

ZOGENIX, INC.
Form 10-Q
August 08, 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 June 30, 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
(State or Other Jurisdiction of
Incorporation or Organization) 20-5300780
(I.R.S. Employer
Identification No.)

12400 High Bluff Drive, Suite 650
San Diego, California 92130
(Address of Principal Executive Offices) (Zip Code)
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 Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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

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The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of August 1, 2013 was 102,354,402.

Table of Contents

ZOGENIX, INC.
FORM 10-Q
For the Quarterly Period Ended June 30, 2013
Table of Contents

	Page
<u>PART I. FINANCIAL INFORMATION</u>	
Item 1 <u>Consolidated Financial Statements:</u>	
<u>Consolidated Balance Sheets as of June 30, 2013 (unaudited) and December 31, 2012</u>	<u>3</u>
<u>Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2013 and 2012 (unaudited)</u>	<u>4</u>
<u>Consolidated Statements of Cash Flows for the six months ended June 30, 2013 and 2012 (unaudited)</u>	<u>5</u>
<u>Notes to the Consolidated Financial Statements (unaudited)</u>	<u>6</u>
Item 2 <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>16</u>
Item 3 <u>Quantitative and Qualitative Disclosures about Market Risk</u>	<u>27</u>
Item 4 <u>Controls and Procedures</u>	<u>27</u>
<u>PART II. OTHER INFORMATION</u>	
Item 1 <u>Legal Proceedings</u>	<u>28</u>
Item 1A <u>Risk Factors</u>	<u>28</u>
Item 2 <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>45</u>
Item 3 <u>Defaults Upon Senior Securities</u>	<u>45</u>
Item 4 <u>Mine Safety Disclosures</u>	<u>45</u>
Item 5 <u>Other Information</u>	<u>45</u>
Item 6 <u>Exhibits</u>	<u>46</u>

Table of Contents

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Zogenix, Inc.

Consolidated Balance Sheets

(In Thousands)

	June 30, 2013 (Unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,121	\$ 41,228
Trade accounts receivable, net	4,138	5,643
Inventory, net	13,185	12,886
Prepaid expenses and other current assets	2,044	2,254
Total current assets	35,488	62,011
Property and equipment, net	13,414	13,561
Other assets	4,496	5,114
Total assets	\$ 53,398	\$ 80,686
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 6,337	\$ 4,592
Accrued expenses	12,052	14,343
Common stock warrant liabilities	12,488	9,493
Accrued compensation	2,518	4,226
Total current liabilities	33,395	32,654
Long-term debt, less current portion	28,638	28,481
Other long-term liabilities	7,452	5,078
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock	101	101
Additional paid-in capital	347,592	343,763
Accumulated deficit	(363,780)	(329,391)
Total stockholders' equity (deficit)	(16,087)	14,473
Total liabilities and stockholders' equity (deficit)	\$ 53,398	\$ 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 June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Revenue:				
Net product revenue	\$8,942	\$8,030	\$15,924	\$17,915
Contract revenue	—	—	—	8,462
Total revenue	8,942	8,030	15,924	26,377
Operating expenses:				
Cost of sales	4,630	4,167	8,789	9,229
Royalty expense	338	315	620	672
Research and development	3,577	6,381	6,814	12,345
Selling, general and administrative	12,000	12,068	26,482	26,717
Restructuring	876	—	876	—
Total operating expenses	21,421	22,931	43,581	48,963
Loss from operations	(12,479) (14,901) (27,657) (22,586
Other income (expense):				
Interest income	3	10	11	29
Interest expense	(1,595) (2,589) (3,208) (5,267
Change in fair value of warrant liabilities	1,264	(91) (2,995) (42
Change in fair value of embedded derivatives	(480) 330	(562) 368
Other income (expense)	(45) 72	22	42
Total other income (expense)	(853) (2,268) (6,732) (4,870
Net loss before income taxes	(13,332) (17,169) (34,389) (27,456
Provision for income taxes	—	—	—	(5
Net loss	\$(13,332) \$(17,169) \$(34,389) \$(27,461
Net loss per share, basic and diluted	\$(0.13) \$(0.26) \$(0.34) \$(0.42
Weighted average shares outstanding, basic and diluted	100,876	65,449	100,843	65,409
Comprehensive loss	\$(13,332) \$(17,169) \$(34,389) \$(27,461
See accompanying notes.				

