

ZOGENIX, INC.
Form 10-Q
May 09, 2013
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2013
OR

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

For the transition period from _____ to _____
Commission file number: 001-34962

Zogenix, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	20-5300780
(State or Other Jurisdiction of	(I.R.S. Employer
Incorporation or Organization)	Identification No.)

12400 High Bluff Drive, Suite 650	92130
San Diego, California	(Zip Code)
(Address of Principal Executive Offices)	
858-259-1165	
(Registrant's Telephone Number, Including Area Code)	

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
-------------------------	--------------------------	-------------------	-------------------------------------

Non-accelerated filer	<input type="checkbox"/>	(Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
-----------------------	--------------------------	---	---------------------------	--------------------------

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

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of May 1, 2013 was 100,808,601.

Table of Contents

ZOGENIX, INC.

FORM 10-Q

For the Quarterly Period Ended March 31, 2013

Table of Contents

	Page
 <u>PART I. FINANCIAL INFORMATION</u>	
Item 1	<u>Consolidated Financial Statements:</u>
	<u>Consolidated Balance Sheets as of March 31, 2013 (unaudited) and December 31, 2012</u> 3
	<u>Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2013 and 2012 (unaudited)</u> 4
	<u>Consolidated Statements of Cash Flows for the three months ended March 31, 2013 and 2012 (unaudited)</u> 5
	<u>Notes to the Consolidated Financial Statements (unaudited)</u> 6
Item 2	<u>Management Discussion and Analysis of Financial Condition and Results of Operations</u> 15
Item 3	<u>Quantitative and Qualitative Disclosures about Market Risk</u> 25
Item 4	<u>Controls and Procedures</u> 25
 <u>PART II. OTHER INFORMATION</u>	
Item 1	<u>Legal Proceedings</u> 26
Item 1A	<u>Risk Factors</u> 26
Item 2	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u> 39
Item 3	<u>Defaults Upon Senior Securities</u> 39
Item 4	<u>Mine Safety Disclosures</u> 39
Item 5	<u>Other Information</u> 39
Item 6	<u>Exhibits</u> 40

Table of Contents

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Zogenix, Inc.

Consolidated Balance Sheets

(In Thousands)

	March 31, 2013 (Unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$25,324	\$41,228
Trade accounts receivable, net	5,755	5,643
Inventory, net	12,663	12,886
Prepaid expenses and other current assets	2,995	1,968
Total current assets	46,737	61,725
Property and equipment, net	13,912	13,561
Other assets	4,921	5,400
Total assets	\$65,570	\$80,686
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$4,541	\$4,592
Accrued expenses	14,909	14,343
Common stock warrant liabilities	13,751	9,493
Accrued compensation	2,982	4,226
Total current liabilities	36,183	32,654
Long-term debt, less current portion	28,557	28,481
Other long-term liabilities	5,826	5,078
Commitments and contingencies		
Stockholders' equity:		
Common stock	101	101
Additional paid-in capital	345,349	343,763
Accumulated deficit	(350,446)	(329,391)
Total stockholders' equity (deficit)	(4,996)	14,473
Total liabilities and stockholders' equity (deficit)	\$65,570	\$80,686
See accompanying notes.		

Table of Contents

Zogenix, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In Thousands, except Per Share Amounts)

(Unaudited)

	Three Months Ended March 31,	
	2013	2012
Revenue:		
Net product revenue	\$6,981	\$9,885
Contract revenue	—	8,462
Total revenue	6,981	18,347
Operating expenses:		
Cost of sales	4,158	5,062
Royalty expense	282	357
Research and development	3,236	5,964
Selling, general and administrative	14,482	14,649
Total operating expenses	22,158	26,032
Loss from operations	(15,177) (7,685
Other income (expense):		
Interest income	8	19
Interest expense	(1,613) (2,678
Change in fair value of warrant liabilities	(4,258) 49
Change in fair value of embedded derivatives	(81) 38
Other income (expense)	66	(30
Total other income (expense)	(5,878) (2,602
Net loss before income taxes	(21,055) (10,287
Provision for income taxes	—	(5
Net loss	\$(21,055) \$(10,292
Net loss per share, basic and diluted	\$(0.21) \$(0.16
Weighted average shares outstanding, basic and diluted	100,809	65,369
Comprehensive loss	\$(21,055) \$(10,292
See accompanying notes.		

