UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For The Quarterly Period Ended June 30, 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	**94-3136179**
(State or other jurisdiction of incorporation or organization)	(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 x No o

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

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

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

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

At July 27, 2012, 100,362,423 shares of common stock, par value $.001 per share, were outstanding.

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PART I: FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

VIVUS, INC.

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

	June 30, 2012 (Unaudited)	December 31, 2011 Note 1
ASSETS		
Current assets:		
Cash and cash equivalents	$ 80,940	$ 39,554
Available-for-sale securities	229,451	107,282
Inventories	3,430	3,107
Prepaid expenses and other assets	7,845	1,793
Total current assets	321,666	151,736
Property and equipment, net	412	320
Total assets	$ 322,078	$ 152,056
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,246	$ 2,940
Accrued research and clinical expenses	967	1,425
Accrued employee compensation and benefits	3,476	3,693
Other accrued liabilities	3,235	1,274
Current liabilities of discontinued operations	899	1,640
Total current liabilities	14,823	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; 100,141 and 88,975 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively	100	89
Additional paid-in capital	696,259	487,235
Accumulated other comprehensive (loss) income	(13)	25
Accumulated deficit	(389,091)	(346,265)
Total stockholders' equity	307,255	141,084
Total liabilities and stockholders' equity	$ 322,078	$ 152,056

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

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

	Three Months Ended June 30		Six Months Ended June 30	
	2012	2011	2012	2011
Operating expenses:				
Research and development	$ 8,873	$ 11,035	$ 15,007	$ 15,515
General and administrative	15,444	5,303	28,082	10,731
Total operating expenses	24,317	16,338	43,089	26,246
Loss from operations	(24,317)	(16,338)	(43,089)	(26,246)
Interest and other income (expense):				
Interest and other income, net	56	38	74	81
Interest expense	(2)	(2)	(3)	(3)
Total interest and other income (expense)	54	36	71	78
Loss from continuing operations before income taxes	(24,263)	(16,302)	(43,018)	(26,168)
Provision for income taxes	(3)	(2)	(10)	(3)
Loss from continuing operations	(24,266)	(16,304)	(43,028)	(26,171)
Discontinued operations:				
Income from discontinued operations, net of tax	218	107	202	121
Net loss	$ (24,048)	$ (16,197)	$ (42,826)	$ (26,050)
Basic and diluted net loss per share:				
Continuing operations	$ (0.24)	$ (0.20)	$ (0.45)	$ (0.32)
Discontinued operations	0.00	0.00	0.00	0.00
Net loss per share	$ (0.24)	$ (0.20)	$ (0.45)	$ (0.32)
Shares used in per share computation:				
Basic and diluted	99,777	81,928	96,022	81,874

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)
(Unaudited)

	Three Months Ended June 30		Six Months Ended June 30	
	2012	2011	2012	2011
Net loss	$ (24,048)	$ (16,197)	$ (42,826)	$ (26,050)
Other comprehensive (loss) income:				
Unrealized (loss) gain on securities, net of taxes	(6)	20	(38)	45
Comprehensive loss	$ (24,054)	$ (16,177)	$ (42,864)	$ (26,005)

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

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

	Six Months Ended June 30	
	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss from continuing operations	$ (43,028)	$ (26,171)
Adjustments to reconcile net loss to net cash used for operating activities from continuing operations:		
Depreciation	54	63
Amortization of discount or premium on available-for-sale securities	1,968	1,500
Share-based compensation expense	6,242	4,105
Changes in assets and liabilities:		
Inventories	(323)	118
Prepaid expenses and other assets	(6,052)	450

Accounts payable	3,306	3,828
Accrued research and clinical expenses	(458)	(705)
Accrued employee compensation and benefits	(217)	(115)
Other accrued liabilities	1,961	(275)
Net cash used for operating activities from continuing operations	(36,547)	(17,202)
Net cash used for operating activities from discontinued operations	(539)	(722)
Net cash used for operating activities	(37,086)	(17,924)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases	(146)	(122)
Purchases of available-for-sale securities	(181,810)	(56,289)
Proceeds from maturity of available-for-sale securities	38,500	63,500
Proceeds from sale of available-for-sale securities	19,135	—
Net cash (used for) provided by investing activities	(124,321)	7,089
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from exercise of common stock options	10,671	1,799
Sale of common stock through employee stock purchase plan	122	132
Net proceeds from issuance of common stock	192,000	—
Net cash provided by financing activities	202,793	1,931
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	41,386	(8,904)
CASH AND CASH EQUIVALENTS:		
Beginning of period	39,554	37,216
End of period	$ 80,940	$ 28,312

See accompanying notes to unaudited condensed consolidated financial statements.

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VIVUS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

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 and six months ended June 30, 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 June 30, 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, except as disclosed in Note 11. 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.

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

Reclassifications

Certain prior year amounts in the condensed consolidated financial statements have been reclassified to conform to the current year presentation.

Use of Estimates

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

Recent Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements during the six months ended June 30, 2012, as compared to the recent accounting pronouncements described in the Company's Form 10-K for the year ended December 31, 2011, that are of significance, or potential significance to the Company.

2. SHARE-BASED COMPENSATION

The Company accounts for share-based compensation arrangements in accordance with the FASB's Accounting Standards Codification, or 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 for all of the Company's share-based awards is as follows (in thousands):

	Three Months Ended June 30		Six Months Ended June 30	
	2012	2011	2012	2011
Research and development	$ 739	$ 529	$ 1,465	$ 1,068
General and administrative	2,785	1,455	4,777	3,037
Share-based compensation expense	$ 3,524	$ 1,984	$ 6,242	$ 4,105

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VIVUS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

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

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

As of June 30, 2012 (in thousands):

Cash and cash equivalents	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
Cash and money market funds	$ 73,937	$ 73,937	$ —	$ —
U.S. Treasury securities	7,003	7,003	—	—
Total cash and cash equivalents	$ 80,940	$ 80,940	$ —	$ —

Available-for-sale securities	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
U.S. Treasury securities	$ 229,464	$ 229,451	$ 5	$ (18)
Total available-for-sale securities	$ 229,464	$ 229,451	$ 5	$ (18)

As of December 31, 2011 (in thousands):

Cash and cash equivalents	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
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	$ —	$ —

Available-for-sale securities	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
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.

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 (in thousands):

		Basis of Fair Value Measurements		
	Balance at June 30, 2012	Level 1	Level 2	Level 3
Cash and cash equivalents:				
Cash and money market funds	$ 73,937	$ 73,937	$ —	$ —
U.S. Treasury securities	7,003	7,003	—	—
Total cash and cash equivalents	$ 80,940	$ 80,940	$ —	$ —

		Basis of Fair Value Measurements		
	Balance at June 30, 2012	Level 1	Level 2	Level 3
Available-for-sale securities:				
U.S. Treasury securities	$ 229,451	$ 229,451	$ —	$ —

Total available-for-sale securities	$ 229,451	$ 229,451	$ —	$ —

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VIVUS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

Reported as:	
Cash and cash equivalents	$ 80,940
Available-for-sale securities	229,451
Total	$ 310,391

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.

4. INVENTORIES

Inventory balances consist of (in thousands):

	June 30, 2012 (unaudited)	December 31, 2011
Raw materials	$ 2,030	$ 3,107
Work in process	1,400	—
Total	$ 3,430	$ 3,107

The raw materials balance at June 30, 2012 and December 31, 2011, consists of the active pharmaceutical ingredients, or APIs, for development and commercialization of the Company's new drug, Qsymia™ (phentermine and topiramate extended-release), which was formerly referred to as Qnexa®. The work in process inventory at June 30, 2012 also relates to Qsymia, which the Company has capitalized in preparation for the commercial launch. Qsymia was approved by the FDA on July 17, 2012.