Table of Contents

Zogenix, Inc.

Consolidated Statements of Cash Flows

(In Thousands)

(Unaudited)

	Six Months Ended June 30,	
	2013	2012
Operating activities:		
Net loss	\$ (34,389) \$ (27,461
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,364	2,794
Stock-based compensation, restructuring	201	—
Depreciation and amortization	945	790
Amortization of debt issuance costs and non-cash interest	276	797
Change in fair value of warrant liabilities	2,995	42
Change in fair value of embedded derivatives	562	(368
Changes in operating assets and liabilities:		
Trade accounts receivable	1,505	19
Inventory, net	(299) 1,237
Prepaid expenses and other current assets	210	(260
Other assets	498	(426
Accounts payable and accrued expenses	(584) 1,832
Restructuring liabilities	146	—
Deferred revenue	—	(8,462
Net cash used in operating activities	(24,570) (29,466
Investing activities:		
Purchases of property and equipment	(798) (291
Net cash used in investing activities	(798) (291
Financing activities:		
Proceeds from revolving credit facility	—	9,899
Payments on borrowings of debt	—	(15,040
Proceeds from exercise of common stock options	—	2
Proceeds from issuance of common stock and common stock warrants	261	345
Net cash provided by (used in) financing activities	261	(4,794
Net decrease in cash and cash equivalents	(25,107) (34,551
Cash and cash equivalents at beginning of period	41,228	56,525
Cash and cash equivalents at end of period	\$ 16,121	\$ 21,974
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 commercializing and developing 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 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, or the 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. The Company did not complete the issuance of any shares of its common stock pursuant to the sales agreement during the three months ended June 30, 2013. Subsequent to June 30, 2013, and through August 7, 2013, the Company agreed to issue 3.0 million shares of its common stock pursuant to the sales agreement at an average stock issuance price of \$1.66 per share, resulting in net proceeds of approximately \$4.9 million. As of August 7, 2013, the Company had the capacity to issue up to \$20.0 million in shares of its common stock under the sales agreement. However, there can be no assurance that Cantor will be successful in consummating further sales based on prevailing market conditions or in the quantities or at the prices that management deems appropriate.

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

Table of Contents

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.

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.

The Company classifies its cash equivalents within Level 1 of the fair value hierarchy because it values our cash equivalents using quoted market prices. The Company classifies its 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 June 30, 2013 and December 31, 2012 are as follows (in thousands):

Table of Contents

	Fair Value Measurements at Reporting Date Using			Total
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
At June 30, 2013				
Assets				
Cash equivalents ⁽¹⁾	\$ 13,415	—	—	\$ 13,415
Liabilities				
Common stock warrant liabilities ⁽²⁾	\$—	—	12,488	\$ 12,488
Embedded derivative liabilities ⁽³⁾	\$—	—	1,554	\$ 1,554
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.

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 6) 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 volatility 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 volatility 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.

(3) 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 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 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.

Table of Contents

The following table provides a reconciliation of liabilities measured at fair value using significant observable inputs (Level 3) for the six months ended June 30, 2013 (in thousands):

	Common Stock Warrant Liabilities	Embedded Derivative Liabilities
Balance at December 31, 2012	\$9,493	\$992
Changes in fair value	2,995	562
Balance at June 30, 2013	\$12,488	\$1,554

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		Six Months Ended	
	June 30, 2013	2012	June 30, 2013	2012
Numerator				
Net loss	\$(13,332) \$(17,169) \$(34,389) \$(27,461
Denominator				
Weighted average common shares outstanding, basic and diluted	100,876	65,449	100,843	65,409
Basic and diluted net loss per share	\$(0.13) \$(0.26) \$(0.34) \$(0.42

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 and Six Months Ended	
	June 30, 2013	2012
Common stock options and restricted stock units	1,710	6,171
	1,710	6,171

Segment Reporting

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

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

9

Table of Contents

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)

	June 30, 2013	December 31, 2012
Raw materials	\$3,517	\$4,867
Work in process	6,606	6,134
Finished goods	3,062	1,885
	\$13,185	\$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 Co-Promotion 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 Co-Promotion Agreement if certain minimum net sales thresholds are not met for any quarter ending after December 31, 2012 or certain levels of prescriptions are not met in a specified period. In addition, either party may terminate the Co-Promotion Agreement related to safety concerns, in the event of a change of control of itself or the other party (excluding with respect to Mallinckrodt, any public spin-off of Mallinckrodt from its corporate parent Covidien plc), upon the introduction of a generic product, in connection with the material breach of the other party's obligations or if a bankruptcy event occurs under certain circumstances.