Table of Contents

Zogenix, Inc.

Consolidated Statements of Cash Flows

(In Thousands)

(Unaudited)

	Three Months Ended March 31,	
	2013	2012
Operating activities:		
Net loss	\$(21,055) \$(10,292
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,586	1,256
Depreciation and amortization	479	393
Amortization of debt issuance costs and non-cash interest	133	681
Change in fair value of warrant liabilities	4,258	(49
Change in fair value of embedded derivatives	81	(38
Changes in operating assets and liabilities:		
Trade accounts receivable	(112) (30
Inventory, net	223	1,995
Prepaid expenses and other current assets	(1,027) (431
Other assets	421	(197
Accounts payable and accrued expenses	(61) 452
Deferred revenue	—	(8,462
Net cash used in operating activities	(15,074) (14,722
Investing activities:		
Purchases of property and equipment	(830) (111
Net cash used in investing activities	(830) (111
Financing activities:		
Proceeds from revolving credit facility	—	5,163
Payments on borrowings of debt	—	(7,013
Proceeds from exercise of common stock options	—	2
Net cash used in financing activities	—	(1,848
Net decrease in cash and cash equivalents	(15,904) (16,681
Cash and cash equivalents at beginning of period	41,228	56,525
Cash and cash equivalents at end of period	\$25,324	\$39,844
See accompanying notes.		

Table of Contents

Zogenix, Inc.

Notes to Consolidated Financial Statements

1. Organization and Basis of Presentation

Zogenix, Inc. (the Company) is a pharmaceutical company developing and commercializing products for the treatment of central nervous system disorders and pain. The Company's first commercial product, Sumavel®DosePro®(sumatriptan injection) Needle-free Delivery System, offers fast-acting, easy-to-use, needle-free subcutaneous delivery of sumatriptan for the acute treatment of migraine and cluster headache in a pre-filled, single-use delivery system. Sumavel DosePro was approved by the U.S. Food and Drug Administration (FDA) on July 15, 2009 and was launched in the United States in January 2010.

The Company was incorporated in the state of Delaware on May 11, 2006 as SJ2Therapeutics, Inc. and commenced operations on August 25, 2006. On August 28, 2006, the Company changed its name to Zogenix, Inc.

The Company has incurred significant net losses since inception and has relied on its ability to fund its operations through equity financings, debt financings, revenues from the sale of its product Sumavel DosePro and proceeds from business collaborations. As the Company continues to incur losses, successful transition to profitability is dependent upon achieving a level of revenues adequate to support the Company's cost structure. This may not occur and, unless and until it does, the Company will continue to need to raise additional cash. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of liabilities in the normal course of business.

Management expects operating losses and negative cash flows to continue for at least the next several years as the Company continues to incur costs related to the continued development of its product candidates and commercialization of its approved product. Management may pursue additional opportunities to raise additional capital through public or private equity offerings, including through a controlled equity offering program, debt financings, receivables financings or through collaborations or partnerships with other companies if required to further support its planned operations. There can be no assurance that the Company will be able to obtain any source of financing on acceptable terms, or at all. If the Company is unsuccessful in raising additional required funds, it may be required to significantly delay, reduce the scope of or eliminate one or more of its development programs or its commercialization efforts, or cease operating as a going concern. The Company also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that it would otherwise seek to develop or commercialize itself on terms that are less favorable than might otherwise be available.