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 U.S. 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 June 30, 2012 and the Company believes that the raw materials inventory is not impaired as of that date.

5. AGREEMENTS

In 2001, the Company entered into a Development, Licensing and Supply Agreement, or the 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. The Agreement contains a number of milestone payments to be made by the Company based on various triggering events. Through June 30, 2012, under the terms of the Agreement, the Company has paid a total of $13 million to MTPC, including a $3 million milestone payment made in June 2012, upon FDA approval of STENDRA™, or avanafil.

The Company expects to make other substantial payments to MTPC in accordance with the Agreement as the Company continues to develop avanafil in its territories outside of the United States and, if approved for sale, commercialize avanafil for the oral treatment of male sexual dysfunction in those territories. Potential future milestone payments include $2 million upon the obtainment of the first regulatory approval in any major European country and $6 million upon achievement of $250 million or more in worldwide net sales during any calendar year.

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.

In August 2012, the Company entered into an amendment to the Agreement with MTPC which, among other matters, allows the Company to manufacture the API and tablets for avanafil and expands its rights to develop and commercialize avanafil for all indications. The amendment permits the Company to manufacture the API and tablets for avanafil itself or through a third party supplier at any time; however, the transition away from MTPC supply will need to occur on or before June 2015. In addition, the Company is obligated to use its best commercial efforts to market STENDRA within 12 months of the April 27, 2012 FDA approval date.

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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 Qsymia 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, through June 30, 2012, the Company has paid a total of $220,000 and has issued options to purchase 40,000 shares of the Company's common stock to Dr. Najarian. 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 the Company's 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 FDA approved Qsymia on July 17, 2012. The Company paid the $1 million milestone to Dr. Najarian in the third quarter of 2012 and intends to issue the option to purchase 20,000 shares of the Company's common stock at the next regularly scheduled meeting of the Compensation Committee of the Board of Directors of the Company. In addition, the Assignment Agreement will require the Company 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 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.

6. DISCONTINUED OPERATIONS

On November 5, 2010, the Company closed on the sale to Meda AB, or Meda, of 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. Prior to the closing of the MUSE Transaction, the Company terminated all of the rights to MUSE and avanafil held by 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. The Company has not received any sales milestones to date and does not anticipate that these sales milestones will be achieved in the near future. Post-closing, Meda is 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, because (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.

7. INCOME TAXES

The income tax provision for the six months ended June 30, 2012 relates to state taxes. The Company has a history of operating losses and has a cumulative loss from inception. ASC Topic 740, *Accounting for Income Taxes* provides for the recognition of deferred tax assets if realization of such assets is more likely than not. The Company has established and continues to maintain a full valuation allowance against the Company's net deferred tax assets as the Company does not believe that realization of those assets is more likely than not.

The total gross unrecognized tax benefits as of June 30, 2012 is $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 June 30, 2012 of $1.2 million includes approximately $1.1 million of unrecognized tax benefits that have been netted against the related deferred tax assets.

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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 is currently under examination by the State of New Jersey for the years ended December 31, 2007 through 2009. In addition, 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 California Franchise Tax Board audit to date, the Company believes adjustments may be required in earlier years that would reduce tax attributes available to offset tax due in 2007. The Company did not increase its unrecognized tax benefits for the three and six months ended June 30, 2012.

8. NET INCOME (LOSS) PER SHARE

The Company computes basic net income (loss) per share applicable to common stockholders based on the weighted average number of common shares outstanding during the period. Diluted net income per share is based on the weighted average number of common and common equivalent shares, which represent shares that may be issued in the future upon the exercise of outstanding stock options. 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 and six months ended June 30, 2012 and 2011, all potential common equivalent shares were excluded for these periods as they were anti-dilutive. For the three months ended June 30, 2012 and 2011, 4,290,507 and 5,412,766 options outstanding, respectively, were not included in the computation of diluted net loss per share because the effect would be anti-dilutive. For the six months ended June 30, 2012 and 2011, 4,038,526 and 5,321,330 options outstanding, respectively, were not included in the computation of diluted net loss per share because the effect would be anti-dilutive.

9. EQUITY TRANSACTIONS

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 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.

10. 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 NDA for Qsymia as a treatment for obesity. In the Amended Class Action Complaint filed on April 4, 2011, the plaintiff alleged generally that the defendants misled investors regarding the prospects for Qsymia'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 Qsymia's NDA approval, and Qsymia's efficacy and safety. On December 30, 2011, defendants filed a motion to dismiss the Second Amended Complaint. Briefing concluded in late March 2012, and the motion was argued to the Court on April 18, 2012. The motion is now under submission. The Company cannot predict the outcome of the motion or when the Court may issue a ruling. Pending the outcome of defendants' motion to dismiss, discovery continues to be stayed.

Additionally, certain of the Company's officers and directors are defendants in a shareholder derivative lawsuit captioned *Turberg v. Logan, et al.*, Case No. CV 10-05271 PJH, 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 the *Kovtun* action. The parties have agreed to stay the litigation pending resolution of the defendants' second motion to dismiss in the *Kovtun* action. The same individuals are also named defendants in consolidated shareholder derivative suits pending in the California Superior Court, Santa Clara County under the caption *In re VIVUS, Inc. Derivative Litigation*, Master File No. 11 0 CV188439. The allegations in the state court derivative suits are substantially similar to the other lawsuits. As with the federal derivative litigation, the parties have agreed to stay these consolidated actions pending resolution of the second motion to dismiss in the *Kovtun* action.

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

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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 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.

11. SUBSEQUENT EVENTS

On July 9, 2012, the Internal Revenue Service notified the Company that it had completed their audit of the Company's income tax returns for the years ended December 31, 2007 and 2008 with no adjustments.

Qsymia was approved by the FDA on July 17, 2012 as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 or greater (obese), or 27 or greater (overweight) in the presence of at least one weight-related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol (dyslipidemia).

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

This Management's Discussion and Analysis of Financial Conditions and Results of Operations and other parts of this Form 10-Q contain "forward looking" statements that involve risks and uncertainties. These statements typically may be identified by the use of forward looking words or phrases such as "may," "believe," "expect," "forecast," "intend," "anticipate," "predict," "should," "planned," "likely," "opportunity," "estimated," and "potential," the negative use of these words or other similar words. All forward looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward looking statements. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Form 10-Q. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including those set forth under Item 1A "Risk Factors" in this Quarterly Report on Form 10-Q. When we refer to "we," "our," "us," the "Company" or "VIVUS" in this document, we mean the current Delaware corporation, or VIVUS, Inc., and its California predecessor, as well as all of our consolidated subsidiaries.

Overview

We are a biopharmaceutical company dedicated to the development and commercialization of therapeutic drugs for large underserved markets, including obesity and men's sexual health. Our drug, Qsymia™ (formerly known as Qnexa®) was approved by the U.S. Food and Drug Administration, or FDA, on July 17, 2012, as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 or greater (obese), or 27 or greater (overweight) in the presence of at least one weight-related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol (dyslipidemia). Qsymia incorporates low doses of active ingredients from two previously approved drugs, phentermine and topiramate. Qsymia is believed to target excessive appetite and a high threshold for satiety, or the feeling of being full, the two main mechanisms that impact eating behavior. We are engaged in activities in preparation for the commercial launch of Qsymia in the United States, which we anticipate will occur in the fourth quarter of 2012.

Qsymia was approved with a Risk Evaluation and Mitigation Strategy, or REMS, with a goal of informing prescribers and patients of reproductive potential about an increased risk of orofacial clefts in infants exposed to Qsymia during the first trimester of pregnancy, the importance of pregnancy prevention for females of reproductive potential receiving Qsymia and the need to discontinue Qsymia immediately if pregnancy occurs. The Qsymia REMS program includes a Medication Guide, Healthcare Provider training, distribution through certified home-delivery pharmacies, implementation system and a time table for assessments.

