attributes were utilized. Tax years 1991 to 2010 remain subject to examination by the appropriate governmental agencies due to tax loss carryovers from those years.

The Company is in various stages of the examination process in connection with all of its tax audits and it is difficult to determine when these examinations will be settled. It is reasonably possible that over the next twelve-month period the Company may experience an increase or decrease in its unrecognized tax benefits. It is not possible to determine either the magnitude or range of any increase or decrease at this time.

9. NET INCOME (LOSS) PER SHARE

The Company computes basic net income (loss) per share applicable to common shareholders based on the weighted average number of common shares outstanding during the period. Diluted net income per share is based on the weighted average number of common and common equivalent shares, which represent shares that may be issued in the future upon the exercise of outstanding stock options. 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. When there is a net loss, potentially dilutive common equivalent shares are not included in the calculation of net loss per share since their inclusion would be anti-dilutive.

As the Company recognized a net loss for the three months ended March 31, 2012 and 2011 all potential common equivalent shares were excluded for these periods as they were anti-dilutive. For the three months ended March 31, 2012 and 2011, 4,546,021 and 5,232,351 options outstanding, respectively, were not included in the computation of diluted net loss per share for the Company because the effect would be anti-dilutive.

10. EQUITY TRANSACTIONS

On August 1, 2011, the Company filed a Form S-8 with the SEC registering 600,000 shares of common stock, par value \$0.001 per share, under the 1994 Employee Stock Purchase Plan, as amended, or 1994 ESPP.

On August 24, 2011, the Company closed on the sale of a total of 6,889,098 shares of its common stock, at a price of \$6.65 per share, pursuant to a previously-reported securities purchase agreement entered into on August 23, 2011 with certain investors in connection with a registered direct offering of the Company's common stock, or the Offering. Gross proceeds to the Company from the sale of the common stock in the Offering totaled approximately \$45.8 million before deduction of approximately \$529,000 in fees and expenses related to the Offering. All of the shares of common stock were offered pursuant to an effective shelf registration statement on Form S-3ASR (Registration No. 333-161948), including the prospectus dated September 16, 2009 contained therein.

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On March 6, 2012, the Company closed the underwritten public offering and sale of 9,000,000 shares of the Company's common stock. Gross proceeds to the Company from this sale totaled approximately \$202.5 million before deduction of approximately \$10.5 million in underwriting discounts and commissions and estimated offering expenses. All of the shares of common stock were offered pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-161948), including the prospectus dated September 16, 2009 (as amended on February 28, 2012) contained therein, as the same has been supplemented.

11. LEGAL MATTERS

Securities Related Class Action Lawsuits

The Company and two of its officers are defendants in a putative class action lawsuit captioned *Kovtun v. Vivus, Inc., et al.*, Case No. CV10-4957 PJH, pending in the U.S. District Court, Northern District of California. The action, filed in November 2010, alleges violations of Section 10(b) and 20(a) of the federal Securities Exchange Act of 1934 based on allegedly false or misleading statements made by the defendants in connection with the Company's clinical trials and New Drug Application, or NDA, for Qnexa as a treatment for obesity. In his Amended Class Action Complaint filed April 4, 2011, the plaintiff alleged generally that the defendants misled investors regarding the prospects for Qnexa's NDA approval, and the drug's efficacy and safety. On June 3, 2011, the defendants filed a motion to dismiss, which was heard by the Honorable Phyllis J. Hamilton on October 12, 2011. At the hearing,

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Judge Hamilton ruled from the bench and granted the defendants' motion to dismiss, with leave to amend. Judge Hamilton also issued an order on October 13, 2011, which confirmed her ruling at the hearing. On November 9, 2011, plaintiff filed his Second Amended Class Action Complaint, again generally alleging that the defendants misled investors regarding the prospects for Qnexa's NDA approval, and Qnexa's efficacy and safety. On November 23, 2011, Judge Hamilton granted a stipulation and order requiring defendants' motion to dismiss to be filed on or before December 30, 2011, plaintiffs opposition to defendants' motion to dismiss to be filed on or before February 22, 2012 and defendants' reply to plaintiff's opposition to be filed on or before March 30, 2012. The hearing on defendants' motion to dismiss was held on April 18, 2012. Pending the outcome of defendants' motion to dismiss, discovery will continue to be stayed.

Additionally, the Company's directors are defendants in a shareholder derivative lawsuit captioned *Turberg v. Logan, et al.*, Case No. CV 10-05271 PJH, also pending in the same federal court. In the plaintiff's Verified Amended Shareholder Derivative Complaint filed June 3, 2011, the plaintiff largely restated the allegations of the *Kovtun* action and alleged that the directors breached fiduciary duties to the Company by purportedly permitting the Company to violate the federal securities laws as alleged in *Kovtun*. The parties have agreed to stay the litigation pending resolution of the defendants' second motion to dismiss in *Kovtun*. The Company's directors are also named defendants in consolidated shareholder derivative suits pending in the California Superior Court, Santa Clara County under the caption *In re VIVUS, Inc. Derivative Litigation*, Master File No. 11 0 CV188439. The allegations in the state court derivative suits are substantially similar to the other lawsuits. As with the federal derivative litigation, the parties have agreed to stay these consolidated actions pending resolution of the second motion to dismiss in *Kovtun*.

The Company and its directors believe that the various shareholder lawsuits are without merit, and they intend to vigorously defend the various actions.

Other Matters

In the normal course of business, the Company receives claims and makes inquiries regarding patent and trademark infringement and other related legal matters. The Company believes that it has meritorious claims and defenses and intends to pursue any such matters vigorously. Additionally, the Company in the normal course of business may become involved in lawsuits and subject to various claims from current and former employees including wrongful termination, sexual discrimination and employment matters. Due to the current economic downturn, employees may be more likely to file employment-related claims following termination of their employment. Employment-related claims also may be more likely following a poor performance review. Although there may be no merit to such claims or legal matters, the Company may be required to allocate additional monetary and personnel resources to defend against these type of allegations. The Company believes the disposition of the current lawsuit and claims is not likely to have a material effect on its financial condition or liquidity.

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

12. STOCK OPTION AND PURCHASE PLANS

On March 29, 2010, the Company's Board of Directors terminated the Company's 2001 Stock Option Plan, or the 2001 Plan. In addition, the Board of Directors adopted and approved a new 2010 Equity Incentive Plan, or the 2010 Plan, with 32,000 shares remaining reserved and

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unissued under the 2001 Plan. In addition, the Board of Directors adopted and approved a new 2010 Equity Incentive Plan, or the 2010 Plan, subject to the approval of the Company's stockholders. The 2001 Plan, however, will continue to govern awards previously granted under it. On June 25, 2010, the Company's stockholders approved the 2010 Plan at the Company's 2010 Annual Meeting of Stockholders. The 2010 Plan provides for the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares and performance units to employees, directors and consultants, to be granted from time to time as determined by the Board of Directors, the Compensation Committee of the Board of Directors, or its designees. The 2010 Plan's share reserve which the stockholders approved is 8,400,000 shares, plus any shares reserved but not issued pursuant to awards under the 2001 Plan as of the date of stockholder approval, plus any shares subject to outstanding awards under the 2001 Plan that expire or otherwise terminate without having been exercised in full, or are forfeited to or repurchased by the Company, up to a maximum of 8,111,273 shares (which is the number of shares subject to outstanding options under the 2001 Plan as of March 11, 2010). Awards exercisable for 1,463,359 shares were granted in the three months ended March 31, 2012 pursuant to the 2010 Plan.

On April 30, 2010, the Company's Board of Directors granted an option to purchase 400,000 shares of the Company's common stock, or the Inducement Grant, to Michael P. Miller, the Company's new Senior Vice President and Chief Commercial Officer. The Inducement Grant was granted outside of the Company's 2010 Plan and without stockholder approval pursuant to NASDAQ Listing Rule 5635(c)(4) and is subject to the terms and conditions of the Stand-Alone Stock Option Agreement between the Company and Michael P. Miller.

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As of March 31, 2012, there were 8,155,619 shares subject to all options outstanding under all stock plans and 6,066,882 shares reserved for issuance under the 2010 Plan. Additionally, the average weighted exercise price of all outstanding options under all stock plans was \$7.54 per share and the average weighted remaining term was 7.17 years.

On June 17, 2011, the Company's stockholders approved amendments to the Company's 1994 ESPP to increase the number of shares reserved for issuance under the 1994 ESPP by 600,000 shares to a new total of 2,000,000, to remove the Plan's 20-year term, and to include certain changes consistent with Treasury Regulations relating to employee stock purchase plans under Section 423 of the Internal Revenue Code of 1986, as amended, and other applicable law.

As of March 31, 2012, 1,363,255 shares have been issued to employees and there are 636,745 shares available for issuance under the 1994 ESPP.

13. SUBSEQUENT EVENT

On April 27, 2012, the Company announced that the FDA had approved avanafil tablets for the treatment of erectile dysfunction, which we intend to market through a partner in the U.S. under the name Stendra®. Accordingly, the Company now owes MTPC, in accordance with its agreement with MTPC, a \$3 million milestone payment, which it intends to pay in May 2012.

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

This Management's Discussion and Analysis of Financial Conditions and Results of Operations and other parts of this Form 10-Q contain forward looking statements that involve risks and uncertainties. These statements typically may be identified by the use of forward looking words or phrases such as may, believe, expect, forecast, intend, anticipate, predict, should, planned, likely, opportunity, or the negative use of these words or other similar words. All forward looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor for such forward looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to: (1) the response from the United States Food and Drug Administration, or FDA, to our resubmission of the New Drug Application, or NDA, for development of our investigational drug candidate, Qnexa®, which we intend to market, if approved, under a different name, for the treatment of obesity, including weight loss and maintenance of weight loss, recommended for obese patients (BMI ≥ 30 kg/m²), or overweight patients (BMI ≥ 27 kg/m²) with weight related co-morbidities such as hypertension, type 2 diabetes, or dyslipidemia, with a contraindication that excludes the use of Qnexa by women who are pregnant; (2) the timing and final results of the retrospective observational study of fetal outcomes in infants born to mothers exposed to topiramate during pregnancy, or FORTRESS; (3) the reliability of the electronic medical claims healthcare databases used in FORTRESS; (4) the FDA's interpretation of and agreement with the information VIVUS submitted relating to teratogenicity and cardiovascular safety; (5) that we may be required to provide further analysis of clinical trial data; (6) our response to questions and requests for additional information including additional pre-clinical or clinical studies from the European Medicines Agency, or EMA, and the Committee for Medicinal Products for Human Use, or CHMP, of the Marketing Authorization Application, or MAA, for Qnexa; (7) the FDA's interpretation of the results of external studies to assess the teratogenic risk of topiramate; (8) the impact of the results of the Risk Evaluation and Mitigation Strategy, or REMS, or cardiovascular outcomes for obesity drugs advisory committee meetings; (9) whether or not the FDA chooses to follow the recommendation of the second advisory committee in its vote in favor of approval of Qnexa; (10) the impact, if any, of the agreement and initiation by one of our competitors with an obesity compound to conduct or complete a cardiovascular outcomes study pre-approval; (11) the impact on future sales based on specific indication and contraindications contained in the label and extent of the REMS and distribution system and patient access program for Qnexa, if approved; (12) our ability to successfully commercialize or establish a marketing partnership for avanafil, which we intend to market through a partner in the U.S. under the name Stendra®, or our partner's ability to obtain and maintain regulatory approval to manufacture and adequately supply avanafil for commercial use; (13) our history of losses and variable quarterly results; (14) substantial competition; (15) risks related to the failure to protect our intellectual property and litigation in which we may become involved; (16) uncertainties of government or third party payer reimbursement; (17) our reliance on sole source suppliers; (18) our limited sales and marketing and manufacturing capabilities; (19) our reliance on third parties and our collaborative partners; (20) failure to continue to develop innovative investigational drug candidates and drugs; (21) risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; (22) our ability to demonstrate through clinical testing the safety and effectiveness of our investigational drug candidates; (23) the timing of initiation and completion of clinical trials and submissions to the FDA or foreign authorities; (24) the volatility and liquidity of the financial markets; (25) our liquidity and capital resources; (26) our expected future revenues, operations and expenditures; (27) our ability to successfully create a commercial infrastructure in the United States to launch Qnexa, if approved, on our own; and (28) 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.

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the quarter ended March 31, 2012, are not necessarily indicative of the results that may be expected for the full fiscal year or any future period.

BUSINESS OVERVIEW

VIVUS, Inc. is a biopharmaceutical company, incorporated in 1991 as a California corporation and reincorporated in 1996 as a Delaware corporation, dedicated to the development and commercialization of therapeutic drugs for large underserved markets, including obesity and related morbidities, such as sleep apnea and diabetes and men's sexual health. Obesity remains an epidemic and in the United States alone, the

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Centers for Disease Control, or CDC, estimates that over 108 million people are obese or overweight. In the European Union, or the EU, estimates are that 50% of adults are obese or overweight. With respect to men's sexual health, annual sales of approved drugs for erectile dysfunction currently exceed \$5 billion.

Currently, our investigational drug candidate, Qnexa, is under review by regulators for approval as a treatment for obesity in the U.S. and the European Union. On October 28, 2010, we received a Complete Response Letter, or CRL, regarding the NDA for

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Qnexa as a treatment for obesity. The CRL stated that in its current form, the NDA for Qnexa was not approvable. The CRL included the following areas: clinical, labeling, REMS, safety update, and drug scheduling. In the clinical section of the CRL, the FDA requested a comprehensive assessment of topiramate's and Qnexa's teratogenic potential including a detailed plan and strategy to evaluate and mitigate the potential teratogenic risks in women of childbearing potential taking the drug for the treatment of obesity. In addition, the FDA asked us to provide evidence that the elevation in heart rate (mean 1.6 beats per minute on the top dose) associated with Qnexa does not increase the risk for major adverse cardiovascular events. The FDA requested that we formally submit the results from the completed SEQUEL study (OB-305), a 52-week extension study for a subset of 675 patients who completed the previously reported 56-week CONQUER study. The FDA reserved the right to comment further on proposed labeling. On REMS, the FDA requested that a discussion of an already submitted REMS plan be continued after we submitted the written response. The agency also requested a safety update of any new adverse events be submitted with the NDA. Finally, the FDA stated that if approved, Qnexa would be a Schedule IV drug due to the phentermine component. No new clinical studies were requested in the CRL.

On January 19, 2011, we held an End-of-Review meeting with the FDA to discuss the items contained in the CRL and the information we planned to include in the resubmission of the NDA for Qnexa. In anticipation of the meeting, we provided a briefing document that included comprehensive assessment of the teratogenic potential of topiramate including analyses integrating existing non-clinical and clinical data. In the Qnexa studies, which included 15 offspring from women exposed to Qnexa or topiramate, there were no reports of congenital malformations. In addition, we provided several new analyses including cardiovascular data from our SEQUEL (OB-305) and Sleep Apnea (OB-204) studies to demonstrate that Qnexa does not increase the risk for major cardiovascular events and that the observed increases in heart rate, which occurred in some patients over the course of the clinical program, did not increase the risk of major cardiovascular events, as evidenced by adverse events reported in the trial. We also provided a synopsis of the final study report for the SEQUEL study. At the meeting, an overview was provided of the teratogenicity and cardiovascular risk material covered by the background package. The discussion also included elements of our proposed REMS program for Qnexa. The primary focus of the FDA at the meeting, however, concerned the teratogenic potential for topiramate, specifically the incidence of oral clefts observed in the North American AED Pregnancy Registry and in the UK Epilepsy and Pregnancy Registry. The FDA requested that we assess the feasibility of performing a retrospective observational study utilizing existing electronic medical claims healthcare databases to review fetal outcomes, including the incidence of congenital malformations and oral cleft, in the offspring of women who received prophylaxis treatment with 100 mg of topiramate for migraine during pregnancy, or the Feasibility Assessment. We held a follow up meeting with the FDA on April 14, 2011 to discuss the Feasibility Assessment. We reached agreement with the FDA on the retrospective observational study objectives and design, primary endpoints, and eligibility criteria. During the April 2011 meeting, it was agreed the study would be expanded to include all doses of topiramate and all diagnoses. It was also agreed that the results would be stratified and that the diagnoses of those exposed to topiramate would be matched with control groups with similar diagnoses and patient profiles. The co-primary endpoints were the relative risk of major congenital malformations and oral cleft in infants born to mothers exposed to topiramate during pregnancy as compared to a control group that was not exposed to topiramate during pregnancy. The retrospective observational study was called FORTRESS, for Fetal Outcome Retrospective TopiRamate ExpoSure Study.

On September 15, 2011, we announced that following a teleconference we had reached agreement with officials of the Division of Metabolism and Endocrinology Products, or DMEP, of the FDA on a plan that allowed for an early resubmission of the Qnexa NDA for the treatment of obesity. Based on this agreement, we resubmitted the Qnexa NDA on October 17, 2011, prior to completion of FORTRESS, and the FDA accepted the NDA for filing. On February 22, 2012, the Food and Drug Administration held a second meeting of the Endocrinology and Metabolic Drugs Advisory Committee, or the Advisory Committee, to discuss the additional data submitted for Qnexa. The FDA asked the Advisory Committee to discuss the following: (1) their interpretation of the available data regarding teratogenicity of topiramate, including whether they believe the data indicate an increase in the risk for oral clefts; (2) the potential strengths and weaknesses of the proposed teratogenicity risk management strategy for Qnexa; (3) the clinical significance of the changes in blood pressure and heart rate in overweight and obese patients treated with Qnexa versus placebo, taking into account the reported changes in antihypertensive therapy; and (4) whether the available data for Qnexa warrant that a cardiovascular outcomes trial be conducted prior to approval. The FDA requested the Advisory Committee to vote on whether, after considering all the available data included in the NDA and the discussions held at the meeting on February 22, 2012, including the questions referred to above, the overall benefit-risk assessment of Qnexa supports its approval for the treatment of obesity in individuals with a BMI ≥ 30 kg/m² or a BMI ≥ 27 kg/m² with weight related co-morbidities. The Advisory Committee voted 20 to 2 to recommend approval. The FDA is not bound by the recommendations of its advisory committees, but will consider their guidance during the review of the NDA that was submitted for Qnexa in October 2011. On April 4, 2012, at the FDA's request, we submitted a comprehensive Risk Evaluation and Mitigation Strategy, or REMS, for Qnexa, which was considered a major amendment to the NDA. The Prescription Drug User Fee Act, or PDUFA, target date for Qnexa was April 17, 2012. However, as the submission of the comprehensive REMS was within three months of the PDUFA target date, to provide time for a full review of the submission, the FDA extended the PDUFA target date by three months

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to July 17, 2012. The FDA has the ability to extend the PDUFA target date under certain circumstances, and there can be no assurance that it will not extend the PDUFA target date further in the future.

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The Qnexa NDA resubmission seeks approval for the treatment of obesity, including weight loss and maintenance of weight loss for obese patients ($\text{BMI} \geq 30 \text{ kg/m}^2$), or overweight patients ($\text{BMI} \geq 27 \text{ kg/m}^2$) with weight-related co-morbidities such as hypertension, type 2 diabetes or dyslipidemia. The proposed labeling for Qnexa submitted on October 17, 2011 included a contraindication that excluded the use of Qnexa by women of childbearing potential. In January 2012, we announced that following discussions with FDA officials, we were asked to remove the Qnexa contraindication for women of childbearing potential contained in the proposed label. Qnexa would remain contraindicated for women who are pregnant. A contraindication typically indicates that a drug should not be used because the risk of use clearly outweighs any possible therapeutic benefit for that population. The proposed Pregnancy Category for Qnexa is Category X.

Included with the October 17, 2011 resubmission of the Qnexa NDA was a proposed REMS framework. We discussed the REMS framework with the FDA and the details of the Qnexa REMS were discussed during the Endocrinologic and Metabolic Drugs Advisory Committee meeting, held February 22, 2012. As discussed above, on April 4, 2012, following the FDA's request, we submitted a comprehensive REMS.

Our resubmission of the NDA for Qnexa states that we plan to conduct a cardiovascular outcomes study post-approval, and we have since submitted a draft protocol to the FDA. The details of this study are under discussion with the FDA. This study could cost \$100 to \$200 million dollars and take as long as five or six years to complete.

Although no other requests for additional information or pre-approval studies were made by the FDA at these meetings or in the CRL, there can be no assurance that the FDA will not request or require us to provide additional information or undertake additional prospective studies or retrospective observational studies in connection with the Qnexa NDA.

Top-line preliminary results from FORTRESS were announced in December 2011. FORTRESS identified 1,945 mother-infant dyads exposed to topiramate either alone (monotherapy) or in combination with other antiepileptic agents (polytherapy) in the first trimester of pregnancy, or the Total Topiramate Cohort. Among the Total Topiramate Cohort, 1,740 dyads were exposed to topiramate monotherapy, or the Topiramate Monotherapy Cohort. There were five oral clefts in the Topiramate Monotherapy Cohort for a prevalence rate of 0.29% (5/1,740). This prevalence rate was compared to a control group of infants of women who had previously taken antiepileptic drugs including topiramate but not during the pregnancy of interest, or the Formerly Exposed Cohort. The prevalence rate for the Formerly Exposed Cohort was 0.16% (21/13,512). The prevalence ratio for Topiramate Monotherapy Cohort versus the Formerly Exposed Cohort was 1.88 (center-standardized, 95% CI 0.70-5.03).

FORTRESS analyzed data from a second control group, infants of women with similar medical profiles to the Total Topiramate Cohort regardless of prior antiepileptic drug use (the Similar Medical Profile Cohort). There were nine oral clefts from a sample of 13,614 dyads in the Similar Medical Profile Cohort, for a prevalence of 0.07%. One data source reported an anomalously low prevalence of oral clefts in the sample from the Similar Medical Profile Cohort. To investigate this finding, investigators performed repeated multiple re-sampling from the group of dyads who were eligible for this cohort and determined that the oral clefts prevalence observed in the cohort was likely due to random error. Based on these findings, the FDA requested that we utilize all of the available data in the entire Similar Medical Profile Cohort to determine the background prevalence of oral cleft. Using the entire Similar Medical Profile Cohort, the background prevalence of OC was found to be 0.16% (383/247614), and the Prevalence Ratio compared to the Topiramate Monotherapy cohort, standardized for center was 1.8 (95% CI 0.8-4.4).

As part of FORTRESS, Major Congenital Malformations, or MCMs, are being evaluated. The MCM analysis is ongoing. The FORTRESS findings are based on a claims-only analysis. All of the results of the study are considered to be preliminary until the results are validated. The results will be final when validation is completed, which is expected in the third quarter of 2012.

On December 17, 2010, we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, for Qnexa Controlled-Release Capsules in the EU. The proposed indication in the EU is for the treatment of obesity, including weight loss and maintenance of weight loss, and should be used in conjunction with a mildly hypocaloric diet. The EMA's review of Qnexa will follow their centralized marketing authorization procedure. If approved, Qnexa could receive marketing authorization in all 27 EU member countries. The MAA was officially validated for central procedure on January 19, 2011. If approved in the EU, Qnexa could be recommended for obese adult patients ($\text{BMI} \geq 30 \text{ kg/m}^2$), or overweight patients ($\text{BMI} \geq 27 \text{ kg/m}^2$) with weight-related co-morbidities such as hypertension, type 2 diabetes or dyslipidemia. In Europe, approximately 150 million adults are considered overweight or obese, and the prevalence is rising rapidly. According to EMA guidelines for medicinal products used in weight control, a demonstration of weight loss of at least 10% of baseline weight, which is at least statistically greater than that associated with placebo, is considered to be a valid primary efficacy criterion. Based on the results of the Phase 3 program, we believe Qnexa has met this efficacy criterion set by the EMA for obesity therapies. In addition, the mean weight loss for the mid and top dose of Qnexa at the end of two years was 10.4% and 11.4%, respectively, which we believe met the efficacy benchmark set by the EMA for obesity therapies. These results were shown to be associated with significant improvements in weight-related co-morbidities such as hypertension, dyslipidemia and diabetes. The MAA is comprised of data from over 4,500 overweight or obese patients with a broad range of weight-related co-morbidities. Two-year, double-blind data from SEQUEL (OB-305) were also included in the filing to demonstrate durability of treatment response and long-term safety.

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In May 2011, we received a response to our MAA from the CHMP. The response was in the form of the 120-day questions. The 120-day questions covered a broad range of topics including, without limitation, issues relating to phentermine, which include historical concerns regarding its potential association with valvulopathy and pulmonary hypertension; heart rate and limited long-term safety data in high-risk patients; and known and suspected effects of topiramate which include CNS and teratogenic potential. The CHMP also had questions concerning our proposed risk management plan for Qnexa. The 120-day questions were consistent with the issues previously raised in the FDA review process. We met with representatives from the CHMP in September 2011 to seek clarification on certain questions. We submitted our response to the 120-day questions in the fourth quarter of 2011. In January 2012, we received the 180-day List of Outstanding Issues, or 180-day LOI, from the CHMP. In order to perform additional analyses to allow further insights into the data as previously presented, we requested and, in April 2012, we received a two-month extension to respond to the 180-day LOI. The 180-day LOI contained requests for additional information including risk minimization activities to address various issues relating to cardiovascular, neuropsychiatric and potential teratogenic effects of Qnexa. In addition, we were asked to discuss the benefit/risk of the different doses of Qnexa, its potential use in different patient populations, and the expected long-term benefit of treatment with Qnexa. We have submitted our response to the 180-day LOI. There can be no assurance that our response will be adequate or that our MAA will be approved by the CHMP. Absent a delay, we anticipate an opinion from the CHMP in the second quarter of 2012.

In May 2011, the *Journal of the American Medical Association* published the results of a study entitled, *Newer-Generation Antiepileptic Drugs and the Risk of Major Birth Defects* by Ditte Mølgaard-Nielsen, MSc, Anders Hviid, MSc, DrMedSci (JAMA. 2011;305(19):1996-2002). The study was a population-based cohort study of 837,795 live-born infants in Denmark from January 1, 1996, through September 30, 2008. Individual-level information on dispensed antiepileptic drugs to mothers, birth defect diagnoses, and potential confounders was obtained from compulsory nationwide health registries. The main outcome measures were Prevalence Odds Ratios (PORs) of any major birth defect diagnosed within the first year of life by fetal exposure to antiepileptic drugs.

Of the 1,532 infants exposed to lamotrigine, oxcarbazepine, topiramate, gabapentin, or levetiracetam (newer-generation antiepileptic drugs) during the first trimester, 49 were diagnosed with a major birth defect compared with 19,911 of the 836,263 who were not exposed to an antiepileptic drug (3.2% vs. 2.4%, respectively; adjusted POR [APOR], 0.99; 95% confidence interval [CI], 0.72-1.36). For the topiramate subgroup, a major birth defect was diagnosed in five of 108 infants (4.6%) exposed to topiramate (APOR, 1.44; 95% CI, 0.58-3.58). The study concluded that among live-born infants in Denmark, first-trimester exposure to newer-generation antiepileptic drugs, including topiramate, compared with no exposure, was not associated with an increased risk of major birth defects.

In July 2011, abstracts for an international epilepsy conference including the top-line results of an additional retrospective study of medical claims data on oral clefts, or OCs, and MCMs associated with *in utero* topiramate exposure became available. This study was conducted using medical claims and pharmacy prescription data from the Wolters Kluwer Pharma Solutions Source® Lx Patient Longitudinal Database, which identified 778 mother-infant dyads exposed to topiramate within 10 months prior to giving birth. The study compared the incidence rate of OC and MCM in topiramate-exposed dyads to two control groups, one comprised of 3,431 dyads exposed to other antiepileptic drugs, or AEDs, during pregnancy and a second of 2,307 dyads with a diagnosis of epilepsy (with or without treatment), but no exposure to topiramate during pregnancy. Dyads exposed to known teratogens were excluded from all cohorts. The results of the study found there were no statistically significant differences in OC or MCM frequency between the topiramate and control groups.

On August 15, 2011, during the International Conference on Pharmacoepidemiology & Therapeutic Risk Management, a new study assessing the risk of oral clefts in topiramate-exposed pregnancies was presented. The presentation entitled *Use of Topiramate and the Risk of Oral Clefts* contained an analysis of data from two large databases including the CDC's National Birth Defects Prevention Study and the Birth Defect Study from the Slone Epidemiology Center at Boston University, together the Slone Study. Data from this new study demonstrated no increase in relative risk of overall major malformations (odds ratio 1.0; 95% CI 0.4-3.2), which provides supporting evidence that topiramate is not a major teratogen. The analysis did indicate an increased risk for oral cleft malformation may be associated with topiramate; however, we believe the magnitude of risk was substantially lower than data reflected in the current topiramate label. The Slone Study provides alternative methodology to assess relative risk with topiramate. The Slone Study assessed all malformations reported in two case-controlled surveillance programs, the Slone Epidemiology Center Birth Defects Study, or SBDS, and the CDC's National Birth Defects Prevention Study, or NBDPS. In contrast to

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other available studies, which assess relative risk based on total topiramate exposure, this analysis assessed the relative risk based on the proportion of identified malformations that were exposed to topiramate. The study identified a total of approximately 34,000 major congenital malformations (11,000 from SBDS and 23,000 from NBDPS), including approximately 3,000 oral cleft malformations (800 SBDS

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and 2,200 NBDPS). Topiramate exposure during the first trimester of pregnancy was reported in 15 of the major malformations and seven of the oral clefts. There were no reports of isolated cleft palate in the topiramate-exposed pregnancies. Pooled data from the two databases showed a relative risk for oral cleft of 5.4 (95% CI 1.5-20.1). Results were pooled due to the small number of topiramate-exposed pregnancies in the individual databases. In the SBDS data base, three topiramate-exposed oral clefts were reported, producing a relative risk of 10.1 (95% CI 1.1-129.2). In the NBDPS data base, four topiramate-exposed oral clefts were reported, producing a relative risk of 3.6 (95% CI 0.7-20.0). The signal of potential risk from these new data is substantially lower than reported from the North American AED (9.6x) and UK pregnancy (16x) registries.

On August 31, 2011, during a poster session at the 29th International Epilepsy Congress (IEC) in Rome, Italy, Dr. Alison Pack, Associate Professor of Clinical Neurology, Columbia University Medical Center, presented the results of this study. The incident rate of OC and MCM in the topiramate-exposed group was compared to OC and MCM incident rates in three non-topiramate-exposed control groups: an antiepileptic drug, or AED group, an epilepsy group, and a diabetes group. The study found that there were no significant differences in oral clefts or major congenital malformations between the topiramate group and the AED or epilepsy groups. The risk for MCMs in infants born to diabetic mothers was significantly higher than the other cohorts, including the infants exposed to topiramate *in utero*. The rates seen in the diabetes control group are comparable to that reported in the literature. In all groups, known or suspected teratogens, including valproate and phenytoin, were excluded.

On September 27, 2011, a poster authored by Dr. Mark W. Green, Director of the Center for Headache and Pain Medicine and Professor of Neurology and Anesthesiology at the Mount Sinai School of Medicine, was presented at the American Neurological Association Meeting in San Diego, CA. In addition to the topiramate exposure data previously reported, the results included the rate of MCMs and OCs in two new control groups, a migraine without epilepsy group, and a sub-group of patients exposed to acute- and preventive migraine drugs, or APMD, during pregnancy. The incident rate of oral clefts and major congenital malformations in the topiramate-exposed group was compared to OC and MCM incident rates in three non-topiramate-exposed control groups: a migraine without epilepsy group, a group of patients exposed to acute-preventive migraine drugs, or APMD, during pregnancy, and a diabetes group. The study found that the risk for MCMs in infants born to diabetic mothers was significantly higher than seen in infants exposed to TPM *in utero*. The MCM and OC rates seen in the diabetes control group are comparable to those reported in the literature. Consistency of these data compared to published references for the diabetes control group and the random sample provides assurance that this data would likely be representative of other clinical settings.

The study, funded by VIVUS, was conducted utilizing Wolters Kluwer datasets from the United States and followed patients Pharmacy and Medical Claims (births from January 2003 December 2010) and covered an estimated 177 million lives. Probable exposure during pregnancy was refined using data on script fill date, days of medication supplied, infant birth date, and ICD-9 codes for birth term. We included the results of this study in the October 17, 2011 resubmission of the Qnexa NDA.

A label update for topiramate was approved in July 2011. The updated label for topiramate reflects a lower than previously reported relative risk of oral cleft. In March 2011, based on data from the North American antiepileptic registry, the reported prevalence of oral cleft from topiramate exposure was 1.4% as compared to a historical control of 0.07%. In July 2011, the label was revised and now includes a prevalence rate for oral cleft of 1.2% (4/321). The historical control was corrected to 0.12%, which is more in line with the expected background rate in the general population. More importantly, the relative risk calculation dramatically improved from 21.3 to 9.6. At the same time, the REMS for topiramate was discontinued as the FDA determined that the Medication Guide, included as part of the labeling, adequately addressed public health risks.

In addition to Qnexa, we have an FDA approved drug, avanafil, which we intend to market through a partner in the U.S. under the name Stendra, to treat erectile dysfunction, or ED. We filed an NDA with the FDA for avanafil in June 2011. The NDA was accepted and we received the FDA's approval on April 27, 2012, in advance of the April 29, 2012 PDUFA target date. In March 2012, we submitted and the EMA accepted our MAA for avanafil in the EU. The unique profile of avanafil suggests that the compound may be selective. Greater selectivity can potentially result in lower incidence of the side effects associated with activation of non-phosphodiesterase type 5, or non-PDE5 isozymes.

Our Future

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

- seeking regulatory approval for Qnexa for the treatment of obesity in the U.S. and the EU and other territories worldwide;
- entering into a collaboration for the commercialization of avanafil for the treatment of ED in the U.S.;
- seeking regulatory approval for avanafil for the treatment of ED in the EU and other territories worldwide;
- establishing internal capabilities or strategic relationships with marketing partners to maximize sales potential for our drugs that require significant commercial support; and
- capitalizing on our clinical and regulatory expertise and experience to advance the development of investigational drug candidates in our pipeline.

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It is our objective to become a leader in the development and U.S. commercialization of drugs for large underserved markets. We believe we have strong intellectual property supporting several opportunities in obesity and related disorders, such as sleep apnea and diabetes, and men's sexual health. Our future growth depends on our ability to further develop and obtain regulatory approval of our investigational drug candidates for indications that we have studied, or plan to study, as well as in-licensing and product line extensions.

We have funded operations primarily through private and public offerings of our common stock, through the sale of the rights to Evamist and through sales of our former product, MUSE (alprostadil). We expect to generate future net losses due to increases in operating expenses as our various investigational drug candidates are advanced through the various stages of clinical development and for pre-commercialization activities. In connection with the sale of Evamist, to date we have received an aggregate of \$150 million. On November 5, 2010, we sold MUSE to Meda A.B., for which we received an upfront payment of \$22 million upon the closing and are eligible to receive an additional \$1.5 million based on future sales of MUSE, provided that certain sales milestones are reached. As of March 31, 2012, we have incurred a cumulative deficit of \$365.0 million and expect to incur operating losses in future years.

Our Investigational Drug Candidates

Our investigational drug pipeline includes one late-stage clinical investigational drug candidate, Qnexa, which has completed Phase 3 clinical trials for obesity and Phase 2 clinical trials for diabetes and obstructive sleep apnea. We submitted an NDA to the FDA for Qnexa in December 2009. On October 28, 2010, we received a CRL from the FDA regarding the Qnexa NDA stating that the NDA could not be approved in its present form. In subsequent meetings with the FDA, we came to an agreement on a retrospective observational study of major congenital malformations and oral clefts, FORTRESS.

On October 17, 2011, we resubmitted the Qnexa NDA and the FDA accepted the NDA for filing. On February 22, 2012, the FDA held an Advisory Committee meeting to discuss the additional information contained in the resubmitted NDA. The Advisory Committee voted 20 to 2 to recommend approval. The FDA is not bound by the recommendations of its advisory committees, but will consider their guidance during the review of the NDA that was submitted for Qnexa in October 2011. On April 4, 2012, at the FDA's request, we submitted a comprehensive REMS for Qnexa, which was considered a major amendment to the NDA. The PDUFA target date for Qnexa was April 17, 2012. However, as the submission of the revised REMS was within three months of the PDUFA target date, to provide time for a full review of the submission, the FDA extended the PDUFA target date by three months to July 17, 2012. The FDA has the ability to extend the PDUFA target date under certain circumstances, and there can be no assurance that it will not extend the PDUFA target date further in the future.

The Qnexa NDA resubmission seeks approval for the treatment of obesity, including weight loss and maintenance of weight loss for obese patients ($\text{BMI} \geq 30 \text{ kg/m}^2$), or overweight patients ($\text{BMI} \geq 27 \text{ kg/m}^2$) with weight-related co-morbidities such as hypertension, type 2 diabetes or dyslipidemia. The proposed labeling for Qnexa submitted on October 17, 2011 included a contraindication that excluded the use of Qnexa by women of childbearing potential. In January 2012, we announced that following discussions with FDA officials, we were asked to remove the Qnexa contraindication for women of childbearing potential contained in the proposed label. Qnexa would remain contraindicated for women who are pregnant. A contraindication typically indicates that a drug should not be used because the risk of use clearly outweighs any possible therapeutic benefit for that population. The proposed Pregnancy Category is Category X.