Amounts payable to Mallinckrodt for service fees are reflected as selling, general and administrative expenses. For the three and six months ended June 30, 2013, the Company incurred \$226,000 and \$369,000, respectively, in service fee expenses under the Co-Promotion Agreement. The Company did not incur any service fee expenses under the Co-Promotion Agreement during the three and six months ended June 30, 2012.

Table of Contents

Astellas Pharma US, Inc. Co-Promotion Agreement

In July 2009, the Company entered into the co-promotion agreement with Astellas (Astellas Co-Promotion Agreement). Under the terms of the agreement, the Company granted Astellas the co-exclusive right (with the Company) to market and sell Sumavel DosePro in the United States until June 30, 2013. Under the Astellas Co-Promotion Agreement, both Astellas and the Company were obligated to collaborate and fund the marketing of Sumavel DosePro and to provide annual minimum levels of sales effort directed at Sumavel DosePro during the term. In December 2011, the Company entered into an amendment to the Astellas Co-Promotion Agreement, or the amended Astellas Co-Promotion Agreement, whereby the agreement terminated on March 31, 2012.

In connection with the execution of the Astellas Co-Promotion Agreement, Astellas made a non-refundable up-front payment of \$2,000,000 and made an additional \$18,000,000 of payments to the Company upon the achievement of a series of milestones. In consideration for Astellas' performance of its commercial efforts, the Company paid Astellas a service fee on a quarterly basis that represents a fixed percentage of between 45% and 55% of Sumavel DosePro net sales to primary care physicians, OB/GYNs, emergency medicine physicians, and urologists in the United States (Astellas Segment).

In accordance with accounting guidance for revenue arrangements with multiple deliverables, the Company initially recorded the \$20,000,000 in upfront and milestone payments received from Astellas as deferred revenue. Beginning with the launch of Sumavel DosePro in January 2010, the Company began amortizing the upfront and milestone payments as contract

revenue in the consolidated statement of operations and comprehensive loss over the term of the Astellas Co-Promotion Agreement. Upon termination of the Astellas Co-Promotion Agreement, the Company concluded that the remaining deferred revenue balance should be recognized ratably through the amended term of the agreement, and consequently, the remaining \$8,462,000 of these deferred contract revenues as of December 31, 2011 was recognized as contract revenue during the three months ended March 31, 2012.

The Company is required to make two annual tail payments to Astellas, calculated as decreasing fixed percentages of net sales in the Astellas Segment in the last 12 months of its active promotion. The value of such tail payments was estimated at a total of \$5,291,000 based upon the agreement termination date of March 31, 2012, and recorded as a long-term liability on the amendment date of December 20, 2011. The fair value of the tail payments is being accreted through interest expense through the dates of payment in July 2013 and July 2014. As of June 30, 2013 and December 31, 2012, the tail payment liability was \$3,082,000 and \$2,795,000 (including the service fee reduction discussed below), respectively. The first tail payment of \$2,032,000, which was made in July 2013, was included in accounts payable as of June 30, 2013. During the three months ended June 30, 2013 and 2012, \$146,000 and \$164,000 of related interest expense was recognized, respectively, and \$287,000 and \$321,000 of related interest expense was recognized during the six months ended June 30, 2013 and 2012, respectively.