As part of the approval of Qsymia, we are committed to conduct post-marketing studies. We will conduct a study to assess the long-term treatment effect of Qsymia on the incidence of major adverse cardiovascular events in overweight and obese subjects with confirmed cardiovascular disease, studies to assess the safety and efficacy of Qsymia for weight management in obese pediatric and adolescent subjects, studies to assess drug utilization and pregnancy exposure, a study to assess renal function, as well as animal and in vitro studies.

On December 17, 2010, we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, to market Qsymia in the European Union, or EU, for the treatment of obesity. The approved trade name for Qsymia in the EU is Qsiva™. We have been invited to participate in oral hearings with the Committee for Medicinal Products for Human Use, or CHMP, of the EMA in September 2012, during which we expect to discuss the benefit/risk profile of Qsiva in light of cognitive side effects and increased heart rate and the design of a proposed risk mitigation plan to ensure access to the appropriate patient population. We anticipate an opinion from the CHMP sometime after the September meeting. If approved, we intend to commercialize Qsiva in the EU through a collaboration arrangement with a third party. We also intend to seek approval for Qsymia in other territories outside the United States and EU. We intend to commercialize Qsymia in territories where we obtain approval through collaboration agreements with third parties.

Our drug, STENDRA™, or avanafil, was approved by the FDA on April 27, 2012, for the treatment of erectile dysfunction, or ED, in the United States. As part of the approval of STENDRA, we are committed to conduct post-marketing studies. In March 2012, we filed an MAA with the EMA to market avanafil in the EU for the treatment of ED. The approved trade name for STENDRA in the EU is SPEDRA™. In July 2012, we received the Day 120 List of Questions from the EMA. We are currently reviewing the Day 120 List of Questions which covers a broad range of topics including, without limitation, questions relating to clinical relevance in certain populations as well as questions regarding drug-drug interaction and pharmacokinetics. We are in the process of preparing our response to the CHMP. Avanafil is an oral PDE5 inhibitor that we license from Mitsubishi Tanabe Pharma Corporation, or MTPC. We intend to market and sell STENDRA in the United States and, if approved, SPEDRA in the EU and other territories outside the United States through collaboration with third parties. We are currently in discussions with potential collaboration partners for all stated territories.

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

Strategy

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

- successfully launching Qsymia in the United States;
- entering into and supporting a collaboration agreement for the commercialization of STENDRA for the treatment of ED in the U.S.;

- obtaining regulatory approval for Qsiva for the treatment of obesity and SPEDRA for the treatment of ED in the EU and other territories worldwide; and

- if approved, entering into and supporting collaboration agreements for the commercialization of Qsiva for the treatment of obesity and SPEDRA for the treatment of ED in the EU and other territories worldwide.

It is our objective to become a leader in the development and 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.

Business Highlights

In preparation for the commercial launch of Qsymia in the United States, we have entered into the following agreements:

- On May 22, 2012, we entered into a Dedicated Sales Team Agreement, or the Sales Team Agreement, with PDI, Inc. to provide us with promotional and commercialization support services for Qsymia. The Sales Team Agreement is effective beginning on July 30, 2012 and ending on July 29, 2014. We have the option to extend the term of the agreement for two consecutive twelve-month periods. Under the terms of the Sales Team Agreement, PDI will provide us with 150 full-time sales representatives, three full-time field liaison managers, and one full-time account manager. In addition, under the Sales Team Agreement, PDI will provide us with program personnel to collect and capture physician information, including physician target call plan reach and frequency, deactivation information related to physician accounts and physician's behavioral or attitudinal response. Our total obligation under the Sales Team Agreement is $57.2 million, including the start-up, deployments fees and compensation costs.

- On July 17, 2012, we entered into the Commercial Manufacturing and Packaging Agreement, or the Manufacturing Agreement, with Catalent Pharma Solutions, LLC, or Catalent, pursuant to which Catalent will manufacture and supply Qsymia capsules, or the Product, for us. Under the Manufacturing Agreement, we will purchase the Product from Catalent during the term of the Manufacturing Agreement for commercial use in the United States, Canada, the European Union and any other country that VIVUS and Catalent mutually agree to in writing. The Manufacturing Agreement commenced on July 17, 2012 and will continue for four years following the date of the first commercial sale of the Product by VIVUS to any third party, unless terminated earlier in accordance with the Manufacturing Agreement. In the first two contract years under the Manufacturing Agreement, Catalent will be the exclusive supplier of the Product to VIVUS. In the third and fourth contract years under the Manufacturing Agreement, Catalent will be a semi-exclusive supplier of the Product to VIVUS, subject to Catalent's right to earn exclusivity based on certain performance criteria and, at VIVUS' election, the build out of a secondary manufacturing site in the European Union.

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CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

As of June 30, 2012, there have been no significant or material changes to our critical accounting policies or estimates since we filed our 2011 Annual Report on Form 10-K for the year ended December 31, 2011 with the Securities and Exchange Commission, or SEC.

RESULTS OF OPERATIONS

For the quarter ended June 30, 2012, we reported a net loss of $24.0 million, or $0.24 net loss per share, as compared to a net loss of $16.2 million, or $0.20 net loss per share during the same period in 2011. The increased net loss in the quarter ended June 30, 2012, as compared to the quarter ended June 30, 2011, was primarily attributable to increased Qsymia pre-commercialization related general and administrative expenses.

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

Continuing operations

Research and development expenses (Unaudited)

	Three Months Ended June 30,			Six Months Ended June 30,		
	2012	2011	2012 vs. 2011 (Decrease)	2012	2011	2012 vs. 2011 (Decrease)
	(In thousands, except percentages)					
Research and development expenses	$ 8,873	$ 11,035	(20)%	$ 15,007	$ 15,515	(3)%

In the second quarter of 2012, the decline in research and development expenses of $2.2 million is primarily due to decreased development activities for avanafil of $3.9 million, partially offset by increased spending on Qsymia for obesity of $1.8 million, as compared to the second quarter of 2011.

In the six months ended June 30, 2012, the decrease in research and development expenses of $0.5 million was primarily due to decreased avanafil spending of $4.8 million, partially offset by a $3.7 million increase in obesity program spending, as compared to the six months ended June 30, 2011.

We anticipate that our research and development expenses for the remainder of 2012 will increase significantly from costs incurred in 2011 as we expect to begin a post-approval cardiovascular outcomes study for Qsymia. The study will be known as ACQLAIM. The details of ACQLAIM have not yet been agreed with the FDA. This study could cost between $200 and $250 million dollars and take as long as five to six years to complete. There are likely to be additional research and development expenses for other post-approval studies related to STENDRA and Qsymia, and for our investigational drug candidates under development. Our research and development expenses may fluctuate from period to period due to the timing and scope of our development activities and the results of clinical and pre-clinical studies.

General and administrative expenses (Unaudited)

	Three Months Ended June 30,			Six Months Ended June 30,		
	2012	2011	2012 vs. 2011 Increase	2012	2011	2012 vs. 2011 Increase
	(In thousands, except percentages)					
General and administrative expenses	$ 15,444	$ 5,303	191%	$ 28,082	$ 10,731	162%

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The increase in general and administrative expenses is primarily due to increased spending for Qsymia pre-commercialization activities of $6.0 million (primarily related to marketing programs, market research and analytics, and personnel costs related to increased headcount), corporate expenses of $1.5 million (primarily compensation and related costs), non-cash share-based compensation expense of $1.3 million, and incremental increases in other general and administrative expenses totaling $1.3 million (including increased expenses related to human resources, facilities, business development, STENDRA pre-commercialization, legal and finance), as compared to the quarter ended June 30, 2011.