On March 27, 2013, the Company entered into a controlled equity offering sales agreement with Cantor Fitzgerald & Co., or Cantor, as sales agent, under which the Company can issue and sell shares of its common stock having an aggregate offering price of up to \$25.0 million from time to time through Cantor. The sales of common stock made under the controlled equity offering sales agreement will be made in "at-the-market" offerings as defined in Rule 415 of the Securities Act of 1933, as amended, or the Securities Act. However, there can be no assurance that Cantor will be successful in consummating such sales based on prevailing market conditions or in the quantities or at the prices that Management deems appropriate. As of March 31, 2013, the Company had not sold any shares under this program.

2. Summary of Significant Accounting Policies

Financial Statement Preparation and Use of Estimates

The unaudited consolidated financial statements contained in this Quarterly Report on Form 10-Q have been prepared by Zogenix, Inc. according to the rules and regulations of the Securities and Exchange Commission (SEC) and, therefore, certain information and disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles (GAAP) have been omitted.

In the opinion of management, the accompanying unaudited consolidated financial statements for the periods presented reflect all adjustments, which are normal and recurring, necessary to fairly state the financial position, results of operations and cash flows. These unaudited consolidated financial statements should be read in conjunction with the audited financial statements included in our Annual Report on Form 10-K for the fiscal year ended

December 31, 2012 filed with the SEC on March 15, 2013.

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ from those estimates.

Table of Contents

The Company has monitored actual product return history for Sumavel DosePro since product launch. Based on the Company's product returns analysis, which considers actual product returns on an individual product lot basis, and factors such as the dating of the Company's product at the time of shipment into the distribution channel, prescription trends and changes in the estimated levels of inventory within the distribution channel, the Company increased its estimate for product returns, resulting in an adjustment of \$1,226,000, which decreased net product sales in the first quarter of 2013.

Principles of Consolidation

The unaudited interim consolidated financial statements include the accounts of Zogenix, Inc. and its wholly owned subsidiary Zogenix Europe Limited, which was incorporated under the laws of England and Wales in June 2010. All intercompany transactions and investments have been eliminated in consolidation. Zogenix Europe Limited's functional currency is the U.S. dollar, the reporting currency of its parent.

Fair Value Measurements

The carrying amount of financial instruments consisting of cash, trade accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses, and accrued compensation included in the Company's consolidated financial statements are reasonable estimates of fair value due to their short maturities. Based on the borrowing rates currently available to the Company for loans with similar terms, management believes the fair value of long-term debt approximates its carrying value. The liability for the annual tail payments due to Astellas Pharma US, Inc. (Astellas) (see Note 4) for the termination of the Company's co-promotion agreement was measured at fair value in December 2011 using a present value technique, which incorporated the Company's own credit risk as measured by the most recent round of debt financing with Healthcare Royalty Partners (Healthcare Royalty) (formerly Cowen Healthcare Royalty Partners II, L.P.).

Authoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Table of Contents

We classify our cash equivalents within Level 1 of the fair value hierarchy because we value our cash equivalents using quoted market prices. We classify our common stock warrant liabilities and embedded derivative liabilities within Level 3 of the fair value hierarchy because they are valued using valuation models with significant unobservable inputs. Assets and liabilities measured at fair value on a recurring basis at March 31, 2013 and December 31, 2012 are as follows (in thousands):

	Fair Value Measurements at Reporting Date Using			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
At March 31, 2013				
Assets				
Cash equivalents ⁽¹⁾	\$22,012	—	—	\$22,012
Liabilities				
Common stock warrant liabilities ⁽²⁾	\$—	—	13,751	\$13,751
Embedded derivative liabilities ⁽³⁾	\$—	—	1,073	\$1,073
At December 31, 2012				
Assets				
Cash equivalents ⁽¹⁾	\$37,605	—	—	\$37,605
Liabilities				
Common stock warrant liabilities ⁽²⁾	\$—	—	9,493	\$9,493
Embedded derivative liabilities ⁽³⁾	\$—	—	992	\$992

(1) Cash equivalents are comprised of money market fund shares and are included as a component of cash and cash equivalents on the consolidated balance sheets.