Further, under the terms of the amended Astellas Co-Promotion Agreement, Astellas contributed its agreed upon portion of marketing expenses through March 31, 2012, and continued to earn a service fee based on product sales to the Astellas Segment during that period. As of April 1, 2012, the Company was no longer required to pay service fees to Astellas for sales of Sumavel DosePro. Additionally, beginning in the second quarter of 2012, the Company's sales force assumed full responsibility for the commercialization and the continued marketing of Sumavel DosePro, expanding their focus to include headache specialists, neurologists and primary care physicians in the United States. Amounts received from Astellas for shared marketing costs and sample product are reflected as a reduction of selling, general and administrative expenses, and amounts payable to Astellas for shared marketing expenses and service fees are reflected as selling, general and administrative expenses, inclusive of the estimated cost of the tail payments owed upon the termination of the agreement.

In August 2012, the Company and Astellas completed a final reconciliation under the terms of the Astellas Co-Promotion Agreement and agreed to adjust the service fees paid to Astellas over the term of the Astellas Co-Promotion Agreement, resulting in a service fee reduction of \$1,500,000, which offsets the two annual tail payments, and a reduction to the annual tail payment liability of \$742,000. The present value of the service fee receivable and tail payment reduction of \$1,924,000 was recorded as a reduction in selling, general and administrative expenses during the twelve months ended December 31, 2012, and an offset to the tail payment liability. The fair

value of the service fee receivable and tail payment reduction for each of the tail payments will be accreted through interest expense through the dates of the two tail payments in July 2013 and July 2014.

For the three and six months ended June 30, 2013 and 2012, the Company recognized shared marketing expense of \$0 and \$56,000, and \$0 and \$253,000, respectively, under the Astellas Co-Promotion Agreement.

For the three and six months ended June 30, 2013 and 2012, and prior to the final reconciliation of service fees, the Company incurred \$0 and \$58,000, and \$0 and \$1,757,000, respectively, in service fee expenses.

Table of Contents

Valeant Pharmaceuticals North America LLC Co-Promotion Agreement

On June 27, 2013, the Company entered into a co-promotion agreement (the Valeant Agreement) with Valeant Pharmaceuticals North America LLC (Valeant). Under the terms of the Valeant Agreement, the Company was granted the exclusive right (with Valeant or any of its affiliates) to promote Migranal® (dihydroergotamine mesylate) Nasal Spray (Migranal) to a prescriber audience of physicians and other health care practitioners in the United States. Under the Valeant Agreement, the Company's sales team will begin selling Migranal to prescribers no later than August 26, 2013. The term of the Valeant Agreement will run through December 31, 2015 (unless otherwise terminated), and can be extended by mutual agreement of the parties in additional twelve month increments. Valeant remains responsible for the manufacture, supply and distribution of Migranal for sale in the United States. In addition, Valeant will supply the Company with a specified amount of product samples every six months, and the Company will reimburse Valeant for the cost of additional samples and any promotional materials ordered by the Company.

In partial consideration of the Company's sales efforts, Valeant will pay the Company a co-promotion fee on a quarterly basis that represents specified percentages of net sales generated by the Company over defined baseline amounts of net sales (Baseline Forecast or Adjusted Baseline Forecast). In addition, upon completion of the co-promotion term, and only if the Valeant Agreement is not terminated by Valeant due to a bankruptcy event (as defined in the Valeant Agreement) or a material failure by the Company to comply with its material obligations under the Valeant Agreement, Valeant will be required to pay the Company an additional tail payment calculated as a fixed percentage of the Company's net sales over the Baseline Forecast (or Adjusted Baseline Forecast) during the first full six months following the last day of the term.

The Company may terminate the Valeant Agreement in the event of a Valeant supply failure (as defined in the Valeant Agreement) or material product recall, or if the net sales price in a fiscal quarter is less than a specified percentage of the net sales price in the immediately preceding quarter, if the reduction in such net sales price would have a material adverse effect on the Company's financial return as a result of performance of its obligation under the Valeant Agreement.

Either party may terminate the Valeant Agreement with six months' notice, provided that neither party may provide notice of termination before January 1, 2014. Either party may terminate the Valeant Agreement with 30 days' prior notice if the Company's net sales within a fiscal quarter fall below the Baseline Forecast (or Adjusted Baseline Forecast) for one or more fiscal quarters, or following the commercial introduction of a generic product to Migranal promoted or otherwise commercialized by a third party in the United States. In addition, either party may terminate the Valeant Agreement in the event of a change of control of itself or the other party (upon 90 days' prior written notice), upon any action taken or objection raised by governmental authority that prevents either party from performing its obligations under the Valeant Agreement, upon the filing of an action alleging patent infringement, in connection with the material breach of the other party's material obligations, or if a bankruptcy event of the other party occurs.