In the six months ended June 30, 2012, the increase in general and administrative expenses is primarily due to increased spending for Qsymia pre-commercialization activities of $9.3 million (primarily related to marketing programs, market research and analytics, and personnel and related costs due to increased headcount), STENDRA pre-commercialization expenses of $2.0 million (primarily market analytics, marketing programs and consulting expenses), corporate expenses of $1.9 million (primarily compensation and related costs), non-cash share-based compensation expense of $1.7 million, and incremental increases in other general and administrative expenses totaling $2.5 million (including increased expenses related to business development, finance, human resources, facilities, legal and investor relations), as compared to the six months ended June 30, 2011.

We anticipate a significant increase in our general and administrative expenses for the remainder of 2012, as compared to 2011, due to pre-commercialization and commercialization activities for Qsymia.

Provision for income taxes

We recorded a provision for income taxes for the three and six months ended June 30, 2012 of $3,000 and $10,000, respectively, as compared to $2,000 and $3,000, respectively for the three and six months ended June 30, 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, 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 three and six months ended June 30, 2012. We recognize interest and penalties accrued on any unrecognized tax benefits as a component of our provision for income taxes.

Income from discontinued operations

Income from discontinued operations of $218,000 and $202,000 in the three and six months ended June 30, 2012, respectively, as compared to $107,000 and $121,000, in the three and six months ended June 30, 2011, respectively, relates primarily to adjustments to our sales reserves for accrued product returns related to the MUSE product.

LIQUIDITY AND CAPITAL RESOURCES

Continuing Operations

Cash. Cash, cash equivalents and available-for-sale securities totaled $310.4 million at June 30, 2012, as compared to $146.8 million at December 31, 2011. The increase of $163.6 million is primarily the net result of cash provided by financing activities and cash used for investing and operating activities. Included in this increase are $10.8 million in net proceeds from common stock option exercises and ESPP purchases and $192.0 million in net proceeds from an underwritten public offering of our common stock during the six months ended June 30, 2012.

Since inception, we have financed operations primarily from the issuance of equity securities. Through June 30, 2012, we have raised $658.2 million from financing activities, received $150 million from the sale of Evamist and had an accumulated deficit of $389.1 million at June 30, 2012.

At June 30, 2012, we had $80.9 million in cash and cash equivalents and $229.5 million in available-for-sale securities. We invest our excess cash balances in money market and marketable securities, primarily U.S. Treasury securities and debt securities of U.S. government agencies, corporate debt securities and asset-backed securities, in accordance with our investment policy. At June 30, 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 stockholders' equity.

Liabilities. Total liabilities were $14.8 million at June 30, 2012, which is $3.8 million higher than at December 31, 2011. The change in total liabilities is primarily due to increased pre-commercialization activities related to Qsymia and the timing of payments.

Operating Activities. Our operating activities used $37.1 million and $17.9 million in cash during the six months ended June 30, 2012 and 2011, respectively. During the six months ended June 30, 2012, our net operating loss of $43.0 million was offset by $6.2 million in non-cash share-based compensation expense and a $3.3 million increase in accounts payable. These positive cash flows to our net operating loss were in turn offset by a $6.1 million increase in prepaid expenses and other assets.

During the six months ended June 30, 2011, our net operating loss of $26.2 million was offset by $4.1 million in non-cash share-based compensation expense and a $3.8 million increase to accounts payable, primarily due to the timing of the $4.0 million milestone payment to MTPC related to the filing of the NDA for STENDRA.

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

Investing Activities. Our investing activities used $124.3 million and provided $7.1 million in cash during the six months ended June 30, 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 $202.8 million and $1.9 million during the six months ended June 30, 2012 and 2011, respectively. In the first six months of 2012, cash provided by financing activities included $192.0 million in net proceeds from an underwritten public offering of our common stock.

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

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs at least through 2013. However, we anticipate that we may require additional funding to continue our commercialization of Qsymia, to conduct post-approval clinical studies for both Qsymia and STENDRA, to conduct non-clinical and clinical research and development work to support regulatory submissions and applications for our current and future investigational drug candidates, to finance the costs involved in filing and prosecuting patent applications and enforcing or defending our patent claims, if any, to fund operating expenses, to establish additional or new manufacturing and marketing capabilities, to manufacture quantities of our drugs and investigational drug candidates and to make payments under our existing license agreements for Qsymia and STENDRA.

While some of our anticipated costs are unknown at the current time, we may need to raise additional capital to continue the funding of our commercialization, product development programs and our research and development plans in future periods beyond 2013. If we require additional capital, we may seek any required additional funding through collaborations, public and private equity or debt financings, capital lease transactions or other available financing sources. Additional financing may not be available on acceptable terms, or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing stockholders may result. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our commercialization or development programs or obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop on our own.

Off-Balance Sheet Arrangements

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

Contractual Obligations

On May 22, 2012, we entered into a Dedicated Sales Team Agreement, or the Sales Team Agreement, with PDI, Inc. to provide us with promotional and commercialization support services for Qsymia. The Sales Team Agreement is effective beginning on July 30, 2012 and ending on July 29, 2014. We have the option to extend the term of the agreement for two consecutive twelve-month periods. Under the terms of the Sales Team Agreement, PDI will provide us with 150 full-time sales representatives, three full-time field liaison managers, and one full-time account manager. In addition, under the Sales Team Agreement, PDI will provide us with program personnel to collect and capture physician information, including physician target call plan reach and frequency, deactivation information related to physician accounts and physician's behavioral or attitudinal response. Our total obligation under the Sales Team Agreement is $57.2 million, including the start-up, deployments fees and compensation costs.

On July 17, 2012, we entered into the Commercial Manufacturing and Packaging Agreement, or the Manufacturing Agreement, with Catalent Pharma Solutions, LLC, or Catalent, pursuant to which Catalent will manufacture and supply Qsymia capsules, or the Product, for us. Under the Manufacturing Agreement, we will purchase the Product from Catalent during the term of the Manufacturing Agreement for commercial use in the United

States, Canada, the European Union and any other country that VIVUS and Catalent mutually agree to in writing. The Manufacturing Agreement commenced on July 17, 2012 and will continue for four years following the date of the first commercial sale of the Product by VIVUS to any third party, unless terminated earlier in accordance with the Manufacturing Agreement. In the first two contract years under the Manufacturing Agreement, Catalent will be the exclusive supplier of the Product to VIVUS. In the third and fourth contract years under the Manufacturing Agreement, Catalent will be a semi-exclusive supplier of the Product to VIVUS, subject to Catalent's right to earn exclusivity based on certain performance criteria and, at VIVUS' election, the build out of a secondary manufacturing site in the European Union.

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 June 30, 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 June 30, 2012 by approximately $1.0 million. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

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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

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 Qsymia 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 Qsymia'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 Qsymia's NDA approval, and Qsymia's efficacy and safety. On December 30, 2011, defendants filed a motion to dismiss the Second Amended Complaint. Briefing concluded in late March 2012, and the motion was argued to the Court on April 18, 2012. The motion is now under submission. We cannot predict the outcome of the motion or when the Court may issue a ruling. Pending the outcome of defendants' motion to dismiss, discovery continues to be stayed.

Additionally, certain of the Company's officers and directors are defendants in a shareholder derivative lawsuit captioned *Turberg v. Logan, et al.*, Case No. CV 10-05271 PJH, 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 same individuals are also named defendants in consolidated shareholder derivative suits pending in the

California Superior Court, Santa Clara County under the caption *In re VIVUS, Inc. Derivative Litigation*, Master File No. 11 0 CV188439. The allegations in the state court derivative suits are substantially similar to the other lawsuits. 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.

