VIVUS INC
Form 10-Q
August 08, 2008
Table of Contents

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, 2008

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**	**94040**
(Address of principal executive office)	(Zip Code)

(650) 934-5200

(REGISTRANT S TELEPHONE NUMBER, INCLUDING AREA CODE)

N/A

(FORMER NAME, FORMER ADDRESS AND FORMER FISCAL YEAR, IF CHANGED SINCE LAST REPORT)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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 o	Accelerated filer x
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 25, 2008, 60,693,330 shares of common stock, par value $.001 per share, were outstanding.

Table of Contents

VIVUS, INC.

Quarterly Report on Form 10-Q

INDEX

Table of Contents

PART I: FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

VIVUS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

	JUNE 30 2008 (UNAUDITED)	DECEMBER 31 2007*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 66,641	$ 37,838
Available-for-sale securities	85,647	141,672
Accounts receivable, (net of allowance for doubtful accounts of $16 and $29 at June 30, 2008 and December 31, 2007, respectively)	3,686	4,202
Inventories, net	2,817	2,567
Prepaid expenses and other assets	3,012	5,313
Total current assets	161,803	191,592
Property, plant and equipment, net	7,028	7,417
Restricted cash	700	700
Available-for-sale securities, non-current	2,808	
Total assets	$ 172,339	$ 199,709
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 11,216	$ 7,768
Accrued product returns	2,521	2,498
Accrued research and clinical expenses	3,480	1,902
Accrued chargeback reserve	1,389	1,314
Accrued employee compensation and benefits	1,842	1,999
Deferred revenue-short term	73,718	84,183
Accrued and other liabilities	1,248	1,698
Total current liabilities	95,414	101,362
Notes payable-long term	5,862	5,062
Deferred revenue-long term	1,492	33,118
Total liabilities	102,768	139,542
Commitments and contingencies		
Stockholders equity:		

Preferred stock; $1.00 par value; 5,000 shares authorized; no shares issued and outstanding at June 30, 2008 and December 31, 2007				
Common stock; $.001 par value; 200,000 shares authorized; 60,673 shares issued and outstanding at June 30, 2008 and 58,873 at December 31, 2007		61		59
Additional paid-in capital		242,966		230,005
Accumulated other comprehensive loss		(114)		(68)
Accumulated deficit		(173,342)		(169,829)
Total stockholders equity		69,571		60,167
Total liabilities and stockholders equity	$	172,339	$	199,709

* Derived from audited consolidated financial statements filed in the Company s 2007 Annual Report on Form 10-K.

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

AND OTHER COMPREHENSIVE INCOME (LOSS)

(In thousands, except per share data)

	THREE MONTHS ENDED JUNE 30		SIX MONTHS ENDED JUNE 30	
	2008	2007	2008	2007
	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)
Revenue:				
United States product, net	$ 2,923	$ 3,037	$ 4,011	$ 3,497
International product	1,300	946	1,854	2,059
License and other revenue	21,046	115	42,092	231
Total revenue	25,269	4,098	47,957	5,787
Operating expenses:				
Cost of goods sold and manufacturing expense	2,929	3,191	5,716	5,762
Research and development	15,335	3,955	38,706	6,966
Selling, general and administrative	4,345	4,192	8,597	8,297
Total operating expenses	22,609	11,338	53,019	21,025
Income (loss) from operations	2,660	(7,240)	(5,062)	(15,238)
Interest income (expense):				
Interest income	1,109	698	1,866	1,465
Interest expense	(185)	(130)	(307)	(284)
	924	568	1,559	1,181
Income (loss) before provision for income taxes	3,584	(6,672)	(3,503)	(14,057)
Provision for income taxes	(5)	(6)	(10)	(12)
Net income (loss)	$ 3,579	$ (6,678)	$ (3,513)	$ (14,069)
Other comprehensive income (loss):				
Unrealized gain (loss) on securities	259	(1)	(46)	3
Comprehensive income (loss)	$ 3,838	$ (6,679)	$ (3,559)	$ (14,066)
Net income (loss) per share:				
Basic and diluted	$ 0.06	$ (0.11)	$ (0.06)	$ (0.24)
Shares used in per share computation:				
Basic	60,351	58,475	59,616	58,359
Diluted	61,850	58,475	59,616	58,359