Included with the October 17, 2011 resubmission of the Qnexa NDA was a proposed REMS framework. We discussed the REMS framework with the FDA and the details of the Qnexa REMS were discussed during the Advisory Committee meeting, held February 22, 2012. As mentioned above, on April 4, 2012, following the FDA's request, we submitted a comprehensive REMS.

Our resubmission of the NDA for Qnexa states that we plan to conduct a cardiovascular outcomes study post-approval, and we have since submitted a draft protocol to the FDA. The details of this study are under discussion with the FDA. This study could cost \$100 to \$200 million dollars and take as long as five or six years to complete.

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Although no other requests for additional information or pre-approval studies were made by the FDA at these meetings or in the CRL, there can be no assurance that the FDA will not request or require us to provide additional information or undertake additional prospective studies or retrospective observational studies in connection with the Qnexa NDA.

In the EU, the MAA for Qnexa is currently under review through the centralized procedure. In May 2011, we received the 120-day questions from the CHMP. We submitted our response to the 120-day questions in the fourth quarter of 2011. In January 2012, we received the 180-day LOI from the CHMP. We have submitted our response to the 180-day LOI. There can be no assurance that our response will be adequate or that our MAA will be approved by the CHMP. Absent a delay, we anticipate an opinion from the CHMP in the second quarter of 2012.

We submitted an NDA for avanafil for the treatment of erectile dysfunction in June 2011. We received the FDA's approval of the NDA for avanafil on April 27, 2012, in advance of the April 29, 2012 PDUFA target date. In addition, we submitted and the EMA accepted our MAA for avanafil in the EU in March 2012. Our FDA approved drug and investigational drug candidates are summarized as follows:

Qnexa (phentermine and topiramate CR)	Obesity	Phase 3 studies completed; NDA submitted; CRL received; NDA resubmitted; PDUFA date July 17, 2012 MAA under review in EU; 180-day LOI response submitted; expect opinion from CHMP in Q2 2012.	Worldwide
Qnexa (phentermine and topiramate CR)	Obstructive Sleep Apnea	Phase 2 study completed	Worldwide
Qnexa (phentermine and topiramate CR)	Diabetes	Phase 2 study completed	Worldwide
Avanafil, to be marketed as Stendra in the U.S. (PDE5 inhibitor)	Erectile dysfunction	Phase 3 completed; NDA submitted; PDUFA date April 29, 2012; NDA approval April 27, 2012 MAA submitted and accepted in the EU March 2012	Worldwide license from Mitsubishi Tanabe Pharma Corporation (excluding certain Asian markets)

Qnexa for Obesity

Obesity is a chronic disease condition that affects millions of people and often requires long-term or invasive treatment to promote and sustain weight loss. In the National Health and Nutrition Examination Survey, or NHANES, conducted for 2007-2008, 68% of adults in the U.S. (72.3% of men and 64.1% of women) were classified as overweight, defined as a body mass index, or BMI > 25, and 33.8% were obese (BMI > 30). The percentage of American men and women classified as overweight and obese has more than doubled since 1962. Researchers fear that the percentage of American adults that are obese could climb as high as 43% in the next 10 years. Obesity is the second leading cause of preventable death in the U.S. According to a study performed by the Centers for Disease Control and Prevention, or CDC, as reported in the Journal of the American Medical Association, an estimated 112,000 excess deaths a year in the U.S. are attributable to obesity. Additionally, Americans spend more than \$30 billion annually on weight-loss products and services.

Qnexa is our proprietary oral investigational drug candidate for the treatment of obesity, incorporating low doses of active ingredients from two previously approved drugs, phentermine and topiramate. We believe that by combining these compounds, Qnexa targets excessive appetite and high threshold for satiety, or the feeling of being full, the two main mechanisms that impact eating behavior. Qnexa is a once-a-day capsule containing a proprietary formulation of extended-release phentermine and topiramate. Our first U.S. patent on Qnexa (U.S. 7,056,890 B2) and our EU patent on Qnexa (EU EP 1187603) both expire in 2020.

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On January 19, 2011, we held an End-of-Review meeting with the FDA to discuss our planned response to the CRL received on October 28, 2010, regarding the NDA for Qnexa as a treatment for obesity. The CRL stated that in its current form, the NDA for Qnexa was not approvable. The CRL included the following areas: clinical, labeling, REMS, safety update, and drug scheduling. In the clinical section of the CRL, the FDA requested a comprehensive assessment of topiramate's and Qnexa's teratogenic potential including a detailed plan and strategy to evaluate and mitigate the potential teratogenic risks in women of childbearing potential taking the drug for the treatment of obesity. In addition, the FDA asked us to provide evidence that the elevation in heart rate (mean 1.6 beats per minute on the top dose) associated with Qnexa does not increase the risk for major adverse cardiovascular events. The FDA requested that we formally submit the results from the completed SEQUEL study (OB-305), a 52-week extension study for a subset of 675 patients who completed the previously reported 56-week CONQUER study. The FDA reserved the right to comment further on proposed labeling. On REMS, the FDA requested that a discussion of an already-submitted REMS plan be continued after we submitted the written response. The agency also requested a safety update of any new adverse events be submitted with the NDA. Finally, the FDA stated that if approved, Qnexa would be a Schedule IV drug due to the phentermine component. No new clinical studies were requested in the CRL.

In anticipation of the meeting held with the FDA on January 19, 2011, we provided a briefing document that included comprehensive assessment of the teratogenic potential of topiramate including analyses integrating existing non-clinical and clinical data. In the Qnexa studies, which included 15 offspring from women exposed to Qnexa or topiramate, there were no reports of congenital malformations. In addition, we provided several new analyses including cardiovascular data from our SEQUEL (OB-305) and Sleep Apnea (OB-204) studies to demonstrate that Qnexa does not increase the risk for major cardiovascular events and that the observed increases in heart rate, which occurred in some patients over the course of the clinical program, did not increase the risk of major cardiovascular events, as evidenced by adverse events reported in the trial. We also provided a synopsis of the final study report for the SEQUEL study. At the meeting, an overview was provided of the teratogenicity and cardiovascular risk material covered in the background package. The discussion also included elements of our proposed REMS program for Qnexa. The primary focus of the FDA at the meeting, however, concerned the teratogenic potential for topiramate. The FDA requested that we complete the Feasibility Assessment. The Feasibility Assessment is complete and in April 2011 we again met with the FDA and agreed to conduct the retrospective observational study, FORTRESS. On October 17, 2011, we resubmitted the Qnexa NDA and the FDA accepted the NDA for filing. On February 22, 2012, the FDA held a second meeting of the Advisory Committee, to discuss the additional data submitted for Qnexa. The FDA asked the Advisory Committee to discuss the following: (1) their interpretation of the available data regarding teratogenicity of topiramate, including whether they believe the data indicate an increase in the risk for oral clefts; (2) the potential strengths and weaknesses of the proposed teratogenicity risk management strategy for Qnexa; (3) the clinical significance of the changes in blood pressure and heart rate in overweight and obese patients treated with Qnexa versus placebo, taking into account the reported changes in antihypertensive therapy; and (4) whether the available data for Qnexa warrant that a cardiovascular outcomes trial be conducted prior to approval. The FDA requested the Advisory Committee to vote on whether, after considering all the available data included in the NDA and the discussions held at the meeting on February 22, 2012, including the questions referred to above, the overall benefit-risk assessment of Qnexa supports its approval for the treatment of obesity in individuals with a BMI ≥ 30 kg/m² or a BMI ≥ 27 kg/m² with weight related co-morbidities. The Advisory Committee voted 20 to 2 to recommend approval. The FDA is not bound by the recommendations of its advisory committees, but will consider their guidance during the review of the NDA that was submitted for Qnexa in October 2011. On April 4, 2012, at the FDA's request, we submitted a comprehensive REMS for Qnexa, which was considered a major amendment to the NDA. The PDUFA target date for Qnexa was April 17, 2012. However, as the submission of the comprehensive REMS was within three months of the PDUFA target date, to provide time for a full review of the submission, the FDA extended the PDUFA target date by three months to July 17, 2012. The FDA has the ability to extend the PDUFA target date under certain circumstances, and there can be no assurance that it will not extend the PDUFA target date further in the future.

The Qnexa NDA resubmission seeks approval for the treatment of obesity, including weight loss and maintenance of weight loss for obese patients (BMI ≥ 30 kg/m²), or overweight patients (BMI ≥ 27 kg/m²) with weight-related co-morbidities such as hypertension, type 2 diabetes or dyslipidemia. The proposed labeling for Qnexa submitted on October 17, 2011 included a contraindication that excluded the use of Qnexa by women of childbearing potential. In January 2012, we announced that following discussions with FDA officials, we were asked to remove the Qnexa contraindication for women of childbearing potential contained in the proposed label. Qnexa would remain contraindicated for women who are pregnant. A contraindication typically indicates that a drug should not be used because the risk of use clearly outweighs any possible therapeutic benefit for that population. The proposed Pregnancy Category is Category X.

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Included with the October 17, 2011 resubmission of the Qnexa NDA was a proposed REMS framework. We discussed the REMS framework with the FDA and the details of the Qnexa REMS were discussed during the Advisory Committee meeting, held February 22, 2012. As mentioned above, on April 4, 2012, following the FDA's request, we submitted a comprehensive REMS.

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Our resubmission of the NDA for Qnexa states that we plan to conduct a cardiovascular outcomes study post-approval, and we have since submitted a draft protocol to the FDA. The details of this study are under discussion with the FDA. This study could cost \$100 to \$200 million dollars and take as long as five or six years to complete.

Although no other requests for additional information or pre-approval studies were made by the FDA at these meetings or in the CRL, there can be no assurance that the FDA will not request or require us to provide additional information or undertake additional prospective studies or retrospective observational studies in connection with the Qnexa NDA.

Top-line preliminary results from FORTRESS were announced in December 2011. FORTRESS identified 1,945 mother-infant dyads exposed to topiramate either alone (monotherapy) or in combination with other antiepileptic agents (polytherapy) in the first trimester of pregnancy, or the Total Topiramate Cohort. Among the Total Topiramate Cohort, 1,740 dyads were exposed to topiramate monotherapy, or the Topiramate Monotherapy Cohort. There were five oral clefts in the Topiramate Monotherapy Cohort for a prevalence rate of 0.29% (5/1,740). This prevalence rate was compared to a control group of infants of women who had previously taken antiepileptic drugs including topiramate but not during the pregnancy of interest, or the Formerly Exposed Cohort. The prevalence rate for the Formerly Exposed Cohort was 0.16% (21/13,512). The prevalence ratio for Topiramate Monotherapy Cohort versus the Formerly Exposed Cohort was 1.88 (center-standardized, 95% CI 0.70-5.03).

FORTRESS analyzed data from a second control group, infants of women with similar medical profiles to the Total Topiramate Cohort regardless of prior antiepileptic drug use (the Similar Medical Profile Cohort). There were nine oral clefts from a sample of 13,614 dyads in the Similar Medical Profile Cohort, for a prevalence of 0.07%. One data source reported an anomalously low prevalence of oral clefts in the sample from the Similar Medical Profile Cohort. To investigate this finding, investigators performed repeated multiple re-sampling from the group of dyads who were eligible for this cohort and determined that the oral clefts prevalence observed in the cohort was likely due to random error. Based on these findings, the FDA requested that we utilize all of the available data in the entire Similar Medical Profile Cohort to determine the background prevalence of oral cleft. Using the entire Similar Medical Profile Cohort, the background prevalence of OC was found to be 0.16% (383/247614), and the Prevalence Ratio compared to the Topiramate Monotherapy cohort, standardized for center was 1.8 (95% CI 0.8-4.4).

As part of FORTRESS, MCMs are being evaluated. The MCM analysis is ongoing. The FORTRESS findings are based on a claims-only analysis. All of the results of the study are considered to be preliminary until the results are validated. The results will be final when validation is completed, which is expected in the third quarter of 2012.

On March 4, 2011, the FDA issued a drug safety communication informing the public of new data that show that there is an increased risk for the development of cleft lip and/or cleft palate (oral clefts) in infants born to women treated with topiramate (Topamax and generic products) during pregnancy. The communication stated that the benefits and the risks of topiramate should be carefully weighed when prescribing this drug to women of childbearing age, particularly for conditions not usually associated with permanent injury or death. The communication also indicated that alternative medications that have a lower risk of oral clefts and other adverse birth outcomes should be considered for these patients. If the decision is made to use topiramate in women of childbearing age, effective birth control should be used. Oral clefts occur in the first trimester of pregnancy before many women know they are pregnant. Topiramate was previously classified as a Pregnancy Category C drug, which means that data from animal studies suggested potential fetal risks, but no adequate data from human clinical trials or studies were available at the time of approval. However, because of preliminary human data that show an increased risk for oral clefts, topiramate was placed in Pregnancy Category D. Pregnancy Category D means there is positive evidence of human fetal risk based on human data but the potential benefits from use of the drug in pregnant women may be acceptable in certain situations despite its risks. The safety communication and changes in the Pregnancy Category were due in part to data from the North American Antiepileptic Drug, or NAAED, Pregnancy Registry which indicated an increased risk of oral clefts in infants born to mothers exposed to topiramate monotherapy during the first trimester of pregnancy. The prevalence of oral clefts was 1.4% (3/289) compared to a prevalence of 0.38% - 0.55% in infants born to mothers exposed to other

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antiepileptic drugs, or AEDs, and a purported prevalence of 0.07% in infants born to mothers without epilepsy or treatment with other AEDs. The relative risk of oral clefts in topiramate-exposed pregnancies in the NAAED Pregnancy Registry was 21.3 as compared to the risk in a background population of untreated women (95% Confidence Interval: 7.9 - 57.1). The UK Epilepsy and Pregnancy Register reported a similarly increased prevalence of oral clefts (3.2%) among infants born to mothers exposed to topiramate monotherapy, a 16-fold increase in risk compared to the risk in their background population (0.2%).

A label update for topiramate was approved in July 2011. The updated label for topiramate reflects a lower than previously reported relative risk of oral cleft. In March 2011, based on data from the North American antiepileptic registry, the reported prevalence of oral cleft from topiramate exposure was 1.4% as compared to a historical control of 0.07%. In July 2011, the label was revised and now includes a prevalence rate for oral cleft of 1.2%. The historical control was corrected to 0.12%, which is more in line with the expected background rate in the general population. More importantly, the relative risk calculation dramatically improved from 21.3 to 9.6. Also at this time, the REMS for topiramate was discontinued as the FDA determined that the Medication Guide as part of the labeling adequately addresses public health risks.

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On August 15, 2011, during the International Conference on Pharmacoepidemiology & Therapeutic Risk Management, a new study assessing the risk of oral clefts in topiramate-exposed pregnancies was presented. The presentation entitled "Use of Topiramate and the Risk of Oral Clefts" contained an analysis of data from two large databases including the CDC's National Birth Defects Prevention Study and the Birth Defect Study from the Slone Epidemiology Center at Boston University, together the Slone Study. Data from this new study demonstrated no increase in relative risk of overall major malformations (odds ratio 1.0; 95% CI 0.4-3.2), which provides supporting evidence that topiramate is not a major teratogen. The analysis did indicate an increased risk for oral cleft malformation may be associated with topiramate; however, we believe the magnitude of risk was substantially lower than data reflected in the current topiramate label. The Slone Study provides alternative methodology to assess relative risk with topiramate. The Slone Study assessed all malformations reported in two case-controlled surveillance programs, the Slone Epidemiology Center Birth Defects Study, or SBDS, and the CDC's National Birth Defects Prevention Study, or NBDPS. In contrast to other available studies, which assess relative risk based on total topiramate exposure, this analysis assessed the relative risk based on the proportion of identified malformations that were exposed to topiramate. The study identified a total of approximately 34,000 major congenital malformations (11,000 from SBDS and 23,000 from NBDPS), including approximately 3,000 oral cleft malformations (800 SBDS and 2,200 NBDPS). Topiramate exposure during the first trimester of pregnancy was reported in 15 of the major malformations and seven of the oral clefts. There were no reports of isolated cleft palate in the topiramate-exposed pregnancies. Pooled data from the two databases showed a relative risk for oral cleft of 5.4 (95% CI 1.5-20.1). Results were pooled due to the small number of topiramate-exposed pregnancies in the individual databases. In the SBDS data base, three topiramate-exposed oral clefts were reported, producing a relative risk of 10.1 (95% CI 1.1-129.2). In the NBDPS data base, four topiramate-exposed oral clefts were reported, producing a relative risk of 3.6 (95% CI 0.7-20.0). The signal of potential risk from these new data is substantially lower than reported from the North American AED (9.6x) and UK pregnancy (16x) registries.

On December 17, 2010, we filed an MAA with the EMA for Qnexa Controlled-Release Capsules in the European Union, or the EU. The proposed indication in the EU is for the treatment of obesity, including weight loss and maintenance of weight loss, and should be used in conjunction with a mildly hypocaloric diet. The EMA's review of Qnexa will follow their centralized marketing authorization procedure. If approved, Qnexa could receive marketing authorization in all 27 EU member countries. The MAA was officially validated for central procedure on January 19, 2011. If approved in the EU, Qnexa could be recommended for obese adult patients ($\text{BMI} \geq 30 \text{ kg/m}^2$), or overweight patients ($\text{BMI} \geq 27 \text{ kg/m}^2$) with weight-related co-morbidities such as hypertension, type 2 diabetes or dyslipidemia. In Europe, approximately 150 million adults are considered overweight or obese, and the prevalence is rising rapidly. According to EMA guidelines for medicinal products used in weight control, a demonstration of weight loss of at least 10% of baseline weight, which is at least statistically greater than that associated with placebo, is considered to be a valid primary efficacy criterion. Based on the results of the Phase 3 program, we believe Qnexa has met this efficacy criterion set by the EMA for obesity therapies. In addition, the mean weight loss for the mid and top dose of Qnexa at the end of two years was 10.4% and 11.4%, respectively, which we believe met the efficacy benchmark set by the EMA for obesity therapies. These results were shown to be associated with significant improvements in weight-related co-morbidities such as hypertension, dyslipidemia and diabetes. The MAA is comprised of data from over 4,500 overweight or obese patients with a broad range of weight-related co-morbidities. Two-year, double-blind data from SEQUEL (OB-305) were also included in the filing to demonstrate durability of treatment response and long-term safety.

In January 2012, we received the 180-day LOI from the CHMP. In order to perform additional analyses to allow further insights into the data as previously presented, we requested and, in April 2012, we received a two-month extension to respond to the 180-day LOI. The 180-day LOI contains requests for additional information including risk minimization activities to address various issues relating to cardiovascular, neuropsychiatric and potential teratogenic effects of Qnexa. In addition, we were asked to discuss the benefit/risk of the different doses of Qnexa, its potential use in different patient populations, and the expected long-term benefit of treatment with Qnexa. We have submitted our response to the 180-day LOI. There can be no assurance that our response will be adequate or that our MAA will be approved by the CHMP. Absent a delay, we anticipate an opinion from the CHMP in the second quarter of 2012.

EQUIP (OB-302) AND CONQUER (OB-303) One-Year Phase 3 Studies

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The Qnexa development program included two large Phase 3 randomized, double-blind, placebo-controlled, 3-arm, prospective studies across 93 centers comparing Qnexa to placebo over a 56-week treatment period. All Phase 3 studies utilized our once-a-day formulation of Qnexa, which at top dose contains 15 mg phentermine and 92 mg of a proprietary extended-release formulation of topiramate. The Phase 3 studies were designed to prospectively demonstrate the safety and efficacy of Qnexa in obese and overweight patients with different baseline characteristics. The co-primary endpoints for these studies evaluated the differences between treatments in mean percent weight loss from baseline to the end of the treatment period and the differences between treatments in the percentage of patients achieving weight loss of 5% or more. Patients were asked to follow a hypocaloric diet representing a 500-calorie/day deficit and were advised to implement a simple lifestyle modification program.

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The first year-long Phase 3 study, known as EQUIP, enrolled 1,267 morbidly obese patients (1,050 females and 217 males) with a BMI that equaled or exceeded 35 kg/m² with or without controlled co-morbidities. The average baseline BMI of the study population was 42.1 kg/m² and baseline weight was 256 pounds. Patients had a 4-week dose titration period followed by 52 weeks of treatment, with patients randomized to receive once-a-day treatment with low dose Qnexa, full dose Qnexa or placebo. Weight loss results from the study are summarized as follows:

	Placebo (n=498)	ITT-LOCF Qnexa low dose (n=234)	Qnexa top dose (n=498)	Placebo (n=241)	Completers Qnexa low dose (n=138)	Qnexa top dose (n=301)
EQUIP (OB-302) 56 weeks						
Mean weight loss (%)	1.6%	5.1%*	10.9%	2.5%	7%*	14.7%*
Greater than or equal to 5% weight loss rate	17%	45%*	67%*	26%	59%*	84%*

ITT-LOCF: Intent-to-treat with last observation carried forward

* p<0.0001 vs. placebo

The EQUIP study met the co-primary endpoints by demonstrating that patients treated with top dose and low dose Qnexa had an average weight loss of 10.9% and 5.1%, respectively, as compared to weight loss of 1.6% in the placebo group (ITT-LOCF p<0.0001). Average weight loss was 37 pounds and 18 pounds with top dose Qnexa and low dose Qnexa, respectively, as compared to six pounds in the placebo group. The proportion of patients losing 5% or more of their initial body weight was 67% for top dose, 45% for low dose and 17% for placebo (ITT-LOCF p<0.0001).

The most common drug-related adverse events reported in the EQUIP study for the top dose, low dose and placebo group were tingling of the extremities, dry mouth, altered taste, headache and constipation. A significantly greater proportion of patients completed the study on Qnexa as compared to placebo patients. Overall average completion rates were 59%, 57% and 47% for patients taking top dose Qnexa, low dose Qnexa and placebo, respectively. In November 2011, the results from the EQUIP study were published in *Obesity*, the peer-reviewed journal of The Obesity Society.

The second year-long Phase 3 trial, known as CONQUER, enrolled 2,487 overweight and obese adult patients (1,737 females and 750 males) with BMI s from 27 kg/m² to 45 kg/m² and at least two co-morbid conditions, such as hypertension, dyslipidemia and type 2 diabetes. The average baseline BMI of the study population was 36.6 kg/m² and baseline weight was 227 pounds. Patients had a 4-week dose titration period followed by 52 weeks of treatment, with patients randomized to receive once-a-day treatment with top dose Qnexa, mid dose Qnexa or placebo. Weight loss results from the study are summarized as follows:

	Placebo (n=979)	ITT-LOCF Qnexa mid dose (n=488)	Qnexa top dose (n=981)	Placebo (n=564)	Completers Qnexa mid dose (n=344)	Qnexa top dose (n=634)
CONQUER (OB 303) 56 weeks						
Mean weight loss (%)	1.8%	8.4%*	10.4%*	2.4%*	10.5%*	13.2%*
	21%	62%*	70%*	26%	75%*	85%*

Greater than or equal to 5% weight
loss rate

* p<0.0001 vs. placebo

The CONQUER study also met the co-primary endpoints by demonstrating that patients treated with top dose and mid dose Qnexa had an average weight loss of 10.4% and 8.4%, respectively, as compared to weight loss of 1.8% in the placebo group (ITT-LOCF p<0.0001). Average weight loss was 30 pounds and 24 pounds with top dose Qnexa and mid dose Qnexa, respectively, as compared to six pounds in the placebo group. The proportion of patients losing 5% or more of their initial body weight was 70% for top dose, 62% for mid dose and 21% for placebo (ITT-LOCF p<0.0001).

The most common drug-related adverse events reported in the CONQUER study for the top dose, mid dose, and placebo group were tingling of the extremities, dry mouth, altered taste, insomnia, dizziness, headache and constipation. A significantly greater proportion of patients completed the study on Qnexa as compared to placebo patients. Overall average completion rates were 64%, 69%, and 57% for patients taking top dose Qnexa, mid dose Qnexa and placebo, respectively.

In April 2011, we announced that detailed results from the 56-week CONQUER study were published in *The Lancet* evaluating the efficacy and safety of investigational drug Qnexa in 2,487 patients across 93 sites in the U.S. Data published in the peer-reviewed journal provided an in-depth examination of Qnexa's effects on weight loss and improvements in various weight-related co-morbidities including cardiovascular, metabolic and inflammatory risk factors.

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We also conducted a one-year extension study of a subset of patients who completed the 56-week CONQUER study. The purpose of this study was to provide long-term safety and efficacy data to support the MAA in Europe. The SEQUEL study was a double-blind, placebo-controlled, 3-arm, prospective extension study across 36 centers comparing Qnexa to placebo over an additional 52-week treatment period for a total treatment duration of 108 weeks, or two years. SEQUEL included 675 obese or overweight patients, all of whom had two or more weight related co-morbidities and an average baseline BMI of 36.1. Patients in SEQUEL continued in a blinded fashion to receive the same treatment they were randomized to in the CONQUER study. The co-primary endpoints for this study were the differences between treatments in mean weight loss and percent weight loss from start of the OB-303 study (baseline) to the end of the treatment period (two years). Secondary endpoints include the differences between treatments in the percentage of patients achieving weight loss of 5% and 10% and the change in waist circumference. Patients were asked to continue a hypocaloric diet representing a 500-calorie/day deficit and were advised to implement a simple lifestyle modification program.

Patients in the study taking the top dose of Qnexa achieved and maintained average weight loss through two years of 26 pounds (ITT-LOCF). Consistent with the first-year experience, Qnexa therapy was well-tolerated, with no new or unexpected adverse events. The most common drug-related side effects reported were constipation, tingling, dry mouth, altered taste and insomnia.

Weight loss with Qnexa in SEQUEL was associated with statistically significant improvements in weight-related co-morbidities such as hypertension, dyslipidemia and diabetes. Among patients without diabetes at baseline, the incidence of new onset of type 2 diabetes was reduced by 54% and 76% for mid and top dose, respectively, as compared to placebo.

Specific SEQUEL findings include the following primary endpoints: Patients taking top and mid dose Qnexa achieved and maintained weight loss over two years of 11.4% and 10.4% of their initial body weight, respectively, as compared to placebo-treated patients with 2.5% weight loss (ITT-LOCF, $p < 0.0001$). A majority of all patients taking Qnexa exceeded 10% weight loss, the goal established by the National Institutes of Health, or NIH, to decrease the severity of obesity-associated risk factors. The percentage of patients achieving categorical weight loss of at least 5%, 10% and 15% on both Qnexa doses was statistically significant compared to placebo:

Categorical Weight Loss (ITT-LOCF)	5%	10%	15%
Top dose	79%*	54%*	32%*
Mid dose	75%*	50%*	24%*
Placebo	30%	12%	7%

* $p < 0.0001$ vs placebo

Treatment-emergent serious adverse event rates in SEQUEL were low (top dose = 4.1%; mid dose = 2.6%) and similar to placebo (4%), with no drug-related serious adverse events reported.

The completion rate in SEQUEL was approximately 83% for both Qnexa doses and 86% for the placebo group. Discontinuations due to adverse events were 3.9% and 4.1% for the mid and top dose, respectively, and 2.6% for the placebo group; with no single adverse event leading to discontinuation in more than 1% of patients. Additionally, SEQUEL data confirms previous safety findings, with no reports of suicidal attempts or behavior. Depression assessments, as measured by the PHQ-9 clinical depression scale, improved from baseline for all treatment groups. The incidence of targeted medical events for sleep disorders, depression, anxiety, cardiac disorders and cognitive disorders in SEQUEL was lower than observed during the one-year CONQUER study but still higher than placebo. Similar to previously presented data, effects of Qnexa in SEQUEL on heart rate were small and seen in conjunction with improvements in blood pressure from baseline. There were no clinically relevant decreases of serum bicarbonate in patients treated with Qnexa compared to patients receiving placebo in year two of SEQUEL. In December 2011, the results from the SEQUEL study were published in *The American Journal of Clinical Nutrition*, a peer-reviewed journal with broad, multidisciplinary readership.

Qnexa therapy was well-tolerated, with no new adverse events reported in the second year of study. The most common side effects were upper respiratory infection, constipation, tingling, sinus infection, dry mouth and runny nose. There were no drug-related serious adverse events reported.

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Across the entire Qnexa development program (4,323 patients), including the two-year data in SEQUEL, serious cardiovascular and neurovascular adverse event rates in patients taking Qnexa were similar to placebo with a relative risk of 0.54 (95% CI: 0.29-0.98). No major congenital malformations or oral clefts were observed across the entire development program in patients taking Qnexa or placebo.

The primary efficacy endpoint for Phase 3 weight loss trials in the U.S., as recommended by the FDA, is at least a 5% mean reduction in baseline body weight compared to placebo or at least 35% of patients losing 5% or more of their baseline body weight. In Europe, the Committee for Medicinal Products for Human Use of the European Medicines Agency has recommended that demonstration of significant weight loss of at least 10% of baseline weight is considered to be a valid primary endpoint for anti-obesity drugs. The FDA and foreign authorities require pivotal obesity studies to be conducted for at least one year. Although the results of our pivotal Phase 3 obesity trials met these current guidelines for efficacy, there can be no assurance that these results will be acceptable to the FDA or the EMA.

We completed a Thorough QT, or TQT, prolongation study evaluating patients taking Qnexa. The QT interval represents the time for both ventricular depolarization and repolarization to occur in the heart, and therefore roughly estimates the duration of an average ventricular action potential. If abnormally prolonged or shortened, there is a risk of developing ventricular arrhythmias. The study was completed with no Qnexa-related signal for QT prolongation. We also conducted studies evaluating cognitive and psychomotor functions in patients taking Qnexa. Patients underwent complex and extensive cognitive and psychomotor testing using validated, FDA recognized testing methodologies. There was no clinically relevant change in overall cognitive function or effect on psychomotor function seen in patients taking Qnexa.

Qnexa for Obstructive Sleep Apnea

Obstructive sleep apnea, or OSA, is a condition in which patients momentarily pause or stop breathing altogether while sleeping. The pauses in breathing can occur frequently throughout the course of sleep. Sleep apnea is often undiagnosed and can lead to severe health problems and even death if left untreated. It is estimated that about 18 million people in the U.S. have OSA. Currently, there are no approved pharmacologic treatments for OSA. Modafinil is approved for the treatment of residual daytime sleepiness associated with OSA, but does not specifically treat the sleep apnea condition.

In January 2010, we announced positive results from a Phase 2 study evaluating the safety and efficacy of Qnexa for the treatment of moderate to severe OSA. This Phase 2 study (OB-204) was a single-center, randomized, double-blind, placebo-controlled parallel group trial including 45 obese men and women (BMI 30 to 40 kg/m² inclusive), 30 to 65 years of age with OSA (apnea-hypopnea index, or AHI, greater than or equal to 15 at baseline) who had not been treated with, or who were not compliant with continuous positive airway pressure, or CPAP, within three months of screening. Patients were randomized to placebo or top dose Qnexa. CPAP is the current standard of care treatment for the majority of patients with moderate or severe OSA, defined as an apnea-hypopnea index, or AHI, of 15 or more events per hour. Although CPAP is reported to be effective in treating OSA when properly and consistently used, compliance (as defined by use for at least four hours per night, on at least 70% of nights) may be as low as 50-60%.

In the OB-204 study, patients underwent a four-week dose titration followed by 24 weeks of additional treatment. All patients were also provided with a lifestyle modification program focusing on diet and exercise. Overnight polysomnography in a sleep laboratory was performed at baseline, Week 8 and Week 28. The primary endpoint was the change in AHI between baseline and Week 28; secondary endpoints included weight loss, improvement in overnight oxygen saturation and reduction in blood pressure.

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The study demonstrated statistically significant improvement in AHI in patients with OSA treated with Qnexa for 28 weeks compared to placebo. Patients treated with Qnexa also experienced significant weight loss, improvements in blood pressure, and overnight blood oxygen saturation.

Sleep apnea is one of the leading co-morbidities associated with obesity and research has shown that weight loss can improve OSA. Qnexa treatment was well-tolerated with no serious adverse events reported in the Qnexa arm; the most common side effects were dry mouth, altered taste and sinus infection.

Qnexa for Diabetes

Diabetes is a significant worldwide disease. Based on the fourth edition of the *Diabetes Atlas* published in 2009, the International Diabetes Federation estimated that in 2008 there were 285 million people with diabetes worldwide, with 27 million of those people living in the U.S. Diabetes, mostly type 2 diabetes, was projected to reach 6.6% of the world's adult population in 2010, with almost 70% of the total in developing countries. Based on the National Diabetes Fact Sheet, 2011, the CDC estimates that nearly 26 million people in the U.S. have diabetes, mostly type 2 diabetes, and that 79 million people have pre-diabetes, a condition that puts

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people at increased risk of diabetes. Type 2 diabetes is characterized by inadequate response to insulin and/or inadequate secretion of insulin as blood glucose levels rise. Currently approved therapies for type 2 diabetes are directed toward correcting the body's inadequate response with oral or injectable medications, or directly modifying insulin levels through injection of insulin or insulin analogs.

The currently approved oral medications for type 2 diabetes include insulin releasers such as glyburide, insulin sensitizers such as Actos and Avandia, inhibitors of glucose production by the liver such as metformin, DPP-IV inhibitors like sitagliptin (FDA approved 2006, marketed by Merck & Co. as Januvia), vildagliptin (EU approved 2007, marketed in the EU by Novartis as Galvus), saxagliptin (FDA approved in 2009, marketed as Onglyza by Astrazenca), and linagliptin (FDA approved in 2011, marketed as Trajenta by Eli Lilly Co. and Boehringer Ingelheim), as well as Precose and Glyset, which slow the uptake of glucose from the intestine. Approved injectable medications for type 2 diabetes treatment include glucagon-like peptide-1, or GLP-1, analogs such as Liraglutide, marketed under the brand name Victoza, developed by Novo Nordisk and Exenatide, marketed under the brand name Byetta, and a long-acting version of Exenatide marketed under the brand name Bydureon, developed by Amylin Pharmaceuticals and Eli Lilly and Company. Studies to date suggest GLP-1s improve control of blood glucose by increasing insulin secretion, delaying gastric emptying, and suppressing prandial glucagon secretion. Clinical studies have reported that patients treated with GLP-1s have reported weight loss of approximately six to eight pounds.

The worldwide market for diabetes medications was estimated at \$24 billion in 2007, according to IMS Health. However, it is estimated that a significant portion of type 2 diabetics fail oral medications and require injected insulin therapy. Current oral medications for type 2 diabetes have a number of common drug-related side effects, including hypoglycemia, weight gain and edema. Numerous pharmaceutical and biotechnology companies are seeking to develop insulin sensitizers, novel insulin formulations and other therapeutics to improve the treatment of diabetes. Previous clinical studies of topiramate, a component of Qnexa, in type 2 diabetics resulted in a clinically meaningful reduction of hemoglobin A1c, a measure used to determine treatment efficacy of anti-diabetic agents.

In December 2008, we announced the results of our DM-230 diabetes study. The DM-230 Phase 2 study enrolled 130 patients, who had completed our Phase 2 study for the treatment of obesity, at 10 study sites in the U.S., to continue in a blinded fashion as previously randomized for an additional 28 weeks. The results of the DM-230 study included assessments from the start of the OB-202 study through the end of the DM-230 study in this population, for a total treatment period of 56 weeks. Patients treated with Qnexa had a reduction in hemoglobin A1c of 1.6%, from 8.8% to 7.2%, as compared to 1.1% from 8.5% to 7.4% in the placebo-treated standard of care group (ITT LOCF $p=0.0381$) at 56 weeks. All patients in the study were actively managed according to American Diabetes Association, or ADA, standards of care with respect to diabetes medications and lifestyle modification. For patients treated with placebo, increases in the number and doses of concurrent anti-diabetic medications were required to bring about the observed reduction in HbA1c. By contrast, concurrent anti-diabetic medications were reduced over the course of the trial in patients treated with Qnexa ($p<0.05$).

Over 56 weeks, patients treated with Qnexa also lost 9.4% of their baseline body weight, or 20.5 pounds, as compared to 2.7%, or 6.1 pounds, for the placebo group ($p<0.0001$). Sixty-five percent of the Qnexa patients lost at least 5% of their body weight, as compared to 24% in the placebo group ($p<0.001$), and 37% of the Qnexa patients lost at least 10% of their body weight, as compared to 9% of patients in the placebo group ($p<0.001$). Patients treated with Qnexa had reductions in blood pressure, triglycerides and waist circumference. Both treatment groups had a study completion rate of greater than 90%.

The most common drug-related side effects reported were tingling, constipation and nausea. Patients on antidepressants such as SSRI's or SNRI's were allowed to participate in the studies. Patients were monitored for depression and suicidality using the PHQ-9 questionnaire, a validated mental health assessment tool agreed to by the FDA for use in our studies. Patients treated with Qnexa demonstrated greater improvements in PHQ-9 scores from baseline to the end of the study than patients in the placebo group.

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Despite a mean baseline HbA1c level of 8.8%, 53% of the patients treated with Qnexa were able to achieve the ADA recommended goal of 7% or lower, versus 40% of the patients in the placebo arm ($p<0.05$). The incidence of hypoglycemia in the treatment and placebo arms was similar (12% and 9%, respectively). Patients in the Qnexa arm experienced no treatment-related serious adverse events.