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ITEM 1A. RISK FACTORS

Set forth below and elsewhere in this Form 10-Q and in other documents we file with the 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 Business

Our success will depend on our ability to effectively and profitably commercialize Qsymia™.

Our success will depend on our ability to effectively and profitably commercialize Qysmia, formerly known as Qnexa®, which will include our ability to:

- create market demand for Qsymia through education, marketing and sales activities;
- achieve market acceptance and generate product sales;
- receive adequate levels of reimbursement from third-party payers, such as private insurance programs;
- comply with the post-marketing requirements established by the U.S. Food and Drug Administration, or FDA, including the Risk Evaluation and Mitigation Strategy, or REMS, and any other requirements established by the FDA in the future;
- conduct the post-marketing studies required by the FDA;
- comply with other healthcare regulatory requirements;
- ensure that the active pharmaceutical ingredient, or API, for Qsymia and the finished product are manufactured in sufficient quantities and in compliance with requirements of the FDA and similar foreign regulatory agencies and with an acceptable quality and pricing level in order to meet commercial demand; and
- ensure that the entire supply chain for Qsymia — from API to finished product — efficiently and consistently delivers Qsymia to our customers.

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

We intend to market and sell STENDRA, or avanafil, in the U. S. under a collaboration arrangement with a third party and to market and sell Qsiva ™ and SPEDRA ™ outside the U. S. , if approved, under collaboration arrangements with third parties, which might subject us to a number of risks.

We intend to enter collaborative arrangements or strategic alliances with pharmaceutical partners or others to commercialize STENDRA in the U.S. and to commercialize Qsiva and SPEDRA outside the U.S. These arrangements may place the commercialization of Qsiva, STENDRA and SPEDRA outside of our control in the relevant territories, may require us to relinquish certain rights or pay royalties, or may otherwise be on terms unfavorable to us.

We may be unable to enter into agreements with third parties on favorable terms or at all, which could delay or impair our ability to commercialize Qsiva, STENDRA and SPEDRA in the relevant territories. 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 drug products;
- our collaborators may experience financial, regulatory or operational difficulties;

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- 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 allowed to expire, which could negatively impact the continued commercialization of our drug products.

We intend to market Qsiva and SPEDRA outside the U.S., if approved, which will subject us to risks related to conducting business internationally.

We, together with our affiliates and partners, intend to manufacture, market, and distribute Qsiva and SPEDRA, if approved, outside the U.S. We expect that we will be subject to risks related to conducting business internationally, including:

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

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We rely in part on a contract sales organization for certain sales and marketing support services for Qsymia.

We have entered into an agreement with PDI, Inc., or PDI, a third party contract sales organization, to assist with the hiring of sales representatives and the promotion of Qsymia to physicians. Our internal sales and marketing personnel will manage and supervise the activities of this sales force. Nevertheless, we face risks in our partial reliance on the third party contract sales organization including the following:

- PDI may not apply the expected financial resources or required expertise to successfully promote Qsymia;
- PDI may not invest in the development of a sales force and the related infrastructure at levels that ensure that sales of Qsymia reach their full potential;
- PDI may not comply with applicable legal or regulatory requirements, including the requirement to promote drugs only for uses for which they have been approved;
- disputes may arise between us and PDI that may delay the commercialization of Qsymia or adversely affect its sales or profitability; and
- PDI may enter into agreements with other parties that have products that could compete with Qsymia.

We depend on the success of PDI in performing its services, and we cannot be certain PDI will cooperate with us to perform its obligations under the agreement. Although they are contractually obligated, we cannot control the amount of resources that will be devoted by PDI to the promotion of Qsymia. Any failure of PDI to perform its obligations or delay in allocating resources to the promotion of Qsymia could adversely affect the commercialization of Qsymia and materially harm our business, financial condition and results of operations.

Our failure to establish, manage and maintain a distribution network could delay or compromise the commercialization of Qsymia.

We do not have the infrastructure necessary for distributing Qsymia to patients. We have contracted with Cardinal Health PTS, LLC, or Cardinal Health, a third-party distribution and supply-chain management company, to warehouse Qsymia and distribute it to our REMS certified home delivery pharmacy suppliers that then distribute Qsymia directly to patients through home delivery. Cardinal Health will also provide billing, collection and returns services. We have not yet completed negotiations of definitive agreements with our selected REMS certified home delivery pharmacies for the distribution of

Qsymia. This distribution network requires significant coordination with our sales and marketing, finance, regulatory and medical affairs teams, in light of the REMS requirements applicable to Qsymia.

We have agreed pursuant to the REMS program that Cardinal Health will be our exclusive supplier of distribution logistics services, and accordingly we depend on Cardinal Health to satisfactorily perform its obligations under the agreement. Similarly, pursuant to the REMS program applicable to Qsymia, our distribution network will be through a small number of home delivery pharmacies, and we rely on these pharmacies to implement a number of safety procedures and report certain information to us. Failure to maintain our contracts with Cardinal Health or to finalize and maintain our contracts with our selected home delivery pharmacies, or the inability or failure of any of them to adequately perform under the contracts, could negatively impact the distribution of Qsymia or adversely affect our ability to comply with the REMS applicable to Qsymia. Failure to coordinate financial systems could also negatively impact our ability to accurately report and forecast product revenue. If we are unable to effectively establish and manage the distribution process, sales of Qsymia could be severely compromised and our business, financial condition and results of operations would be harmed.

If we are unable to enter into agreements with suppliers or our suppliers fail to supply us with the active pharmaceutical ingredients, or APIs, for our drugs or if we rely on sole source suppliers, we may experience delays in commercializing our drugs.

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

We anticipate that we will rely on single source suppliers for phentermine and topiramate for the foreseeable future. Any production shortfall on the part of our suppliers that impairs the supply of phentermine or topiramate could have a material adverse effect on our business, financial condition and results of operations. If we are unable to obtain a sufficient quantity of these compounds, there could be a substantial delay in successfully developing a second source supplier. An inability to continue to source

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product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could adversely affect our ability to satisfy demand for Qsymia, which could adversely affect our product sales and operating results materially, which could significantly harm our business.

The API and the tablets for avanafil are manufactured by Mitsubishi Tanabe Pharma Corporation, or MTPC. 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 STENDRA, or the approval, or the timing of approval, of SPEDRA 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's API or tablets in sufficient quantities to meet projected demand, the EU approval, the U.S. commercial launch, and future sales of STENDRA and SPEDRA 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 STENDRA and SPEDRA, if approved. In August 2012, we entered into an amendment to our agreement with MTPC that permits us to manufacture the API and tablets for avanafil ourselves or through third party suppliers at any time. The transition away from MTPC supply will need to occur on or before June 2015. We currently do not have any manufacturing facilities and intend to rely on third parties for the supply of the API and tablets. However, we cannot be certain that we will be successful in entering into such agreements with other suppliers or that we will be able to obtain the necessary regulatory approvals for these suppliers in a timely manner or at all.

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

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

In particular, we license the rights to avanafil from MTPC, and in August 2012, we entered into an amendment to our agreement with MTPC which, among other matters, allows us to manufacture the active pharmaceutical ingredient and tablets for avanafil and expands our rights to develop and commercialize avanafil for all indications. In addition, we are obligated to use our best commercial efforts to market STENDRA within 12 months of the April 27, 2012 FDA approval date. Failure to market the drug within the 12 month period may have an adverse impact on the commercial future of STENDRA. We license the rights to Qsymia from Dr. Najarian. We believe we are in compliance with the material terms of our license agreements with MPTC and Dr. Najarian. However, there can be no assurance that this compliance will continue or that the licensors will not have a differing interpretation of the material terms of the agreements. If the license agreements were terminated early or if the terms of the licenses were contested for any reason, it would have a material adverse impact on our ability to commercialize products subject to these agreements, our ability to raise funds to finance our operations, our stock price and our overall financial condition. The monetary and disruption costs of any disputes involving our agreements could be significant despite rulings in our favor.