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	SIX MONTHS ENDED JUNE 30 2008 (UNAUDITED)	SIX MONTHS ENDED JUNE 30 2007 (UNAUDITED)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (3,513)	$ (14,069)
Adjustments to reconcile net loss to net cash used in operating activities:		
Provision for doubtful accounts	(14)	(12)
Provision for excess inventory		(2)
Depreciation	564	535
Net realized gain on investments	(89)	
Other-than-temporary loss on investments	1,567	
Share-based compensation expense	2,649	1,845
Loss on disposal of property and equipment		2
Sale of Evamist assets		559
Changes in assets and liabilities:		
Accounts receivable	530	1,674
Inventories	(250)	(126)
Prepaid expenses and other assets	2,301	(429)
Accounts payable	3,448	490
Accrued product returns	23	(356)
Accrued research and clinical expenses	1,578	681
Accrued chargeback reserve	75	(621)
Accrued employee compensation and benefits	(157)	(411)
Deferred revenue	(42,091)	9,769
Accrued and other liabilities	(477)	(346)
Net cash used for operating activities	(33,856)	(817)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases	(175)	(180)
Proceeds from sale of property and equipment		3
Investment purchases		(16,195)
Proceeds from sale/maturity of securities	51,693	16,673
Net cash provided by investing activities	51,518	301
CASH FLOWS FROM FINANCING ACTIVITIES:		
Borrowing under note agreements	889	379
Principal payments under note agreements	(62)	(6,757)
Exercise of common stock options	485	1,499
Sale of common stock through employee stock purchase plan	141	149
Proceeds from issuance of common stock	9,688	
Net cash provided by (used for) financing activities	11,141	(4,730)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	28,803	(5,246)
CASH AND CASH EQUIVALENTS:		
Beginning of period	37,838	44,628

End of period	$	66,641	$	39,382
SUPPLEMENTAL CASH FLOW DISCLOSURE:				
Reclassification of income taxes payable to accumulated deficit	$		$	1,206

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

VIVUS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2008

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. 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. 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-month period ended June 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. The unaudited 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, 2007, as filed on March 7, 2008 with the Securities and Exchange Commission. The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

Use of Estimates

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

2. REVENUE RECOGNITION

The Company recognizes product revenue when the following four criteria are met:

- persuasive evidence of an arrangement exists;
- shipment has occurred;
- the sales price is fixed or determinable; and
- collectibility is reasonably assured.

The Company recognizes revenue upon shipment when title passes to the customer and risk of loss is transferred to the customer. The Company does not have any post shipment obligations.

United States

The Company primarily sells its products through wholesalers in the United States. The Company provides for government chargebacks, rebates, returns and other adjustments in the same period the related product sales are recorded. Reserves for government chargebacks, rebates, returns and other adjustments are based upon analysis of historical data. Each period the Company reviews its reserves for government chargebacks, rebates, returns and other adjustments based on data available at that time. Any adjustment to these reserves results in charges to the amount of product sales revenue recognized in the period.

International

The Company has supply agreements with Meda AB (Meda) to market and distribute MUSE internationally in some Member States of the European Union. In Canada, the Company has entered into a license and supply agreement with Paladin Labs, Inc. (Paladin) for the marketing and distribution of MUSE. Sales to Meda, who supplies MUSE in the European marketplace, for 2007,

Table of Contents

2006 and 2005 were 95.8%, 91.7% and 93.4% of international sales, respectively. The balance of international sales was made to Paladin.

The Company invoices its international distributors based on an agreed transfer price per unit, which is subject to revision upon quarterly reconciliations based on contractual formulas. Final pricing for product shipments to international distributors is subject to contractual formulas based on the distributor s net realized price to its customers. The Company recognizes additional revenue, if any, upon finalization of pricing with its international distributors. International distributors generally do not have the right to return products unless the products are damaged or defective.