We also studied the effect of Qnexa on well-controlled diabetics as part of OB-303. The results were consistent and supportive of the Phase 2 results.

On December 7, 2011, an oral presentation was given at the International Diabetes Federation's World Diabetes Congress, in Dubai, United Arab Emirates. The presentation highlighted excess weight loss, improvement of glycemic parameters in diabetic patients with a $BMI \geq 35$ and effects on diabetes status. The presentation reported on a subset of patients within the CONQUER study who had diabetes and a $BMI \geq 35$. Within this patient population ($n=147$), excess weight loss, defined as the weight loss required to

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achieve a healthy BMI of 25, was 33% with Qnexa as compared to 7.4% for the placebo group after 56 weeks of treatment (LS mean $p < 0.0001$ compared to placebo). Excess weight loss is typically reported in patients who have undergone weight loss surgery. Weight loss was highly correlated to improvements in glycemic parameters including fasting glucose ($p < 0.0001$), fasting insulin ($p = 0.0024$) and hemoglobin A1c ($p < 0.0001$). Normalization of glucose levels and withdrawal of all antidiabetic medications occurred in 15% of patients treated with full dose Qnexa as compared to 2% with placebo ($p = 0.0287$). The safety profile in this subpopulation, based on reported adverse events, is consistent with that seen in the whole study population. The most common adverse events seen were constipation, upper respiratory infection, and tingling.

On December 8, 2011, we announced that results from the SEQUEL study were published in *The American Journal of Clinical Nutrition*, or *AJCN*, a peer-reviewed journal with broad, multidisciplinary readership. The SEQUEL study evaluated the long-term efficacy and safety of Qnexa in 675 overweight and obese patients with cardiometabolic disease. In addition to 10% sustained weight loss, the study also found that significantly more placebo patients became diabetic over the two years as compared to patients treated with Qnexa. The data suggest that Qnexa, in conjunction with lifestyle modification, may provide a well-tolerated and effective option for the sustained treatment of obesity and the potential to prevent many in this population from progressing to type 2 diabetes.

Qnexa for Other Indications

We believe Qnexa may be helpful in treating other obesity-related diseases including nonalcoholic steatohepatitis, or NASH, or its precursor, nonalcoholic fatty liver disease, or NAFLD, also known as fatty liver disease. We believe Qnexa may also be helpful in treating hyperlipidemia, or an elevation of lipids (fats) in the bloodstream. These lipids include cholesterol, cholesterol esters (compounds), phospholipids and triglycerides. In addition, we believe Qnexa may be helpful in patients with hypertension that do not respond well to antihypertensive medication.

Avanafil for Erectile Dysfunction

Erectile dysfunction, or ED, is defined as the inability to attain or maintain an erection sufficient for intercourse. ED was reported by 52% of men between the ages of 40 to 70 in the Massachusetts Male Aging Study, with the incidence increasing with age. Erectile dysfunction, frequently associated with vascular problems, is particularly common in men with diabetes and in those who have had a radical prostatectomy for prostate cancer. Phosphodiesterase type 5, or PDE5, inhibitors such as sildenafil (Viagra), vardenafil (Levitra) and tadalafil (Cialis), which inhibit the breakdown of cyclic guanosine monophosphate, have been shown to be effective oral treatments for ED.

The worldwide sales in 2011 of PDE5 inhibitor products for the treatment of ED were approximately \$4.2 billion, including approximately \$2.0 billion in sales of Viagra, approximately \$1.9 billion in sales of Cialis and approximately \$300 million in estimated sales of Levitra. While increased use of PDE5 inhibitors has been modest in recent years, we believe the market for PDE5 inhibitors will continue to represent a sizable market opportunity.

Avanafil is an oral PDE5 inhibitor investigational drug candidate that we licensed from Tanabe Seiyaku Co., Ltd., or Tanabe, in 2001. In October 2007, Tanabe and Mitsubishi Pharma Corporation completed their merger and announced their name change to Mitsubishi Tanabe Pharma Corporation, or MTPC. Our U.S. patent on avanafil (U.S. 6,656,935) expires in September of 2020.

We have exclusive worldwide development and commercialization rights for avanafil with the exception of China, South Korea, North Korea, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Vietnam and the Philippines.

In June 2011, we submitted an NDA to the FDA seeking approval of avanafil for the treatment of ED. The NDA was submitted and we received the FDA's approval of the NDA for avanafil on April 27, 2012, in advance of the April 29, 2012 PDUFA target date. The NDA submission follows the successful completion of a Phase 3 program for avanafil. More than 1,200 men with ED participated in clinical studies evaluating the efficacy and safety of avanafil. Avanafil at all doses tested (50mg, 100mg and 200mg) met all primary efficacy endpoints. We submitted and the EMA accepted our MAA for avanafil for the treatment of ED in the EU in March 2012.

In November 2009, we announced results from the first of several pivotal Phase 3 studies of avanafil. The first study, REVIVE (TA-301), was a randomized, double-blind, placebo-controlled Phase 3 study of avanafil in 646 men.

Patients underwent a four-week, non-treatment run-in period followed by 12 weeks of treatment with one of three doses of avanafil: 50 mg, 100 mg and 200 mg or placebo. Patients were instructed to attempt sexual intercourse 30 minutes after taking avanafil, with no restrictions on food or alcohol consumption. The primary endpoints of the study were improvement in erectile

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function as measured by the Sexual Encounter Profile, or SEP, and improvement in the International Index of Erectile Function, or IIEF, score; secondary endpoints included patient satisfaction with erections and with sexual experience. This Phase 3 study was conducted under a Special Protocol Assessment, or SPA, with the FDA.

The REVIVE study met all primary endpoints across the three doses studied by demonstrating statistically significant improvement in erectile function as measured by the SEP and improvement in the IIEF score. Highlights of the study include:

- Nearly 80% of sexual attempts among patients on the 200 mg dose of avanafil had erections sufficient for intercourse (SEP2);
- All FDA-approved primary endpoints were met across all three doses of avanafil; and
- There were no reported drug-related serious adverse events in the study.

Patients on all three dose levels achieved a dose-related overall improvement in erectile function, as measured by improvement in the IIEF. IIEF scores range from 0-30 and measure the severity of erectile dysfunction as follows: severe dysfunction is less than or equal to 10; moderate is 11-16; and mild/minimal is 17-25. IIEF results of the study were:

	Baseline	End of Treatment
Placebo	12.4	15.3
Avanafil 50 mg	12.7	18.1
Avanafil 100 mg	12.6	20.9
Avanafil 200 mg	12.7	22.2

(p<=0.001 vs. placebo)

Patients on avanafil had erections sufficient for vaginal penetration as measured by the Sexual Encounter Profile question number 2 (SEP2):

	Baseline	End of Treatment
Placebo	47%	54%
Avanafil 50 mg	45%	64%
Avanafil 100 mg	46%	74%
Avanafil 200 mg	48%	77%

(p<0.001 vs. placebo)

Patients taking avanafil experienced successful intercourse as measured by the Sexual Encounter Profile question 3 (SEP3):

	Baseline	End of Treatment
Placebo	13%	27%
Avanafil 50 mg	13%	41%
Avanafil 100 mg	14%	57%
Avanafil 200 mg	12%	57%

(p<0.001 vs. placebo)

The most commonly reported side effects in patients taking avanafil (all doses combined) included headache (7% vs. 1.2% placebo), flushing (4.6% vs. 0% placebo) and nasal congestion (2.3% vs. 1.2%). The results from the REVIVE study were published in *The Journal of Sexual Medicine*, a peer-reviewed journal with broad, multidisciplinary readership.

We completed a Phase 1 Thorough QT, or TQT, study evaluating 100 mg and 800 mg of avanafil compared to placebo and a known positive control. The study was successfully completed with no concern associated with QT prolongation.

In June 2010, we announced results from the Phase 3 REVIVE-Diabetes (TA-302) study, which evaluated the safety and efficacy of avanafil for the treatment of ED in men with type 1 and type 2 diabetes. The REVIVE-Diabetes study met all three primary endpoints across the two doses studied by demonstrating statistically significant improvement in erectile function as measured by the

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SEP and improvement in the IIEF score. The study also demonstrated a favorable tolerability profile and successful intercourse (as measured by SEP 3), without any restrictions for food or alcohol intake.

Highlights of the TA-302 study include:

- Eighty percent (80%) of sexual attempts among patients on avanafil had erections sufficient for intercourse (SEP2);
- Sixty-seven percent (67%) of patients taking avanafil experienced successful intercourse (SEP3);
- Avanafil was well-tolerated as evidenced by a low rate of discontinuations due to adverse events (2.8%);
- The most common side effects reported were headache (5.6%), flushing (3.5%), nasopharyngitis (3.4%) and nasal congestion (2.1%);
and
- There were no drug-related serious adverse events reported in the study.

In December 2010, we announced the positive results of the long term safety study, TA-314. TA-314 was conducted over one year in approximately 675 patients across 40 U.S. centers. Patients completing either the 12-week REVIVE or REVIVE-Diabetes studies were eligible to participate in TA-314. The study met all primary endpoints by demonstrating improvement from baseline in erectile function as measured by the SEP (both SEP2 and SEP3) and improvement in the IIEF. TA-314 confirms the longer term safety and efficacy results observed in the previously reported placebo-controlled Phase 3 studies of avanafil in patients with ED.

In May 2011, we announced positive results from a Phase 3, placebo-controlled clinical trial of avanafil for the treatment of ED in patients following a radical prostatectomy. The study, REVIVE-RP (TA-303), met all primary endpoints by demonstrating improvement from baseline in erectile function as measured by the SEP (both SEP2 and SEP3) and improvements in the IIEF. The most common side effects were headache, flushing and nasopharyngitis, and dropouts due to adverse events were low. There were no serious adverse events reported in the study. The results of the TA-303 study were not required for the NDA, but the final study report will be submitted to the FDA upon completion.

Highlights of the TA-303 study include:

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- Treatment with both doses of avanafil (100 mg and 200 mg) was associated with significant improvements in each of the co-primary endpoints, SEP2, SEP3 and IIEF-EF in comparison with placebo ($p < 0.001$);
- Patients treated with 100 mg and 200 mg of avanafil improved their ability to have successful intercourse (SEP3) four- and five-fold, respectively, from the start of treatment;
- Treatment with avanafil improved erectile function in a dose-dependent manner with significant increases in the IIEF scores from the beginning of treatment through the end of treatment. Erectile function scores increased 38% and 55% for patients on the 100 mg and 200 mg doses, respectively, as compared to the placebo group with an increase of 1%;
- The most commonly reported side effects in patients taking avanafil included headache, flushing, and nasopharyngitis; and
- There were no serious adverse events or deaths reported in the study.

As part of the approval for avanafil, the FDA is requiring us to perform two post-approval clinical studies. One study will be a randomized, double-blind, placebo-controlled, parallel group multicenter clinical trial on the effect of avanafil on spermatogenesis in healthy adult males and males with mild erectile dysfunction. The other study will be a double-blind, randomized, placebo-controlled, single-dose vision clinical trial to assess the effects of avanafil on multiple parameters of vision, including, but not limited to visual acuity, intraocular pressure, pupillometry, and color vision discrimination in healthy male subjects. The protocols for both studies are to be submitted to the FDA on or before August 2012.

As mentioned above, avanafil has been approved for marketing in the U.S. and will be prescribed to treat erectile dysfunction (ED).

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We have an agreement with MTPC to supply the active pharmaceutical ingredient, or API, and the tablets for avanafil. The MTPC manufacturing sites for avanafil have been inspected by the U.S. and EU authorities. We do not believe the results of those inspections will have an impact on MTPC's ability to supply avanafil, or the approval, or the timing of approval, of avanafil in the EU. However, if MTPC is unable to receive approval from the foreign regulators and maintain ongoing FDA or foreign regulatory compliance, or manufacture avanafil API or tablets in sufficient quantities to meet projected demand, the EU approval, the U.S. commercial launch, and future sales of avanafil will be adversely effected, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration for the commercialization of avanafil.

MUSE for Erectile Dysfunction

In 1997, we commercially launched MUSE in the U.S. MUSE was the first minimally invasive therapy for erectile dysfunction approved by the FDA. On October 1, 2010, we entered into a definitive Asset Purchase Agreement with Meda AB, or Meda, to sell certain rights and assets related to MUSE, transurethral alprostadil, for the treatment of erectile dysfunction, or the MUSE Transaction. Meda had been our European distributor of MUSE since 2002. The assets sold in the MUSE Transaction include the U.S. and foreign MUSE patents, existing inventory, and the manufacturing facility located in Lakewood, New Jersey. We retained all of the liabilities associated with the pre-closing operations and products of the MUSE business and the accounts receivables for pre-closing MUSE sales. The transaction closed on November 5, 2010. Prior to the closing of the MUSE Transaction, we regained all of the rights to MUSE and avanafil held by Deerfield Management Company, L.P., and affiliates, and Crown Bank, N.A., or Crown.

On October 15, 2010, in preparation for the closing of the MUSE Transaction and in accordance with the terms of the agreements with Crown, we paid \$4.8 million to Crown in satisfaction of all obligations owed to them under these agreements. As a result, the security interests and Certificate of Deposit held by Crown were terminated in our favor. On October 21, 2010, we exercised the Option under the Option and Put Agreement with the Deerfield Affiliates and the Deerfield Sub, dated April 3, 2008, and an Amended and Restated Option and Put Agreement dated March 16, 2009, or the OPA, and we paid an aggregate amount totaling \$27.1 million, which consisted of the Base Option Price of \$25 million, less the Option Premium Adjustment of \$2 million, plus the Cash Adjustment of \$2.8 million and the Royalty Adjustment of \$1.3 million. These payments satisfied all of the financial obligations under the Funding and Royalty Agreement, or FARA, and the OPA. As a result, all of the outstanding shares and the \$2.8 million of cash of the Deerfield Sub are owned by us, all of the outstanding loans owed by the Deerfield Sub have been repaid and the security interests in the collateral related to MUSE and avanafil held by the Deerfield Sub and the Deerfield Affiliates as part of the FARA and OPA were terminated. In December 2010, the Deerfield Sub was dissolved.

Under the terms of the MUSE Transaction, we received an upfront payment of \$22 million upon the closing, on November 5, 2010, and are eligible to receive an additional \$1.5 million based on future sales of MUSE, provided that certain sales milestones are reached. Meda is now responsible for the manufacturing, selling and marketing of MUSE. Meda also assumed all post-closing expenses and liabilities associated with MUSE. We have agreed not to develop, manufacture or sell any transurethral erectile dysfunction drugs for a period of three years following the closing of the MUSE Transaction. The assets and liabilities and results of operations associated with MUSE have been reported as discontinued operations for all periods presented.

Other Programs

We have licensed and intend to continue to license from third parties the rights to other investigational drug candidates to treat various diseases and medical conditions. We also sponsor early stage clinical trials at various research institutions and intend to conduct early stage proof of concept studies on our own. For example, in the third quarter of 2011 we initiated a randomized, placebo-controlled, double-blind, crossover

Phase 2 study to evaluate the safety, tolerability and efficacy of VI-1121 in patients with Alzheimer's disease. The study is expected to enroll approximately 50 patients in several sites in the United States. We expect to continue to use our expertise in designing clinical trials, formulation and investigational drug candidate development to commercialize pharmaceuticals for unmet medical needs or for disease states that are underserved by currently approved drugs. We intend to develop products with a proprietary position or that complement our other products currently under development.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The discussion and analysis of our financial condition and results of operations are based upon our 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 and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to available-for-sale securities, research and development expenses, income taxes, inventories, contingencies and litigation and share-based compensation. We base our estimates on historical experience, information received from third parties and on various other 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 from these estimates under different assumptions or conditions.

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We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our condensed consolidated financial statements:

Research and Development Expenses

Research and development, or R&D, expenses include license fees, related compensation, consultants' fees, facilities costs, accrued milestones, administrative expenses related to R&D activities and clinical trial costs at other companies and research institutions under agreements that are generally cancelable, among other related R&D costs. We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by clinical research organizations, or CROs, and clinical sites and include advertising for clinical trials and patient recruitment costs. These costs are recorded as a component of R&D expenses and are expensed as incurred. Under our agreements, progress payments are typically made to investigators, clinical sites and CROs. We analyze the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

Income Taxes

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes.

As part of the process of preparing our condensed consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included in our condensed consolidated balance sheets.

We assess the likelihood that we will be able to recover our deferred tax assets. We consider all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is not more likely than not that we will recover our deferred tax assets, we will increase our provision for taxes by recording a valuation allowance against the deferred tax assets that we estimate will not ultimately be recoverable. As a result of our analysis of all available evidence, both positive and negative, as of March 31, 2012, it was considered more likely than not that our deferred tax assets would not be realized. However, should there be a change in our ability to recover our deferred tax assets; we would recognize a benefit to our tax provision in the period in which we determine that it is more likely than not that we will recover our deferred tax assets.

Inventories

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Inventories are valued at the lower of cost (first in, first out) or market. We record inventory reserves for estimated obsolescence, unmarketable or excess inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, or if our investigational product candidates do not receive approval, inventory write-downs may be required.

Cash and Cash Equivalents

The Company considers highly liquid investments with maturities from the date of purchase of three months or less to be cash equivalents. At March 31, 2012, all cash equivalents are invested in money market funds and U.S. Treasury securities. These accounts are recorded at fair value.

Available-for-Sale Securities

We focus on liquidity and capital preservation in our investments in available-for-sale securities. Our investment policy, as approved by the Audit Committee of the Board of Directors, allows us to invest our excess cash balances in money market and marketable securities, primarily U.S. Treasury securities and debt securities of U.S. government agencies, corporate debt securities and asset-backed securities. We periodically evaluate our investments to determine if impairment charges are required.

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We determine the appropriate classification of marketable securities at the time of purchase and reevaluate such designation at each balance sheet date. Our marketable securities have been classified and accounted for as available-for-sale. We may or may not hold securities with stated maturities greater than 12 months until maturity. In response to changes in the availability of and the yield on alternative investments as well as liquidity requirements, we may sell these securities prior to their stated maturities. As these securities are viewed by us as available to support current operations securities with maturities beyond 12 months are classified as current assets.

Securities are carried at fair value, with the unrealized gains and losses, net of taxes, reported as a component of stockholders' equity, unless the decline in value is deemed to be other-than-temporary and we intend to sell such securities before recovering their costs, in which case such securities are written down to fair value and the loss is charged to other-than-temporary loss on impaired securities. We evaluate our investment securities for other-than-temporary declines based on quantitative and qualitative factors. Any realized gains or losses on the sale of marketable securities are determined on a specific identification method, and such gains and losses are reflected as a component of interest income.

Contingencies and Litigation

We are periodically involved in disputes and litigation related to a variety of matters. When it is probable that we will experience a loss, and that loss is quantifiable, we record appropriate reserves. We record legal fees and costs as an expense when incurred.

Share-Based Payments

We follow the fair value method of accounting for share-based compensation arrangements in accordance with FASB ASC topic 718, *Compensation - Stock Compensation*, or ASC 718. Under ASC 718, the estimated fair value of share-based compensation, including stock options and restricted stock units granted under our stock option plans and purchases of common stock by employees at a discount to market price under the employee stock purchase plan, or the ESPP, is recognized as compensation expense. Compensation expense for purchases under the ESPP is recognized based on the estimated fair value of the common stock purchase rights during each offering period and the percentage of the purchase discount.

We recorded \$2.7 million and \$2.1 million of share-based compensation expense for the quarters ended March 31, 2012 and 2011, respectively. Share-based compensation expense is allocated among research and development, general and administrative expenses and discontinued operations based on the function of the related employee. This charge had no impact on our cash flows for the periods presented.

We use the Black-Scholes option pricing model to estimate the fair value of the share-based awards as of the grant date. The Black-Scholes model, by its design, is highly complex, and dependent upon key data inputs estimated by management. The primary data inputs with the greatest degree of judgment are the estimated lives of the share-based awards and the estimated volatility of our stock price. The Black-Scholes model is highly sensitive to changes in these two data inputs. The expected term of the options represents the period of time that options granted are expected to be outstanding and is derived by analyzing the historical experience of similar awards, giving consideration to the contractual terms of the share-based awards, vesting schedules and expectations of future employee behavior. We determine expected volatility using the historical method, which is based on the daily historical trading data of our common stock over the expected term of the option. Management selected the historical method primarily because we have not identified a more reliable or appropriate method to predict future volatility.

Fair Value

Financial Instruments Measured at Fair Value. Our cash and cash equivalents and available-for-sale financial instruments are carried at fair value and we make estimates regarding valuation of these assets measured at fair value in preparing the condensed consolidated financial statements.

Fair Value Measurement Definition and Hierarchy. ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (i.e., the exit price) in an orderly transaction between market participants at the measurement date.

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Valuation Technique. ASC 820 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of VIVUS. Unobservable inputs are inputs that reflect our assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. ASC 820 prescribes three valuation techniques that shall be used to measure fair value as follows:

1. **Market Approach** uses prices or other relevant information generated by market transactions involving identical or comparable assets or liabilities.

2. **Income Approach** uses valuation techniques to convert future cash flow amounts to a single present value amount (discounted).

3. **Cost Approach** the amount that currently would be required to replace the service capacity of an asset (i.e., current replacement cost).

One or a combination of the approaches above can be used to calculate fair value, whichever results in the most representative fair value.

Fair Value Measurements

As of March 31, 2012, our cash and cash equivalents and available-for-sale securities measured at fair value on a recurring basis totaled \$333.4 million.

All of our cash and cash equivalents and available-for-sale securities are in cash, money market instruments and U.S. Treasury securities at March 31, 2012, and these are classified as Level 1. The valuation techniques used to measure the fair values of these financial instruments were derived from quoted market prices, as substantially all of these instruments have maturity dates, if any, within one year from the date of purchase and active markets for these instruments exists.

Recent Accounting Pronouncements

In May 2011, the FASB issued ASU No. 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, which amends Topic 820, Fair Value Measurement. ASU No. 2011-04 issues additional guidance on fair value measurements that clarifies the application of existing guidance and disclosure requirements, changes certain fair value measurement principles and requires additional disclosures about fair value measurements. The updated guidance is effective on a prospective basis for financial

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statements issued for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2011. The adoption of this guidance did not have a material impact on our financial statements.

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income*, to increase the prominence of other comprehensive income in the financial statements. ASU No. 2011-05 gives businesses two options for presenting other comprehensive income (OCI), which until now has typically been placed near the statement of shareholder's equity. An OCI statement can be included with the net income statement, and together the two will make a statement of total comprehensive income. Alternatively, businesses can have an OCI statement separate from a net income statement, but the two statements will have to appear consecutively within a financial report. This standard eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. In December 2011, the FASB issued ASU 2011-12, *Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05*. ASU 2011-12 indefinitely defers the effective date of the requirement in ASU 2011-05 to disclose on the face of the financial statements the effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income. All other requirements in ASU 2011-05 are not affected by ASU 2011-12. ASU 2011-05 and ASU 2011-12 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, with early adoption permitted and full retrospective application required. The adoption of ASU 2011-05 effective June 30, 2011 and ASU 2011-12 effective March 31, 2012 did not have a material effect on the determination or reporting of our financial results.

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RESULTS OF OPERATIONS

Executive Overview

For the quarter ended March 31, 2012, we reported a net loss of \$18.8 million or \$0.20 net loss per share, as compared to a net loss of \$9.9 million, or \$0.12 net loss per share during the same period in 2011. The increased net loss in the quarter ended March 31, 2012, as compared to the quarter ended March 31, 2011, was primarily attributable to increased Qnexa pre-commercialization related general and administrative expenses.

In June 2011, we submitted an NDA to the FDA seeking approval of avanafil for the treatment of ED. We received the FDA's approval of the avanafil NDA on April 27, 2012, in advance of the April 29, 2012 PDUFA target date. The NDA submission follows the successful completion of a Phase 3 program for avanafil. More than 1,200 men with ED participated in clinical studies evaluating the efficacy and safety of avanafil. Avanafil at all doses tested (50mg, 100mg and 200mg) met all primary efficacy endpoints. As part of the approval for avanafil, the FDA is requiring us to perform two post-approval clinical studies. One study will be a randomized, double-blind, placebo-controlled, parallel group multicenter clinical trial on the effect of avanafil on spermatogenesis in healthy adult males and males with mild erectile dysfunction. The other study will be a double-blind, randomized, placebo-controlled, single-dose vision clinical trial to assess the effects of avanafil on multiple parameters of vision, including, but not limited to visual acuity, intraocular pressure, pupillometry, and color vision discrimination in healthy male subjects. The protocols for both studies are to be submitted to the FDA on or before August 2012. In addition, we submitted and the EMA accepted our MAA for avanafil in the EU in March 2012.

On October 28, 2010, we received a CRL from the FDA regarding the Qnexa NDA. The FDA issued the CRL to communicate its decision that the NDA could not be approved in its present form. No new clinical studies were requested in the CRL. On January 19, 2011, we held an End-of-Review meeting with the FDA to discuss the items contained in the CRL and the information we planned to include in the resubmission. In anticipation of the meeting, we provided a briefing document that included comprehensive assessment of the teratogenic potential of topiramate including analyses integrating existing non-clinical and clinical data. In the Qnexa studies, which included 15 offspring from women exposed to Qnexa or topiramate, there were no reports of congenital malformations. In addition, we provided several new analyses including cardiovascular data from our SEQUEL (OB-305) and Sleep Apnea (OB-204) studies to demonstrate that Qnexa does not increase the risk for major cardiovascular events and that the observed increases in heart rate, which occurred in some patients over the course of the clinical program, did not increase the risk of major cardiovascular events, as evidenced by adverse events reported in the trial. We also provided a synopsis of the final study report for the SEQUEL study. At the meeting, an overview was provided of the teratogenicity and cardiovascular risk material covered in the background package. The discussion also included elements of our proposed REMS program for Qnexa. The primary focus of the FDA at the meeting, however, concerned the teratogenic potential for topiramate, specifically the incidence of oral clefts observed in the North American AED Pregnancy Registry and in the UK Epilepsy and Pregnancy Registry. The FDA requested that we assess the feasibility of performing a retrospective observational study utilizing existing electronic medical claims healthcare databases to review fetal outcomes, including the incidence of congenital malformations and oral cleft, in the offspring of women who received prophylaxis treatment with 100 mg of topiramate for migraine during pregnancy, or the Feasibility Assessment. In the Qnexa studies, which included 15 births from women exposed to Qnexa or topiramate, there were no reports of congenital malformations or low birth weight.

We met with the FDA in April 2011 to discuss the Feasibility Assessment. We reached agreement with the FDA on the retrospective observational study objectives and design, primary endpoints, and eligibility criteria. During the April 2011 meeting, it was agreed the study would be expanded to include all doses of topiramate and all diagnoses. It was also agreed that the results would be stratified and that the diagnoses of those exposed to topiramate would be matched with control groups with similar diagnoses and patient profiles. The co-primary endpoints were the relative risk of major congenital malformations and oral cleft in the offspring of women exposed to topiramate during pregnancy as compared to a control group that was not exposed to topiramate during pregnancy. The retrospective observational study was

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called FORTRESS, for Fetal Outcome Retrospective TopiRamate ExpoSure Study. Top-line results from FORTRESS were announced in December 2011, with validation of FORTRESS expected in the third quarter of 2012. There can be no assurance that the validation of this information will be successfully completed.

On September 15, 2011, we announced that following a teleconference we had reached agreement with officials of the DMEP of the FDA on a plan that allowed for an early resubmission of the Qnexa NDA for the treatment of obesity. Based on this agreement, we resubmitted the Qnexa NDA on October 17, 2011, prior to completion of FORTRESS, and the FDA accepted the NDA for filing. On February 22, 2012, the FDA held a second meeting of the Advisory Committee to discuss the additional data submitted for Qnexa. The FDA asked the Advisory Committee to discuss the following: (1) their interpretation of the available data regarding teratogenicity of topiramate, including whether they believe the data indicate an increase in the risk for oral clefts; (2) the potential strengths and weaknesses of the proposed teratogenicity risk management strategy for Qnexa; (3) the clinical significance of the

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changes in blood pressure and heart rate in overweight and obese patients treated with Qnexa versus placebo, taking into account the reported changes in antihypertensive therapy; and (4) whether the available data for Qnexa warrant that a cardiovascular outcomes trial be conducted prior to approval. The FDA requested the Advisory Committee to vote on whether, after considering all the available data included in the NDA and the discussions held at the meeting on February 22, 2012, including the questions referred to above, the overall benefit-risk assessment of Qnexa supports its approval for the treatment of obesity in individuals with a BMI ≥ 30 kg/m² or a BMI ≥ 27 kg/m² with weight related co-morbidities. The Advisory Committee voted 20 to 2 to recommend approval. The FDA is not bound by the recommendations of its advisory committees, but will consider their guidance during the review of the NDA that was submitted for Qnexa in October 2011. On April 4, 2012, at the FDA's request, we submitted a comprehensive REMS for Qnexa, which was considered a major amendment to the NDA. The PDUFA target date for Qnexa was April 17, 2012. However, as the submission of the comprehensive REMS was within three months of the PDUFA target date, to provide time for a full review of the submission, the FDA extended the PDUFA target date by three months to July 17, 2012. The FDA has the ability to extend the PDUFA target date under certain circumstances, and there can be no assurance that it will not extend the PDUFA target date further in the future.

The Qnexa NDA resubmission seeks approval for the treatment of obesity, including weight loss and maintenance of weight loss for obese patients (BMI > 30 kg/m²), or overweight patients (BMI > 27 kg/m²) with weight-related co-morbidities such as hypertension, type 2 diabetes or dyslipidemia. The proposed labeling for Qnexa submitted on October 17, 2011 included a contraindication that excluded the use of Qnexa by women of childbearing potential. In January 2012, we announced that following discussions with FDA officials, we were asked to remove the Qnexa contraindication for women of childbearing potential contained in the proposed label. Qnexa would remain contraindicated for women who are pregnant. A contraindication typically indicates that a drug should not be used because the risk of use clearly outweighs any possible therapeutic benefit for that population. The proposed Pregnancy Category is Category X.

Included with the October 17, 2011 resubmission of the Qnexa NDA was a proposed REMS framework. We discussed the REMS framework with the FDA and the details of the Qnexa REMS were discussed during the Advisory Committee meeting, held February 22, 2012. As mentioned above, on April 4, 2012, following the FDA's request, we submitted a comprehensive REMS.

Our resubmission of the NDA for Qnexa states that we plan to conduct a cardiovascular outcomes study post-approval, and we have since submitted a draft protocol to the FDA. The details of this study are under discussion with the FDA. This study could cost \$100 to \$200 million dollars and take as long as five or six years to complete.

Although no other requests for additional information or pre-approval studies were made by the FDA at these meetings or in the CRL, there can be no assurance that the FDA will not request or require us to provide additional information or undertake additional prospective studies or retrospective observational studies in connection with the Qnexa NDA.

On December 17, 2010, we filed an MAA with the EMA for Qnexa Controlled-Release Capsules in the European Union, or the EU. The proposed indication in the EU is for the treatment of obesity, including weight loss and maintenance of weight loss, and should be used in conjunction with a mildly hypocaloric diet. The EMA's review of Qnexa will follow their centralized marketing authorization procedure. If approved, Qnexa could receive marketing authorization in all 27 EU member countries. The MAA was officially validated for central procedure on January 19, 2011. If approved in the EU, Qnexa could be recommended for obese adult patients (BMI > 30 kg/m²), or overweight patients (BMI > 27 kg/m²) with weight-related co-morbidities such as hypertension, type 2 diabetes or dyslipidemia. In Europe, approximately 150 million adults are considered overweight or obese, and the prevalence is rising rapidly. According to EMA guidelines for medicinal products used in weight control, a demonstration of weight loss of at least 10% of baseline weight, which is at least statistically greater than that associated with placebo, is considered to be a valid primary efficacy criterion. Based on the results of the Phase 3 program, we believe Qnexa has met this efficacy criterion set by the EMA for obesity therapies. In addition, the mean weight loss for the mid and top dose of Qnexa at the end of two years was 10.4% and 11.4%, respectively, which we believe met the efficacy benchmark set by the EMA for obesity therapies. These

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results were shown to be sustained over a two-year period and were associated with significant improvements in weight-related co-morbidities such as hypertension, dyslipidemia and diabetes. The MAA is comprised of data from over 4,500 overweight or obese patients with a broad range of weight-related co-morbidities. Two-year, double-blind data from SEQUEL (OB-305) were also included in the filing to demonstrate durability of treatment response and long-term safety.

In May 2011, we received a response to our MAA from the CHMP. The response was in the form of the 120-day questions. The 120-day questions covered a broad range of topics including, without limitation, issues relating to phentermine, which include historical concerns regarding its potential association with valvulopathy and pulmonary hypertension; heart rate and limited long-term safety data in high-risk patients; and known and suspected effects of topiramate which include CNS and teratogenic potential. The CHMP also had questions concerning our proposed risk management plan for Qnexa. The 120-day questions were consistent with the issues previously raised in the FDA review process. We met with representatives from the CHMP in September

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2011 to seek clarification on certain questions. We submitted our response to the 120-day questions in the fourth quarter of 2011. In January 2012, we received the 180-day List of Outstanding Issues, or 180-day LOI, from the CHMP. In order to perform additional analyses to allow further insights into the data as previously presented, we requested and, in April 2012, we received a two-month extension to respond to the 180-day LOI. The 180-day LOI contained requests for additional information including risk minimization activities to address various issues relating to cardiovascular, neuropsychiatric and potential teratogenic effects of Qnexa. In addition, we were asked to discuss the benefit/risk of the different doses of Qnexa, its potential use in different patient populations, and the expected long-term benefit of treatment with Qnexa. We have submitted our response to the 180-day LOI. There can be no assurance that our response will be adequate or that our MAA will be approved by the CHMP. Absent a delay, we anticipate an opinion from the CHMP in the second quarter of 2012.

On October 1, 2010, we entered into a definitive Asset Purchase Agreement with Meda to sell certain rights and assets related to MUSE, transurethral alprostadil, for the treatment of erectile dysfunction, or the MUSE Transaction. Meda had been our European distributor of MUSE since 2002. The assets sold in the MUSE Transaction include the U.S. and foreign MUSE patents, existing inventory, and the manufacturing facility located in Lakewood, New Jersey. We retained all of the liabilities associated with the pre-closing operations and products of the MUSE business and the accounts receivables for pre-closing MUSE sales. The transaction closed on November 5, 2010. The sale of MUSE allowed us to focus on the approval and commercialization of Qnexa and the development of avanafil. Prior to the closing of the MUSE Transaction, we regained all of the rights to MUSE and avanafil held by Deerfield Management Company, L.P., and affiliates, and Crown Bank, N.A., or Crown. On October 15, 2010, in preparation for the closing of the MUSE Transaction and in accordance with the terms of the agreements with Crown, we paid \$4.8 million to Crown in satisfaction of all obligations owed to them under these agreements. As a result, the security interests and Certificate of Deposit held by Crown were terminated in our favor. Under the terms of the MUSE Transaction, we received an upfront payment of \$22 million upon the closing and are eligible to receive an additional \$1.5 million based on future sales of MUSE, provided that certain sales milestones are reached. Upon the closing of the MUSE Transaction, Meda is now responsible for the manufacturing, selling and marketing of MUSE. Meda also assumed all post-closing expenses and liabilities associated with MUSE. We have agreed not to develop, manufacture or sell any transurethral erectile dysfunction drugs for a period of three years following the closing of the MUSE Transaction. The assets and liabilities and results of operations associated with MUSE have been reported as discontinued operations for all periods presented.

We may have continued losses in future years, depending on the timing of our research and development expenditures, and we plan to continue to invest in clinical development of our current research and investigational drug candidates to bring those potential drugs to market.

Continuing operations***Research and development expenses (Unaudited)***

	Three Months Ended March 31		2012 vs. 2011 Increase
	2012	2011	
	(In thousands, except percentages)		
Research and development expenses	\$ 6,134	\$ 4,480	37%

Research and development expenses in the first quarter of 2012 increased \$1.6 million, or 37%, to \$6.1 million, as compared to \$4.5 million in the first quarter of 2011. In the first quarter of 2012, this increase in spending was primarily due to increased spending for Qnexa for obesity of \$2.0 million due to Qnexa support including preparation for the second Qnexa advisory committee meeting and FORTRESS expenses, increases in other study expenses of \$384,000 and other net research and development spending increases of \$198,000 (primarily an incremental increase

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in non-cash share-based compensation expense of \$188,000), partially offset by lower spending for avanafil of \$903,000, as compared to the first quarter of 2011.

We anticipate that our research and development expenses in 2012 will increase significantly from costs incurred in 2011 as we begin the cardiovascular study for our investigational drug candidate, Qnexa, if approved by the FDA. There are likely to be additional research and development expenses related to avanafil and Qnexa and our other investigational drug candidates under development. Our research and development expenses may fluctuate from period to period due to the timing and scope of our development activities and the results of clinical and pre-clinical studies. Regardless, if we are successful in obtaining FDA regulatory approval for any new investigational drug candidates being developed through our research and development efforts, except for Qnexa, currently under FDA regulatory review, and avanafil, approved by the FDA on April 27, 2012, we do not expect to recognize revenue from sales of such new drugs, if any, for at least a year or more due to the length of time required to develop investigational drug candidates into commercially viable products.