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

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

- our distribution system for Qsymia, which will be limited to a certified home-delivery pharmacy network;
- contraindications for Qsymia and STENDRA;
- competition and timing of market introduction of competitive drugs;

- efficacy and safety in the approved setting;
- prevalence and severity of any side effects;
- emergence of previously unknown side effects;
- results of any post-approval studies;

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

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

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

As part of the approval for STENDRA, the FDA is requiring us to perform two post-approval clinical studies. The first is a randomized, double-blind, placebo-controlled, parallel group multicenter clinical trial on the effect of STENDRA on spermatogenesis in healthy adult males and males with mild erectile dysfunction, or ED. The other study is a double-blind, randomized, placebo-controlled, single-dose vision clinical trial to assess the effects of STENDRA on multiple parameters of vision, including, but not limited to visual acuity, intraocular pressure, pupillometry, and color vision discrimination in healthy male subjects. If we are unable to complete these studies or the results of these studies reveal unacceptable safety risks, we could be required to perform additional tests and even lose approval of STENDRA.

As part of the approval of Qsymia, we are committed to conduct post-marketing studies. We will conduct a study to assess the long-term treatment effect of Qsymia on the incidence of major adverse cardiovascular events in overweight and obese subjects with confirmed cardiovascular disease, studies to assess the safety and efficacy of Qsymia for weight management in obese pediatric and adolescent subjects, studies to assess drug utilization and pregnancy exposure, a study to assess renal function, and two non-clinical studies, one to support the pediatric studies and the other to characterize effects on human transporters, in vitro. The details of the cardiovascular outcomes study, known as ACQLAIM, have not yet been agreed with the FDA. This study could cost between $200 and $250 million dollars and take as long as five to six years to complete. 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 ACQLAIM.

In addition, at the FDA's request, we initiated a retrospective observational study utilizing existing electronic medical claims healthcare databases to review fetal outcomes, including the incidence of congenital malformations and oral cleft, in the offspring of women who received treatment with topiramate, or FORTRESS. We announced preliminary results from FORTRESS in December 2011. The results of the study are considered to be preliminary until the results are validated, which we expect to complete in the first half of 2013. If the results of this study reveal unacceptable safety risks, we could be required to perform additional studies.

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In addition to these studies, the FDA may also require us to commit to perform other lengthy post-approval studies, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results, financial condition and stock price. Failure to comply with the applicable regulatory requirements can result in, among other things, civil penalties, suspensions of regulatory approvals, operating restrictions and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition, results of operations and stock price.

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

We intend to market and sell Qsiva and SPEDRA, if approved, in the EU and in other territories outside the U.S. through collaboration arrangements with third parties. In order to market these products in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. On December 17, 2010, we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, to market Qsiva in the EU for the treatment of obesity. We have been invited to participate in oral hearings with the Committee for Medicinal Products for Human Use, or CHMP, of the EMA in September 2012, during which we expect to discuss the benefit/risk profile of Qsiva in light of cognitive side effects and increased heart rate and the design of a proposed risk mitigation plan to ensure access to the appropriate patient population. We anticipate an opinion from the CHMP sometime after the September meeting. In March 2012, we filed an MAA with the EMA to market SPEDRA in the EU for the treatment of ED. In July 2012, we received the Day 120 List of Questions for SPEDRA from the EMA. We are currently reviewing the Day 120 List of Questions which covers a broad range of topics including, without limitation, questions relating to clinical relevance in certain populations as well as questions regarding drug-drug interaction and pharmacokinetics. We are in the process of preparing our response to the CHMP. We have had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional testing. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. Foreign regulatory approvals may not be obtained on a timely basis, or at all, and the failure to receive regulatory approvals in a foreign country would prevent us from marketing our products in that country, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

Although Qsymia is a once-a-day, proprietary extended-release formulation, each of the approved active pharmaceutical ingredients that is combined to produce Qsymia is commercially available in drug products at prices that together are lower than the price at which we would seek to market Qsymia. In addition, neither of these drug products has a REMS. We cannot be sure that physicians will view Qsymia as sufficiently superior to a treatment regimen of Qsymia's individual active pharmaceutical ingredients to justify the significantly higher cost we expect to seek for Qsymia, and they may prescribe the individual generic drugs already approved and marketed by other companies instead of our combination drug. Although our U.S. and European patents contain composition, product formulation and method-of-use claims that we believe protect Qsymia, those patents may be ineffective or impractical to prevent physicians from prescribing the individual drug products marketed by other companies instead of our combination drug. Phentermine and topiramate are currently available in generic form, although the doses used in Qsymia are currently not available and no extended-release formulation of topiramate exists. Topiramate, one of the ingredients in Qsymia, is not approved for obesity treatment. Phentermine is only approved for short-term treatment of obesity. However, to the extent that the price of Qsymia is significantly higher than the prices of the individual components as marketed by other companies, physicians may have a greater incentive to write prescriptions for the individual components outside of their approved indication, instead of for our combination drug, and this may limit how we price or market Qsymia. Similar concerns could also limit the reimbursement amounts private health insurers or government agencies in the U.S. are prepared to pay for Qsymia, which could also limit market and patient acceptance of our drug and could negatively impact our revenues.

In many regions and countries where we may plan to market Qsymia, 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 Qsymia should be based on prices for its active pharmaceutical ingredients when sold separately, rather than allowing us to market Qsymia at a premium as a new drug.

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

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

Although we believe there is an active insurance market for products such as ours, we may be unable to obtain product liability coverage for our approved drugs in amounts or scope sufficient to provide us with adequate coverage against all potential risks. A product liability claim in excess of, or excluded from, our insurance coverage would have to be paid out of cash reserves and could have a material adverse effect upon our business, financial condition and results of operations. Product liability insurance is expensive, difficult to maintain, and current or increased coverage may not be available on acceptable terms, if at all.

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

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

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

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

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

Competition in the pharmaceutical and medical products industries is intense and is characterized by costly and extensive research efforts and rapid technological progress. We are aware of several pharmaceutical companies also actively engaged in the development of therapies for the treatment of obesity, diabetes and sexual health and medical device companies for the treatment of sleep apnea. Many of these companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. Our competitors may develop technologies and products that are more effective than those we are currently marketing or researching and developing. Such developments could render Qsymia and STENDRA less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience.

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We anticipate that Qsymia for the treatment of chronic weight management will compete with several investigational drug candidates and approved anti-obesity drugs. For example, Orexigen Therapeutics, Inc. submitted an NDA to the FDA for their investigational obesity drug candidate, and the FDA approved Arena's investigational drug candidate, lorcaserin, to be marketed as Belviq, in June 2012. In addition, we anticipate that Qsymia also will compete with several approved anti-obesity drugs, including Xenical (orlistat), marketed by Roche; alli, the over-the-counter version of orlistat, marketed by GlaxoSmithKline; and Suprenza (phentermine hydrochloride), marketed by Akrimax Pharmaceuticals, LCL. There are also several drugs in development for obesity including an investigational drug candidate, liraglutide, in Phase 3 clinical trials being developed by Novo Nordisk A/S and several other investigational drug candidates in Phase 2 clinical trials. There are a number of generic pharmaceutical drugs that are prescribed for obesity, predominantly phentermine. Phentermine is sold at much lower prices than we intend to charge for Qsymia. The availability of a branded prescription drugs, generic drugs and over-the-counter drugs could limit the demand for, and the price we are able to charge for, Qsymia.