(2) Common stock warrant liabilities include liabilities associated with warrants issued in connection with the Company's July 2012 public offering of common stock and warrants (see Note 5) and warrants issued in connection with the Healthcare Royalty financing agreement (see Note 4), which are measured at fair value using the Black-Scholes option pricing valuation model. The assumptions used in the Black-Scholes option pricing valuation model for both common stock warrant liabilities were: (a) a risk-free interest rate based on the rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the remaining contractual term of the warrants; (b) an assumed dividend yield of zero based on the Company's expectation that it will not pay dividends in the foreseeable future; (c) an expected term based on the remaining contractual term of the warrants; and (d) given the Company's lack of relevant historical data due to the Company's limited historical experience, an expected volatility based upon the Company's historical volatility, supplemented with historical volatility of comparable companies whose share prices have been publicly available for a sufficient period of time. The significant unobservable input used in measuring the fair value of the common stock warrant liabilities associated with the Healthcare Royalty financing agreement is the expected volatility. Significant increases in the volatility of comparable companies would result in a higher fair value measurement. The following additional assumptions were used in the Black-Scholes option pricing valuation model to measure the fair value of the warrants sold in the July 2012 public offering: (a) management's projections regarding the probability of the occurrence of an extraordinary event that would require cash settlement of the warrants; and for the valuation scenario in which an extraordinary event occurs, (b) a volatility rate equal to the lesser of 40% and the 180-day volatility rate obtained from the HVT function on Bloomberg as of the trading day immediately following the public announcement of an

extraordinary transaction. The significant unobservable input used in measuring the fair value of the common stock warrant liabilities associated with the July 2012 public offering is the expected volatility and probability of the occurrence of an extraordinary event. Significant increases in the volatility of comparable companies would result in a higher fair value measurement and significant increases in the probability of an extraordinary event occurring would result in a significantly lower fair value measurement.

Embedded derivative liabilities measured at fair value using various discounted cash flow valuation models are included as a component of other long-term liabilities on the consolidated balance sheets. The assumptions used in the discounted cash flow valuation models include: (a) management's revenue projections and a revenue sensitivity (3) analysis based on possible future outcomes; (b) probability weighted net cash flows based on the likelihood of Healthcare Royalty receiving revenue interest payments over the term of the financing agreement; (c) probability of bankruptcy; (d) weighted average cost of capital that included the addition of a company specific risk premium to account for

Table of Contents

uncertainty associated with the Company achieving future cash flows; (e) the probability of a change in control occurring during the term of the Healthcare Royalty financing agreement; and (f) the probability of an exercise of the embedded derivative instruments. The significant unobservable inputs used in measuring the fair value of the embedded derivatives are management's revenue projections. Significant decreases in these significant inputs would result in a higher fair value measurement.

The following table provides a reconciliation of liabilities measured at fair value using significant observable inputs (Level 3) for the three months ended March 31, 2013 (in thousands):

	Common Stock Warrant Liabilities	Embedded Derivative Liabilities
Balance at December 31, 2012	\$9,493	\$992
Changes in fair value	4,258	81
Balance at March 31, 2013	\$13,751	\$1,073

Changes in fair value of the liabilities shown in the table above are recorded through change in fair value of warrant liabilities and change in fair value of embedded derivatives in other income (expense) in the consolidated statements of operations and comprehensive loss.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, reduced by weighted average shares subject to repurchase, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method and as-if converted method, as applicable. For purposes of this calculation, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following table presents the computation of basic and diluted net loss per share (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2013	2012
Numerator		
Net loss	\$(21,055)	\$(10,292)
Denominator		
Weighted average common shares outstanding, basic and diluted	100,809	65,369
Basic and diluted net loss per share	\$(0.21)	\$(0.16)

The following table presents potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive (in thousands, of common equivalent shares):

	Three Months Ended March 31,	
	2013	2012
Common stock options and restricted stock units	123	87
	123	87

Segment Reporting

Management has determined that the Company operates in one business segment, which is the commercialization and development of pharmaceutical products.