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	Three Months Ended March 31		2012 vs. 2011 Increase
	2012	2011	
(In thousands, except percentages)			
General and administrative expenses	\$ 12,638	\$ 5,428	133%

General and administrative expenses in the three months ended March 31, 2012 of \$12.6 million increased \$7.2 million, or 133% as compared to the three months ended March 31, 2011. In the quarter ended March 31, 2012, this increase is primarily due to higher spending on Qnexa pre-commercialization of \$3.5 million (primarily related to marketing programs, market research and analytics) and avanafil pre-commercialization of \$1.8 million (primarily related to marketing programs, consultants and market analytics), incremental increases in accounting expenses and related professional fees of \$461,000 (primarily professional fees related to international tax planning), non-cash share-based compensation expense of \$410,000, corporate expenses of \$303,000 (primarily compensation and related increases), legal expenses of \$254,000, and net increases in other general and administrative expenses totaling \$464,000 (primarily human resources and investor relations related expenses), as compared to the quarter ended March 31, 2011.

We anticipate a significant increase in our general and administrative expenses in 2012, as compared to 2011, due to pre-commercialization activities for our investigational drug candidate, Qnexa, and if approved by the FDA, the commercialization of Qnexa.

Interest income and expense

Interest and other income, net for the quarter ended March 31, 2012 was \$18,000, as compared to \$43,000 for the quarter ended March 31, 2011. The decrease in interest and other income in the quarter ended March 31, 2012 as compared to the same period last year was largely due to lower investment yields on our cash, cash equivalents and available-for-sale securities.

Provision for income taxes

We recorded a provision for income taxes for the quarter ended March 31, 2012 of \$7,000 as compared to \$1,000 for the quarter ended March 31, 2011. Our income tax return for the year ended December 31, 2007 is currently under examination by the California Franchise Tax Board. Based on the progress of the audit to date, we believe adjustments may be made in earlier years that will reduce tax attributes available to offset tax due in 2007. We did not increase our unrecognized tax benefits for the quarter ended March 31, 2012. We recognize interest and penalties accrued on any unrecognized tax benefits as a component of our provision for income taxes. During the quarter ended March 31, 2012, \$2,000 of interest on the unrecognized tax benefits was recorded.

Discontinued operations

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Selling, general and administrative expenses (Unaudited)

	Three Months Ended March 31,		2012 vs. 2011 Increase
	2012	2011	
	(In thousands, except percentages)		
Selling, general and administrative expenses	\$ 16	\$ (14)	214%

Selling, general and administrative expenses were \$16,000 in the three months ended March 31, 2012, as compared to \$(14,000) in the three months ended March 31, 2011.

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LIQUIDITY AND CAPITAL RESOURCES

Continuing Operations

Cash. Cash, cash equivalents and available-for-sale securities totaled \$333.4 million at March 31, 2012, as compared to \$146.8 million at December 31, 2011. The increase in cash, cash equivalents and available-for-sale securities of \$186.6 million is primarily the net result of cash provided by financing activities and used for investing and operating activities. Included in these amounts are \$8.7 million in net proceeds from common stock option exercises and \$192.0 million in net proceeds from an underwritten public offering of our common stock during the quarter ended March 31, 2012.

Since inception, we have financed operations primarily from the issuance of equity securities. Through March 31, 2012, we have raised \$656.1 million from financing activities, received \$150 million from the sale of Evamist and had an accumulated deficit of \$365.0 million at March 31, 2012.

At March 31, 2012, we had \$200.7 million in cash and cash equivalents and \$132.7 million in available-for-sale securities. We invest our excess cash balances in money market and marketable securities, primarily U.S. Treasury securities and debt securities of U.S. government agencies, corporate debt securities and asset-backed securities, in accordance with our investment policy. At March 31, 2012, all of our cash equivalents and available-for-sale securities were invested in either U.S. government securities or money market funds that invest only in U.S. Treasury securities. The investment policy has the primary investment objectives of preservation of principal; however, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy. If those securities are downgraded or impaired, we would experience realized or unrealized losses in the value of our portfolio, which would have an adverse effect on our results of operations, liquidity and financial condition.

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

Liabilities. Total liabilities were \$13.1 million at March 31, 2012, which is \$2.1 million higher than at December 31, 2011. The change in total liabilities includes a \$1.9 million increase in accounts payable primarily due to increased operating activities and the timing of payments, a \$1.9 million increase in other accrued liabilities, partially offset by a \$280,000 decrease in accrued research and development expenses, a \$1.1 million decrease in accrued employee compensation and benefits and a \$301,000 decrease in current liabilities of discontinued operations.

Operating Activities. Our operating activities used \$13.8 million and \$9.9 million in cash during the three months ended March 31, 2012 and 2011, respectively. During the three months ended March 31, 2012, our net operating loss of \$18.8 million was offset by \$2.7 million in non-cash share-based compensation expense, a \$1.9 million increase in other accrued liabilities and a \$1.9 million increase in accounts payable. These positive cash flows to our net operating loss were in turn offset by a \$1.1 million decrease in accrued employee compensation and benefits.

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During the quarter ended March 31, 2011, our net operating loss of \$9.9 million was offset by \$2.1 million in non-cash share-based compensation expense. This positive cash flow to our net operating loss was in turn offset by an \$808,000 decrease in accounts payable, a \$488,000 decrease in other accrued liabilities, a \$469,000 decrease in accrued employee compensation and benefits and a \$432,000 decrease in accrued research and clinical expenses.

We anticipate cash used in operations in 2012 will be higher than cash used in operations in 2011, primarily due to pre-commercialization activities for Qnexa.

Investing Activities. Our investing activities used \$25.5 million and provided \$2.9 million in cash during the three months ended March 31, 2012 and 2011, respectively. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturity of investment securities.

Financing Activities. Financing activities provided cash of \$200.7 million and \$1.5 million during the three months ended March 31, 2012 and 2011, respectively. In the first three months of 2012, cash provided by financing activities included \$8.7 million in proceeds from the exercise of stock options and \$192.0 million in net proceeds from an underwritten public offering of our common stock. In the first three months of 2011, cash provided by financing activities included \$1.5 million in proceeds from the exercise of stock options.

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Discontinued Operations

Cash used for operating activities in the three months ended March 31, 2012 was \$316,000. In the three months ended March 31, 2012, our cash used for operating activities included our \$16,000 net loss as well as a decrease in our accounts payable balance of \$12,000 in accounts payable and a \$289,000 decrease in our accrued product returns liability. The extinguishment of the largest liability of the discontinued operations, accrued product returns, will be settled in accordance with the returns policy by cash payments made to former customers for the return of expired MUSE product sold by VIVUS. The return window for expired MUSE product will end in 2013.

Cash used for operating activities in the quarter ended March 31, 2011 was \$367,000. In the quarter ended March 31, 2011, the \$14,000 net income was offset by a \$115,000 decrease in accounts payable, a \$48,000 decrease in accrued product returns, a \$75,000 decrease in accrued chargeback reserve, and a \$149,000 decrease in other accrued liabilities.

Financing Activities

On August 1, 2011, we filed a Form S-8 (File Number 333-175926) with the SEC registering 600,000 shares of common stock, par value \$0.001 per share, under the 1994 Employee Stock Purchase Plan, as amended.

On August 24, 2011, we closed on the sale of a total of 6,889,098 shares of our common stock, at a price of \$6.65 per share, pursuant to a previously-reported securities purchase agreement entered into on August 23, 2011 with certain investors in connection with a registered direct offering of the Company's common stock, or the Offering. Gross proceeds to VIVUS from the sale of the common stock in the Offering totaled approximately \$45.8 million before deduction of approximately \$529,000 in fees and expenses related to the Offering. All of the shares of common stock were offered pursuant to an effective shelf registration statement on Form S-3ASR (Registration No. 333-161948), including the prospectus dated September 16, 2009 contained therein.

On March 6, 2012, we closed the public offering and sale of 9,000,000 shares of our common stock resulting in net proceeds to VIVUS of approximately \$192.0 million after deducting underwriting discounts and commissions and estimated offering expenses. All of the shares of common stock were offered pursuant to an effective shelf registration statement on Form S-3 (Registration No. 333-161948), including the prospectus dated September 16, 2009 (as amended on February 28, 2012) contained therein, as the same has been supplemented.

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

The nature and efforts required to develop our investigational drug candidates into commercially viable drugs include research to identify a clinical candidate, pre-clinical development, clinical testing, FDA approval and commercialization. This process is very costly and can take in

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excess of 10 years to complete for each investigational drug candidate. The duration and the cost of clinical trials may vary significantly over the life of a project as a result of matters arising during the clinical studies, including, among others, the following:

- we or the FDA may suspend trials;
- we may discover that an investigational drug candidate may cause harmful side effects or is not effective;
- patient recruitment may be slower than expected; and
- patients may drop out of the trials.

For each of our investigational drug candidate development programs, we periodically assess the scientific progress and the merits of the programs to determine if continued research and development is economically viable. Certain of our programs were terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. As such, the ultimate timeline and costs to commercialize a drug cannot be accurately estimated.

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With the exception of avanafil, our investigational drug candidates have not yet achieved FDA regulatory approval, which is required before we can market them as therapeutic products. In order to achieve regulatory approval, the FDA must conclude that our clinical data establish substantial evidence of safety and efficacy. The results from pre-clinical testing and early clinical trials may not be predictive of results in later clinical trials. It is possible for a candidate to show promising results in early clinical trials, but subsequently fail to demonstrate safety and efficacy data necessary to obtain regulatory approvals.

As a result of the uncertainties discussed above, among others, the duration and completion of our investigational drug candidate development programs are difficult to estimate and are subject to considerable variation. Our inability to complete our research and investigational drug candidate development programs in a timely manner or our failure to enter into collaborative agreements, when appropriate, could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our business strategy. Our inability to raise capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

We may also be required to make further substantial expenditures if unforeseen difficulties arise in other areas of our business. In particular, our future capital and additional funding requirements will depend upon or be impacted by numerous factors, including:

- the cost, timing and final outcome of FORTRESS;
- the FDA's interpretation of the data we submitted and may submit relating to teratogenicity and cardiovascular safety;
- whether or not the FDA or EMA requires us to perform additional studies for Qnexa;
- whether or not the FDA chooses to follow the recommendation of the second Advisory Committee in its vote in favor of approval of Qnexa;
- the cost and time required to set up a distribution system, patient access system and REMS program for Qnexa that is suitable to address any FDA concerns;
- the impact of the results of the REMS or cardiovascular outcomes for obesity drugs advisory committee meetings;
- our ability to successfully commercialize by establishing marketing partnerships for avanafil in the U.S., and in our territories outside the U.S., if approved;

- MTPC's ability to obtain foreign regulatory approval and maintain FDA or foreign regulatory approval to manufacture and adequately supply avanafil for commercial use;
- the cost, timing and outcome of the two post-approval clinical studies the FDA has required us to perform as part of the approval for avanafil;
- the progress and costs of our research and development programs;
- the scope, timing 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 planned and future clinical trials;
- the costs involved in seeking regulatory approvals for our investigational drug candidates;
- the costs involved in filing and pursuing patent applications and enforcing patent claims;
- the establishment of collaborations, sublicenses and strategic alliances and the related costs, including milestone payments;
- the costs involved in establishing a commercial operation and in launching a product without a partner;

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- the cost of manufacturing and commercialization activities and arrangements;
- the results of operations;
- the cost, timing and outcome of regulatory reviews;
- the rate of technological advances;
- ongoing determinations of the potential commercial success of our investigational drug candidates under development;
- the state of the economy and financing environment;
- the level of resources devoted to sales and marketing capabilities;
- the regulatory approval environment and regulatory hurdles for safety assessment for new products;
- the cost, timing and outcome of litigations;
- the healthcare reimbursement system or the impact of healthcare reform, if any, imposed by the U.S. federal government;
- perceptions and interpretations of Qnexa or the data by outside analysts or others; and
- the activities of competitors.

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We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs at least through 2013. However, we anticipate that we may require additional funding to continue our research and investigational drug candidate development programs, to conduct pre-clinical, clinical and retrospective studies and trials, to fund operating expenses, to pursue regulatory approvals for our investigational drug candidates, to finance the costs involved in filing and prosecuting patent applications and enforcing or defending our patent claims, if any, and we may require additional funding to establish additional or new manufacturing and marketing capabilities in the future and to manufacture quantities of our investigational drug candidates for approval and commercialization. In particular, we expect to make other substantial payments to the inventor of Qnexa pending approval by the FDA and to MTPC, in accordance with our agreement with MTPC in connection with the licensing of avanafil. These payments are based on certain development, regulatory and sales milestones. In addition, we are required to make royalty payments on any future product sales. Similar to the transaction with Evamist, we may consider selling or licensing any of our investigational drug candidates in development in order to raise additional funding. We may seek to access the public or private equity markets at any time. The sale of additional equity securities would result in additional dilution to our stockholders. We may also seek additional funding through strategic alliances, acquisitions of companies with cash balances and other financing mechanisms. We cannot assure you that adequate funding will be available on terms acceptable to us, if at all. If adequate funds are not available, we may be required to curtail significantly one or more of our investigational drug candidate development programs or obtain funds through arrangements with collaborators or others. This may require us to relinquish rights to certain of our technologies or investigational drug candidates and to pay royalties on future product sales. To the extent that we are unable to obtain third party funding for such expenses, we expect that increased expenses may result in future losses from operations. We are continually evaluating our existing portfolio and we may choose to divest or sell one or more of our investigational drug candidates at any time. We cannot assure you that we will successfully develop our products under development or that our products, if approved for sale, will generate revenues sufficient to enable us to earn a profit.

Table of Contents***Contractual Obligations***

The following table summarizes our contractual obligations at March 31, 2012 excluding amounts already recorded on our condensed consolidated balance sheet as accounts payable, and the effect such obligations are expected to have on our liquidity and cash flow in future fiscal years. This table includes our enforceable and legally binding obligations and future commitments, as well as obligations related to contracts that we are likely to continue, regardless of the fact that they were cancelable as of March 31, 2012. These do not include milestones and assumes non-termination of agreements. These obligations, commitments and supporting arrangements represent payments based on current operating plans, which are subject to change:

Contractual obligations	Total	Payments Due by Period			
		2012	2013- 2015 (in thousands)	2016- 2017	Thereafter
Operating leases	\$ 2,444	\$ 924	\$ 1,240	\$ 281	\$
Other agreements	27,234	27,135	98		
Clinical trials	4,654	4,654			
Total contractual obligations	\$ 34,332	\$ 32,713	\$ 1,338	\$ 281	\$

Operating Leases

In November 2006, we entered into a 30-month lease for our corporate headquarters located in Mountain View, California, or Lease. On December 16, 2008, November 12, 2009, December 3, 2010 and February 14, 2012, we entered into a first, second, third and fourth amendment, respectively, to this Lease. Under the fourth amendment to the Lease, the average base rent for the current premises is set at \$2.50 per square foot or \$45,015 per month. The fourth amendment also extended the lease term for the current premises for a period of twelve months commencing August 1, 2012 and terminating July 31, 2013 and provided us one additional option to extend the term of the Lease of the current premises for one year from the expiration of the Lease. In addition, the fourth amendment included a new lease on an additional 4,914 square feet of office space located at 1174 Castro Street, Mountain View, California, or the Expansion Space, which is adjacent to the Company's corporate headquarters. The average base rent for the Expansion Space is approximately \$2.75 per square foot or \$13,513 per month. The new lease for the Expansion Space has a term of 60 months commencing on March 15, 2012, with an option to extend the term for one year from the expiration of the new lease.

Other Agreements

Purchase obligations consist of agreements to purchase goods or services that are enforceable and legally binding on us and that specify all significant terms, including: fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. These include obligations for research and development, pre-commercial obligations, general and administrative services, and media/market research contracts, as well as obligations related to those contracts that we are likely to continue, regardless of the fact that they were cancelable as of March 31, 2012.

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We have remaining commitments under various general and administrative services agreements totaling \$13.6 million at March 31, 2012, including \$1.6 million related to Leland F. Wilson's Employment Agreement. On December 19, 2007, the Compensation Committee of the Board of Directors of the Company approved an employment agreement, or the Employment Agreement, with Leland F. Wilson, the Company's Chief Executive Officer. The Employment Agreement includes salary, incentive compensation, retirement benefits and length of employment, among other items, as agreed to with Mr. Wilson. The Employment Agreement had an initial term of two years commencing on the effective date, June 1, 2007, or the Effective Date. On January 23, 2009, the Compensation Committee approved an amendment to the Employment Agreement, or the Amendment, which amends the Employment Agreement. Pursuant to the Amendment, the initial term of the Employment Agreement was increased from two to three years commencing on June 1, 2007 and other relevant dates were also extended to reflect the three-year initial term. On January 21, 2011, the Compensation Committee approved the second amendment to Mr. Wilson's Employment Agreement. Pursuant to the second amendment, the initial term of the Employment Agreement is increased to four years commencing on June 1, 2007. As neither party provided notice of termination, the Employment Agreement was automatically extended for an additional one-year term commencing on June 1, 2011. On January 27, 2012, the Compensation Committee approved the third amendment to the Employment Agreement which increased the initial term of the Employment Agreement from four (4) to five (5) years commencing on June 1, 2007.

We have also entered into various agreements with our research consultants and other contractors to perform regulatory services, drug research and testing and, at March 31, 2012, our remaining commitment under these agreements totaled \$6.3 million. These amounts represent the remaining contractual amounts due under various contracts, although all of these contracts could be cancelled by us, in which case we would only be liable to the vendors for work performed to the date of cancellation. We have placed orders with MTPC for avanafil product testing and finished goods and our remaining commitment under these purchase obligations at March 31, 2012 totaled \$7.3 million.

Clinical Trials

We have entered into various agreements with clinical consultants, investigators, clinical suppliers and clinical research organizations to perform clinical trial management and clinical studies on our behalf and, at March 31, 2012, our remaining commitment under these agreements totaled \$4.7 million, which includes nearly all of the accrued research and clinical expenses of

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\$1.1 million in the condensed consolidated balance sheet as of March 31, 2012. We make payments to these providers based upon the number of patients enrolled and the length of their participation in the trials. These obligations, however, are contingent on future events, e.g. the rate of patient accrual in our clinical trials. This amount represents the remaining contractual amounts due under various contracts, although all of these contracts could be cancelled by us, in which case we would only be liable to the vendors for work performed to the date of cancellation.

Additional Payments

We have entered into development, license and supply agreements that contain provisions for payments upon completion of certain development, regulatory and sales milestones. Due to the uncertainty concerning when and if these milestones may be completed or other payments are due, we have not included these potential future obligations in the above table.

Mitsubishi Tanabe Pharma Corporation

In January 2001, we entered into an exclusive development, license and supply agreement with Tanabe Seiyaku Co., Ltd., or Tanabe, now Mitsubishi Tanabe Pharma Corporation, or MTPC, and hereinafter collectively referred to as MTPC, for the development and commercialization of avanafil, a PDE5 inhibitor compound for the oral and local treatment of male and female sexual dysfunction. Under the terms of the agreement, MTPC agreed to grant an exclusive license to us for products containing avanafil outside of Japan, North Korea, South Korea, China, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Vietnam and the Philippines. We agreed to grant MTPC an exclusive, royalty-free license within those countries for oral products that we develop containing avanafil. In addition, we agreed to grant MTPC an exclusive option to obtain an exclusive, royalty-bearing license within those countries for non-oral products that we develop containing avanafil. MTPC agreed to manufacture and supply us with avanafil for use in clinical trials, which was our primary responsibility.

We have paid upfront licensing fees of \$5 million to MTPC and have agreed to make additional payments upon the completion of certain development, regulatory and sales milestones. During the first quarter of 2004, we initiated a Phase 2 clinical trial with avanafil, which triggered one of the clinical development milestone criteria noted above. In 2006, we paid MTPC \$2 million in connection with this milestone. We have further agreed to pay royalties on net sales of products containing avanafil. No payments were made under this agreement with MTPC in the years ended December 31, 2007 and 2008; however, we paid MTPC \$4 million in January 2009 following the enrollment in December 2008 of the first patient in the first Phase 3 clinical studies and in August 2011, VIVUS paid MTPC a \$4 million milestone related to the filing of an NDA to the FDA for avanafil in June 2011. We expect to make other substantial payments to MTPC in accordance with our agreement with MTPC as we continue to develop and, if approved for sale, commercialize avanafil for the oral treatment of male sexual dysfunction. Such potential future milestone payments total \$11 million in the aggregate and include payments upon: the obtainment of the first regulatory approval in the U.S. and any major European country; and achievement of \$250 million or more in calendar year sales. In April 2012, the FDA approved the NDA for avanafil. Accordingly, we now owe MTPC, in accordance with our agreement with MTPC, a \$3 million milestone payment, which we intend to pay in May 2012.

The term of the MTPC agreement is based on a country-by-country and on a product-by-product basis. The term shall continue until the later of (i) 10 years after the date of the first sale for a particular product, or (ii) the expiration of the last-to-expire patents within the MTPC patents covering such product in such country. In the event that our product is deemed to be (i) insufficiently effective or insufficiently safe relative to other PDE5 inhibitor compounds based on published information, or (ii) not economically feasible to develop due to unforeseen regulatory hurdles or costs as measured by standards common in the pharmaceutical industry for this type of product, we have the right to terminate the agreement with MTPC with respect to such product.

Other

On October 16, 2001, we entered into an assignment agreement, or the Assignment Agreement, with Thomas Najarian, M.D. for a combination of pharmaceutical agents for the treatment of obesity and other disorders, or the Combination Therapy, that has since been the focus of our investigational drug candidate development program for Qnexa for the treatment of obesity, obstructive sleep apnea and diabetes. The Combination Therapy and all related patent applications, or the Patents, were transferred to us with worldwide rights to develop and commercialize the Combination Therapy and exploit the Patents. Pursuant to the Assignment Agreement, we have paid a total of \$220,000 to Dr. Najarian through March 31, 2012 and have issued him options to purchase 40,000 shares of our common stock. We are obligated under the terms of the Assignment Agreement to make a milestone payment of \$1 million and issue an option to purchase 20,000 shares of our common stock to Dr. Najarian upon marketing approval by the FDA of a product for the treatment of obesity that is based upon the Combination Therapy and Patents. The Assignment Agreement will require us to pay royalties on worldwide net sales of a product for the treatment of obesity that is based upon the Combination Therapy and Patents until the last-to-expire of the assigned Patents. To the extent that we decide not to commercially exploit the Patents, the Assignment Agreement will terminate and the Combination Therapy and Patents will be assigned back to Dr. Najarian. In 2006, Dr. Najarian joined us as a part-time employee and currently serves as a Principal Scientist.

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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.

Indemnifications

In the normal course of business, the Company provides indemnifications of varying scope to customers, third party service providers and business partners against claims of intellectual property infringement made by third parties arising from the use of its products and to its clinical research organizations and investigators sites against liabilities incurred in connection with any third-party claim arising from the work performed on behalf of the Company, among others. Historically, costs related to these indemnification provisions have not been significant and we are unable to estimate the maximum potential impact of these indemnification provisions on our future results of operations.

Pursuant to the terms of the Asset Purchase Agreement for the sale of the Evamist product to K-V, the Company made certain representations and warranties concerning its rights and assets related to Evamist and the Company's authority to enter into and consummate the transaction. The Company also made certain covenants that survive the closing date of the transaction, including a covenant not to operate a business that competes, in the U.S., and its territories and protectorates, with the Evamist product.

Pursuant to the terms of the Asset Purchase Agreement the Company entered into with Meda AB, or Meda, to sell certain of the assets related to the MUSE business to Meda, or the MUSE Transaction, the Company agreed to indemnify Meda in connection with the representations and warranties that it made concerning its rights, liabilities and assets related to the MUSE business and its authority to enter into and consummate the MUSE Transaction. The Company also made certain covenants in the Asset Purchase Agreement which survive the closing of the MUSE Transaction, including a three year covenant not to develop, manufacture, promote or commercialize a trans-urethral erectile dysfunction drug.

To the extent permitted under Delaware law, we have agreements whereby we indemnify our officers and directors for certain events or occurrences while the officer or director is, or was, serving at our request in such capacity. The indemnification period covers all pertinent events and occurrences during the officer's or director's lifetime. The maximum potential amount of future payments we could be required to make under these indemnification agreements is unlimited; however, we have director and officer insurance coverage that reduces our exposure and enables us to recover a portion of any future amounts paid. We believe the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Market and Interest Rate Risk

Our cash, cash equivalents and available-for-sale securities as of March 31, 2012 consisted primarily of money market funds and U.S. Treasury securities. Our cash is invested in accordance with an investment policy approved by our Board of Directors that specifies the categories (money market funds, U.S. Treasury securities and debt securities of U.S. government agencies, corporate bonds, asset-backed securities, and other securities), allocations, and ratings of securities we may consider for investment. Currently, we have focused on investing in U.S. Treasuries until market conditions improve.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable debt securities. The primary objective of our investment activities is to preserve principal. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment may decline. A hypothetical 100 basis point increase in interest rates would reduce the fair value of our available-for-sale securities at March 31, 2012 by approximately \$359,000. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

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There is ongoing concern in the credit markets regarding the value of a variety of mortgage-backed, asset-backed and auction rate securities and the resultant effect on various securities markets. In addition, continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways including making it more difficult for us to raise funds if necessary and may cause stock price volatility. Our investment policy, as approved by our Board of Directors, allows us to invest in cash, cash equivalents and available-for-sale securities that are not federally insured. Given the current economic instability, we cannot provide assurance that we will not experience losses on these investments.

ITEM 4. CONTROLS AND PROCEDURES

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

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

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

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Securities Related Class Action Lawsuits

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The Company and two of its officers are defendants in a putative class action lawsuit captioned *Kovtun v. Vivus, Inc., et al.*, Case No. CV10-4957 PJH, pending in the U.S. District Court, Northern District of California. The action, filed in November 2010, alleges violations of Section 10(b) and 20(a) of the federal Securities Exchange Act of 1934 based on allegedly false or misleading statements made by the defendants in connection with the Company's clinical trials and New Drug Application, or NDA, for Qnexa as a treatment for obesity. In his Amended Class Action Complaint filed April 4, 2011, the plaintiff alleged generally that the defendants misled investors regarding the prospects for Qnexa's NDA approval, and the drug's efficacy and safety. On June 3, 2011, the defendants filed a motion to dismiss, which was heard by the Honorable Phyllis J. Hamilton on October 12, 2011. At the hearing, Judge Hamilton ruled from the bench and granted the defendants' motion to dismiss, with leave to amend. Judge Hamilton also issued an order on October 13, 2011, which confirmed her ruling at the hearing. On November 9, 2011, plaintiff filed his Second Amended Class Action Complaint, again generally alleging that the defendants misled investors regarding the prospects for Qnexa's NDA approval, and Qnexa's efficacy and safety. On November 23, 2011, Judge Hamilton granted a stipulation and order requiring defendants' motion to dismiss to be filed on or before December 30, 2011, plaintiff's opposition to defendants' motion to dismiss to be filed on or before February 22, 2012 and defendants' reply to plaintiff's opposition to be filed on or before March 30, 2012. The hearing on defendants' motion to dismiss was held on April 18, 2012. Pending the outcome of defendants' motion to dismiss, discovery will continue to be stayed.

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Additionally, the Company's directors are defendants in a shareholder derivative lawsuit captioned *Turberg v. Logan, et al.*, Case No. CV 10-05271 PJH, also pending in the same federal court. In the plaintiff's Verified Amended Shareholder Derivative Complaint filed June 3, 2011, the plaintiff largely restated the allegations of the *Kovtun* action and alleged that the directors breached fiduciary duties to the Company by purportedly permitting the Company to violate the federal securities laws as alleged in *Kovtun*. The parties have agreed to stay the litigation pending resolution of the defendants' second motion to dismiss in *Kovtun*. The Company's directors are also named defendants in consolidated shareholder derivative suits pending in the California Superior Court, Santa Clara County under the caption *In re VIVUS, Inc. Derivative Litigation*, Master File No. 11 0 CV188439. The allegations in the state court derivative suits are substantially similar to the other lawsuits. As with the federal derivative litigation, the parties have agreed to stay these consolidated actions pending resolution of the second motion to dismiss in *Kovtun*.

The Company and its directors believe that the various shareholder lawsuits are without merit, and they intend to vigorously defend the various actions.

Other Matters

In the normal course of business, the Company receives claims and makes inquiries regarding patent and trademark infringement and other related legal matters. The Company believes that it has meritorious claims and defenses and intends to pursue any such matters vigorously. Additionally, the Company in the normal course of business may become involved in lawsuits and subject to various claims from current and former employees including wrongful termination, sexual discrimination and employment matters. Due to the current economic downturn, employees may be more likely to file employment-related claims following termination of their employment. Employment-related claims also may be more likely following a poor performance review. Although there may be no merit to such claims or legal matters, the Company may be required to allocate additional monetary and personnel resources to defend against these type of allegations. The Company believes the disposition of the current lawsuit and claims is not likely to have a material effect on its financial condition or liquidity.

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

ITEM 1A. RISK FACTORS

Set forth below and elsewhere in this Form 10-Q and in other documents we file with the Securities and Exchange Commission, or 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 Investigational Drug Candidate Development Efforts

We face significant risks in our investigational drug candidate development efforts.

The process of developing new drugs and/or therapeutic products is inherently complex, unpredictable, time-consuming, expensive and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will result in drugs that will receive regulatory approval and achieve market acceptance. Investigational drug candidates that appear to be promising at all stages of development may not reach the market for a number of reasons that may not be predictable based on results and data of the non-clinical and clinical program. Investigational drug candidates may be found ineffective or may cause harmful side effects during clinical trials, may take longer to progress through clinical trials than had been anticipated, may not be able to achieve the pre-defined clinical endpoints due to statistical anomalies even though clinical benefit may have been achieved, may fail to receive necessary regulatory approvals, may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality, or may fail to achieve market acceptance.

We are largely dependent on the success of our investigational drug candidate Qnexa® for treatment of obesity, and cannot be certain that Qnexa will receive timely regulatory approval, if at all, or that, if approved, Qnexa will be successfully commercialized.

We currently have only a limited number of investigational drug candidates in clinical development, and our business depends on their successful development and, if approved, commercialization. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries, which regulations differ by agency and country. We are not permitted to market our investigational drug candidates in the U.S. until we receive approval of a New Drug Application, or NDA, from the FDA, or in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries.

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Regulatory approval of an NDA is not guaranteed. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional pre-clinical studies and clinical trials. The number of pre-clinical studies and clinical trials that will be required for FDA approval varies depending on the investigational drug candidate, the disease or condition that the investigational drug candidate is designed to target and the regulations applicable to any particular investigational drug candidate. The FDA may also ask for retrospective observational studies or trials. These studies are designed to assess a certain risk or outcome of interest that may be attributed to a particular drug exposure. A typical retrospective observational study involves the review and analysis of existing medical records or claims of groups of individuals that have been exposed to a certain medication to determine the incidence of a particular outcome. These results are compared to those from a similar group of individuals that have not been exposed to the medication of interest. In cases where the outcome of interest is rare, inadequate sample size can make interpretation of results difficult.

We met with the FDA in April 2011, to discuss the feasibility of performing a retrospective observational study utilizing existing electronic medical claims healthcare databases to review fetal outcomes, including the incidence of major congenital malformations and oral cleft in the offspring of women who were exposed to topiramate during pregnancy. We reached agreement with the FDA on the retrospective observational study objectives and design, primary endpoints, and eligibility criteria. During the April 2011 meeting, it was agreed the study would be expanded to include all doses of topiramate and all diagnoses. It was also agreed that the results would be stratified and that the diagnoses of those exposed to topiramate would be matched with control groups with similar diagnoses and patient profiles. The co-primary endpoints are the relative risk of major congenital malformations and oral cleft in the offspring of women exposed to topiramate during pregnancy as compared to a control group that was not exposed to topiramate during pregnancy. The retrospective observational study is known as FORTRESS. Top-line preliminary results from FORTRESS were announced in December 2011. FORTRESS identified 1,945 mother-infant dyads exposed to topiramate either alone (monotherapy) or in combination with other antiepileptic agents (polytherapy) in the first trimester of pregnancy, or the Total Topiramate Cohort. Among the Total Topiramate Cohort, 1,740 dyads were exposed to topiramate monotherapy, or the Topiramate Monotherapy Cohort. There were five oral clefts in the Topiramate Monotherapy Cohort for a prevalence rate of 0.29% (5/1,740). This prevalence rate was compared to a control group of infants of women who had previously taken antiepileptic drugs including topiramate but not during the pregnancy of interest, or the Formerly Exposed Cohort. The prevalence rate for the Formerly Exposed Cohort was 0.16% (21/13,512). The prevalence ratio for Topiramate Monotherapy Cohort versus the Formerly Exposed Cohort was 1.88 (center-standardized, 95% CI 0.70-5.03).

FORTRESS analyzed data from a second control group, infants of women with similar medical profiles to the Total Topiramate Cohort regardless of prior antiepileptic drug use (the Similar Medical Profile Cohort). There were nine oral clefts from a sample of 13,614 dyads in the Similar Medical Profile Cohort, for a prevalence of 0.07%. One data source reported an anomalously low prevalence of oral clefts in the sample from the Similar Medical Profile Cohort. To investigate this finding, investigators performed repeated multiple re-sampling from the group of dyads who were eligible for this cohort and determined that the oral clefts prevalence observed in the cohort was likely due to random error. Based on these findings, the FDA requested that we utilize all of the available data in the entire Similar Medical Profile Cohort to determine the background prevalence of oral cleft. Using the entire Similar Medical Profile Cohort, the background prevalence of OC was found to be 0.16% (383/247614), and the Prevalence Ratio compared to the Topiramate Monotherapy cohort, standardized for center was 1.8 (95% CI 0.8-4.4).

As part of FORTRESS, Major Congenital Malformations, or MCMs, are being evaluated. The MCM analysis is ongoing. The FORTRESS findings are based on a claims-only analysis. All of the results of the study are considered to be preliminary until the results are validated. The results will be final when validation is completed, which is expected in the third quarter of 2012. There can be no assurance that the validation of this information will be successfully completed.

Subsequent to our April 2011 meeting with the FDA, several new studies that examined the teratogenic risk of topiramate were published or presented. These studies concluded that topiramate was not a major teratogen; however, the results from one study, the Slone Study, suggested that topiramate may be associated with an increased risk for oral cleft.

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On September 15, 2011, we announced that following a teleconference we had reached agreement with officials of the Division of Metabolism and Endocrinology Products, or DMEP, of the FDA on a plan that allowed for an early resubmission of the Qnexa NDA for the treatment of obesity. Based on this agreement, we resubmitted the Qnexa NDA on October 17, 2011, prior to completion of FORTRESS, and the FDA accepted the NDA for filing. On February 22, 2012, the FDA held a second meeting of the Endocrinology and Metabolic Drugs Advisory Committee, or the Advisory Committee, to discuss the additional data submitted for Qnexa. The FDA asked the Advisory Committee to discuss the following: (1) their interpretation of the available data regarding teratogenicity of topiramate, including whether they believe the data indicate an increase in the risk for oral clefts; (2) the potential

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strengths and weaknesses of the proposed teratogenicity risk management strategy for Qnexa; (3) the clinical significance of the changes in blood pressure and heart rate in overweight and obese patients treated with Qnexa versus placebo, taking into account the reported changes in antihypertensive therapy; and (4) whether the available data for Qnexa warrant that a cardiovascular outcomes trial be conducted prior to approval. The FDA requested the Advisory Committee to vote on whether, after considering all the available data included in the NDA and the discussions held at the meeting on February 22, 2012, including the questions referred to above, the overall benefit-risk assessment of Qnexa supports its approval for the treatment of obesity in individuals with a BMI ≥ 30 kg/m² or a BMI ≥ 27 kg/m² with weight related co-morbidities. The Advisory Committee voted 20 to 2 to recommend approval. The FDA is not bound by the recommendations of its advisory committees, but will consider their guidance during the review of the NDA that was submitted for Qnexa in October 2011. On April 4, 2012, at the FDA's request, we submitted a comprehensive Risk Evaluation and Mitigation Strategy, or REMS, for Qnexa, which was considered a major amendment to the NDA. The Prescription Drug User Fee Act, or PDUFA, target date for Qnexa was April 17, 2012. However, as the submission of the comprehensive REMS was within three months of the PDUFA target date, to provide time for a full review of the submission, the FDA extended the PDUFA target date by three months to July 17, 2012. The FDA has the ability to extend the PDUFA target date under certain circumstances, and there can be no assurance that it will not extend the PDUFA target date further in the future.