We also may face competition from the off-label use of the generic components in our drugs. In particular, it is possible that patients will seek to acquire phentermine and topiramate, the generic components of Qsymia. The off-label use of the generic components in the U.S. or the importation of the generic components from foreign markets could adversely affect the commercial potential for our drugs and adversely affect our overall business, financial conditions and results of operations.

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

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

As patents for the three major PDE5 inhibitors, sildenafil citrate, tadalafil and vardenafil, expire beginning in 2017, we anticipate that generic PDE5 inhibitors will enter the market. Generic PDE5 inhibitors would likely be sold at lower prices and may reduce the demand for STENDRA especially at the prices we would be required to charge for STENDRA to cover our manufacturing and other costs. In addition, PDE5 inhibitors are in various stages of development by other companies. Warner-Chilcott plc has licensed the U.S. rights to udenafil, a PDE5 inhibitor from Dong-A. Warner-Chilcott continues Phase 3 development of this compound. Other treatments for ED exist, such as needle injection therapies, vacuum constriction devices and penile implants, and the manufacturers of these products will most likely continue to develop or improve these therapies.

Qsymia and avanafil may also face challenges and competition from newly developed generic products. Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, newly approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act stimulates competition by providing incentives to generic pharmaceutical manufacturers to introduce non-infringing forms of patented pharmaceutical products and to challenge patents on branded pharmaceutical products. If we are unsuccessful at challenging an abbreviated new drug application filed pursuant to the Hatch-Waxman Act, a generic version of Qsymia or avanafil may be launched, which would harm our business.

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

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

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

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

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

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

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

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

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

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

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

Further, any investigational drug candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and obtaining approval by the FDA and applicable foreign regulatory authorities. All investigational drug candidates are prone to certain

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

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

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

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

We do not have the ability to manufacture the materials we use in our pre-clinical and clinical trials and 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 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 Qsymia for the treatment of obesity. Catalent supplied the product for the Phase 3 program. In addition, Catalent is our sole source of clinical and commercial supplies for Qsymia. While Catalent has significant experience in commercial scale up manufacturing, there is no assurance that they will be successful with the commercial scale up of Qsymia, 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 currently rely on MTPC to supply the API and the tablets. In August 2012, we entered into an amendment to our agreement with MTPC that permits us to manufacture the API and tablets for avanafil ourselves or through third parties. The transition away from MTPC supply will need to occur on or before June 2015. 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 STENDRA, or the approval, or the timing of approval, of SPEDRA 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 STENDRA will be adversely effected, which in turn could have a detrimental impact on our financial results and could impact our ability to enter into a collaboration for the commercialization of STENDRA. Additionally, any future manufacturing sites would need to be inspected by the U.S. and EU authorities, and any failure of such manufacturing sites to receive approval from FDA or foreign authorities, obtain and maintain ongoing FDA or foreign regulatory compliance, or manufacture avanafil API or tablets in expected quantities, could adversely affect future sales of STENDRA, 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 STENDRA.

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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.

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

Even though we do not 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, offering 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, as amended by the Health Information Technology for Economic and Clinical Health, or HITECH, Act, 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. Some state laws also require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures.

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

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

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

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

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

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

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

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

We obtain the necessary raw materials and components for the manufacture of Qsymia and STENDRA as well as certain services, such as analytical testing packaging and labeling, from third parties. In particular, we rely on Catalent Pharma Solutions, LLC to supply Qsymia capsules. We and these suppliers and service providers are required to follow cGMP requirements and are subject to routine and unannounced inspections by the FDA and by state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Upon inspection of these facilities, the FDA or foreign regulatory agencies may find the manufacturing process or facilities are not in compliance with cGMP requirements and other regulations. Because manufacturing processes are highly complex and are subject to a lengthy regulatory approval process, alternative qualified supply may not be available on a timely basis or at all. Difficulties or delays in our suppliers' manufacturing and supply of raw materials and components could delay our clinical trials, increase our costs, damage our reputation and cause us to lose revenue or market share if we are unable to timely meet market demands.

We have an agreement with MTPC to supply the active pharmaceutical ingredient, or API, and the tablets for STENDRA. 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 STENDRA, or the approval, or the timing of approval, of SPEDRA in the EU.

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.

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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 measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide. These changes could impact our ability to maximize revenues in the Federal marketplace.

The Affordable Care Act substantially changed the way health care is financed by both governmental and private insurers, and could have a material adverse effect on our future business, cash flows, financial condition and results of operations, including by operation of the following provisions:

- Effective March 23, 2010, Medicaid managed care programs became eligible for drug rebates. This expanded eligibility affects our rebate liability for those state entities which have Medicaid managed care programs.

- Effective January 1, 2011, pharmaceutical companies must provide rebates to cover a portion of the Medicare Part D coverage gap or "donut hole," which is a portion of the gap between Medicare funding and Medicare recipients' drug deductibles. We currently do not anticipate coverage under Medicare Part D, but this could change in the future.

- We expect the number of Medicaid patients to increase gradually through 2014. We further expect this expansion more likely to impact the number of adults in Medicaid because many states have already set their eligibility criteria for children at or above the level designated in the Healthcare Reform Acts. An increase in the proportion of patients who receive our drugs and who are covered by Medicaid could adversely affect our net sales.

Presently, uncertainty exists as many of the specific determinations necessary to implement the Affordable Care Act have yet to be decided and communicated to industry participants. At this time, we cannot predict the full impact of the Affordable Care Act, or the timing and impact of any future rules or regulations promulgated to implement the Affordable Care Act.

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

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

Both of the active ingredients in Qsymia, phentermine and topiramate are available as generics. Based on the research we have completed to date, we are unable to determine whether Qsymia will be subject to reimbursement or at what level reimbursement may occur. The exact doses of the active ingredients in the final formulation of Qsymia 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 Qsymia is dependent on the titration, dosing and formulation, which we believe could not be easily duplicated, if at all, with the use of

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generic substitutes. However, there can be no assurance that we will be able to provide for optimal reimbursement of Qsymia as a treatment for obesity or 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 Qsymia in order to treat obesity at a potential lower cost.

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

Setbacks in the pharmaceutical and biotechnology industries, such as those caused by safety concerns relating to high-profile drugs like Avandia, Vioxx and Celebrex, or investigational drug candidates, as well as competition from generic drugs, litigation, and industry consolidation, may have an adverse effect on us. For example, pharmaceutical companies may be less willing to enter into new collaborations or continue existing collaborations if they are integrating a new operation as a result of a merger or acquisition or if their therapeutic areas of focus change following a merger. Moreover, our and our collaborators' ability to commercialize any of our approved drugs or future investigational drug candidates will depend in part on government regulation and the availability of coverage and adequate reimbursement from third-party 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. Adoption of legislation and regulations could 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 drugs could limit market acceptance of these drugs.

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 discounts that a manufacturer may provide are a factor that the plan can consider in determining a drug's 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 Qsymia 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 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

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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.

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.

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 STENDRA is located in Japan near known earthquake fault zones and is vulnerable to damage from earthquakes and tsunamis. We are also vulnerable to damage from other disasters, such as power loss, fire, floods and similar events. If a significant disaster occurs, our ability to continue our operations could be seriously impaired and we may not have adequate insurance to cover any resulting losses. Any significant unrecoverable losses could seriously impair our operations and financial conditions.

Risks Relating to our Intellectual Property

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

We hold various patents and patent applications in the U.S. and abroad targeting obesity and morbidities related to obesity, including sleep apnea and diabetes, and male sexual health, among other indications. The procedures for obtaining a patent in the U.S. and in most foreign countries are complex. These procedures require an analysis of the scientific technology related to the invention and many sophisticated legal issues. 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, even if our patent applications issue as patents, we cannot make assurances as to how much protection, if any, will be provided by these patents. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Others may independently develop similar or alternative technologies or design around our patented technologies or products. These companies would then be able to develop,

manufacture and sell products that compete directly with our products. In that case, our revenues and operating results could decline. Other entities may also challenge the validity or enforceability of our patents and patent applications in litigation or administrative proceedings. If a competitor or a generic pharmaceutical provider successfully challenges one or more of our patents, the protection provided by these patents could be reduced or eliminated.