Table of Contents

Recent Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board issued an Accounting Standards Update which requires entities to separately present amounts reclassified out of accumulated other comprehensive income (AOCI) for each component of AOCI and to disclose, for each affected line item in the income statement, the amount of AOCI that has been reclassified into that line item. For AOCI reclassification items that are not reclassified in their entirety into net income, it is acceptable to cross reference that amount to another footnote that provides the required disclosure. The updated guidance became effective for fiscal and interim periods beginning after December 15, 2012. The Company adopted this guidance on January 1, 2013 and it did not have a material impact on the Company's results of operations.

3. Inventory, net (in thousands)

	March 31, 2013	December 31, 2012
Raw materials	\$3,921	\$4,867
Work in process	7,907	6,134
Finished goods	835	1,885
	\$12,663	\$12,886

4. Collaboration and Financing Agreements

Mallinckrodt LLC Co-Promotion Agreement

On June 6, 2012, the Company and Mallinckrodt LLC (Mallinckrodt) entered into a co-promotion agreement (the Co-Promotion Agreement). Under the terms of the Co-Promotion Agreement, Mallinckrodt was granted a co-exclusive right (with the Company) to promote Sumavel DosePro to a mutually agreed prescriber audience in the United States. Mallinckrodt's sales team began selling Sumavel DosePro to its customer base of prescribers in August 2012. Mallinckrodt has committed to a minimum number of sales representatives for the initial term of the Co-Promotion Agreement, which runs through June 30, 2014, and can be extended by mutual agreement of the parties in additional six month increments. The Company remains responsible for the manufacture, supply and distribution of commercial product for sale in the United States. In addition, the Company will supply product samples to Mallinckrodt at an agreed upon transfer price and Mallinckrodt will reimburse the Company for all other promotional materials used.

In partial consideration of Mallinckrodt's sales efforts, the Company pays Mallinckrodt a service fee on a quarterly basis that represents a specified fixed percentage of net sales of prescriptions generated from Mallinckrodt's prescriber audience over a baseline amount of net sales to the same prescriber audience (the Baseline Net Sales). In addition, upon completion of the co-promotion term in June 30, 2014 (unless otherwise extended), and only if the Co-Promotion Agreement is not terminated as a result of certain circumstances, the Company will be required to pay Mallinckrodt an additional tail payment calculated as a fixed percentage of the Mallinckrodt net sales over the Baseline Net Sales during the first full 12 months following the last day of the term.

Mallinckrodt may terminate the Agreement with sixty days' notice in the event a material change is made to the net sales price of Sumavel DosePro that would result in a material adverse effect to Mallinckrodt's financial return (as defined in the Co-Promotion Agreement). Mallinckrodt may also terminate the Co-Promotion Agreement if its request for the inclusion on its call list of a certain number of additional prescribers is not mutually agreed upon. Lastly, Mallinckrodt may terminate the Co-Promotion Agreement if a governmental authority takes action or raises an objection that prevents or would reasonably be expected to make it unlawful for Mallinckrodt to perform, or subject Mallinckrodt to any penalty or claim, investigation or similar action related to, its obligations under the Co-Promotion Agreement, in the event of Company's inability to meet trade demand for commercial product or where a third party files an action alleging that the making or selling of Sumavel DosePro infringes the intellectual property rights of such third party.

The Company may terminate the Co-Promotion Agreement with sixty days' notice if Mallinckrodt does not achieve an agreed-upon minimum sales effort. Either party may terminate the agreement if certain