The Company initially recorded $1.5 million of unearned revenue related to an upfront payment in accordance with the international supply agreement signed with Meda in September 2002. In January 2006, the Company received a milestone payment from Meda of $2 million. The milestone payment provides Meda with the right to continue to sell and distribute MUSE in its European territories. These amounts are being recognized as income ratably over the term of the supply agreement. Through June 30, 2008, $1.6 million has been recognized as revenue.

License and Other Revenue

The Company recognizes license revenue in accordance with the Securities and Exchange Commission s Staff Accounting Bulletin No. 104, Revenue Recognition, and Emerging Issues Task Force (EITF) Issue 00-21, *Revenue Arrangements with Multiple Deliverables*. Revenue arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the delivered item has standalone value to the customer, and whether there is objective, reliable evidence of the fair value of the undelivered items. Consideration received is allocated among the separate units of accounting based on their relative fair values, and the applicable revenue recognition criteria are identified and applied to each of the units.

Revenue from non-refundable, upfront license fees where the Company has continuing involvement is recognized ratably over the development or agreement period. Revenue associated with performance milestones is recognized based upon the achievement of the milestones, as defined in the respective agreements.

Sale of Evamist product

On May 15, 2007, the Company closed its transaction with K-V Pharmaceutical Company for the sale of its product candidate, Evamist. At the time of the sale, Evamist was an investigational product and was not yet approved by the FDA for marketing. The sale transaction contained multiple deliverables, including: the delivery at closing of the Evamist assets, a grant of a sublicense of the Company s rights under a license related to Evamist, and a license to the metered-dose transdermal spray, or MDTS, applicator; the delivery upon receipt of regulatory approval of the approved drug along with all regulatory submissions; and, lastly, the delivery after FDA approval of certain transition services and a license to improvements to the MDTS applicator. The Company received approval from the FDA to market Evamist on July 27, 2007 (FDA Approval), and on August 1, 2007, the Company transferred and assigned the Evamist FDA submissions, and all files related thereto, to K-V. The Company received an upfront payment of $10 million upon the closing and received an additional $140 million milestone payment in August 2007 upon FDA Approval. These payments are non-refundable.

Upon FDA Approval, the two remaining deliverables are the transition services to be performed under the Transition Services Agreement (TSA) and a license to improvements to the MDTS applicator during the two-year period commencing with the closing, or May 15, 2007, and ending on May 15, 2009. The Company has been able to establish fair value for the TSA. Given the unique nature of the license to improvements, the Company is unable to obtain objective, reliable evidence of its fair value.

Accordingly, the delivered items, together with the undelivered items, are treated as one unit of accounting. Since the deliverables are treated as a single unit of accounting, the total cash received, $150 million, will be recognized as revenue on a pro-rata basis over the term of the last deliverable, which in this case is the license to improvements that expires on May 15, 2009. As a result, the initial $10 million paid at closing and the $140 million paid upon FDA Approval have been recorded as deferred revenue and will be recognized as revenue together with the future billings, if any, under the TSA, ratably over the remaining 21.5-month term of the license to improvements, from August 1, 2007 to May 15, 2009. Through June 30, 2008, $76.7 million has been recognized as revenue.

The Company may also receive milestone payments of up to $30 million based upon sales of Evamist through the term of the agreements. Revenue associated with performance milestones will be recognized based upon the achievement of the milestones, as defined in the respective agreements.

7

Table of Contents

3. SHARE-BASED COMPENSATION

The Company accounts for share-based compensation in accordance with SFAS No. 123R, *Share-Based Payment*, which was adopted January 1, 2006, utilizing the modified prospective transition method.