We believe the United States Supreme Court's ruling in *KSR International Co. v. Teleflex, Inc.* raised the standards for patentability and eased the requirements for proving that a patent is obvious. This ruling may make it more difficult to obtain patents for combination pharmaceutical drugs and to defend successfully against claims that such patents are invalid. 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 successfully 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.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The U.S. Patent Office is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

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

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

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

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

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

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

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

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

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

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;

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

Further, any investigational drug candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and 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.

Risks Relating to our Financial Position and Need for Financing

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

We expect that our existing capital resources combined with future anticipated cash flows will be sufficient to support our operating activities at least through 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 and time required to set up a distribution system and REMS program for Qsymia that is suitable to address any FDA concerns;
- our ability to successfully commercialize Qsymia in the U.S.;
- our ability to successfully commercialize by establishing marketing partnerships for STENDRA in the U.S. and Qsiva and SPEDRA, if approved, in our territories outside the U.S.;
- the cost, timing and outcome of the post-approval clinical studies the FDA has required us to perform as part of the approval for STENDRA and the post-approval cardiovascular outcomes study we agreed to perform for Qsymia;
- the progress and costs of our research and development programs;
- the scope, timing, costs and results of pre-clinical, clinical and retrospective observational studies and trials;
- the cost of access to electronic records and databases that allow for retrospective observational studies;
- patient recruitment and enrollment in future clinical trials;
- the costs involved in seeking regulatory approvals for future drug candidates;
- the costs involved in filing and pursuing patent applications, defending and enforcing patent claims;

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- 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;
- the cost of manufacturing and commercialization activities and arrangements;
- the level of resources devoted to our future sales and marketing capabilities;
- the cost, timing and outcome of litigation, if any;
- the impact of healthcare reform, if any, imposed by the federal government; and

- the activities of competitors.

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

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

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

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. We have financed our operations, and we expect to continue to finance our operations, primarily by issuing and selling our common stock. For example, in March 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.

We may also raise additional capital through the incurrence of debt, and the holders of any debt we may issue would have rights superior to our stockholders' rights in the event we are not successful and are forced to seek the protection of bankruptcy laws. In addition, debt financing typically contains covenants that restrict operating activities. Any future debt financing we enter into may involve similar or more onerous covenants that restrict our operations.

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

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

At June 30, 2012, we had $80.9 million in cash and cash equivalents and $229.5 million in available-for-sale securities. While at June 30, 2012, our excess cash balances were invested in money market and U.S. Treasury securities, our investment policy as approved by our Board of Directors, also provides for investments in debt securities of U.S. government agencies, corporate debt securities and asset-backed securities. Our investment policy has the primary investment objectives of preservation of principal. However, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy.

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Although the U.S. congress was able to resolve the debt ceiling issue in time to avoid default, the major credit rating agencies have expressed their ongoing concern about the high levels of debt that the U.S. government has taken on. Standard & Poor's announced that it had revised its outlook on the long-term credit rating of the U.S. to negative, which could affect the trading market for U.S. government securities. These factors could impact the liquidity or valuation of our available-for-sale securities, all of which were invested in U.S. treasury securities as of June 30, 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.

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

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

We have an accumulated deficit of $389.1 million as of June 30, 2012, and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of $389.1 million for the period from our inception through June 30, 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 our sale of Evamist. Utilization of our net operating loss and tax credit carryforwards, or Tax Attributes, may be subject to substantial annual limitations provided by the Internal Revenue Code and similar state provisions to the extent certain ownership changes are deemed to occur. Such an annual limitation could result in the expiration of the Tax Attributes before utilization. The Tax Attributes reflected above have not been reduced by any limitations. To the extent it is determined upon completion of the analysis that such limitations do apply, we will adjust the Tax Attributes accordingly. We face the risk that our ability to use our Tax Attributes will be substantially restricted if we undergo an "ownership change" as defined in Section 382 of the U.S. Internal Revenue Code, or Section 382. An ownership change under Section 382 would occur if "5-percent shareholders," within the meaning of Section 382, collectively increased their ownership in the Company by more than fifty percentage points over a rolling three-year period. There can be no assurance that a Section 382 ownership change has not occurred or will not occur in the future.

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

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

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Risks Relating to an Investment in our Common Stock

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

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

- our ability to meet the expectations of investors related to the commercialization of Qsymia and STENDRA;
- the costs, timing and outcome of post-approval clinical studies which the FDA has required us to perform as part of the approval for STENDRA and the post-approval cardiovascular outcomes study we are undertaking for Qsymia;
- the cost and time required to set up a distribution system and a REMS program for Qsymia that is suitable to address any FDA concerns;
- results within the clinical trial programs for Qsymia and STENDRA or other results or decisions affecting the development of our investigational drug candidates;
- announcements of technological innovations or new products by us or our competitors;
- approval of or announcements of Phase 3 data of other anti-obesity compounds in development;
- publication of generic drug combination weight loss data by outside individuals or companies;
- actual or anticipated fluctuations in our financial results;
- our ability to obtain needed financing;
- sales by insiders or major stockholders;
- economic conditions in the U.S. and abroad;
- the volatility and liquidity of the financial markets;
- comments by or changes in assessments of us or financial estimates by security analysts;
- adverse regulatory actions or decisions;
- any loss of key management;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- discussions about us or our stock price by the financial and scientific press and in online investor communities;
- investment activities employed by short sellers of our common stock;
- developments or disputes concerning patents or other proprietary rights;
- licensing, product, patent or securities litigation; and

- public concern as to the safety and efficacy of our drugs or future investigational drug candidates developed by us.

These factors and fluctuations, as well as political and other market conditions, may adversely affect the market price of our common stock. Securities related class action litigation is often brought against a company 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.

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

Our operating results will likely fluctuate from fiscal quarter to fiscal quarter, and from year to year, and are difficult to predict. We have not commenced sales of Qsymia or entered a marketing, sales or promotional arrangement with a pharmaceutical partner to commercialize STENDRA. Our operating expenses are largely independent of sales in any particular period. We believe that our quarterly and annual results of operations may be negatively affected by a variety of factors. These factors include, but are not limited to, the level of patient demand for Qsymia and STENDRA, the ability of our distribution partners to process and ship product on a timely basis, the success of our third-party's manufacturing efforts to meet customer demand, fluctuations in foreign exchange rates, investments in sales and marketing efforts to support the sales of Qsymia and STENDRA, investments in the research and development efforts, and expenditures we may incur to acquire additional products.

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

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

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

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

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

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

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. REMOVED AND RESERVED

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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)†	Commercial Manufacturing and Packaging Agreement by and between the Registrant and Catalent Pharma Solutions, LLC dated as of July 17, 2012.
31.1	Certification of Chief Executive Officer, dated August 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 August 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 June 30, 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).

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

(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, filed with the Commission on March 28, 1997.

(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 July 23, 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: August 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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Exhibit 31.1

CERTIFICATION

I, Leland F. Wilson, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 7, 2012

By: /s/ LELAND F. WILSON
Leland F. Wilson
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Timothy E. Morris, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 7, 2012

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

Exhibit 32

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

I, Leland F. Wilson, Chief Executive Officer of VIVUS, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended June 30, 2012 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: August 7, 2012

By: /s/ LELAND F. WILSON
Leland F. Wilson

I, Timothy E. Morris, Sr. Vice President Finance and Global Corporate Development, Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended June 30, 2012 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: August 7, 2012

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