The Qnexa NDA resubmission seeks approval for the treatment of obesity, including weight loss and maintenance of weight loss for obese patients (BMI ≥ 30 kg/m²), or overweight patients (BMI ≥ 27 kg/m²) with weight-related co-morbidities such as hypertension, type 2 diabetes or dyslipidemia. The proposed labeling for Qnexa submitted on October 17, 2011 included a contraindication that excluded the use of Qnexa by women of childbearing potential. In January 2012, we announced that following discussions with FDA officials, we were asked to remove the Qnexa contraindication for women of childbearing potential contained in the proposed label. There can be no assurance, however, that, if approved, the final Qnexa label would not include contraindications or warnings for specific populations, including women of childbearing potential. Qnexa would remain contraindicated for women who are pregnant. A contraindication typically indicates that a drug should not be used because the risk of use clearly outweighs any possible therapeutic benefit for that population. The proposed Pregnancy Category is

Category X. Drugs in Category X are designated as such when studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits.

Included with the October 17, 2011 resubmission of the Qnexa NDA was a proposed REMS framework. We discussed the REMS framework with the FDA and the details of the Qnexa REMS were discussed during the Endocrinologic and Metabolic Drugs Advisory Committee meeting, held February 22, 2012. As mentioned above, on April 4, 2012, following the FDA's request, we submitted a comprehensive REMS.

Our resubmission of the NDA for Qnexa states that we plan to conduct a cardiovascular outcomes study post-approval, and we have since submitted a draft protocol to the FDA. The details of this study are under discussion with the FDA. This study could cost \$100 to \$200 million dollars and take as long as five or six years to complete.

Although no other requests for additional information or pre-approval studies were made by the FDA at these meetings or in the CRL, there can be no assurance that the FDA will not request or require us to provide additional information or undertake additional prospective studies or retrospective observational studies in connection with the Qnexa NDA.

On March 28 and 29, 2012, the FDA convened an advisory committee of the Division of Metabolism and Endocrinology Products to discuss the role of cardiovascular assessment in the pre-approval and post-approval settings for drugs and biologics developed for the treatment of obesity. A majority of the advisory committee members in attendance voted in favor of requiring obesity drugs without a theoretic risk or signal for cardiovascular harm to rule out a certain degree of excess cardiovascular risk either through a meta-analysis of pooled Phase 2/Phase 3 data or a cardiovascular outcomes trial. The advisory committee vote is a non-binding recommendation to the FDA and the FDA may or may not prepare formal guidance based upon the advisory committee's recommendation. Although we continue to believe that the advisory committee's

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recommendation stemming from this meeting will not apply to us, there can be no assurance that the FDA would not in the future require us to perform a cardiovascular safety outcomes study, pre- or post-approval, for Qnexa as a treatment for obesity.

On December 17, 2010, we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, for Qnexa Controlled-Release Capsules in the European Union, or the EU. The proposed indication in the EU is for the treatment of obesity, including weight loss and maintenance of weight loss, and should be used in conjunction with a mildly hypocaloric diet. The EMA's review of Qnexa will follow their centralized marketing authorization procedure. If approved, Qnexa could receive marketing authorization in all 27 EU member countries. The MAA was officially validated for central procedure on January 19, 2011. If approved in the EU, Qnexa could be recommended for obese adult patients ($\text{BMI} \geq 30 \text{ kg/m}^2$), or overweight patients ($\text{BMI} \geq 27 \text{ kg/m}^2$) with weight-related co-morbidities such as hypertension, type 2 diabetes or dyslipidemia. In Europe,

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approximately 150 million adults are considered overweight or obese, and the prevalence is rising rapidly. According to EMA guidelines for medicinal products used in weight control, a demonstration of weight loss of at least 10% of baseline weight, which is at least statistically greater than that associated with placebo, is considered to be a valid primary efficacy criterion. Based on the results of the Phase 3 program, we believe Qnexa has met this efficacy criterion set by the EMA for obesity therapies. In addition, the mean weight loss for the mid and top dose of Qnexa at the end of two years was 10.4% and 11.4%, respectively, which we believe met the efficacy benchmark set by the EMA for obesity therapies. These results were shown to be associated with significant improvements in weight-related co-morbidities such as hypertension, dyslipidemia and diabetes. The MAA is comprised of data from over 4,500 overweight or obese patients with a broad range of weight-related co-morbidities. Two-year, double-blind data from SEQUEL (OB-305) were also included in the filing to demonstrate durability of treatment response and long-term safety.

In May 2011, we received a response to our MAA from the Committee for Medicinal Products for Human Use, or CHMP. The response was in the form of the 120-day questions. The 120-day questions covered a broad range of topics including, without limitation, issues relating to phentermine, which include historical concerns regarding its potential association with valvulopathy and pulmonary hypertension; heart rate and limited long-term safety data in high-risk patients; and known and suspected effects of topiramate which include CNS and teratogenic potential. The CHMP also had questions concerning our proposed risk management plan for Qnexa. The 120-day questions were consistent with the issues previously raised in the FDA review process. We met with representatives from the CHMP in September 2011 to seek clarification on certain questions. We submitted our response to the 120-day questions in the fourth quarter of 2011. In January 2012, we received the 180-day List of Outstanding Issues, or 180-day LOI, from the CHMP. In order to perform additional analyses to allow further insights into the data as previously presented, we requested and, in April 2012, we received a two-month extension to respond to the 180-day LOI. The 180-day LOI contained requests for additional information including risk minimization activities to address various issues relating to cardiovascular, neuropsychiatric and potential teratogenic effects of Qnexa. In addition, we were asked to discuss the benefit/risk of the different doses of Qnexa, its potential use in different patient populations, and the expected long-term benefit of treatment with Qnexa. We have submitted our response to the 180-day LOI. There can be no assurance that our response will be adequate or that our MAA will be approved by the CHMP. Absent a delay, we anticipate an opinion from the CHMP in the second quarter of 2012.

Notwithstanding our belief that the data collected from our three Phase 3 trials of Qnexa is promising, and even if we believe that data collected from our pre-clinical studies and clinical trials of our other investigational drug candidates are promising and that our information and procedures regarding chemistry, manufacturing and controls are sufficient, our data may not be sufficient to support approval by the FDA or any other foreign regulatory authority.

The FDA can delay, limit or deny approval of an investigational drug candidate for many reasons, including:

- the FDA may not deem an investigational drug candidate or its components safe and effective;
- the FDA may disagree with a favorable recommendation of its advisory committee;
- the FDA may be persuaded or influenced by a subsequent recommendation by its advisory committee at a later meeting;

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- the FDA position can change or be adversely impacted due to unexpected or unpredictable external circumstances;
- the FDA may not find the data from pre-clinical, clinical or retrospective observational studies or trials sufficient to support approval;
- the FDA may require additional pre-clinical, clinical or retrospective observational studies or trials;
- the FDA may not accept our stability data for commercial product;
- the FDA may not approve of our third-party manufacturers' processes and facilities;
- the FDA may not accept NDA submissions from us due to, among other reasons, the formatting of the submission; or
- the FDA may change its approval policies, adopt new regulations or provide new guidance with significant requirements not currently included or considered by us when seeking NDA approval.

We may not receive FDA approval for Qnexa, despite the vote of the FDA advisory committee to recommend approval.

On October 17, 2011, we resubmitted the Qnexa NDA and the FDA accepted the NDA for filing. On February 22, 2012, the FDA held an Advisory Committee meeting to discuss the additional information contained in the resubmitted NDA. The Advisory Committee voted 20 to 2 to recommend approval. The FDA is not bound by the recommendations of its advisory committees, but will

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consider their guidance during the review of the NDA. On April 4, 2012, at the FDA's request, we submitted a comprehensive REMS for Qnexa, which was considered a major amendment to the NDA. The PDUFA target date for Qnexa was April 17, 2012. However, as the submission of the comprehensive REMS was within three months of the PDUFA target date, to provide time for a full review of the submission, the FDA extended the PDUFA target date by three months to July 17, 2012. The FDA has the ability to extend the PDUFA target date under certain circumstances, and there can be no assurance that it will not extend the PDUFA target date further in the future.

On February 27, 2012, our chief executive officer in a televised interview on CNBC stated his personal belief that Qnexa will be approved by the FDA on or near the PDUFA target date. This statement is a forward-looking statement. There is no assurance that we will receive approval for Qnexa on the PDUFA target date or ever. The FDA may decide not to approve Qnexa, may issue another CRL, may further extend the PDUFA target date or may take various other actions. If Qnexa is not approved for commercial sale or if its development is delayed for any reason, our full investment in Qnexa may be at risk and we may be forced to write-off existing inventory, face significant costs to dispose of unusable inventory, and our business and financial condition could be materially adversely affected.

We received a Complete Response Letter, or CRL, from the FDA regarding our NDA for Qnexa as a treatment for obesity, and we may not be able to satisfy the FDA's concerns.

On October 28, 2010, we received a CRL regarding the NDA for Qnexa as a treatment for obesity. The CRL stated that in its current form, the NDA for Qnexa was not approvable. The CRL included the following areas: clinical, labeling, REMS, safety update, and drug scheduling. In the clinical section of the CRL, the FDA requested a comprehensive assessment of topiramate's and Qnexa's teratogenic potential including a detailed plan and strategy to evaluate and mitigate the potential teratogenic risks in women of childbearing potential taking the drug for the treatment of obesity. In addition, the FDA asked us to provide evidence that the elevation in heart rate (mean 1.6 beats per minute on the top dose) associated with Qnexa does not increase the risk for major adverse cardiovascular events. The FDA requested that we formally submit the results from the completed SEQUEL study (OB-305), a 52-week extension study for a subset of 675 patients who completed the previously reported 56-week CONQUER study. The FDA reserved the right to comment further on proposed labeling. On REMS, the FDA requested that a discussion of an already-submitted REMS plan be continued after we submitted the written response. The agency also requested a safety update of any new adverse events be submitted with the NDA. Finally, the FDA stated that if approved, Qnexa would be a Schedule IV (of the five categories of drugs with potential for abuse under the Controlled Substances Act) drug due to the phentermine component. No new clinical studies were requested in the CRL.

On January 19, 2011, we held an End-of-Review meeting with the FDA to discuss the items contained in the CRL and the information we planned to include in the resubmission of the NDA for Qnexa. In anticipation of the meeting, we provided a briefing document that included comprehensive assessment of the teratogenic potential of topiramate including analyses integrating existing non-clinical and clinical data. In the Qnexa studies, which included 15 offspring from women exposed to Qnexa or topiramate, there were no reports of congenital malformations. In addition, we provided several new analyses including cardiovascular data from our SEQUEL (OB-305) and Sleep Apnea (OB-204) studies to demonstrate that Qnexa does not increase the risk for major cardiovascular events and that the observed increases in heart rate, which occurred in some patients over the course of the clinical program, did not increase the risk of cardiovascular events, as evidenced by adverse events reported in the trial. We also provided a synopsis of the final study report for the SEQUEL study. At the meeting, an overview was provided of the teratogenicity and cardiovascular risk material covered in the background package. The discussion also included elements of our proposed REMS program for Qnexa. The primary focus of the FDA at the meeting, however, concerned the teratogenic potential for topiramate, specifically the incidence of oral clefts observed in the North American AED Pregnancy Registry and in the UK Epilepsy and Pregnancy Registry. The FDA requested that we assess the feasibility of performing a retrospective observational study utilizing existing electronic medical claims healthcare databases to assess fetal outcomes, which include major congenital malformations and oral cleft, in the offspring of women who were exposed to topiramate during pregnancy.

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In April 2011 we reached agreement with the FDA on the study objectives and design, primary endpoints and eligibility criteria for the study, FORTRESS. During the April 2011 meeting, it was agreed the study would be expanded to include all doses of topiramate and all diagnoses. It was also agreed that the results would be stratified and that the diagnoses of those exposed to topiramate would be matched with control groups with similar diagnoses and patient profiles.

On October 17, 2011, we resubmitted the Qnexa NDA and the FDA accepted the NDA for filing. On February 22, 2012, the FDA held an Advisory Committee meeting to discuss the additional information contained in the resubmitted NDA. The Advisory Committee voted 20 to 2 to recommend approval. The FDA is not bound by the recommendations of its advisory committees, but will consider their guidance during the review of the NDA that was submitted for Qnexa in October 2011. On April 4, 2012, at the FDA's request, we submitted a comprehensive REMS for Qnexa, which was considered a major amendment to the NDA. The PDUFA target date for Qnexa was April 17, 2012. However, as the submission of the comprehensive REMS was within three months of the PDUFA

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target date, to provide time for a full review of the submission, the FDA extended the PDUFA target date by three months to July 17, 2012. The FDA has the ability to extend the PDUFA target date under certain circumstances, and there can be no assurance that it will not extend the PDUFA target date further in the future.

The Qnexa NDA resubmission seeks approval for the treatment of obesity, including weight loss and maintenance of weight loss for obese patients ($\text{BMI} \geq 30 \text{ kg/m}^2$), or overweight patients ($\text{BMI} \geq 27 \text{ kg/m}^2$) with weight-related co-morbidities such as hypertension, type 2 diabetes or dyslipidemia. The proposed labeling for Qnexa submitted on October 17, 2011 included a contraindication that excluded the use of Qnexa by women of childbearing potential. In January 2012, we announced that following discussions with FDA officials, we were asked to remove the Qnexa contraindication for women of childbearing potential contained in the proposed label. There can be no assurance, however, that, if approved, the final Qnexa label would not include contraindications or warnings for specific populations, including women of childbearing potential. Qnexa would remain contraindicated for women who are pregnant. A contraindication typically indicates that a drug should not be used because the risk of use clearly outweighs any possible therapeutic benefit for that population. The proposed Pregnancy Category is Category X.

Included with the October 17, 2011 resubmission of the Qnexa NDA was a proposed REMS framework. We discussed the REMS framework with the FDA and the details of the Qnexa REMS were discussed during the Advisory Committee meeting, held February 22, 2012. As mentioned above, on April 4, 2012, following the FDA's request, we submitted a comprehensive REMS.

Our resubmission of the NDA for Qnexa states that we plan to conduct a cardiovascular outcomes study post-approval, and we have since submitted a draft protocol to the FDA. The details of this study are under discussion with the FDA. This study could cost \$100 to \$200 million dollars and take as long as five or six years to complete.

Although no other requests for additional information or pre-approval studies were made by the FDA at these meetings or in the CRL, there can be no assurance that the FDA will not request or require us to provide additional information or undertake additional prospective studies or retrospective observational studies in connection with the Qnexa NDA.

Top-line preliminary results from FORTRESS were announced in December 2011. As part of FORTRESS, MCMs are being evaluated and the analysis is ongoing. The FORTRESS findings are based on a claims-only analysis. All of the results of the study are considered to be preliminary until the results are validated. The results will be final when validation is completed, which is expected in the third quarter of 2012. There can be no assurance that the validation of this information will be successfully completed. There are no guarantees that the results from FORTRESS will be sufficient to satisfy the FDA's safety concerns, that the FDA will not require us to conduct additional clinical or retrospective observational studies, that the FDA will approve our resubmission or that Qnexa will receive regulatory approval for any indication or prove to be commercially successful.

On August 15, 2011, during the International Conference on Pharmacoepidemiology & Therapeutic Risk Management, a new study assessing the risk of oral clefts in topiramate-exposed pregnancies was presented. The presentation entitled "Use of Topiramate and the Risk of Oral Clefts" contained an analysis of data from two large databases including the CDC's National Birth Defects Prevention Study and the Birth Defect Study from the Slone Epidemiology Center at Boston University, together the Slone Study. Data from this new study demonstrated no increase in relative risk of overall major malformations (odds ratio 1.0; 95% CI 0.4-3.2), which provides supporting evidence that topiramate is not a major teratogen. The analysis did indicate an increased risk for oral cleft malformation may be associated with topiramate; however, we believe the magnitude of risk was substantially lower than data reflected in the current topiramate label. The Slone Study provides alternative methodology to assess relative risk with topiramate. The Slone Study assessed all malformations reported in two case-controlled surveillance programs, the

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Slone Epidemiology Center Birth Defects Study, or SBDS, and the CDC's National Birth Defects Prevention Study, or NBDPS. In contrast to other available studies, which assess relative risk based on total topiramate exposure, this analysis assessed the relative risk based on the proportion of identified malformations that were exposed to topiramate. The study identified a total of approximately 34,000 major congenital malformations (11,000 from SBDS and 23,000 from NBDPS), including approximately 3,000 oral cleft malformations (800 SBDS and 2,200 NBDPS). Topiramate exposure during the first trimester of pregnancy was reported in 15 of the major malformations and seven of the oral clefts. There were no reports of isolated cleft palate in the topiramate-exposed pregnancies. Pooled data from the two databases showed a relative risk for oral cleft of 5.4 (95% CI 1.5-20.1). Results were pooled due to the small number of topiramate-exposed pregnancies in the individual databases. In the SBDS data base, three topiramate-exposed oral clefts were reported, producing a relative risk of 10.1 (95% CI 1.1-129.2). In the NBDPS data base, four topiramate-exposed oral clefts were reported, producing a relative risk of 3.6 (95% CI 0.7-20.0). The signal of potential risk from these new data is substantially lower than reported from the North American AED (9.6x) and UK pregnancy (16x) registries.

We are unable to determine the impact, if any, that the results of the Slone Study or FORTRESS may have on the approvability of Qnexa or our stock price. If the results of any or all of these studies are viewed negatively by the FDA and/or investors, they will have a material adverse impact on our ability to gain approval for Qnexa and our ability to raise additional capital at acceptable terms.

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Our investigational drug candidates will likely be subject to enhanced scrutiny to demonstrate adequate safety than investigational drug candidates for more acute or life-threatening diseases.

We believe that the regulatory review of NDAs for investigational drug candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. In this regard, it is likely that our investigational drug candidate, Qnexa, will be subject to increased scrutiny to show adequate safety than would an investigational drug candidate addressing more acute or life-threatening diseases, such as cancer or HIV. In 2010, the FDA notified healthcare professionals that the review of additional data from a post-approval study of sibutramine indicates an increased risk of heart attack and stroke in patients with a history of cardiovascular disease using sibutramine. Meridia (sibutramine) was marketed by Abbott Laboratories; however, in October 2010, Abbott Laboratories withdrew Meridia in the U.S. at the FDA's request. In March 2011, the FDA issued a safety communication to the public and healthcare professionals about an increased risk of oral clefts in children born to mothers taking topiramate (one of the components in Qnexa). The pregnancy classification of topiramate was changed from Category C (which means that data from animal studies suggested potential fetal risks, but no adequate data from human clinical trials or studies were available at the time of approval) to Category D (which means there is positive evidence of human fetal risk based on human data but the potential benefits from use of the drug in pregnant women may be acceptable in certain situations despite its risks). We are unable to determine the impact of this communication and label change for topiramate on the potential approval of Qnexa.

The European Medicines Agency's CHMP also completed a review of the safety and effectiveness of sibutramine. The CHMP has concluded that the benefits of sibutramine do not outweigh its risks, and that all marketing authorizations for medicines containing sibutramine should be suspended throughout Europe. We are unable to determine the impact on Qnexa, if any, of the recent actions in the U.S. and Europe with regard to sibutramine. Orexigen Therapeutics, manufacturers of Contrave, an investigational drug for the treatment of obesity, received a CRL from the FDA requesting that a long-term, randomized, placebo-controlled cardiovascular outcomes study be completed prior to refiling the NDA. According to Orexigen, the FDA requested a cardiovascular outcomes trial with an interim analysis to enable possible FDA approval of Contrave if the upper bound of the 95% confidence interval is less than 2. They further estimate that the interim analysis will require 87 major cardiovascular events (CV death, myocardial infarction and stroke) and will cost less than \$100 million. Orexigen has agreed to complete this study. To date, the FDA has not requested that we perform any additional studies, including cardiovascular outcome studies pre-approval, other than the request to perform FORTRESS. Our resubmission of the NDA for Qnexa states that we plan to conduct a cardiovascular outcomes study post-approval; however, the details of this study have not yet been agreed to with the FDA. There can be no assurance that the FDA will not request or require us to provide additional information or undertake additional prospective studies or retrospective observational studies or that we will be able to agree with the FDA on the details of the cardiovascular outcomes study for Qnexa.

The CHMP may request the results of FORTRESS and may request additional studies including cardiovascular outcome studies or justification for not completing an outcomes study, prior to granting approval of Qnexa in the EU. In January 2012, we received the 180-day LOI from the CHMP. In order to perform additional analyses to allow further insights into the data as previously presented, we requested and, in April 2012, we received a two-month extension to respond to the 180-day LOI. The 180-day LOI contains requests for additional information including risk minimization activities to address various issues relating to cardiovascular, neuropsychiatric and potential teratogenic effects of Qnexa. In addition, we were asked to discuss the benefit/risk of the different doses of Qnexa, its potential use in different patient populations, and the expected long-term benefit of treatment with Qnexa. We have submitted our response to the 180-day LOI. There can be no assurance that our response will be adequate or that our MAA will be approved by the CHMP. Absent a delay, we anticipate an opinion from the CHMP in the second quarter of 2012.

Cardiovascular outcomes studies can take several years, cost millions of dollars and may result in showing an increased risk for major adverse cardiovascular events for patients undergoing drug treatment. If any regulatory agency were to require additional studies, including studies to address cardiovascular events, the impact on the timing of approval and, if approved, commercialization of Qnexa, avanafil, or any of our investigational drug candidates could be delayed or adversely impacted. Even if approved, investigational drug candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed and may have restricted access programs. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our investigational drug candidates. As a result, we cannot predict when or whether regulatory approval

will be obtained for any of our investigational drug candidates currently under development.

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The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current investigational drug candidates may not have favorable results in later studies or trials.

Pre-clinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of an investigational drug candidate in the general population, but rather to test initial safety, to study pharmacokinetics and pharmacodynamics, to study limited efficacy in a small number of study patients in a selected disease population, and to identify and attempt to understand the investigational drug candidate's side effects at various doses and dosing schedules. Success in pre-clinical studies or completed clinical trials does not ensure that later studies or trials, including continuing pre-clinical studies and large-scale clinical trials, will be successful nor does it necessarily predict future results. Favorable results in early studies or trials may not be repeated in later studies or trials, and investigational drug candidates in later stage trials may fail to show acceptable safety and efficacy despite having progressed through earlier trials. In addition, the placebo rate in larger studies may be higher than expected.

We have previously announced results from two pivotal Phase 3 clinical trials for safety and efficacy of our most advanced investigational drug candidate Qnexa, as a treatment for obesity, and we continue to analyze the data collected in these trials. In addition, the briefing documents prepared by us and the FDA ahead of any advisory committee meetings, as well as materials used during those meetings, have been made available to the public. The meeting materials contain information not previously disclosed to the public. The results of the CONQUER study were published in *The Lancet*, the results of the EQUIP study were published in *Obesity* and the results of SEQUEL were published in *The American Journal of Clinical Nutrition*, all of which are peer-reviewed medical journals. Top-line results of the extension study, OB-305, were released in the third quarter of 2010. Additional details of the results of the SEQUEL study have been and will continue to be disclosed at medical meetings and additional details will be available at future meetings. Consequently, it is possible that further analysis, presentation and publication of this information and other data on Qnexa may yield information or suggest conclusions not yet known that may negatively impact our ability to obtain regulatory approval for Qnexa as a treatment for obesity or, if approved, market acceptance.

Pre-clinical data and the limited clinical results that we have obtained for our investigational drug candidates may not predict results from studies in larger numbers of patients in multiple sites drawn from more diverse populations treated for longer periods of time. The smaller and shorter clinical trials also may not predict the ability of these investigational drugs to achieve or sustain the desired effects in the broad intended population or to do so safely. We may decide to not conduct additional Phase 2 studies prior to the initiation of pivotal Phase 3 studies. We may also elect to enter into pivotal Phase 3 studies with a new formulation, dosage, dosing schedule, delivery system or choose to study different populations than had been studied in previous clinical trials.

Qnexa is our proprietary capsule formulation investigational drug candidate containing the active ingredients phentermine and topiramate. Phentermine was approved for the short-term treatment of obesity by the FDA in 1959. Topiramate is approved for seizures (1996), pediatric epilepsy (1999) and migraine prevention (2004). Published studies on topiramate reported that topiramate treatment produced weight loss. By combining topiramate with phentermine, Qnexa attempts to simultaneously address excessive appetite and a high threshold for satiety, the two main mechanisms believed to impact eating behavior. Earlier studies with Qnexa were completed using a twice-a-day dose. The twice-a-day dose and timing of the administration of the immediate-release active ingredients was determined by the inventor through the treatment of patients in his private practice. We used a once-a-day, extended-release formulation in our completed Phase 3 studies of Qnexa. We have completed various pharmacokinetic studies of the once-a-day formulations to characterize the pharmacokinetic profile of the once-a-day, extended-release formulation of Qnexa. The FDA also asked us to study the effects of a lower dose of Qnexa, which we did in the Phase 3 obesity trials. To date, the FDA has not raised any issues or concerns around the formulation of Qnexa. While we believe we can adequately address any future issues raised in the FDA review process, there can be no assurance that we will be successful in obtaining or maintaining regulatory approval for Qnexa.

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We may be required to demonstrate through large, long-term outcome trials that our investigational drug candidates are safe and effective for use in a broad population prior to obtaining regulatory approval. Included with the October 17, 2011 resubmission of the Qnexa NDA was a proposed REMS framework. We discussed the REMS framework with the FDA and the details of the Qnexa REMS were discussed during the Advisory Committee meeting, held February 22, 2012. On April 4, 2012, following the FDA's request, we submitted a comprehensive REMS for Qnexa, which was considered a major amendment to the NDA.

Our resubmission of the NDA for Qnexa states that we plan to conduct a cardiovascular outcomes study post-approval, and we have since submitted a draft protocol to the FDA. The details of this study are under discussion with the FDA. This study could cost \$100 to \$200 million dollars and take as long as five or six years to complete.

Although no other requests for additional information or pre-approval studies were made by the FDA at these meetings or in the CRL, there can be no assurance that the FDA will not request or require us to provide additional information or undertake additional prospective studies or retrospective observational studies in connection with the Qnexa NDA.

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There is typically a high rate of attrition from the failure of investigational drug candidates proceeding through clinical trials. If any of our investigational drug candidates fail to demonstrate sufficient safety and efficacy in any clinical trial, we will experience potentially significant delays in, or may decide to abandon development of, that investigational drug candidate. If we abandon or are delayed in our development efforts related to any of our investigational drug candidates, we may not be able to generate sufficient revenues to continue our operations and clinical studies at the current level or become profitable. Our reputation in the industry and in the investment community would likely be significantly damaged. It may not be possible for us to raise funds in the public or private markets, and our stock price would likely decrease significantly.

If the results of current or future pre-clinical studies, clinical testing, clinical trials or retrospective observational studies indicate that our proposed investigational drug candidates are not safe or effective for human use, our business will suffer.

Unfavorable results from ongoing or future pre-clinical studies, clinical testing, clinical trials or retrospective observational studies could result in delays, modifications or abandonment of ongoing or future clinical trials or development programs. A number of companies in the pharmaceutical industry have suffered significant setbacks in late stage clinical trials, even after promising results in mid to late-stage trials. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated, modified or terminated. In addition, failure to design appropriate clinical trial protocols could result in the test or control group experiencing a disproportionate number of adverse events and could cause a clinical trial to be delayed, repeated, modified or terminated.

All of the investigational drug candidates that we are currently developing require extensive pre-clinical and/or clinical testing before we can submit any application for regulatory approval. Before obtaining regulatory approvals for the commercial sale of any of our investigational drug candidates, we must demonstrate with substantial evidence through pre-clinical testing and/or clinical trials that our investigational drug candidates are safe and effective in humans for the indication being studied. We may also be asked to conduct retrospective observational studies. The FDA requested that we conduct FORTRESS. Top-line preliminary results from FORTRESS were announced in December 2011. As part of FORTRESS, MCMs are being evaluated and the analysis is ongoing. The FORTRESS findings are based on a claims-only analysis. All of the results of the study are considered to be preliminary until the results are validated. The results will be final when validation is completed, which is expected in the third quarter of 2012.

Retrospective observational studies can be complex and involve multiple data sources and electronic records that may not contain all the required information and that information may not be properly validated. We may be required to obtain consents from patients to further investigate findings in a retrospective observational study. In addition, the sample size selected may not be adequate to perform statistical analysis or may not satisfy the requirements for approval. Conducting clinical trials and retrospective observational studies are complex, lengthy, expensive and uncertain processes. Completion of clinical trials and retrospective observational studies and approval by the FDA may take several years or more. Our ability to conduct clinical trials and retrospective observational studies may be delayed, suspended or terminated by many factors, including, but not limited to:

- inability to obtain or manufacture sufficient quantities of investigational drug candidates for use in clinical trials;
- inability of the manufactured product to meet stability or release requirements;

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- failure to receive approval by the FDA of our clinical trial and retrospective observational studies protocols;
- changes in clinical trial and retrospective observational studies protocols or analysis plans made by us or imposed by the FDA;
- poor safety or effectiveness of our investigational drug candidates;
- slower than expected rate of and higher than expected cost of patient recruitment;
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators, or in the case of retrospective observational studies, failure to reach agreement with investigators, data providers, the institutional review board, or IRB, patients, programmers and others on any aspect of a study;

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- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- unfavorable results from ongoing clinical trials and pre-clinical studies;
- uncertainty regarding proper dosing;
- difficulty or inability to achieve bioequivalence between commercial formulations and clinical trial formulations;
- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- termination of clinical trials by one or more clinical trial sites;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- inability to adequately follow patients after treatment;
- insufficient data to support regulatory approval;
- collecting, reviewing and analyzing our clinical trial data;
- unforeseen safety issues;

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- unforeseen issues with formulation or stability of investigational drug candidates;
- obtaining IRB approval to conduct a clinical trial at a prospective site;
- government or regulatory delays;
- inability to raise the necessary cash to start or complete the trials;
- inability to obtain access to historical records and information necessary to conduct a retrospective observational study or the inability to validate or confirm that the information in the historical records is accurate or insufficiency of adequate numbers of mother/infant dyads to meet requirements for acceptable degree of risk reduction to the FDA; or
- inability to obtain consents from patients which, in the case of retrospective observational studies, can be several years after diagnosis.

Many of these factors may also ultimately lead to denial of regulatory approval of our investigational drug candidates. If we experience delays, suspensions or terminations in our retrospective observational studies or clinical trials for a particular investigational drug candidate, the commercial prospects for that investigational drug candidate will be harmed, and we may be unable to raise additional funds on favorable terms, if at all, or generate product revenues from that investigational drug candidate or revenues would be delayed, our reputation in the industry and in the investment community would likely be significantly damaged, and our stock price would likely decrease significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials and retrospective observational studies may also ultimately lead to the denial of regulatory approval of an investigational drug candidate.

Our bioequivalence studies may fail to demonstrate acceptable comparability between formulations of investigational drug candidates used in our Phase 3 clinical trials and new formulations, if any, of investigational drug candidates we might choose to launch commercially, or choose to commercialize later, after launch.

We may choose to develop a new formulation of any or all of our investigational drug candidates that may be different from the formulation used in our Phase 3 clinical trials. If changes are made, or if a new formulation is used, we will need to demonstrate comparable bioequivalence between the formulation used in our Phase 3 clinical trials and the new formulation, should we choose to launch or later commercialize this new formulation. If we are unable to demonstrate that the formulation used in our Phase 3 clinical

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trials is bioequivalent to the new formulation we intend to launch or later commercialize, then we may be required to conduct additional clinical trials or repeat some or all of our Phase 3 clinical trials for our investigational drug candidate, or we may need to develop an alternative commercial formulation for the investigational drug candidate that is bioequivalent. As a result, our ability to obtain approval of the investigational drug candidate, if any, may be delayed. We have performed a bioequivalence study on a new formulation of Qnexa that we intend to launch, if approved, which was determined to be equivalent to the formulation used in the Phase 3 trials.

Association with fen-phen could lead to increased scrutiny of our investigational drug candidate, Qnexa.

One of the active ingredients in Qnexa, phentermine, had previously been used in combination with fenfluramine and dexfenfluramine. Phentermine is the most commonly prescribed anti-obesity drug. As phentermine is an older drug, no new efficacy trials have been conducted, with the exception of several trials on the combination of phentermine and fenfluramine in the early and mid-1990s, OB-201 that contained a phentermine treatment arm, and the EQUATE Phase 3 study that contained two phentermine arms. The combination of fenfluramine or PONDIMIN, or fen, and phentermine, or phen, was known as fen-phen. Fenfluramine received FDA approval in 1973 for the short-term treatment of obesity. Together, phentermine and fenfluramine were used by doctors to treat obesity. The FDA never approved the fen-phen combination; however, since the FDA approved fenfluramine, doctors were able to prescribe it as needed. The use of these drugs together for treatment of obesity was considered an off-label and unapproved use. In 1992, a published study cited fen-phen as a more effective method than dieting or exercise in reducing the weight of the chronically obese.

The fen-phen combination, however, was never tested for safety. During the summer of 1997, the Mayo Clinic reported 24 cases of heart valve disease in patients that had taken the fen-phen combination. The cluster of unusual cases of heart valve disease in fen-phen users suggested a correlation between fen-phen use and heart valve disease. On July 8, 1997, the FDA issued a Public Health Advisory to report the Mayo findings. The FDA continued to receive additional reports of heart valve disease, including reports from patients who had taken only fenfluramine or dexfenfluramine. Further evaluations of patients taking fenfluramine or dexfenfluramine showed that approximately 30% had abnormal valve findings. This figure was much higher than expected for abnormal test results and suggested fenfluramine and dexfenfluramine as the likely causes of Primary Pulmonary Hypertension, or PPH, and valvular heart disease. Ultimately, a pharmacological mechanism for the PPH and valvulopathy effects of dexfenfluramine and fenfluramine was identified that involved the activation of the 5HT_{2b} serotonin receptor. Phentermine does not bind to this or any other serotonin receptors.

In September 1997, the FDA requested drug manufacturers to voluntarily withdraw fenfluramine and dexfenfluramine. At the same time, the FDA recommended that patients using either fenfluramine or dexfenfluramine stop taking them. The FDA did not, however, request the withdrawal of phentermine. Although studies to date have not demonstrated that phentermine causes PPH and valvular heart disease, when used in larger populations over long periods of time, there is currently no conclusive study data indicating that Qnexa will not demonstrate rare, but significant cardiovascular or other detrimental side effects when used by the general population. Moreover, the adverse clinical history of fen-phen and dexfen-phen combinations for obesity may result in increased FDA regulatory scrutiny of the safety or the risk/benefit profile of Qnexa and may raise potential adverse publicity in the marketplace, which could affect market acceptance if Qnexa is approved for commercial sale. Our October 17, 2011 resubmission of the NDA for Qnexa states that we plan to conduct a cardiovascular outcomes study post-approval, and we have since submitted a draft protocol to the FDA. The details of this study are under discussion with the FDA. This study could cost \$100 to \$200 million dollars and take as long as five or six years to complete.

Benfluorex is an anorectic and hypolipidemic agent that is structurally related to fenfluramine. Clinical studies have shown it may improve glycemic control and decrease insulin resistance in people with poorly controlled type 2 diabetes. On December 18, 2009, the European Medicines Agency recommended the withdrawal of all medicines containing benfluorex in the European Union because their risks, particularly the risk of heart valve disease (fenfluramine-like cardiovascular side effects), are greater than their benefits. In France, the medication had been marketed as Mediator by Servier as an adjuvant antidiabetic. It was on the market between 1976 and 2009 and is thought to have caused between

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500 and 2,000 deaths. The drug was also used in Portugal and Cyprus. The withdrawal of Mediator has created controversy, litigation and investigation into the manufacturer, Servier, and the French regulatory authorities (French Agency for Safety and Health Products, or AFSSAPS) as to why the drug was allowed to stay on the market for 10 years after the withdrawal of fenfluramine. A report issued by the Inspection Generale des Affaires Sociales, or IGAS, suggests several failures at all levels that allowed Mediator to stay on the market. The head of the AFSSAPS resigned shortly after the publication of the IGAS report. We are unable to determine the impact of the benfluorex withdrawal and subsequent controversy, if any, on the Marketing Authorization Application, or MAA, our rapporteur or co-rapporteur, Sweden and France, respectively, for Qnexa.

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Our investigational drug candidates or approved drugs may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or limit the commercial profile of an approved label.

Side effects caused by our investigational drug candidates or approved drugs could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. For example, the FDA approved label for avanafil is contraindicated in patients taking nitrates. This contraindication may limit the commercial profile of avanafil. The most common side effects reported in the first Phase 3 study of avanafil were headache, flushing and nasal congestion. The most common side effects reported in our Phase 3 trials of Qnexa were paresthesia (tingling of the extremities), dry mouth, altered taste, headache and constipation. In addition, the constituent drugs of Qnexa each have their own side effect profiles that are included in their current respective product labels. If Qnexa is approved by the FDA, we would anticipate that the label would, at a minimum, include the side effect profiles of each of the constituent drugs. We also expect the label to include a warning or contraindication on use in pregnant women. While the constituent drugs that make up Qnexa have post-marketing safety records and while we have tested these constituent drugs in combination in our clinical trials of Qnexa, to date, the combination of these constituent drugs has not received regulatory approval. While we believe our Phase 3 Qnexa clinical trials have generated sufficient safety and efficacy data, the approvability and eventual labeling of Qnexa will be determined by the FDA. For example, in 2007, the Endocrinologic and Metabolic Drugs Advisory Committee convened by the FDA reviewed another company's investigational obesity drug candidate, rimonabant, and voted not to recommend approval of the investigational drug candidate to the FDA, based on concerns regarding the safety profile of that investigational drug candidate, in particular, depression, suicidality and seizures. Two other obesity medications have also been rejected by the FDA citing specific safety concerns. However, in June 2011, the FDA approved an NDA for Suprenza (phentermine hydrochloride) orally dissolving tablets. Suprenza was approved by the same division of the FDA (Division of Metabolism and Endocrinology). There were no clinical trials performed with Suprenza. Suprenza has a pregnancy Category X. Drugs in Category X are designated as such when studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits.