Total estimated share-based compensation expense, related to all of the Company s share-based awards, recognized for the three and six months ended June 30, 2008 and 2007 was comprised as follows (in thousands, except per share data):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2008		2007		2008		2007	
Cost of goods sold and manufacturing expense	$	153	$	146	$	290	$	269
Research and development		334		226		817		454
Selling, general and administrative		756		567		1,542		1,122
Share-based compensation expense before taxes		1,243		939		2,649		1,845
Related income tax benefits								
Share-based compensation expense, net of taxes	$	1,243	$	939	$	2,649	$	1,845
Basic and diluted per common share	$	0.02	$	0.02	$	0.04	$	0.03

At June 30, 2008, a total of 6,766,167 stock options and restricted stock units were outstanding under the Company s stock option plans. Stock-based compensation expense recognized for the quarters and six months ended June 30, 2008 and 2007 included compensation expense for stock options granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123. Included in stock-based compensation expense was $1,222,000 and $895,000 related to stock options, $13,000 and $29,000 related to the employee stock purchase plan, and $8,000 and $15,000 related to restricted stock units, net of the estimated forfeitures for the second quarters of 2008 and 2007, respectively. For the six months ended June 30, 2008 and 2007, included in stock-based compensation expense was $2.6 million and $1.8 million related to stock options, $43,000 and $62,000 related to the employee stock purchase plan, and $16,000 and $29,000 related to restricted stock units, net of the estimated forfeitures for the first six months of 2008 and 2007, respectively.

As of June 30, 2008, unrecognized estimated compensation expense totaled $5 million related to non-vested stock options, $35,000 related to the employee stock purchase plan, and $44,000 related to restricted stock units. The weighted average remaining requisite service period of the non-vested options was 1.4 years, of the employee stock purchase plan was 4.5 months, and of the restricted stock units was 3.1 years.

A summary of stock option award activity under these plans is as follows:

	Six Months Ended June 30, 2008		
	Shares	Weighted Average Exercise Price	
Outstanding at January 1, 2008	5,348,501	$	4.25
Granted	1,531,944	$	6.05
Exercised	(140,524)	$	3.45
Cancelled	(36,254)	$	5.66
Outstanding at June 30, 2008	6,703,667	$	4.67
Options exercisable at June 30, 2008	3,827,798		
Weighted average fair value of options granted		$	4.41

8

Table of Contents

A summary of restricted stock units award activity under the 2001 Plan as of June 30, 2008 and changes during the six-month period then ended are presented below:

	Six Months Ended June 30, 2008					
	Number of Restricted Stock Units		Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (Years)		Aggregate Intrinsic Value
Restricted stock units outstanding January 1, 2008	62,500	$	2.04	3.7	$	255,000
Granted						
Vested						
Forfeited						
Restricted stock units outstanding, June 30, 2008	62,500	$	2.04	3.1	$	255,000

At June 30, 2008, stock options were outstanding and exercisable as follows:

		Options Outstanding			Options Exercisable		
Range of Exercise Prices	Number Outstanding at June 30, 2008	Weighted-Average Remaining Contractual Life		Weighted-Average Exercise Price	Number Exercisable June 30, 2008		Weighted-Average Exercise Price
$ 2.00 - $4.15	2,515,028	5.46 years	$	3.54	2,045,961	$	3.55
$ 4.25 - $5.67	2,356,552	7.16 years	$	4.54	1,288,719	$	4.67
$ 5.69 - $8.08	1,832,087	8.25 years	$	6.39	493,118	$	7.29
$ 2.00 - $8.08	6,703,667	6.82 years	$	4.67	3,827,798	$	4.41

The aggregate intrinsic value of outstanding options as of June 30, 2008 was $13.9 million, of which $9.1 million related to exercisable options.

At June 30, 2008, 974,436 options remain available for grant. 1,000,000 shares were registered on a Form S-8 filed with the SEC on May 5, 2008. In the six months ended June 30, 2008, in accordance with the terms of the 2001 Plan, the Company transferred a net total of 5,000 expired plan shares to the 2001 Plan. Options under these plans generally vest over four years, and all options expire after 10 years.