Phentermine and topiramate are each separately approved by the FDA and have been on the market for many years. In general, significant adverse events and side effects observed in pre-clinical, clinical and post-marketing studies are included in the full prescribing information or label for each drug. The label for TOPAMAX and generic topiramate contains reports of side effects, warnings and precautions including metabolic acidosis, acute myopia and secondary angle closure glaucoma, decreased sweating and hyperthermia, cognitive-related dysfunction, psychiatric and behavioral disturbances including one completed suicide in a patient during a bipolar trial, somnolence and fatigue, sudden unexplained death in epileptics, kidney stones, paresthesia, various drug interactions, congenital malformations and low birth weight in infants born to mothers exposed to topiramate during pregnancy. The label for ADIPEX, a popular branded form of phentermine, contains warnings and precautions including recommendation against co-administration of phentermine with other drugs for weight loss. Adverse side effects include, among other things, pulmonary hypertension, valvular heart disease, drug abuse and dependence, overstimulation, restlessness, dizziness, insomnia, euphoria, dysphoria, tremor, headache, dryness of the mouth, diarrhea, constipation, impotence and changes in libido. The warnings and precautions for both of these drugs are evaluated and or/updated by the FDA and other health authorities often.

Previously published studies suggest that the administration of topiramate alone, in conjunction with diet and a behavioral modification program, results in weight reduction in obese patients. The most prominent side effect seen in the published studies was paresthesia (tingling of the extremities), experienced by 42% to 59% of patients. In these studies, dropouts due to paresthesia were 5% or less. In the EQUATE, EQUIP and CONQUER Phase 3 obesity studies, tingling was experienced in 23%, 19% and 21%, respectively, of the patients on the top dose of Qnexa. In the Phase 2 diabetes study, paresthesia was experienced by 17% of the patients. The other common adverse events reported in the published topiramate monotherapy studies were also central nervous system, or CNS, related including fatigue, difficulty with attention, memory and concentration, and depression. In our obesity and diabetes studies, these CNS-related side effects were low, but they were higher than placebo. The pharmaceutical company performing research of topiramate alone for the treatment of obesity announced they had discontinued their development program including their controlled-release formulation for safety reasons.

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The FDA has also issued an alert on the use of antiepileptic drugs and a potential risk of increased suicidal ideation. As part of our Phase 3 obesity trials for Qnexa, we prospectively assessed the potential risk of suicidal tendencies. The results of the extensive assessments performed in our Phase 3 trials for Qnexa indicated no signal for suicidal behavior or ideation. On July 10, 2008, the FDA held a Joint Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee and the Psychopharmacologic Drugs Advisory Committee. The advisory committee and representatives from the Pediatric Advisory Committee, and the Drug Safety and Risk Management Advisory Committee considered the results of FDA's analysis of suicidality (both suicidal ideation and behavior) from placebo-controlled clinical studies of 11 antiepileptic drugs. One of the drugs included in the discussion was topiramate (marketed as TOPAMAX, Ortho-McNeil-Janssen Pharmaceuticals Inc.). The FDA discussed with the committee, in light of the

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results, whether any additional actions were necessary. The committee recognized that there was an increased risk of suicidality and recommended to the FDA that additional information should be provided to patients regarding the risks and benefits of antiepileptic drugs; however, the committee strongly recommended against a black box warning to be applied to antiepileptic drugs. In December 2008, the FDA asked the manufacturers of the antiepileptic drugs included in the analysis to add warnings about suicidality to the labels and to issue a medication guide covering the results of the meta-analysis. In April 2009, the FDA approved these new labels. We anticipate that the label for Qnexa, if approved, will, at a minimum, contain the similar suicidality warnings to those contained in the topiramate label.

The preliminary experience from an observational registration study conducted in the United Kingdom on women with epilepsy who became pregnant, published in the July 22, 2008 edition of *Neurology*, stated that the MCM rate observed in the study among infants born to women who were taking topiramate and other antiepileptics during their pregnancy raised some concerns. The UK Epilepsy and Pregnancy Register is a voluntary registry in the United Kingdom that collects information in order to gather and publish information on the relative safety of antiepileptic drugs in this population. The results of the study were updated and published in the October 21, 2010 edition of the *Journal of Neurology, Neurosurgery and Psychiatry*. In the study, 245 pregnancies were followed, of which 14 of 162, or 8.6%, had an MCM on polytherapy and three of 83, or 3.6%, had an MCM on topiramate monotherapy. The MCMs included oral clefts and hypospadias. It has been reported that prenatal exposure to certain antiepileptic drugs increases the risk of MCM from a background risk of between 1% and 2% to between 4% and 9%.

Pregnant women or women who planned on becoming pregnant were not eligible to participate in the Qnexa clinical trials. Women of childbearing potential were advised to use and agreed to use two forms of birth control during the study. Patients who became pregnant during the study period were required to immediately discontinue study medication. In our studies, we had 15 births from women exposed to Qnexa or topiramate. They were taken off the study medication and followed through to delivery. While we did not observe any congenital malformations in those pregnancies, we anticipate the labeling for Qnexa, if approved, will contain a contraindication or warning against use by women who are or are considering becoming pregnant. The FDA has stated that Qnexa would be listed as a Category X drug. We have discussed with the FDA a post-approval pregnancy exposure registry for Qnexa. The goal of pregnancy exposure registries is to provide clinically relevant human data that can be used in a product's labeling to provide medical care providers with useful information for treating or counseling patients who are pregnant or anticipating pregnancy.

In the U.S., the label for topiramate has been modified and includes warnings for pregnant mothers. The warnings suggest that topiramate may cause serious adverse fetal effects, based on pregnancy registry and non-clinical data. There are no adequate and well-controlled studies using topiramate in pregnant women. Topiramate should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus. Pregnancy registry data suggest that there may be an association between the use of topiramate during pregnancy and congenital malformations (e.g., craniofacial defects, such as cleft lip/palate, hypospadias, and anomalies involving various body systems). This has been reported with topiramate monotherapy and topiramate as part of a polytherapy regimen. Compared with a reference group not taking antiepileptic drugs, registry data for topiramate monotherapy showed a higher prevalence of low birth weight; however, the dose of topiramate and the duration of use during pregnancy were not reported. A causal relationship has not been established. Several factors affect infant birth weight including maternal weight, maternal health, concomitant drug use, smoking or alcohol use during pregnancy and use of prenatal vitamins. In the Qnexa clinical studies, none of the infants to mothers exposed to Qnexa or topiramate during pregnancy achieved low birth weight.

Two antiepileptic pregnancy registries have reported post-marketing reports of major congenital malformations in infants whose mothers were epileptic and exposed to topiramate during pregnancy. The dose and duration of topiramate exposure from the North American Registry are unknown. In the UK registry, for the two oral clefts reported in infants, the maternal topiramate exposure was 200 mg and 600 mg. These two registries suggest the MCM rate is higher than compared to various control groups. These reports have been included in the label for topiramate and, if Qnexa is approved, we may be required to include these reports in the label for Qnexa.

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Top-line preliminary results from FORTRESS were announced in December 2011. FORTRESS identified 1,945 mother-infant dyads exposed to topiramate either alone (monotherapy) or in combination with other antiepileptic agents (polytherapy) in the first trimester of pregnancy, or the Total Topiramate Cohort. Among the Total Topiramate Cohort, 1,740 dyads were exposed to topiramate monotherapy, or the Topiramate Monotherapy Cohort. There were five oral clefts in the Topiramate Monotherapy Cohort for a prevalence rate of 0.29% (5/1,740). This prevalence rate was compared to a control group of infants of women who had previously taken antiepileptic drugs including topiramate but not during the pregnancy of interest, or the Formerly Exposed Cohort. The prevalence rate for the Formerly Exposed Cohort was 0.16% (21/13,512). The prevalence ratio for Topiramate Monotherapy Cohort versus the Formerly Exposed Cohort was 1.88 (center-standardized, 95% CI 0.70-5.03).

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FORTRESS analyzed data from a second control group, infants of women with similar medical profiles to the Total Topiramate Cohort regardless of prior antiepileptic drug use (the Similar Medical Profile Cohort). There were nine oral clefts from a sample of 13,614 dyads in the Similar Medical Profile Cohort, for a prevalence of 0.07%. One data source reported an anomalously low prevalence of oral clefts in the sample from the Similar Medical Profile Cohort. To investigate this finding, investigators performed repeated multiple re-sampling from the group of dyads who were eligible for this cohort and determined that the oral clefts prevalence observed in the cohort was likely due to random error. Based on these findings, the FDA requested that we utilize all of the available data in the entire Similar Medical Profile Cohort to determine the background prevalence of oral cleft. Using the entire Similar Medical Profile Cohort, the background prevalence of OC was found to be 0.16% (383/247614), and the Prevalence Ratio compared to the Topiramate Monotherapy cohort, standardized for center was 1.8 (95% CI 0.8-4.4).

As part of FORTRESS, MCMs are being evaluated. The MCM analysis is ongoing. The FORTRESS findings are based on a claims-only analysis. All of the results of the study are considered to be preliminary until the results are validated. The results will be final when validation is completed, which is expected in the third quarter of 2012. There can be no assurance that the validation of this information will be successfully completed.

We resubmitted the Qnexa NDA on October 17, 2011, prior to completion of FORTRESS, and the FDA accepted the NDA for filing. On February 22, 2012, the FDA held an Advisory Committee meeting to discuss the additional information contained in the resubmitted NDA. The Advisory Committee voted 20 to 2 to recommend approval. The FDA is not bound by the recommendations of its advisory committees, but will consider their guidance during the review of the NDA that was submitted for Qnexa in October 2011. On April 4, 2012, at the FDA's request, we submitted a comprehensive REMS for Qnexa, which was considered a major amendment to the NDA. The PDUFA target date for Qnexa was April 17, 2012. However, as the submission of the comprehensive REMS was within three months of the PDUFA target date, to provide time for a full review of the submission, the FDA extended the PDUFA target date by three months to July 17, 2012. The FDA has the ability to extend the PDUFA target date under certain circumstances, and there can be no assurance that it will not extend the PDUFA target date further in the future.

The Qnexa NDA resubmission seeks approval for the treatment of obesity, including weight loss and maintenance of weight loss for obese patients ($\text{BMI} \geq 30 \text{ kg/m}^2$), or overweight patients ($\text{BMI} \geq 27 \text{ kg/m}^2$) with weight-related co-morbidities such as hypertension, type 2 diabetes or dyslipidemia. The proposed labeling for Qnexa submitted on October 17, 2011 included a contraindication that excluded the use of Qnexa by women of childbearing potential. In January 2012, we announced that following discussions with FDA officials, we were asked to remove the Qnexa contraindication for women of childbearing potential contained in the proposed label. There can be no assurance, however, that, if approved, the final Qnexa label would not include contraindications or warnings for specific populations, including women of childbearing potential. Qnexa would remain contraindicated for women who are pregnant. A contraindication typically indicates that a drug should not be used because the risk of use clearly outweighs any possible therapeutic benefit for that population. The proposed Pregnancy Category is Category X.

Included with the October 17, 2011 resubmission of the Qnexa NDA was a proposed REMS framework. We discussed the REMS framework with the FDA and the details of the Qnexa REMS were discussed during the Advisory Committee meeting, held February 22, 2012. As mentioned above, on April 4, 2012, following the FDA's request, we submitted a comprehensive REMS.

Our resubmission of the NDA for Qnexa states that we plan to conduct a cardiovascular outcomes study post-approval, and we have since submitted a draft protocol to the FDA. The details of this study are under discussion with the FDA. This study could cost \$100 to \$200 million dollars and take as long as five or six years to complete.

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Although no other requests for additional information or pre-approval studies were made by the FDA at these meetings or in the CRL, there can be no assurance that the FDA will not request or require us to provide additional information or undertake additional prospective studies or retrospective observational studies in connection with the Qnexa NDA.

On March 4, 2011, the FDA issued a drug safety communication informing the public of new data that show that there is an increased risk for the development of cleft lip and/or cleft palate (oral clefts) in infants born to women treated with topiramate (Topamax and generic products) during pregnancy. The communication stated that the benefits and the risks of topiramate should be carefully weighed when prescribing this drug to women of childbearing potential, particularly for conditions not usually associated with permanent injury or death. The communication also indicated that alternative medications that have a lower risk of oral clefts and other adverse birth outcomes should be considered for these patients. If the decision is made to use topiramate in women of childbearing potential, effective birth control should be used. Oral clefts occur in the first trimester of pregnancy before many women know they are pregnant. Topiramate was previously classified as a Pregnancy Category C drug, which means that data from animal studies suggested potential fetal risks, but no adequate data from human clinical trials or studies were available at the time of approval. However, because of preliminary human data that show an increased risk for oral clefts, topiramate was placed in Pregnancy Category D. Pregnancy Category D means there is positive evidence of human fetal risk based on human data but the potential benefits from use of the drug in pregnant women may be acceptable in certain situations despite its risks. The safety communication and changes in the Pregnancy Category were due in part to data from the North American Antiepileptic Drug, or NAAED, Pregnancy

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Registry which indicated an increased risk of oral clefts in infants born to mothers exposed to topiramate monotherapy during the first trimester of pregnancy. The prevalence of oral clefts was 1.4% (3/289) compared to a prevalence of 0.38% - 0.55% in infants born to mothers exposed to other antiepileptic drugs, or AEDs, and a purported prevalence of 0.07% in infants born to mothers without epilepsy or treatment with other AEDs. The relative risk of oral clefts in topiramate-exposed pregnancies in the NAAED Pregnancy Registry was 21.3 as compared to the risk in a background population of untreated women (95% Confidence Interval: 7.9 - 57.1). The UK Epilepsy and Pregnancy Register reported a similarly increased prevalence of oral clefts (3.2%) among infants born to mothers exposed to topiramate monotherapy, a 16-fold increase in risk compared to the risk in their background population (0.2%).

A label update for topiramate was approved in July 2011. The updated label for topiramate reflects a lower than previously reported relative risk of oral cleft. In March 2011, based on data from the North American antiepileptic registry, the reported prevalence of oral cleft from topiramate exposure was 1.4% as compared to a historical control of 0.07%. In July 2011, the label was revised and now includes a prevalence rate for oral cleft of 1.2%. The historical control was corrected to 0.12%, which is more in line with the expected background rate in the general population. More importantly, the relative risk calculation dramatically improved from 21.3 to 9.6. Also at this time, the REMS for topiramate was discontinued as the FDA determined that the Medication Guide as part of the labeling adequately addresses public health risks.

In May 2011, the *Journal of the American Medical Association* published the results of a study entitled, *Newer-Generation Antiepileptic Drugs and the Risk of Major Birth Defects* by Ditte Mølgaard-Nielsen, MSc, Anders Hviid, MSc, DrMedSci (JAMA. 2011;305(19):1996-2002). The study was a population-based cohort study of 837,795 live-born infants in Denmark from January 1, 1996, through September 30, 2008. Individual-level information on dispensed antiepileptic drugs to mothers, birth defect diagnoses, and potential confounders was obtained from compulsory nationwide health registries. The main outcome measures were Prevalence Odds Ratios, or PORs, of any major birth defect diagnosed within the first year of life by fetal exposure to antiepileptic drugs.

Of the 1,532 infants exposed to lamotrigine, oxcarbazepine, topiramate, gabapentin, or levetiracetam (newer-generation antiepileptic drugs) during the first trimester, 49 were diagnosed with a major birth defect compared with 19,911 of the 836,263 who were not exposed to an antiepileptic drug (3.2% vs. 2.4%, respectively; adjusted POR [APOR], 0.99; 95% confidence interval [CI], 0.72-1.36). For the topiramate subgroup, a major birth defect was diagnosed in five of 108 infants (4.6%) exposed to topiramate (APOR, 1.44; 95% CI, 0.58-3.58). The study concluded that among live-born infants in Denmark, first-trimester exposure to newer-generation antiepileptic drugs, including topiramate, compared with no exposure, was not associated with an increased risk of major birth defects.

In July 2011, abstracts for an international epilepsy conference including the top-line results of an additional retrospective study of medical claims data on oral clefts, or OCs, and MCMs associated with *in utero* topiramate exposure became available. This study was conducted using medical claims and pharmacy prescription data from the Wolters Kluwer Pharma Solutions Source® Lx Patient Longitudinal Database, which identified 778 mother-infant dyads exposed to topiramate within 10 months prior to giving birth. The study compared the incidence rate of OC and MCM in topiramate-exposed dyads to two control groups, one comprised of 3,431 dyads exposed to other antiepileptic drugs, or AEDs, during pregnancy and a second of 2,307 dyads with a diagnosis of epilepsy (with or without treatment), but no exposure to topiramate during pregnancy. Dyads exposed to known teratogens were excluded from all cohorts. The results of the study found there were no statistically significant differences in OC or MCM frequency between the topiramate and control groups.

On August 15, 2011, during the International Conference on Pharmacoepidemiology & Therapeutic Risk Management, a new study assessing the risk of oral clefts in topiramate-exposed pregnancies was presented. The presentation entitled *Use of Topiramate and the Risk of Oral Clefts* contained an analysis of data from two large databases including the CDC's National Birth Defects Prevention Study and the Birth Defect Study from the Slone Epidemiology Center at Boston University, together the Slone Study. Data from this new study demonstrated no increase in relative risk of overall major malformations (odds ratio 1.0; 95% CI 0.4-3.2), which provides supporting evidence that topiramate is not a major teratogen. The analysis did indicate an increased risk for oral cleft malformation may be associated with topiramate; however, we believe the

magnitude of risk was lower than data reflected in the current topiramate label. The Slone Study provides alternative methodology to assess relative risk with topiramate. The Slone Study assessed all malformations reported in two case-controlled surveillance programs, the Slone Epidemiology Center Birth Defects Study, or SBDS, and the CDC's National Birth Defects Prevention Study, or NBDPS. In contrast to other available studies, which assess relative risk based on total topiramate exposure, this analysis assessed the relative risk based on the proportion of identified malformations that were exposed to topiramate. The study identified a total of approximately 34,000 major congenital malformations (11,000 from SBDS and 23,000 from NBDPS), including approximately 3,000 oral cleft malformations (800 SBDS and 2,200 NBDPS). Topiramate exposure during the first trimester of pregnancy was reported in 15 of the major malformations and seven of the oral clefts. There were no reports of isolated cleft palate in the topiramate-exposed pregnancies. Pooled data from the two databases showed a relative risk for oral cleft of 5.4 (95% CI 1.5-20.1). Results were pooled due to the small number of topiramate-exposed pregnancies in the individual databases. In the SBDS data base, three topiramate-exposed oral clefts were reported, producing a relative risk of 10.1 (95% CI 1.1-129.2). In the NBDPS data base, four topiramate-exposed oral clefts were reported, producing a relative risk of 3.6 (95% CI 0.7-20.0). The signal of potential risk from these new data is substantially lower than reported from the North American AED (9.6x) and UK pregnancy (16x) registries.

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On August 31, 2011, during a poster session at the 29th International Epilepsy Congress (IEC) in Rome, Italy, Dr. Alison Pack, Associate Professor of Clinical Neurology, Columbia University Medical Center, presented the results of this study. The incident rate of OC and MCM in the topiramate-exposed group was compared to OC and MCM incident rates in three non-topiramate-exposed control groups: an antiepileptic drug, or AED group, an epilepsy group, and a diabetes group. The study found that there were no significant differences in oral clefts or major congenital malformations between the topiramate group and the AED or epilepsy groups. The risk for MCMs in infants born to diabetic mothers was significantly higher than the other cohorts, including the infants exposed to topiramate *in utero*. The rates seen in the diabetes control group are comparable to that reported in the literature. In all groups, known or suspected teratogens, including valproate and phenytoin, were excluded.

On September 27, 2011, a poster authored by Dr. Mark W. Green, Director of the Center for Headache and Pain Medicine and Professor of Neurology and Anesthesiology at the Mount Sinai School of Medicine, was presented at the American Neurological Association Meeting in San Diego, CA. In addition to the topiramate exposure data previously reported, the results included the rate of MCMs and OCs in two new control groups, a migraine without epilepsy group, and a sub-group of patients exposed to acute- and preventive migraine drugs, or APMD, during pregnancy. The incident rate of oral clefts and major congenital malformations in the topiramate-exposed group was compared to OC and MCM incident rates in three non-topiramate-exposed control groups: a migraine without epilepsy group, a group of patients exposed to acute-preventive migraine drugs, or APMD, during pregnancy, and a diabetes group. The study found that the risk for MCMs in infants born to diabetic mothers was significantly higher than seen in infants exposed to TPM *in utero*. The MCM and OC rates seen in the diabetes control group are comparable to those reported in the literature. Consistency of these data compared to published references for the diabetes control group and the random sample provides assurance that this data would likely be representative of other clinical settings.

The study, funded by VIVUS, was conducted utilizing Wolters Kluwer datasets from the United States and followed patients Pharmacy and Medical Claims (births from January 2003 December 2010) and covered an estimated 177 million lives. Probable exposure during pregnancy was refined using data on script fill date, days of medication supplied, infant birth date, and ICD-9 codes for birth term. We included the results of this study in the October 17, 2011 resubmission of the Qnexa NDA.

Patients in the year-long Qnexa studies had a mean elevation in heart rate at the end of the 56-week studies of 1.3, 0.6 and 1.6 beats per minute on the low, mid and top dose, respectively, as compared to no change in the placebo group. Patients also had a decrease in systolic blood pressure of 3.3, 5.2 and 5.2 mmHg on the low, mid and top dose, respectively, as compared to a decrease of 2.1 mmHg in the placebo group. The clinical relevance of the increase in heart rate at these levels is unknown. In the CRL, the FDA asked us to provide evidence that the elevations in heart rate associated with Qnexa do not increase the risk for major adverse cardiovascular events. We have provided evidence from existing information and data analyses to show that the increase in heart rate associated with Qnexa does not increase the risk for major cardiovascular events, nor was it associated with a higher incidence of cardiovascular adverse events in the clinical program; however, there can be no assurance that the FDA will accept or agree with the evidence we provide, that the FDA and/or EMA will not require us to conduct long-term cardiovascular outcomes studies or other clinical studies prior to approval, or that we will be able to rule out, to the FDA's and/or EMA's satisfaction, that the elevations in heart rate associated with Qnexa do not increase the risk for major adverse cardiovascular events now or in the future. Our resubmission of the NDA for Qnexa states that we plan to conduct a cardiovascular outcomes study post-approval, and we have since submitted a draft protocol to the FDA. The details of this study are under discussion with the FDA. There can be no assurance that we will be able to agree with the FDA on the details of the cardiovascular outcomes study for Qnexa. A company with a potentially competitive compound has recently agreed to complete a cardiovascular study pre-approval. The potentially competitive compound has shown in Phase 3 studies that patients treated with it had small but statistically significant mean increases in systolic and diastolic blood pressure relative to placebo. In contrast, Qnexa has been shown to decrease blood pressure relative to placebo.

If our trials are not successful or are perceived as not successful by the FDA, physicians, analysts, investors, the media or the public in general our business, financial condition and results of operations will be materially harmed.

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If we, or others, identify unknown side effects caused by our investigational drug candidates or approved drugs, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the drug;
- regulatory authorities may require the addition of labeling statements, such as a black box warning with Qnexa or a contraindication;

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- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way the drug is administered, conduct additional clinical trials or change the labeling of the drug;
- we could be asked to formulate a REMS that could include a program of post-marketing surveillance or restricted distribution for physicians who prescribe our drugs and patients being treated with our drugs;
- prescribing physicians may be requested to complete certain education programs on the drugs and their intended use;
- patient access to the drug may be limited to certain populations and patients may be requested to provide certain information prior to receiving their new or refill prescription;
- infants *in utero* may have unplanned exposure to the drug and experience adverse side effects;
- we could be sued and held liable for injury to individuals exposed to or taking our drugs; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of Qnexa and could substantially increase the costs of commercializing our investigational drug candidates.

Our investigational drug candidate, Qnexa, is a combination of drugs approved individually by the FDA that are commercially available and marketed by other companies. As a result, our drug may be subject to substitution with individual drugs contained in the Qnexa formulation and immediate competition.

Each of the approved drugs that are combined to produce our investigational drug candidate, Qnexa, is commercially available at prices lower than the price at which we would seek to market Qnexa, if approved. We cannot be sure that physicians will view Qnexa as sufficiently superior to a treatment regime of Qnexa's individual active pharmaceutical ingredients as to justify the significantly higher cost we expect to seek for Qnexa, 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 Qnexa,

those patents may be ineffective to protect against physicians prescribing the individual drugs marketed by other companies instead of our combination drug. Our patents and pending patent applications do not prevent physicians from prescribing the generic constituents of our investigational drug candidates. Phentermine and topiramate are currently available in generic form, although the doses used in Qnexa are currently not available and no controlled, extended or sustained release formulation of topiramate exists. We believe that a practitioner seeking safe and effective therapy is not likely to prescribe such off-label generics in place of Qnexa because of state pharmacy laws, the dosage strengths, pharmacokinetic profiles and titration regimens recommended for Qnexa are not available using existing generic preparations of immediate release, or IR, phentermine or topiramate. However, to the extent that the price of Qnexa 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 Qnexa. Similar concerns could also limit the reimbursement amounts private health insurers or government agencies in the U.S. are prepared to pay for Qnexa, which could also limit market and patient acceptance of our drug, and could negatively impact our revenues. A physician could seek to prescribe off-label generics in place of Qnexa. Off-label use occurs when a drug that is approved by the FDA for one indication is legally prescribed by physicians for a different indication not approved by the FDA. Topiramate, one of the ingredients in Qnexa, is not approved for obesity treatment. Phentermine is only approved for short-term treatment of obesity.

With regard to off-label substitution at the pharmacy level, we cannot be certain that pharmacists and/or pharmacy benefit managers will not seek prescriber authorization to substitute generics in place of Qnexa, which could significantly diminish its market potential. Wide scale generic substitution by physicians and at the pharmacy level could have substantial negative consequences to our business.

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

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We may choose or be required by regulatory authorities to restrict distribution of Qnexa to specialty pharmacies and to registered physicians and patients. Our success in distributing our investigational drug candidate, if approved, in this manner could be limited, which could have an adverse effect on our business, financial condition, results of operations and cash flow.

The FDA and other regulatory agencies have required more extensive and/or expensive trials for our combination investigational drug candidate, Qnexa, than may be required for single agent pharmaceuticals.

To obtain regulatory approval for Qnexa, we are required to show that each active pharmaceutical ingredient in our investigational drug candidate makes a contribution to the combined investigational drug candidate's claimed effects and that the dosage of each component, including amount, frequency and duration, is such that the combination is safe and more effective than each of the components. As a result, we were required to include in our clinical trial protocols an evaluation of each component drug as well as for the component drug in combination. This required us to conduct more extensive and more expensive clinical trials than would be the case for many single agent pharmaceuticals. The need to conduct such trials has made and is expected to continue to make it more difficult and costly to obtain regulatory approval of Qnexa than of a new drug containing only a single active pharmaceutical ingredient. The OB-201 study was a randomized, double-blind study in 200 obese adults that compared combination phentermine and topiramate with each component, at matching doses as monotherapy, and with placebo for 24 weeks. The OB-301, or EQUATE, Phase 3 trial was designed to meet the combination guidelines set by the FDA. The EQUATE study contained separate component arms as well as the combination. We believe the results of the EQUATE study meet FDA guidelines for combination therapy studies; however, there can be no assurance that we have satisfied the combination requirements to the FDA's satisfaction or that further testing of the combination will not be required. The EQUATE study also contained a mid dose of Qnexa containing 7.5 mg of phentermine and 46 mg of topiramate CR. The mid dose was also included in the CONQUER, or OB-303, study. We did not complete a component study for the low dose. We have filed for approval of all three doses. The number of patients on the low dose in OB-302 or the mid dose in the OB-303 study may not be sufficient for approval. We have no assurance that any of the doses of Qnexa will be approved or that additional pre-clinical and clinical testing may not be needed prior to approval. In addition, if the FDA does not approve the top dose of Qnexa, there is no assurance that they would approve the mid dose or any other dose of Qnexa. In the CRL received on October 28, 2010, there were no deficiencies noted relating to the combination guidelines or exposure numbers by dose; however, until approval, there can be no assurance that these items will not be subject to further review and comment by the FDA.

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

We have in-licensed and otherwise contracted for rights to our investigational drug candidates and approved drugs, and we may enter into similar licenses in the future to supplement our investigational drug candidate pipeline. 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, the rights to avanafil were licensed from Tanabe Seiyaku Co., Ltd., or Tanabe, in 2001. In October 2007, Tanabe and Mitsubishi Pharma Corporation completed their merger and announced their name change to Mitsubishi Tanabe Pharma Corporation, or MTPC. We are in discussion with MTPC about certain aspects of the license agreement relating to the manufacture and supply of products. In addition, we are currently obligated to use our best commercial efforts to market avanafil within six months of the April 27, 2012 FDA approval date. Failure to reach agreement with MTPC or to market the drug within the six-month period may have an adverse impact on the commercial future of avanafil. The rights to Qnexa were licensed from Dr. Najarian in 2001. We believe we are in compliance with all the material terms of our current agreements; however, there can be no assurance that this compliance will continue or that the licensors would not have a differing

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interpretation of the material terms of the agreements. If the license agreements were terminated early or if the terms of the license 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 collaborative agreements could be significant despite rulings in our favor.

For example, VIVUS and Acrux Limited, through its wholly owned subsidiary FemPharm Pty Ltd., or Acrux, were parties to the Testosterone Development and Commercialization Agreement dated February 12, 2004, or the Testosterone Agreement. The Testosterone Agreement covered our investigational drug candidate, Luramist, which was licensed from Acrux under the Testosterone Agreement. On November 5, 2007, Acrux made a demand for arbitration under the Testosterone Agreement regarding certain claims related to Luramist. Acrux's demand sought a reversion of all rights assigned to us related to Luramist, monetary damages and the payment of a milestone payment for Luramist under the Testosterone Agreement and declaratory relief. We asserted counterclaims against Acrux in the arbitration and sought the enforcement of our rights under the Testosterone Agreement. The arbitration hearing

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concluded on January 23, 2009, and on April 6, 2009 the panel of arbitrators, or the Panel, issued its Interim Arbitration Award finding in favor of the Company that we were in compliance with the Testosterone Agreement and denying all of the relief sought by Acrux in its demand. The Panel found that we had used diligent, commercially reasonable efforts to develop Luramist. The Panel further ruled in our favor on our counterclaim that Acrux had breached the Testosterone Agreement by failing to provide certain know-how and certain improvements in the formulation and delivery device for Luramist. The Panel denied the Acrux claim for additional milestone payments. The Panel ordered Acrux to turn over certain information to us that was previously withheld in violation of the Testosterone Agreement by Acrux. After the parties failed to agree on a new Outside Date by which we were to commence our first Phase 3 trial for Luramist, the Panel reset the Outside Date of April 30, 2006 to April 1, 2010 to reflect the regulatory environment. On March 30, 2010, we provided written notice to Acrux of our intent to terminate the Testosterone Agreement. On April 6, 2010, in connection with Acrux's request for further briefing on the issue of damages in light of the our termination of the Testosterone Agreement, the Panel ordered the parties to enter into settlement discussions and to report back to the Panel no later than May 17, 2010 on whether a settlement had been reached. On May 6, 2010, the parties agreed to the terms of a settlement agreement and mutual release, or the Settlement Agreement, resolving any and all claims or potential claims in the arbitration and that may have or could have arisen from any case whatsoever, other than certain rights and obligations that survive the termination of the Testosterone Agreement or are required by the Settlement Agreement. Pursuant to the Settlement Agreement, we have transferred Luramist-related assets to Acrux, including clinical trial material, batch release documents, inventory of applicators, FDA correspondence, intellectual property and know-how and trademarks. In addition, we have ceased our clinical study program for Luramist as part of the settlement. The parties have not exchanged cash payments as a result of the settlement and termination of the Testosterone Agreement. The Panel retains jurisdiction over the matter to enforce the terms of the Settlement Agreement. Although we have returned the rights to Luramist to Acrux and resolved the arbitration, there can be no assurance that Acrux will not pursue legal action against us for any of our continued obligations under the settlement or the provisions of the Testosterone Agreement that survive the termination. The monetary and disruption costs of this arbitration have been significant despite the favorable rulings by the Panel.

While we may be entitled to future milestone payments under existing contractual arrangements, we may not receive these payments.

Certain of our contractual arrangements include future milestone payments to us based upon the other party achieving defined sales targets. Meeting those milestone targets is dependent on the performance of the other party to the contractual arrangement and we have little, or no, control over those outcomes. We have no assurance any of those milestone targets will be achieved and that the milestones will be paid to us.

For example, on March 30, 2007, we entered into a definitive agreement with K-V Pharmaceutical Company, or K-V, to transfer the assets and grant a sublicense of our rights under our licensing agreement with Acrux related to Evamist, a metered-dose transdermal spray for the treatment of menopause symptoms, to K-V. Under the terms of this agreement, we are also eligible to receive certain one-time payments of up to \$30 million based on K-V achieving certain annual net sales thresholds for Evamist. In 2009, K-V and certain of its subsidiaries announced a voluntary recall of most of its prescription drugs. In addition, K-V voluntarily suspended the manufacturing and shipping of all of its products and is currently operating under a consent decree. K-V reduced its workforce and replaced and reorganized its management team and Board of Directors. Evamist is not manufactured by K-V and was not subject to the recall. In 2011, K-V raised \$225 million through the sales of senior secured notes. Given the uncertainties with K-V, it is difficult to determine the extent of the adverse impact on Evamist. Although we are entitled to additional milestone payments from future sales of Evamist by K-V, at the present time we do not anticipate receiving any additional milestone payments from sales of Evamist.

On October 1, 2010, we entered into a definitive Asset Purchase Agreement with Meda AB, or Meda, to sell certain rights and assets related to MUSE. The transaction closed on November 5, 2010. Under the terms of the transaction, we are eligible to receive an additional \$1.5 million based on future sales of MUSE, provided that certain sales milestones are reached. There can be no guarantee that these future sales milestones will be achieved or that we will receive this additional compensation related to the sale of MUSE.

We are dependent upon collaborative arrangements and strategic alliances.

We are, and in the future expect to be, dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of some of our investigational drug candidates, particularly after the Phase 2 stage of clinical testing. These arrangements may place the development of our investigational drug candidates outside of our control, may require us to relinquish certain rights or pay royalties, or may otherwise be on terms unfavorable to us. In October 2007, Tanabe and Mitsubishi Pharma Corporation completed their merger and announced their name change to Mitsubishi Tanabe Pharma Corporation, or MTPC. The rights and obligation of our license agreement with Tanabe have been transferred to MTPC. It is unclear at this time what effect, if any, the merger has had on our agreement with MTPC. There can be no guarantee that the merger will not have an adverse material effect on the performance by MTPC under our agreement, which in turn could lead to a material adverse effect on our business, financial condition and results of operations.

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We may be unable to enter into favorable agreements with third parties, which could delay or impair our ability to develop and commercialize our investigational drug candidates and could increase our costs of development and commercialization. Dependence on collaborative arrangements or strategic alliances will subject us to a number of risks, including the risk that:

- we may not be able to control the amount, timing and quality of resources that our collaborators may devote to the investigational drug candidates;
- our collaborators may experience financial, regulatory or operational difficulties;
- our collaborators may be required to disclose our confidential information or may fail to protect our confidential information;
- we may be required to relinquish important rights 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 obligations to meet our requirements under any arrangement;
- legal disputes or disagreements may occur with our collaborative partners;
- a collaborator could independently move forward with a competing investigational drug candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our investigational drug candidates.

Although we may terminate an existing collaborative arrangement or other agreement, we could be subject to continued costs or obligations thereunder.

The majority of our agreements with third parties contain termination clauses that provide for cancellation or termination of the agreement under certain circumstances. We may decide to terminate our agreements with third parties for business or other reasons at any time. Although we may terminate these or any other agreements, we could be subject to continued costs or obligations under the terminated agreements.

We face significant governmental regulation during our investigational drug candidate development and approved drug commercialization activities.

The research, testing, manufacturing, selling and marketing of investigational drug candidates and approved pharmaceuticals is subject to extensive regulations by the FDA and other regulatory agencies in the U.S. and other countries. We cannot predict with certainty if or when we might submit for regulatory review our investigational drug candidates currently under development, except for Qnexa, for which the NDA was submitted to the FDA on December 29, 2009 and for which we resubmitted the NDA in October 2011, and for avanafil for which the NDA was submitted to the FDA in June 2011 and for which we received FDA approval of the NDA on April 27, 2012, in advance of the April 29, 2012 PDUFA target date. We intend to market avanafil through a partner in the U.S. under the name Stendra®. The Advisory Committee of the FDA reviewed the Qnexa NDA on February 22, 2012 and voted 20 to 2 to recommend approval. The FDA is not bound by the recommendations of its advisory committees, but will consider their guidance during the review of the NDA. On April 4, 2012, at the FDA's request, we submitted a comprehensive REMS for Qnexa, which was considered a major amendment to the NDA. The PDUFA target date for Qnexa was April 17, 2012. However, as the submission of the comprehensive REMS was within three months of the PDUFA target date, to provide time for a full review of the submission, the FDA extended the PDUFA target date by three months to July 17, 2012. The FDA has the ability to extend the PDUFA target date under certain circumstances, and there can be no assurance that it will not extend the PDUFA target date further in the future. Even if submitted, the FDA can suspend or modify clinical studies at any time if the agency believes that the patients participating in such studies are being exposed to unacceptable health risks.

Regulatory approval is never guaranteed, and the approval process typically takes several years and is extremely expensive. The FDA has substantial discretion in the drug approval process. Despite the time and expense involved, failure can occur at any and every stage.

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In July 2008, an FDA advisory committee discussed the role of cardiovascular outcomes assessment in the pre-approval and post-approval settings for drugs and biologics developed for the treatment of type 2 diabetes mellitus. The advisory committee recommended that sponsors conduct a long-term cardiovascular trial or to provide other equivalent evidence to rule out an unacceptable cardiovascular risk. The FDA has since published a guidance document in December 2008 for the evaluation of cardiovascular risk in new antidiabetic therapies specifically for the treatment of type 2 diabetes. In general, the FDA recommends that sponsors should compare the incidence of important cardiovascular events occurring with the antidiabetic investigational agent to the incidence of the same type of events with the control group to estimate the relative risk of the investigational antidiabetic agent. This may be accomplished by either conducting an integrated analysis (meta-analysis) of the Phase 2 and Phase 3 studies, if the investigational drug was in late-stage development at the time the December 2008 guidance was published, or conduct a single, large, prospective long-term cardiovascular safety outcomes study prior to NDA submission. A long-term cardiovascular study would take several years to complete and would require financial and personnel resources that may be beyond our current capabilities. Qnexa, in development for diabetes is subject to this recommendation. Our resubmission of the NDA for Qnexa states that we plan to conduct a cardiovascular outcomes study post-approval, and we have since submitted a draft protocol to the FDA. The details of this study are under discussion with the FDA. On March 28 and 29, 2012, the FDA convened an advisory committee of the Division of Metabolism and Endocrinology Products to discuss the role of cardiovascular assessment in the pre-approval and post-approval settings for drugs and biologics developed for the treatment of obesity. A majority of the advisory committee members in attendance voted in favor of requiring obesity drugs without a theoretic risk or signal for cardiovascular harm to rule out a certain degree of excess cardiovascular risk either through a meta-analysis of pooled Phase 2/Phase 3 data or a cardiovascular outcomes trial. The advisory committee vote is a non-binding recommendation to the FDA and the FDA may or may not prepare formal guidance based upon the advisory committee's recommendation. Although we continue to believe that the advisory committee's recommendation stemming from this meeting will not apply to us, there can be no assurance that the FDA would not in the future require us to perform a cardiovascular safety outcomes study, pre-approval, for Qnexa as a treatment for obesity.

Previously, the FDA notified healthcare professionals that the review of data from a post-approval outcomes trial of an anti-obesity agent, sibutramine, indicates an increased risk of heart attack and stroke in patients with a history of cardiovascular disease. Based on the serious nature of the review findings, the FDA requested, and the manufacturer agreed, to add a new contraindication to the sibutramine drug label stating that sibutramine is not to be used in patients with a history of cardiovascular disease. In 2010, sibutramine was withdrawn from the market in the U.S. and in the EU. Orexigen Therapeutics, the developer of Contrave, received a CRL and reported that the CRL stated that before the NDA could be approved they must conduct a randomized, double-blind, placebo-controlled trial of sufficient size and duration to demonstrate that the risk of major adverse cardiovascular events in overweight and obese patients treated with naltrexone/bupropion does not adversely affect the drug's benefit-risk profile. According to Orexigen, the FDA requested a cardiovascular outcomes trial with an interim analysis to enable possible FDA approval of Contrave if the upper bound of the 95% confidence interval is less than 2. They further estimate that the interim analysis will require 87 major cardiovascular events (CV death, myocardial infarction and stroke) and will cost less than \$100 million. Orexigen has agreed to complete this study. If we are required to complete a long-term cardiovascular safety outcomes study for Qnexa pre-approval, the ultimate approval may be delayed for several years and, whether a long-term cardiovascular safety outcomes study is required pre- or post-approval, the overall cost of the development program will significantly increase.

In June 2007, an FDA advisory committee recommended against approval of rimonabant, an oral obesity treatment that targets the CB1 receptor system. Rimobabant was a centrally-acting drug that reduced patients' desire to eat being developed by another company. The advisory committee expressed concerns about the impact of the drug on depressed patients and also expressed concerns about patients having thoughts about suicide. In addition, concerns about rimonabant's mechanism of action and interference with the CB1 receptor pathway were also voiced. The company withdrew its NDA for rimonabant shortly after the advisory committee meeting. Although the active ingredients in Qnexa have been previously approved by FDA at higher doses for other indications, Qnexa is a centrally-acting drug that may increase the risk of psychiatric side effects such as depression and/or suicidal ideation.

We are not permitted to market any of our investigational drug candidates in the U.S. until we receive approval from the FDA. As a consequence, any failure to obtain or delay in obtaining FDA approval for our investigational drug candidates would delay or prevent our ability to generate revenue from our investigational drug candidates, which would adversely affect our financial results and our business.

Our applications for regulatory approval could be delayed or denied due to problems with studies conducted before we licensed some of our investigational drug candidates from third parties.

We currently license some of our investigational drug candidates from third parties. Our present development programs involving these investigational drug candidates rely in part upon previous development work conducted by third parties over whom we had no control and before we licensed the investigational drug candidates. In order to receive regulatory approval of an investigational drug candidate, we must present to the FDA for its review all relevant data and information obtained during research and

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development, including research conducted prior to our license of the investigational drug candidate. Although we are not currently aware of any such problems, any problems that emerge with research and testing conducted prior to our licensing an investigational drug candidate may affect future results or our ability to document prior research and to conduct clinical trials, which could delay, limit or prevent regulatory approval for our investigational drug candidates.

Following regulatory approval of any investigational drug candidates, and in connection with the marketing of approved drugs, we will be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our drugs.

If one of our investigational drug candidates is approved by the FDA or by another regulatory authority for a territory outside of the U.S., or if avanafil is marketed in the U.S., we will be required to comply with extensive regulations for drug manufacturing, labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion and record keeping. 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 if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a drug's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. For example, the label ultimately approved for Qnexa, if any, may include restrictions on use, including restrictions based on pregnancy status, level of obesity and duration of treatment or a boxed warning related to concerns regarding antidepressants, antiepileptics or otherwise. If so, we may be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize Qnexa. The FDA may also require the distribution of a Medication Guide to patients outlining the increased risk of suicidal thinking or behavior in children and adolescents or other populations. The FDA could also require a registry to track the patients utilizing the drug or implement a REMS that could restrict access to the drug, reduce our revenues and/or increase our costs.

Included with the October 17, 2011 resubmission of the Qnexa NDA was a proposed REMS framework. We discussed the REMS framework with the FDA and the details of the Qnexa REMS were discussed during the Advisory Committee meeting, held February 22, 2012. On April 4, 2012, following the FDA's request, we submitted a comprehensive REMS, which was considered a major amendment to the NDA.

Potentially costly post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Our resubmission of the NDA for Qnexa states that we plan to conduct a cardiovascular outcomes study post-approval, and we have since submitted a draft protocol to the FDA. The details of this study are under discussion with the FDA. This study could cost \$100 to \$200 million dollars and take as long as five or six years to complete. Although no other requests for additional information or pre-approval studies were made by the FDA at these meetings or in the CRL, there can be no assurance that the FDA will not request or require us to provide additional information or undertake additional prospective studies or retrospective observational studies in connection with the Qnexa NDA.

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our future approved drugs, if any, and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject a drug, its manufacturer and the manufacturer's facilities to continual review and inspections. The subsequent discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured, may result in restrictions on the marketing of that drug, up to and including withdrawal of the drug from the market. If the manufacturing facilities of our suppliers fail to comply with applicable regulatory requirements, it could result in regulatory action and additional costs to us. Failure to comply with applicable FDA and other regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed

sanctions, including:

- issuance of Form 483 notices, warning letters and adverse publicity by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties due to product liability or other issues;
- criminal prosecutions;
- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing clinical trials;
- total or partial suspension of manufacturing;

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- delays in commercialization;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our collaborators;
- refusals to permit drugs to be imported into or exported from the U.S.;
- restrictions on operations, including costly new manufacturing requirements; and
- product recalls or seizures.

We have an agreement with MTPC to supply the active pharmaceutical ingredient, or API, and the tablets for avanafil. The MTPC manufacturing sites have been inspected by the U.S. and EU authorities. We do not believe the results of those inspections will have an impact on MTPC's ability to supply avanafil, or the approval, or the timing of approval, of avanafil in the EU. However, if MTPC is unable to receive approval from foreign authorities, and maintain ongoing FDA or foreign regulatory compliance, or manufacture avanafil API or tablets in sufficient quantities to meet projected demand, the EU approval, the U.S. commercial launch, and future sales of avanafil will be adversely effected, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration for the commercialization of avanafil.

In addition, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our investigational drug candidates. Contract Manufacturing Organizations, or CMOs, and their vendors or suppliers may also face changes in regulatory requirements from governmental agencies in the U.S. and other countries. We cannot predict the likelihood, nature, extent or effects of government regulation that may arise from future legislation or administrative action, either in the U.S. or elsewhere. If we are not able to maintain regulatory compliance, we might not be permitted to market any future approved drugs and our business could suffer.

Even if we receive regulatory approval to commercialize our investigational drug candidates, our ability to generate revenues will be subject to a variety of risks, many of which are out of our control.

Even if our investigational drug candidates obtain regulatory approval, or if we market avanafil in the U.S., those drugs may not gain market acceptance among physicians, patients, healthcare payers or the medical community. The indication may be limited to a subset of the population or we may implement a distribution system and patient access program that is limited. For example, the FDA approved label for avanafil in the U.S. is contraindicated in patients taking nitrates. This contraindication may limit the commercial profile of avanafil, which we intend to market through a partner in the U.S. under the name Stendra. Coverage and reimbursement of our investigational drug candidates or approved drugs by third-party payers, including government payers, generally is also necessary for optimal commercial success. 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:

- timing of market introduction of competitive drugs;
- efficacy and safety of our investigational drug candidates or approved drugs;
- prevalence and severity of any side effects;
- results of any post-approval studies of the drug;
- potential or perceived advantages or disadvantages over alternative treatments including generics;
- the relative convenience and ease of administration and dosing schedule;
- strength of sales, marketing and distribution support;
- price of any future drugs, if approved, or avanafil in the U.S., both in absolute terms and relative to alternative treatments;
- the effectiveness of our or any future collaborators' sales and marketing strategies;

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- the effect of current and future healthcare laws on our investigational drug candidates, or avanafil in the U.S.;
- availability of coverage and reimbursement from government and other third-party payers;
- patient access programs that require patients to provide certain information prior to receiving new and refill prescriptions;
- requirements for prescribing physicians to complete certain educational programs for prescribing drugs;
- the willingness of patients to pay out of pocket in the absence of government or third-party coverage; and
- product labeling or product insert requirements of the FDA or other regulatory authorities.

If approved, our investigational drug candidates or approved drugs may fail to achieve market acceptance or generate significant revenue to achieve or sustain profitability. In addition, our efforts to educate the medical community and third-party payers on the safety and benefits of our investigational drug candidates or approved drugs may require significant resources and may never be successful.

We have limited sales and marketing experience and no sales capabilities and we may not be able to effectively market and sell our investigational drug candidates, if approved, or our approved drugs, in the U.S. and/or internationally without a global pharmaceutical partner.

We are developing Qnexa, our investigational drug candidate for the treatment of obesity, for large markets traditionally served by general and family practitioners and internists. Generalist physicians number in the several hundred thousands in the U.S. Traditional pharmaceutical companies employ groups of sales representatives numbering in the thousands to call on this large generalist physician population. In order to adequately address these physician groups, we must establish sales and marketing collaborations or co-promotion arrangements or expend significant resources to develop our own sales and marketing presence. We currently have limited resources and may not be successful in developing our own sales and marketing presence or establishing sales and marketing collaborations or co-promotion arrangements on acceptable terms, if at all. We may also decide to forego any form of collaboration and develop sales and marketing capabilities on our own. We also face competition in our search for collaborators, co-promoters and sales force personnel. We may rely on third parties to develop or commercialize our investigational drug candidates or approved drugs. These third parties may fail to develop or effectively commercialize our investigational drug candidates or approved drugs because they cannot obtain the necessary regulatory approvals, decide to pursue a competitive potential product that may be developed outside of the collaboration or fail to devote the resources necessary to realize the full commercial potential of our investigational drug candidates or approved drugs.

Even if our investigational drug candidates receive regulatory approval in the U.S., we may never receive approval for or commercialize our drugs outside of the U.S.

To market any of our investigational drug candidates outside of the U.S., we and our partners must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the U.S. As described above, such effects include the risks that our investigational drug candidates may not be approved for all indications requested, which could limit the uses of our investigational drug candidates and have an adverse effect on their commercial potential or require costly, post-marketing follow-up studies.

On December 17, 2010, we filed an MAA, with the EMA for Qnexa Controlled-Release Capsules in the EU. The proposed indication in the EU is for the treatment of obesity, including weight loss and maintenance of weight loss, and should be used in conjunction with a mildly hypocaloric diet. The EMA's review of Qnexa will follow their centralized marketing authorization procedure. If approved, Qnexa could receive marketing authorization in all 27 EU member countries. The MAA was officially validated for central procedure on January 19, 2011. If approved in the EU, Qnexa could be recommended for obese adult patients ($\text{BMI} \geq 30 \text{ kg/m}^2$), or overweight patients ($\text{BMI} \geq 27 \text{ kg/m}^2$) with weight-related co-morbidities such as hypertension, type 2 diabetes or dyslipidemia. In May 2011, we received a response to our MAA from the CHMP. The response was in the form of the 120-day questions. The 120-day questions covered a broad range of topics including, without limitation, issues relating to phentermine, which

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include historical concerns regarding its potential association with valvulopathy and pulmonary hypertension; heart rate and limited long-term safety data in high-risk patients; and known and suspected effects of topiramate which include CNS and teratogenic potential. The CHMP also had questions concerning our proposed risk management plan for Qnexa. The 120-day questions were consistent with the issues previously raised in the FDA review process. We met with representatives from the CHMP in September 2011 to seek clarification on certain questions. We submitted our response to the 120-day questions in the fourth quarter of 2011. In January 2012, we received the 180-day List of Outstanding Issues, or 180-day LOI, from the CHMP. In order to perform additional analyses to allow further insights into the data as previously presented, we requested and, in April 2012, we received a two-month extension to respond to the 180-day LOI. The 180-day LOI contained requests for additional information including risk minimization activities to address various issues relating to cardiovascular, neuropsychiatric and potential teratogenic effects of Qnexa. In addition, we were asked to discuss the benefit/risk of the different doses of Qnexa, its potential use in different patient populations, and the expected long-term benefit of treatment with Qnexa. We have submitted our response to the 180-day LOI. There can be no assurance that our response will be adequate or that our MAA will be approved by the CHMP. Absent a delay, we anticipate an opinion from the CHMP in the second quarter of 2012.

In June 2011, we submitted an NDA to the FDA seeking approval of avanafil for the treatment of ED. We received the FDA's approval of the avanafil NDA on April 27, 2012, in advance of the April 29, 2012 PDUFA target date. We submitted and the EMA accepted our MAA for avanafil in the EU in March 2012. While we have obtained FDA approval of avanafil, there can be no guarantee that the MAA for avanafil will be approved in the EU.

We rely on third parties to conduct pre-clinical, clinical and retrospective observational trials and studies for our investigational drug candidates and those third parties may not perform satisfactorily.

We do not have the ability to conduct pre-clinical, clinical or retrospective observational studies for our investigational drug candidates without the assistance of third parties who conduct the studies on our behalf. These third parties are usually toxicology facilities, safety monitoring companies, epidemiologists, clinical investigators and clinical sites and clinical research organizations, or CROs, which have significant resources and experience in the conduct of pre-clinical and clinical studies. The toxicology facilities conduct the pre-clinical safety studies as well as all associated tasks connected with these studies. Safety monitoring companies collect reported adverse events that are reported from patients and healthcare providers during clinical trials. Clinical investigators and clinical sites enroll patients and conduct clinical testing according to clinical protocols. Epidemiologists employ programmers and have access to electronic databases that allow them to perform historical studies. The CROs typically review data generated by clinical investigators, perform project management, data management, statistical analysis, and other reporting functions. We intend to use several different facilities and CROs for all of our pre-clinical and clinical studies. We have contracted with a safety monitoring company that we intend to use for all of our clinical trials. If these third party toxicology facilities, the safety monitoring company, clinical investigators, clinical sites or CROs do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approvals for our investigational drug candidates on a timely basis, if at all, and we may not be able to successfully commercialize these investigational drug candidates. For example, in July 2011, the FDA notified pharmaceutical companies that studies conducted by Cetero Research between April 2005 and June 2010 in support of marketing applications may need to be repeated or confirmed due to concerns related to data integrity. We have not used and do not intend to utilize the services of Cetero. If our third party toxicology facilities, safety monitoring company, clinical investigators, epidemiologists, clinical sites or CROs do not perform satisfactorily, we may not be able to locate acceptable replacement third parties or enter into favorable agreements with these third parties. These third parties may also fail economically, which would impact our ability to obtain and utilize the results of the studies performed by these third parties.

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 future commercial operations and an interruption to this service may harm our business.

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

We or our third-party manufacturers and collaborative partners may encounter delays and problems in manufacturing our investigational drug candidates or approved drugs for a variety of reasons, including accidents during operation, failure of equipment, delays in receiving materials, natural or other disasters, political or governmental changes, or other factors inherent in operating complex manufacturing facilities. Supply chain management is difficult. Commercially available starting materials, reagents and excipients may become scarce or more expensive to procure, and we may not be able to obtain favorable terms in agreements with

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subcontractors. We or our third-party manufacturers may not be able to operate our respective manufacturing facilities in a cost-effective manner or in a time frame that is consistent with our expected future manufacturing needs. If we or 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.

We have completed the development of a once-a-day formulation of Qnexa for the treatment of obesity. The contract manufacturer we selected to develop a once-a-day formulation supplied the entire product for the Phase 3 program. In addition, this contract manufacturer is our sole source of clinical and commercial supplies for Qnexa. While this contract manufacturer has significant experience in commercial scale up manufacturing, there is no assurance that they will be successful with the commercial scale up of Qnexa, which could have a material adverse impact on our development plan, market price of our common stock and financial condition.

In the case of avanafil, we rely on MTPC to supply the API and the tablets. The MTPC manufacturing sites for avanafil have been inspected by the U.S. and EU authorities. We do not believe the results of those inspections will have an impact on MTPC's ability to supply avanafil, or the approval, or the timing of approval, of avanafil in the EU. However, if MTPC is unable to receive approval from foreign authorities, and maintain ongoing FDA or foreign regulatory compliance, or manufacture avanafil API or tablets in sufficient quantities to meet projected demand, the EU approval, the U.S. commercial launch, and future sales of avanafil will be adversely effected, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration for the commercialization of avanafil.

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

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

Risks Relating to our Operations

If we, or our suppliers, fail to comply with FDA and other regulatory agency regulations relating to our commercial manufacturing operations, we may be prevented from manufacturing our approved drugs, or may be required to undertake significant expenditures to become compliant with such regulations.

After regulatory approval for a product is obtained, the product is subject to continual regulatory review. Manufacturing, labeling and promotional activities are continually regulated by the FDA and equivalent foreign regulatory agencies. For example, our third party manufacturers are required to maintain satisfactory compliance with current Good Manufacturing Practices, or cGMP. If these manufacturers fail to comply with applicable regulatory requirements, our ability to manufacture, market and distribute our drugs may be adversely affected. In

addition, the FDA could issue warning letters or could require the seizure or recall of products. The FDA could also impose civil penalties or require the closure of our contract manufacturing facility until cGMP compliance is satisfactorily achieved.

We obtain the necessary raw materials and components for the manufacture of Qnexa and avanafil as well as certain services, such as analytical testing packaging and labeling, from third parties. We currently contract with suppliers and service providers, including foreign manufacturers. We and these suppliers and service providers are required to follow cGMP requirements and are subject to routine and unannounced inspections by the FDA and by state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Upon inspection of these facilities, the FDA or foreign regulatory agencies may find the manufacturing process or facilities are not in compliance with cGMP requirements and other regulations.

Failure to achieve satisfactory cGMP compliance as confirmed by routine and unannounced inspections could have a material adverse effect on our ability to continue to manufacture and distribute avanafil in the U.S., and any other commercial drugs, if approved, and, in the most serious case, result in the issuance of a regulatory warning letter or seizure or recall of products, injunction and/or civil penalties or closure of our manufacturing facility until cGMP compliance is achieved.

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

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third party payers, certain federal and state healthcare laws and regulations pertaining to fraud, abuse and patients' rights are and will be applicable to our business. We are subject to healthcare fraud, abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, but are not limited to:

- the federal healthcare program Anti-Kickback Law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payers that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

Any pre-marketing and marketing activities for our investigational drug candidates, or approved drugs, are subject to continued governmental regulation.

Prior to and after product approval by the FDA, any pre-marketing and marketing activities will be subject to FDA and other regulatory review. Certain activities undertaken prior to approval may be considered pre-approval promotion. Pre-approval promotion of investigational drug candidates is prohibited by FDA regulations. Failure to comply with these regulations may result in delays in the ultimate approval of our investigational drug candidates. After approval, if products are marketed in contradiction with FDA mandates, the FDA may issue warning letters that require specific remedial measures to be taken, as well as an immediate cessation of the impermissible conduct resulting in adverse publicity. The FDA may also order 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. Qnexa, if approved, and avanafil, would be subject to these regulations. Failure to comply with state requirements may affect our ability to promote or sell pharmaceuticals drugs in certain states. This in turn could have a material adverse impact on our financial results and financial condition.

We must continue to monitor the use of our drugs, if approved, and may be required to complete post-approval studies mandated by the FDA.

Even if we receive regulatory approval of our investigational drug candidates, such approval may involve limitations on the indicated uses or marketing claims we may make for our drugs and distribution channels. The FDA may also require us to commit to perform lengthy post-approval studies, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results, financial condition and stock price. Failure to comply with the applicable regulatory requirements can result in, among other things, civil penalties, suspensions of regulatory approvals, product recalls, 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.

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As part of the approval for avanafil, the FDA is requiring us to perform two post-approval clinical studies. One study will be a randomized, double-blind, placebo-controlled, parallel group multicenter clinical trial on the effect of avanafil on spermatogenesis in healthy adult males and males with mild erectile dysfunction. The other study will be a double-blind, randomized, placebo-controlled, single-dose vision clinical trial to assess the effects of avanafil on multiple parameters of vision, including, but not limited to visual acuity, intraocular pressure, pupillometry, and color vision discrimination in healthy male subjects. The protocols for both studies are to be submitted to the FDA on or before August 2012.

Sales of any future drugs are subject to continued governmental regulation, as well as our ability to accurately forecast demand and our ability to produce sufficient quantities to meet demand.

Sales of any future drugs both inside and outside the U.S. will be subject to regulatory requirements governing marketing approval. These requirements vary widely from country to country and could delay the introduction of our proposed drugs in those countries. After the FDA and international regulatory authorities approve a product, we must manufacture sufficient volumes to meet market demand. This is a process that requires accurate forecasting of market demand. There is no guarantee that there will be market demand for any future drugs or that we will be able to successfully manufacture or adequately support sales of any future drugs.

We have limited sales and marketing capabilities in the U.S.

If we are unable to establish capabilities to sell, market and distribute our investigational drug candidates, if approved, or our approved drugs, either by developing our own capabilities or entering into agreements with others, we will not be able to successfully launch our investigational drug candidates, or approved drugs, upon FDA approval. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need. We may not be able to enter into any marketing or distribution agreements with third party providers on acceptable terms, if at all. In that event, our ability to generate revenues will be adversely affected.

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

Competition in the pharmaceutical and medical products industries is intense and is characterized by costly and extensive research efforts and rapid technological progress. We are aware of several pharmaceutical companies also actively engaged in the development of therapies for the treatment of obesity, diabetes and sexual health and medical device companies for the treatment of sleep apnea. Many of these companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. In addition, many of these companies have significantly greater experience than us in undertaking pre-clinical testing, human clinical trials and other regulatory approval procedures. 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 avanafil and any other drugs, if approved, or our investigational drug candidates less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience. Mergers, acquisitions, joint ventures and similar events may also significantly change the competition.

Currently approved anti-obesity drugs include Xenical (orlistat), marketed by Roche, the over-the-counter version, alli, marketed by GlaxoSmithKline, and phentermine, in several dosage forms and strengths which are available from several generic manufacturers. Orlistat

works by inhibiting lipase, thus preventing digestion and absorption of dietary fat in the gastrointestinal tract. Meridia (sibutramine) was previously marketed by Abbott Laboratories; however, in October 2010, Abbott Laboratories withdrew Meridia in the U.S. at the FDA's request. The FDA requested the withdrawal because they believed Meridia's risks were not justified compared with the modest weight loss that patients achieved on the drug. In January 2010, the EMA suspended the marketing authorization of sibutramine in Europe. The impact on Qnexa of the withdrawal of sibutramine is unknown at this time. There are several drugs in development for obesity including an investigational drug candidate, liraglutide (3.0 mg for subcutaneous injection), in Phase 3 clinical trials being developed by Novo Nordisk A/S and several other investigational drug candidates in Phase 2 clinical trials. Amylin Pharmaceuticals, Inc. and Takeda Pharmaceutical Company Limited announced that they have discontinued clinical activities in an ongoing Phase 2 study examining the safety and effectiveness of the investigational combination therapy pramlintide/metreleptin for the treatment of obesity. Arena Pharmaceuticals, Inc. and Orexigen Therapeutics, Inc. have each submitted an NDA to the FDA for their investigational obesity drug candidates. Neither of these investigational drug candidates was approved by the FDA citing concerns around carcinogenicity in the case of Arena and the need to complete a pre-approval cardiovascular outcomes study in the case of Orexigen. According to Orexigen, the FDA requested a cardiovascular outcomes trial with an interim analysis to enable possible FDA approval of Contrave if the upper bound of the 95% confidence interval is less than 2. They further estimate that the interim analysis will require 87 major cardiovascular events (CV death, myocardial infarction and stroke) and will

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cost less than \$100 million. Orexigen has agreed to complete this study. In January 2012, Arena announced that the FDA accepted for filing and review their resubmission of the NDA for lorcaserin, informed Arena that there will be an Endocrinologic and Metabolics Advisory Committee meeting, and assigned a new PDUFA target date of June 27, 2012. The future of the Arena and Orexigen compounds is uncertain at this time.

In June 2011, the FDA approved an NDA, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for Suprenza (phentermine hydrochloride) orally dissolving tablets, 15 mg and 30 mg to be marketed and distributed by Akrimax Pharmaceuticals, LLC of New Jersey. This new drug application provides for the use of Suprenza (phentermine hydrochloride) orally dissolving tablets, 15 mg and 30 mg as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification, and caloric restriction in the management of exogenous obesity for patients with an initial body mass index ≥ 30 kg/m², or ≥ 27 kg/m² in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). No clinical trials were conducted for Suprenza, rather drugs submitted for approval under section 505(b)(2) are typically approved through the use of bioequivalence studies which show blood levels of the active pharmaceutical ingredient (API) of the drug seeking approval are consistent with those that had been previously approved. We are uncertain as to the impact, if any, of the approval of Suprenza on the approvability or future commercial success of Qnexa.

The currently approved oral medications for type 2 diabetes include insulin releasers such as glyburide, insulin sensitizers such as Actos and Avandia, inhibitors of glucose production by the liver such as metformin, DPP-IV inhibitors like sitagliptin (FDA approved 2006, marketed by Merck & Co. as Januvia), vildagliptin (EU approved 2007, marketed in the EU by Novartis as Galvus), saxagliptin (FDA approved in 2009, marketed as Onglyza by AstraZenca), and linagliptin (FDA approved in 2011, marketed as Trajenta by Eli Lilly Co. and Boehringer Ingelheim), as well as Precose and Glyset, which slow the uptake of glucose from the intestine. Approved injectable medications for type 2 diabetes treatment include glucagon-like peptide-1, or GLP-1, analogs such as Liraglutide, marketed under the brand name Victoza, developed by Novo Nordisk and Exenatide, marketed under the brand name Byetta, and a long-acting version of Exenatide marketed under the brand name Bydureon, developed by Amylin Pharmaceuticals and Eli Lilly and Company. Studies to date suggest GLP-1s improve control of blood glucose by increasing insulin secretion, delaying gastric emptying, and suppressing prandial glucagon secretion. Clinical studies have reported that patients treated with GLP-1s have reported weight loss of approximately six to eight pounds.

Many of these drugs, if approved, are or will be marketed by pharmaceutical companies with substantially greater resources than us. In addition, a number of generic pharmaceutical drugs are prescribed for obesity, predominantly phentermine. Phentermine is sold at much lower prices than we intend to charge for our investigational drug candidate, Qnexa, if approved. The availability of a branded prescription drug, generic drugs and over-the-counter drugs could limit the demand for, and the price we are able to charge for Qnexa, if approved.

There are also surgical approaches to treat severe obesity that are becoming increasingly accepted and could become competitors against our investigational drug candidate, Qnexa. Two of the most well established surgical procedures are gastric bypass surgery and adjustable gastric banding, or lap bands. In February 2011, the FDA approved the use of a lap band in patients with a BMI of 30 (reduced from 35) with co-morbidities. The lowering of the BMI requirement will make more obese patients eligible for lap band surgery. It is indicated for use in adult patients who have failed more conservative weight reduction alternatives, such as supervised diet, exercise and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives. The potential impact on Qnexa and/or other weight loss pharmacotherapy is unknown. 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. If approved, the companies that market these drugs may have substantially greater resources than we have.

Significant competitive therapies exist for avanafil in the form of oral medications marketed by Pfizer, Inc. under the name Viagra®, Cialis®, marketed by Eli Lilly and Company, and Levitra®, which is co-marketed by GlaxoSmithKline plc and Schering-Plough Corporation in the U.S. In 2010, the European Commission approved a new formulation of Levitra (vardenafil HCl). Levitra 10mg oral-disintegrating tablet, or ODT, is the first erectile dysfunction, or ED, medication available in an ODT form. In the U.S., the medication was approved in June 2010 and is

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marketed by GlaxoSmithKline and Merck & Co., Inc. under the tradename STAXYN . We are uncertain how the launch of ODT vardenafil will impact the future commercial potential of avanafil, which we intend to market through a partner in the U.S. under the name Stendra.

There are currently three PDE5 inhibitors approved for the treatment of erectile dysfunction in the U.S.: sildenafil, vardenafil, and tadalafil. Worldwide sales of these products were approximately \$4.2 billion in 2011. As the patents for the three major PDE5 inhibitors currently being sold expire, generic PDE5s will enter the marketplace. Generic PDE5s would likely be sold at lower prices and may reduce the demand for avanafil and the prices we intend to charge for avanafil. For example, we are in discussion with MTPC about certain aspects of the license agreement relating to the manufacture and supply of avanafil. We have become aware that the cost of goods sold under this agreement may be higher than expected. As a result, we may charge more for avanafil, which could limit the profitability of avanafil. Failure to reach agreement with MTPC may have an adverse impact on the commercial future of

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avanafil. Additional PDE5 inhibitors are in various stages of development by other companies. Warner-Chilcott plc has licensed the U.S. rights to udenafil, a PDE5 inhibitor from Dong-A. Warner-Chilcott continues the Phase 3 development of this compound for ED. In April 2010, Warner-Chilcott and Dong-A expanded their agreement to include the right to develop, and if approved, market, the treatment of lower urinary tract symptoms, or LUTS, associated with Benign Prostatic Hyperplasia, or BPH, in the U.S. and Canada. Recently, Cialis has been approved for treatment of enlarged prostate.

In March 2010, Pfizer brought a patent-infringement action in the U.S. District Court for the Eastern District of Virginia against Teva Pharmaceuticals USA, Inc., or Teva USA, and Teva Pharmaceutical Industries Ltd., or Teva Pharmaceutical Industries, which had filed an abbreviated new drug application with the FDA seeking approval to market a generic version of Viagra. Teva USA and Teva Pharmaceutical Industries assert the invalidity and non-infringement of the Viagra use patent, which expires in 2019, but have not challenged the basic patent, which expires in 2012. In August 2011, Pfizer prevailed in this case against Teva.

Teva filed a Notice of Appeal on September 9, 2011 and the case is Federal Circuit Appeal Case No. 2011-1594. Briefing on the appeal has not yet been completed. In October 2010, Pfizer filed a patent-infringement action with respect to Viagra in the U.S. District Court for the Southern District of New York against Apotex Inc. and Apotex Corp., Mylan Pharmaceuticals Inc. and Mylan Inc., Actavis and Amneal Pharmaceuticals LLC. These generic manufacturers have filed abbreviated new drug applications with the FDA seeking approval to market their generic versions of Viagra. They assert the invalidity and non-infringement of the Viagra use patent, but have not challenged the basic patent. The case against Apotex *et al.* was stayed on February 24, 2012 pending the final disposition of Appeal No. 2011-1594 in the Teva action, including any *en banc* review.

Other treatments for ED exist, such as needle injection therapies, vacuum constriction devices and penile implants, and the manufacturers of these products will most likely continue to develop or improve these therapies.

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 investigational drug candidates obsolete or noncompetitive. Compared to us, many of our potential competitors have substantially greater:

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

- access to strategic partners and capital resources.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our investigational drug candidates. Our competitors may also develop drugs or surgical approaches that are more effective, more useful and less costly than ours and may also be more successful in manufacturing and marketing their products. In addition, our competitors may be more effective in commercializing their products. We currently outsource our manufacturing and therefore rely on third parties for that competitive expertise. There can be no assurance that we will be able to develop or contract for these capabilities on acceptable economic terms, or at all. Orexigen Therapeutics, manufacturers of Contrave, an investigational drug for the treatment of obesity, received a CRL from the FDA requesting that a long-term, randomized, placebo-controlled cardiovascular outcomes study be completed prior to refiling the NDA. To date, the FDA has not requested that we perform any additional studies, including cardiovascular outcome studies pre-approval, other than FORTRESS. Cardiovascular outcomes studies can take several years, cost tens to hundreds of millions of dollars and may result in showing an increased risk for major adverse cardiovascular events for patients in the treatment arm. Our resubmission of the NDA for Qnexa states that we plan to conduct a cardiovascular outcomes study post-approval, which could impact the commercialization of Qnexa, if approved. If any regulatory agency were to require additional studies, pre- or post-approval, the impact on the timing of approval and, if approved, commercialization of Qnexa or any of our investigational drug candidates, could be delayed or adversely impacted. The FDA is requiring us to conduct post-approval studies for avanafil which may delay or adversely impact the commercialization of avanafil, including our ability to enter into a collaboration for the commercialization of avanafil in the U.S.

If our raw material supplier fails to supply us with the active pharmaceutical ingredients, or APIs, for our investigational drug candidates or approved drugs, for which availability is limited, we may experience delays in our investigational drug candidate development and approved drug commercialization.

We currently do not have supply agreements in place for phentermine or topiramate, the APIs used in our investigational drug candidate, Qnexa, nor do we have a supply agreement for the commercial manufacture of Qnexa, if approved. There can be no guarantees that we will be able to enter into such agreements under reasonable terms, if at all. We cannot guarantee that should we be successful in entering into such agreements we will be able to obtain the necessary prior regulatory approvals for these suppliers.

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MTPC manufactures the API and the tablets for avanafil. To date, MTPC has never manufactured commercial quantities of API or tablets for us. The MTPC manufacturing sites for avanafil have been inspected by the U.S. and EU authorities. We do not believe the results of those inspections will have an impact on MTPC's ability to supply avanafil, or the approval, or the timing of approval, of avanafil in the EU. However, if MTPC is unable to receive approval from foreign regulators and maintain ongoing FDA or foreign regulatory compliance, or manufacture avanafil API or tablets in sufficient quantities to meet projected demand, the EU approval, the U.S. commercial launch, and future sales of avanafil will be adversely effected, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration for the commercialization of avanafil.

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 obtain regulatory approval for our investigational drug candidates 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.

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, sales and marketing, research and development, regulatory and legal affairs, clinical trial design, execution and analysis, and pre-clinical testing. There can be no assurance that we will be able to hire or retain such personnel, as we must compete with other companies, academic institutions, government entities and other agencies. The loss of any of our key personnel or the failure to attract or retain necessary new employees could have an adverse effect on our research, investigational drug candidate development, approved drug commercialization and business operations.

Allegations of discrimination, wrongful termination or other employment matters, regardless of merit, could negatively affect our operations by causing us to allocate additional monetary and personnel resources in defense of such matters.

In the normal course of business we may become involved in lawsuits and subject to various claims from current and former employees including wrongful termination, sexual discrimination, retaliation, hostile work environment and other employment-related matters. We were party to a lawsuit involving a former employee which lawsuit was dismissed without prejudice to the plaintiff to refile certain of his state law claims. We have also been named as a potential defendant in a complaint filed by a former employee. We have investigated each of the former employee claims and believe the allegations have no merit and that we have meritorious defenses to any such allegations. Due to the current economic downturn, former employees may be more likely to file employment-related claims. Employment-related claims also appear more likely following a poor performance review. Although there may be no merit to such claims or legal matters, we may be required to allocate additional monetary and personnel resources to defend against these type of allegations.

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

In the U.S. and abroad, sales of pharmaceutical drugs are dependent, in part, on the availability of reimbursement to the consumer from third party payers, such as government and private insurance plans. Third party payers are increasingly challenging the prices charged for medical products and services. Some third party payer benefit packages restrict reimbursement 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 payers.

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 payers 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

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measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide. These changes could impact our ability to maximize revenues in the Federal marketplace. In addition, healthcare reform legislation could affect the price of our approved drugs or our investigational drug candidates, if approved, under certain healthcare programs. These proposals include expanding the 340B drug pricing program to allow additional types of healthcare providers to purchase drugs at significant discounts and to require those discounts on inpatient drugs as well, increasing the minimum Medicaid drug rebate percentage, expanding Medicaid rebate liability to drugs purchased under Medicaid managed care contracts, increasing the Medicaid rebate on new formulations of existing drugs, and requiring Medicaid rebates to be paid on drugs provided to certain enrollees in the Medicare Part D prescription drug benefit. Due to uncertainties regarding the outcome of healthcare reform initiatives and their enactment and implementation, we cannot predict which, if any, of the reform proposals will be adopted or the effect such adoption may have on us. 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 Qnexa, if approved.

We expect to experience pricing pressures in connection with the sale of avanafil 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. If we fail to successfully secure and maintain reimbursement coverage for our investigational drug candidates or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our investigational drug candidates and our business will be harmed. Congress has enacted healthcare reform and may enact further reform, which could adversely affect the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business.

Both of the active ingredients in Qnexa, phentermine and topiramate are available as generics. Based on the research we have completed to date, we are unable to determine whether Qnexa, if approved, will be subject to reimbursement or at what level reimbursement may occur. The exact doses of the active ingredients in the final formulation of Qnexa will be different than those currently available. State pharmacy laws prohibit pharmacists from substituting drugs with differing doses and formulations. The safety and efficacy of Qnexa 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 Qnexa as a treatment for obesity or any other indication, if approved, from third party payers 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 Qnexa in order to treat obesity at a potential lower cost.

Federal legislation may increase the pressure to reduce prices of pharmaceutical drugs paid for by Medicare, which could adversely affect our future revenues, if any.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, expanded Medicare coverage for drug purchases by the elderly and disabled beginning in 2006. Under the MMA, private insurance plans subsidized by the government offer prescription drug coverage to Medicare beneficiaries who elect to enroll in their plans. Although almost all prescription drugs are potentially available to plan enrollees, the plans are allowed to use formularies, preferred drug lists and similar mechanisms to favor selected drugs and limit access to other drugs except in certain circumstances. The price of a drug as negotiated between the manufacturer and a plan is a factor that the plan can consider in determining its availability to enrollees.

As a result, we expect that there will be increased pressure to reduce prices for drugs to obtain favorable status for them under the plans offering prescription drug coverage to Medicare beneficiaries. This pressure could decrease the coverage and price that we receive for our approved drugs or our investigational drug candidates, if approved, in the future and could seriously harm our business. It is possible that our investigational drug candidate, Qnexa, if approved, could be particularly subject to price reduction initiatives because it is based on combinations of lower priced existing drugs.

In addition, some members of Congress advocate that the federal government should negotiate directly with manufacturers for lower prices for drugs in the Medicare program, rather than rely on private plans. If the law were changed to allow or require such direct negotiation, there could be additional reductions in the coverage of and prices that we receive for any future approved drugs.

Federal legislation and actions by state and local governments may permit re-importation of drugs from foreign countries into the U.S., including foreign countries where the drugs are sold at lower prices than in the U.S., which could adversely affect our operating results and our overall financial condition.

We may face competition for our approved drugs or our investigational drug candidates, if approved, from lower priced products from foreign countries that have placed price controls on pharmaceutical products. The MMA contains provisions that may change U.S. importation laws and expand consumers' ability to import lower priced versions of our investigational drug candidates and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not

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take effect unless and until the Secretary of Health and Human Services certifies that the changes will lead to substantial savings for consumers and will not create a public health safety issue. The Secretary of Health and Human Services has not yet announced any plans to make this required certification. As directed by Congress, a task force on drug importation conducted a comprehensive study regarding the circumstances under which drug importation could be safely conducted and the consequences of importation on the health, medical costs and development of new medicines for U.S. consumers. The task force issued its report in December 2004, finding that there are significant safety and economic issues that must be addressed before importation of prescription drugs is permitted. In addition, a number of federal legislative proposals have been made to implement the changes to the U.S. importation laws without any certification, and to broaden permissible imports in other ways. Even if the changes do not take effect, and other changes are not enacted, imports from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, the U.S. Customs Service and other government agencies. For example, Pub. L. No. 109-295, which was signed into law in October 2006 and provides appropriations for the Department of Homeland Security for the 2007 fiscal year, expressly prohibits the U.S. Customs Service from using funds to prevent individuals from importing from Canada less than a 90-day supply of a prescription drug for personal use, when the drug otherwise complies with the Federal Food, Drug, and Cosmetic Act. Further, several states and local governments have implemented importation schemes for their citizens and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts. The importation of foreign products that compete with our future approved drugs, if any, could negatively impact our financial condition.

Defending against claims relating to improper handling, storage or disposal of hazardous materials could be time consuming and expensive.

Our research and development involves the controlled use of hazardous materials and our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from those materials. Various laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

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

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

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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, in 2005, our clinical trials in the New Orleans area were interrupted by Hurricane Katrina. In addition, our offices are located in the San Francisco Bay Area near known earthquake fault zones and are therefore vulnerable to damage from earthquakes. In October 1989, a major earthquake in our area caused significant property damage and a number of fatalities. Our supplier of avanafil is located in Japan near known earthquake fault zones and is vulnerable to damage from earthquakes and tsunamis. We are also vulnerable to damage from other disasters, such as power loss, fire, floods and similar events. If a significant disaster occurs, our ability to continue our operations could be seriously impaired and we may not have adequate insurance to cover any resulting losses. Any significant unrecoverable losses could seriously impair our operations and financial conditions.

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Risks Relating to our Intellectual Property

We may be sued for infringing the intellectual property rights of others or others may infringe on our intellectual property rights.

There can be no assurance that our investigational drug candidates or approved drugs do not or will not infringe on the patent 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. 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 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 future approved drugs and our operating results would be harmed.

We believe the Supreme Court ruling in *KSR International Co. v. Teleflex, Inc.* raised the standards for patentability and ease the ability to show that a patent is obvious. This ruling will make it more difficult to obtain patents for combination pharmaceutical drugs. At the present time, we are unable to predict the impact, if any, that this ruling will have on our current or future patents and patent applications. If we are unable to defend the patents currently issued on our investigational drug candidates or approved drugs, or to obtain new patents for any reason, our ability to commercialize any approved drugs would be at risk.

Our inability to adequately protect our proprietary technologies could harm our competitive position and have a material adverse effect on our business.

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 male sexual health among other indications. Qnexa is our investigational drug candidate involving low doses of phentermine and topiramate. On June 6, 2006, the initial U.S. patent was issued by the USPTO. This patent contains composition, product, and other claims that should protect Qnexa, if approved, as a proprietary product for the treatment of obesity. The term of this patent extends into 2020. In August 2007, the European Patent Office granted European patent No. 1,187,603, which broadly covers Qnexa and its use as a weight loss treatment. The patent extends the intellectual property protection of Qnexa beyond the already issued patents in the U.S. and abroad. Patents have also been granted on Qnexa in Canada and Australia. We are in the process of prosecuting additional patent applications in these and other countries as well, to obtain significant foreign patent coverage for both Qnexa and future generations of Qnexa. Furthermore, we have filed additional patent applications in the U.S. to expand the coverage that will be provided by U.S. Patent No. 7,056,890. On March 9, 2010, U.S. Patent No. 7,674,776 issued with method, composition, and dosage form claims, including claims drawn to a method for treating Syndrome X, a common multisymptomatic disorder often found in obese patients, and to a method for treating side effects of obesity. On February 9, 2010, U.S. Patent No. 7,659,256 was issued, broadening both the method and composition-of-matter protection afforded Qnexa by our initial U.S. Patent No. 7,056,890. On June 30, 2009, U.S. Patent No. 7,553,818 was issued drawn to a method for effecting weight loss by co-administration of varying doses of phentermine and topiramate. This patent also expands on the initial coverage provided by our U.S. Patent No. 7,056,890 B2. Each of these U.S. patents for Qnexa expires in 2020. The primary focus of the patent applications is on combination therapy using a sympathomimetic agent (such as phentermine) and an anticonvulsant (such as topiramate) for the treatment of obesity and other related disorders, and on compositions and dosage forms employed in the therapy. We are aware of issued patents for the use of topiramate alone or in combination with other specific agents (zonisamide and mirtazapine) for treatment of obesity and related indications, e.g., prevention of weight gain. We have worked closely with our patent counsel to put together a cogent patent strategy and are building a strong patent portfolio in an attempt to obtain exclusivity over the life of the patents.

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. Obtaining patent rights outside the U.S. often requires the translation of highly technical documents and an improper translation could lead to the loss of, or otherwise jeopardize, the patent protection of our inventions. Ensuring adequate quality of translators and foreign patent attorneys is often very challenging. 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 be considered sufficient by parties reviewing our patent positions pursuant to a potential licensing or financing transaction.

In addition, other entities may challenge the validity or enforceability of our patents and patent applications in litigation or administrative proceedings. Even the issuance of a patent is not conclusive as to its validity or enforceability. We cannot make assurances as to how much protection, if any, will be given to our patents if we attempt to enforce them or they are challenged. It is possible that a competitor or a generic pharmaceutical provider may successfully challenge our patents and those challenges may result in reduction or elimination of our patents coverage.

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The USPTO has over the last few years tried to enact and/or has proposed changes in the rules governing a number of aspects of patent prosecution practice, including (i) the duties of patent applicants to disclose material information that relates to their applications, (ii) the ability of patent applicants to file unlimited numbers of patent applications and patent claims that concern closely related inventions and/or different aspects of the same invention, and (iii) the manner in which the USPTO will decide whether to require patent applicants to separate closely related inventions into separate patent applications. Some of these rule changes are being challenged in the courts. It is unclear which of these rule changes, if any, will be allowed by the courts and which of them will continue to be pursued. In addition, the Leahy Smith America Invents Act, or AIA, signed into law by President Obama on September 16, 2011, has significantly changed the federal patent laws in multiple ways, including, but not limited to: (i) a transition to a first-to-file system from the long-standing first-to-invent system, (ii) consequent elimination of interference proceedings and the ability to swear behind a prior art reference, (iii) expansion of information usable as prior art by eliminating the distinction between disclosures in the U.S. and other countries, and (iv) the implementation of formal opposition proceedings as well as an expanded third-party submission system. Most of the provisions of the AIA will take effect on September 16, 2012.

We believe that the U.S. is by far the largest single market for pharmaceuticals in the world. Because of the critical nature of patent rights to the pharmaceutical industry, changes in U.S. patent rules and laws could have a profound effect on our future profits. Several of the patent rule and law changes that are being considered could significantly weaken patent protections in the U.S. in general. They may also have a disproportionately large negative impact on the biotechnology and pharmaceutical industries in particular, as well as tilt the balance of market control and distribution of profits between the manufacturers of patented pharmaceutical products and the manufacturers of generic pharmaceutical products towards the generics manufacturers. At present there is considerable uncertainty as to which patent rules and laws will be changed and whether changes to the patent rules will ultimately be enforced or struck down by the courts.

Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Others may independently develop similar or alternative technologies or design around our patented technologies or products. These companies would then be able to develop, manufacture and sell products that compete directly with our products. In that case, our revenues and operating results would decline.

We seek to protect our confidential information by entering into confidentiality agreements with employees, collaborators, CROs, consultants and potential investors. Nevertheless, employees, collaborators, consultants or potential investors may still disclose or misuse our 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.

A dispute regarding the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be costly and result in delays or termination of our future research, development, manufacturing and sales activities.

Our commercial success also depends upon our ability to develop and manufacture our investigational drug candidates and market and sell future approved drugs and conduct our research and development activities without infringing or misappropriating the proprietary rights of others. There are many patents and patent applications filed, and that may be filed, by others relating to drug discovery and development programs that could be determined to be similar, identical or superior to ours or our licensors or collaborators. We may be exposed to future litigation by others based on claims that our investigational drug candidates, approved drugs, technologies or activities infringe the intellectual property rights of others. Numerous U.S. and foreign issued patents and pending patent applications owned by others also exist in the therapeutic areas in, and for the therapeutic targets for, which we are developing investigational drug candidates and have approved drugs. There are also numerous issued patents and patent applications to chemical compounds or synthetic processes that may be necessary or useful to use in our research, development, manufacturing or commercialization activities. These could materially affect our ability to develop our investigational drug candidates or manufacture, import or sell any approved drugs, and our activities, or those of our licensors or collaborators, could be

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determined to infringe these patents. 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 investigational drug candidates, approved drugs or technologies may infringe. There also may be existing patents, of which we are not aware, that our investigational drug candidates, approved drugs or technologies may infringe. Further, there may be issued patents or pending patent applications in fields relevant to our business, of which we are or may become aware, that we believe (i) are invalid or we do not infringe; (ii) relate to immaterial portions of our overall drug discovery, development, manufacturing and commercialization efforts; or (iii) in the case of pending patent applications, the resulting patent would not be granted or, if granted, would not likely be enforced in a manner that would materially impact such efforts. We cannot

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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. We also cannot assure you that, in the event of litigation, we will be able to successfully assert any belief we may have as to non-infringement, invalidity or immateriality, or that any infringement claims will be resolved in our favor.

In addition, others may infringe or misappropriate our proprietary rights, and we may have to institute costly legal action to protect our intellectual property rights. We may not be able to afford the costs of enforcing or defending our intellectual property rights against others.

There could also be significant litigation and other administrative proceedings in our industry that affect us regarding patent and other intellectual property rights. Any legal action or administrative action against us, or our collaborators, claiming damages or seeking to enjoin commercial activities relating to our drug discovery, development, manufacturing and commercialization activities could:

- require us, or our collaborators, to obtain a license to continue to use, manufacture or market the affected drugs, methods or processes, which may not be available on commercially reasonable terms, if at all;
- prevent us from importing, making, using, selling or offering to sell the subject matter claimed in patents held by others and subject us to potential liability for damages;
- consume a substantial portion of our managerial, scientific and financial resources; or
- be costly, regardless of the outcome.

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 cannot protect our intellectual property rights throughout the world.

Filing, prosecuting, defending and enforcing patents on all of our drug discovery technologies and all of our potential investigational drug candidates throughout the world would be prohibitively expensive. 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 investigational drug candidates and may not be covered by any of our patent claims or other intellectual property rights. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S., and many companies have encountered significant problems in protecting and defending such

rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to work the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our investigational drug candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which makes it difficult for us to stop the infringement of our patents. Proceedings 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.

We may face additional competition outside of the U.S. as a result of a lack of patent enforcement in foreign countries and off-label use of other dosage forms of the generic components in our investigational drug candidates.

While we have filed patent applications in many countries outside the U.S., and have obtained some patent coverage for certain of our investigational drug candidates in certain foreign countries, we do not currently have widespread patent protection for Qnexa outside the U.S. and have no protection in many foreign jurisdictions. 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. 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.

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We may face competition from the off-label use of other dosage forms of the generic components in our investigational drug candidates. In addition, others may attempt to commercialize our investigational drug candidate combinations in countries or other markets where we do not have patent protection for all of our investigational drug candidates. In particular, it is possible that patients will seek to acquire the generic components of our investigational drug candidate Qnexa (phentermine and topiramate). 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 investigational drug candidates and adversely affect our overall business and financial results.

We may be subject to claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although we have no knowledge of any pending or overtly threatened claims, we may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We may be unable to in-license intellectual property rights or technology necessary to develop and commercialize our investigational drug candidates.

Depending on its ultimate formulation and method of use, before we can develop, clinically test, make, use, or sell a particular investigational drug candidate, we may need to obtain a license from one or more third parties who have patent or other intellectual property rights covering components of our investigational drug candidate or its method of use. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If a third party does not offer us a necessary license or offers a license only on terms that are unattractive or unacceptable to us, we might be unable to develop and commercialize one or more of our investigational drug candidates.

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

As part of our growth strategy, we may acquire, in-license, develop and/or market additional products and investigational drug candidates. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical investigational drug candidates and products.

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

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

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

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Further, any investigational drug candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All investigational drug candidates are prone to risks of failure typical of pharmaceutical investigational drug candidate 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 provide assurance that any drugs that we develop or approved products that we may acquire will be commercialized profitably or achieve market acceptance.

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

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

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 investigational drug candidates that may be approved will depend in part on government regulation and the availability of coverage and adequate reimbursement from third-party payers, including private health insurers and government payers, such as the Medicaid and Medicare programs, increases in government-run, single-payer health insurance plans and compulsory licenses of drugs. Government and third-party payers 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. Moreover, legislation and regulations affecting the pricing of pharmaceuticals may change before regulatory agencies approve our investigational drug candidates for marketing. Adoption of such legislation and regulations could further limit pricing approvals for, and reimbursement of, drugs. A government or third-party payer decision not to approve pricing for, or provide adequate coverage and reimbursements of, our investigational drug candidates could limit market acceptance of such drugs, if approved.

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We will need to obtain FDA approval of our proposed product names and any failure or delay associated with such approval may adversely impact our business.

Any name we intend to use for our investigational drug candidates will require approval from the FDA, regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a rigorous review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product name if it

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believes the name inappropriately implies medical claims. If the FDA objects to one of our proposed product names, we will be required to adopt an alternative name for that investigational drug candidate. If we adopt an alternative name, we would lose the benefit of our existing trademark applications and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA, which could cause delays that would adversely impact our business. For example, the FDA has notified us that we will be unable to use the product name Qnexa for marketing our investigational product candidate for obesity, if approved. Accordingly, we must identify a new name for Qnexa and submit the same for FDA review and approval. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our investigational drug candidates.

Risks Relating to our Financial Position and Need for Financing

We require additional capital for our future operating plans, including, if approved, the commercial launch of Qnexa in the United States, 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 investigational drug candidate development programs or commercialization efforts.

We expect that our existing capital resources combined with future anticipated cash flows will be sufficient to support our operating activities at least through 2013. However, we anticipate that we will be required to obtain additional financing to fund the development of our research and development pipeline in future periods. Our future capital requirements will depend upon numerous factors, including:

- the cost, timing and final outcome of FORTRESS;
- the FDA's interpretation of the data we submitted and may submit relating to teratogenicity and cardiovascular safety;
- whether or not the FDA or EMA requires us to perform additional clinical studies for Qnexa;
- whether or not the FDA chooses to follow the recommendation of the second Advisory Committee in its vote in favor of approval of Qnexa;
- the cost and time required to set up a distribution system, patient access system and REMS program for Qnexa that is suitable to address any FDA concerns;
- our ability to successfully commercialize by establishing marketing partnerships for avanafil in the U.S., and in our territories outside the U.S., if approved;

- MTPC's ability to obtain foreign regulatory authority and maintain FDA or foreign regulatory approval to manufacture and adequately supply avanafil for commercial use;
- the cost, timing and outcome of the two post-approval clinical studies the FDA has required us to perform as part of the approval for avanafil;
- the progress and costs of our research and development programs;
- the scope, timing 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 planned and future clinical trials;
- the costs involved in seeking regulatory approvals for our investigational 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 costs involved in establishing a commercial operation and in launching a product without a partner;

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- the cost of manufacturing and commercialization activities and arrangements;
- the results of operations;
- the cost, timing and outcome of regulatory reviews;
- the rate of technological advances;
- ongoing determinations of the potential commercial success of our investigational drug candidates under development;
- the state of the economy and financing environment;
- the level of resources devoted to any future sales and marketing capabilities;
- the regulatory approval environment and regulatory hurdles for safety assessment for new investigational drug candidates;
- the cost, timing and outcome of litigations;
- the healthcare reimbursement system or the impact of healthcare reform, if any, imposed by the federal government;
- perceptions and interpretations of Qnexa or the data by outside analysts or others; and
- the activities of competitors.

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

We have substantially less money than we need to develop our investigational drug compounds into commercially available drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a pre-clinical or early clinical compound into an approved and commercially marketed drug, and our efforts may not result in any marketed drugs. We may need additional funds or a partner to bring avanafil, or our most advanced investigational drug candidate, Qnexa, to market, if ever.

To obtain additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of equity or debt securities, corporate alliances, joint ventures and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all. We are continually evaluating our existing portfolio and we may choose to divest, sell or spin-off one or more of our investigational drug candidates at any time. We cannot assure you that we will successfully develop our investigational drug candidates under development or, if successfully developed or approved, 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 and selling our common stock. In light of our need for additional financing, we may issue additional shares of common stock that could dilute your ownership in our company and may include terms that give new investors rights that are superior to yours. For example, on March 6, 2012, we sold 9,000,000 shares of our common stock resulting in net proceeds to us of approximately \$192.0 million. 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.

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We may also raise additional funds through the incurrence of debt, and the holders of any debt we may issue would have rights superior to your 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, our loan with Crown Bank, N.A., was secured by the land and buildings, among other assets, located at our former principal manufacturing facility and a \$700,000 Certificate of Deposit held by Crown. Additionally, our intellectual property and all of the accounts receivable, inventory and equipment arising out of or relating to MUSE and avanafil were pledged as collateral for the Deerfield transaction, which also contained a variety of covenants, including requiring us to use commercially reasonable efforts to preserve our intellectual property, manufacture, promote and sell MUSE, and develop avanafil. We have divested MUSE and the related assets and repaid all debt obligations secured by these assets. Any future debt financing we enter into may involve similar or more onerous covenants that restrict our operations.

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

The current global economic environment poses severe challenges to our business strategy, which relies on access to capital from the markets and our collaborators.

The global economy, including credit markets and the financial services industry, has been experiencing a period of substantial turmoil and uncertainty. These conditions have generally made equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. The duration and severity of these conditions is uncertain, as is the extent to which they may adversely affect our business and the business of current and prospective collaborators and vendors. If the global economy does not improve or worsens, we may be unable to secure additional funding to sustain our operations or to find suitable partners to advance our internal programs, even if we receive positive results from our research and development or business development efforts.

Our investment in the clinical development and manufacture of a commercial supply of Qnexa may not result in any benefit to us if Qnexa is not approved for commercial sale.

We have invested significant resources in the clinical development of Qnexa. We are planning for and may invest significant resources now in preparation for marketing approval and planning for manufacture of commercial supply and sales and marketing. Our engagement in these resource-intensive activities puts significant investment at risk if we do not obtain regulatory approval and successfully commercialize Qnexa in the U.S. On October 28, 2010, we received a CRL regarding the NDA for Qnexa as a treatment for obesity. The CRL stated that in its current form, the NDA for Qnexa was not approvable. On February 22, 2012, the FDA held a second meeting of the Advisory Committee, to discuss the additional data submitted for Qnexa. The FDA asked the Advisory Committee to discuss the following: (1) their interpretation of the available data regarding teratogenicity of topiramate, including whether they believe the data indicate an increase in the risk for oral clefts; (2) the potential strengths and weaknesses of the proposed teratogenicity risk management strategy for Qnexa; (3) the clinical significance of the changes in blood pressure and heart rate in overweight and obese patients treated with Qnexa versus placebo, taking into account the reported changes in antihypertensive therapy; and (4) whether the available data for Qnexa warrant that a cardiovascular outcomes trial be conducted prior to approval. The FDA requested the Advisory Committee to vote on whether, after considering all the available data included in the NDA and the discussions held at the meeting on February 22, 2012, including the questions referred to above, the overall benefit-risk assessment of Qnexa supports its approval for the treatment of obesity in individuals with a BMI ≥ 30 kg/m² or a BMI ≥ 27 kg/m² with weight related co-morbidities. The Advisory Committee voted 20 to 2 to recommend approval. The FDA is not bound by the recommendations of its advisory committees, but will consider their guidance during the review of the NDA that was submitted for Qnexa in October 2011. On April 4, 2012, at

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the FDA's request, we submitted a comprehensive REMS for Qnexa, which was considered a major amendment to the NDA. The PDUFA target date for Qnexa was April 17, 2012. However, as the submission of the comprehensive REMS was within three months of the PDUFA target date, to provide time for a full review of the submission, the FDA extended the PDUFA target date by three months to July 17, 2012. The FDA has the ability to extend the PDUFA target date under certain circumstances, and there can be no assurance that it will not extend the PDUFA target date further in the future.

There is no assurance that our development of Qnexa will lead successfully to regulatory approval, or that obtaining regulatory approval will lead to commercial success. If Qnexa is not approved for commercial sale or if its development is delayed for any reason, our full investment in Qnexa may be at risk, we may be forced to write-off existing inventory, face significant costs to dispose of unusable inventory and our business and financial condition could be materially adversely affected.

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

At March 31, 2012, we had \$200.7 million in cash and cash equivalents and \$132.7 million in available-for-sale securities. While at March 31, 2012, our excess cash balances were invested in money market and U.S. Treasury securities, our investment policy as approved by the Board of Directors, also provides for investments in debt securities of U.S. government agencies, corporate debt securities and asset-backed securities. The investment policy has the primary investment objectives of preservation of principal; however, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy. Although the U.S. congress was able to resolve the debt ceiling issue in time to avoid default, the major credit rating agencies have expressed their ongoing concern about the high levels of debt that the U.S. government has taken on. Standard & Poor's announced that it had revised its outlook on the long-term credit rating of the United States to negative, which could affect the trading market for U.S. government securities. These factors could impact the liquidity or valuation of our available-for-sale securities, all of which were invested in U.S. treasury securities as of March 31, 2012. 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.

The holders of our stock and other securities may take actions that are contrary to your interests, including selling their stock.

A small number of our stockholders hold a significant amount of our outstanding stock. These stockholders may support competing transactions and have interests that are different from yours. Sales of a large number of shares of our stock by these large stockholders or other stockholders within a short period of time could adversely affect our stock price.

Capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our stock for the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities related class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their investigational drug candidate development programs and the FDA's review of their NDAs. We are a defendant in a federal securities class action lawsuit and federal and consolidated state shareholder derivative lawsuits. These securities related class action lawsuits generally allege that the Company and its officers misled the investing public regarding the safety and efficacy of Qnexa and the prospects for the FDA's approval of the Qnexa 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.

We have an accumulated deficit of \$365.0 million as of March 31, 2012, and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of \$365.0 million for the period from our inception through March 31, 2012, 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, 2011, we had approximately \$285.8 million and \$132.9 million of net operating loss, or NOL, carryforwards with which to offset our future taxable income for federal and state income tax reporting purposes, respectively. We used \$121.2 million federal and \$32.2 million state NOLs to offset our year ended December 31, 2007 federal and state taxable income, which included the \$150 million in gain recognized from the Evamist sale. 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, the Company will adjust the Tax Attributes accordingly.

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We face the risk that our ability to use our Tax Attributes will be substantially restricted if we undergo an ownership change as defined in Section 382 of the U.S. Internal Revenue Code, or Section 382. An ownership change under Section 382 would occur if 5-percent shareholders, within the meaning of Section 382, collectively increased their ownership in the Company by more than fifty percentage points over a rolling three-year period. There can be no assurance that a Section 382 ownership change will not occur in the future.

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

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

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

Past sales of our previously owned commercial product, MUSE, and our clinical trials expose us to a significant risk of product liability claims. In addition, pharmaceutical products are subject to heightened risk for product liability claims due to inherent side effects. We identified potential side effects in the patient package insert and physician insert, both of which were distributed with MUSE. While we believe that we are reasonably insured against these risks, we may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Further, we may be unable to obtain product liability coverage for Qnexa, our investigational product candidate, if approved, in amounts or scope sufficient to provide us with adequate coverage against all potential risks. A product liability claim in excess of, or excluded from, our insurance coverage would have to be paid out of cash reserves and could have a material adverse effect upon our business, financial condition and results of operations. Product liability insurance is expensive, difficult to maintain, and current or increased coverage may not be available on acceptable terms, if at all.

In addition, we develop, test and manufacture investigational drug candidates that are used by humans. We face an inherent risk of product liability exposure related to the testing of our investigational drug candidates in clinical trials. An individual may bring a liability claim against us if one of our investigational drug candidates or future approved drugs, if any, causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against a product liability claim, we will 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 related litigation;
- substantial monetary awards to patients or other claimants; and
- the inability to commercialize our investigational drug candidates.

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.

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:

- the final outcome of FORTRESS and the other items included in the Complete Response Letter;

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- the FDA's and/or EMA's interpretation of the data we submitted and may submit relating to teratogenicity and cardiovascular safety;
- the impact of the results of the Risk Evaluation and Mitigation Strategy, or REMS, or cardiovascular outcomes for obesity drugs advisory committee meetings;
- whether or not the FDA and/or EMA require us to conduct additional clinical studies for Qnexa;
- the costs, timing and outcome of the two post-approval clinical studies which the FDA has required us to perform as part of the approval for avanafil;
- the cost and time required to set up a distribution system, patient access program and a REMS program for Qnexa that is suitable to address any FDA concerns;
- results within the clinical trial programs for Qnexa and avanafil 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;
- announcements of Phase 3 data of other anti-obesity compounds in development;
- announcements by licensors of our technology;
- actual or anticipated fluctuations in our financial results;
- our ability to obtain needed financing;
- sales by insiders or major shareholders;

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- 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;
- adverse regulatory actions or decisions;
- any loss of key management;
- the results of our clinical trials relative to those of our competitors;
- 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;
- developments or disputes concerning patents or other proprietary rights;
- licensing, product, patent or securities litigation; and
- public concern as to the safety and efficacy of investigational drug candidates or any future approved drugs developed by us.

These factors and fluctuations, as well as political and other market conditions, may adversely affect the market price of our common stock. Securities related class action litigation is often brought against a company following periods of volatility in the market price of its securities. We are currently a defendant in a number of federal and state securities related class action lawsuits and may be the target of similar litigation in the future. Securities related litigation, whether with or without merit, could result in substantial costs and divert management's attention and financial resources, which could harm our business and financial condition, as well as the market price of our common stock.

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Additionally, volatility or a lack of positive performance in our stock price may adversely affect our ability to retain or recruit key employees, all of whom have been or will be granted stock options as an important part of their compensation packages.

We may be unable to receive the full sales consideration from the sale of the MUSE assets to Meda AB.

Under the terms of the Asset Purchase Agreement we entered into with Meda AB, or Meda, to sell certain of the assets related to the MUSE business to Meda, or the MUSE Transaction, we received \$22 million upon the closing of the MUSE Transaction. The MUSE Transaction closed on November 5, 2010. We may also receive a one-time payment of \$1.5 million should Meda achieve a \$50 million sales milestone for MUSE in any one calendar year during any of the three full calendar years following the date of the Purchase Agreement.

Should Meda fail to achieve the sales milestone for MUSE, the potential milestone payment under the Purchase Agreement with Meda could be delayed or not occur at all.

Volatility in the stock prices of other companies may contribute to volatility in our stock price.

The stock market in general, and the NASDAQ Global Market and the market for life sciences companies in particular, have experienced significant price and volume fluctuations. Further, there has been particular volatility in the market prices of securities of early stage and development stage life sciences companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

Our stock price could decline significantly based on the results and timing of prospective, retrospective observational and pre-clinical studies of, and decisions affecting, our most advanced investigational drug candidates.

The results and timing of prospective and retrospective observational trials and pre-clinical studies can affect our stock price. Pre-clinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies include all drug studies except those conducted in human patients, and may occur before or after initiation of clinical trials for a particular compound. Results of prospective and retrospective observational trials and pre-clinical studies of Qnexa, avanafil or our other investigational drug candidates may not be viewed favorably by us or third parties, including investors, analysts, potential collaborators, the academic and medical community, and regulators. The same may be true of how we design the development programs of our most advanced investigational drug candidates and regulatory decisions (including by us or regulatory authorities) affecting those development programs. Biotechnology and biopharmaceutical company stock prices have declined significantly when such results and decisions were unfavorable or perceived negatively or when an investigational drug candidate did not otherwise meet expectations.

Our share ownership is concentrated, and our officers, directors and principal stockholders acting collectively can exert significant control over matters requiring stockholder approval.

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Due to their combined stock holdings, our officers, directors and principal stockholders (stockholders holding greater than 5% of our common stock) acting collectively may have the ability to exercise significant influence over matters requiring stockholder approval including the election of directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in control of our company and may make some transactions more difficult or impossible to complete without the support of these stockholders.

Our operating results may fluctuate from quarter to quarter and this fluctuation may cause our stock price to decline.

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. Factors contributing to these fluctuations include, among other items, the timing and enrollment rates of clinical trials for our investigational drug candidates, timing of milestone payments and our need for clinical and pre-commercialization supplies. Thus, quarter-to-quarter comparisons of our operating results are not indicative of what we might expect in the future. As a result, in some future quarters our operating results may not meet the expectations of securities analysts and investors, which could result in a decline in the price of our stock.

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

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

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There may not be an active, liquid trading market for our common stock.

There is no guarantee that an active trading market for our common stock will be maintained on the NASDAQ Global Market. Investors may not be able to sell their shares quickly or at the latest market price if trading in our stock is not active.

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

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

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

- authorize the issuance of preferred stock by the Board of Directors without prior stockholder approval, commonly referred to as blank check preferred stock, with rights senior to those of common stock;
- prohibit stockholder actions by written consent;
- specify procedures for director nominations by stockholders and submission of other proposals for consideration at stockholder meetings; and
- eliminate cumulative voting in the election of directors.

In addition, we are governed by the provisions of Section 203 of Delaware General Corporate 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.

Changes in financial accounting standards related to share-based payments are expected to continue to have a significant effect on our reported results.

On January 1, 2006, we adopted FASB ASC topic 718, *Compensation - Stock Compensation*, or ASC 718, which requires that we record compensation expense in the condensed consolidated statements of operations for share-based payments, such as employee stock options, using the fair value method. The adoption of this new standard is expected to continue to have a significant effect on our reported earnings, although it will not affect our cash flows, and could adversely impact our ability to provide accurate guidance on our future reported financial results due to the variability of the factors used to estimate the values of share-based payments. If factors change and we employ different assumptions or different valuation methods in the application of ASC 718 in future periods, the compensation expense that we record under ASC 718 may differ significantly from what we have recorded in the current period, which could negatively affect our stock price.

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ Global Market rules, are creating significant obligations and uncertainty of compliance for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting and our external auditors' review and audit of our internal control over financial reporting has required the commitment of significant financial and managerial resources. We expect these efforts to require the continued commitment of significant resources. If we fail to comply with new or changed laws, regulations and standards, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our financial results and the market price of our common stock.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. REMOVED AND RESERVED

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The following documents are filed as Exhibits to this report:

EXHIBIT NUMBER	DESCRIPTION
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2(2)	Amended and Restated Bylaws of the Registrant.
3.3(3)	Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Registrant.
4.1(4)	Specimen Common Stock Certificate of the Registrant.
4.2(5)	Preferred Stock Rights Agreement dated as of March 27, 2007 between the Registrant and Computershare Investor Services, LLC.
10.1(6)	Third Amendment dated January 27, 2012 to the Employment Agreement dated December 20, 2007 by and between the Registrant and Leland F. Wilson.

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10.2(7) Lease Amendment dated February 14, 2012.

31.1 Certification of Chief Executive Officer, dated May 7, 2012, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.

31.2 Certification of Chief Financial Officer, dated May 7, 2012, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.

32 Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101 The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, formatted in Extensible Business Reporting Language (XBRL), include: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) related notes (furnished herewith).

(1) Incorporated by reference to Exhibit 3.2 filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1996.

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- (2) Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on April 20, 2012.
- (3) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form 8-A filed with the Commission on March 28, 2007.
- (4) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 1996 filed with the Commission on April 16, 1997.
- (5) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Registration Statement on Form 8-A filed with the Commission on March 28, 2007.
- (6) Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K filed with the Commission on February 16, 2012.
- (7) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Current Report on Form 8-K filed with the Commission on January 27, 2012.

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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: May 7, 2012

VIVUS, Inc.

/s/ TIMOTHY E. MORRIS

Timothy E. Morris

Sr. Vice President Finance and Global Corporate Development,
Chief Financial Officer

/s/ LELAND F. WILSON

Leland F. Wilson

Chief Executive Officer

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VIVUS, INC.

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