Healthcare Royalty Financing Agreement

On July 18, 2011, the Company closed the royalty financing agreement (the Financing Agreement) with Healthcare Royalty. Under the terms of the Financing Agreement, the Company borrowed \$30,000,000 from Healthcare Royalty (the Borrowed Amount) and the Company agreed to repay such Borrowed Amount together with a return to Healthcare Royalty, as described below, out of the Company's direct product sales, co-promotion revenues and out-license revenues (collectively, Revenue Interest) that the Company may record or receive as a result of worldwide commercialization of the Company's products including Sumavel DosePro, Zohydro ER and other future products. In addition, upon the closing of and in connection with the Financing Agreement, the Company issued and sold to Healthcare Royalty \$1,500,000 of the Company's common stock, or 388,601 shares, at a price of \$3.86 per share. The Company also issued to Healthcare Royalty a warrant exercisable for up to 225,000 shares of the Company's common stock. The warrant is exercisable at \$9.00 per share and has a term of 10 years. As the warrant contains covenants where compliance with such covenants may be outside the control of the Company, the warrant was recorded as a current liability and marked to market at each reporting date using the Black-Scholes option pricing valuation model (see Note 2).

Under the Financing Agreement, the Company is obligated to pay to Healthcare Royalty:

5% to 5.75% of the first \$75,000,000 of Revenue Interest recorded (in the case of net product sales) or received (in the case of co-promotion revenues and license fees) by the Company in a calendar year (initially 5% and then 5.75% after the co-promotion agreement with Astellas terminated on March 31, 2012);

2.5% of the next \$75,000,000 of Revenue Interest recorded (in the case of net product sales) or received (in the case of co-promotion revenues and license fees) by the Company in a calendar year; and

Table of Contents

0.5% of Revenue Interest over and above \$150,000,000 recorded (in the case of net product sales) or received (in the case of co-promotion revenues and license fees) by the Company in a calendar year.

Net sales of Sumavel DosePro outside the United States are only included in the Revenue Interest if such net sales exceed \$10,000,000. Once the aggregate payments, including the fixed payments described below, made by the Company to Healthcare Royalty equal \$75,000,000, the percentage of Revenue Interest owed to Healthcare Royalty is reduced to 0.5% for the remainder of the term of the Financing Agreement, with only Sumavel DosePro and Zohydro ER subject to the Revenue Interest payments thereafter. The Company is also obligated to make three fixed payments of \$10,000,000 on (or before at the option of the Company) each of January 31, 2015, January 31, 2016 and January 31, 2017. Unless terminated as discussed below, the Financing Agreement terminates on March 31, 2018. As security for the payment of the Company's obligations under the Financing Agreement, the Company also entered into a security agreement whereby the Company granted to Healthcare Royalty a security interest in all assets of the Company, including intellectual property and other rights of the Company to the extent necessary or used to commercialize the Company products. Healthcare Royalty entered into an intercreditor agreement under which its security interest was junior to the security interest of the lenders under the Company's \$25.0 million loan and security agreement. The intercreditor agreement terminated on July 30, 2012 when the Company terminated its \$25.0 million loan and security agreement. Healthcare Royalty's security interest will be extinguished at the end of the term or once the aggregate payments made by the Company to Healthcare Royalty equal to \$75,000,000, whichever is sooner. The Company has agreed to specified positive and negative covenants in connection with the Financing Agreement. The Company has the option to terminate the Financing Agreement at the Company's election in connection with a change of control of the Company, upon the payment of a base amount of \$52,500,000, or, if higher, an amount that generates a 19% internal rate of return on the Borrowed Amount as of the date of prepayment, in each case reduced by the Revenue Interest and principal payments received by Healthcare Royalty up to the date of prepayment. Healthcare Royalty has the option to terminate the Financing Agreement at its election in connection with a change of control of the Company (which includes the sale, transfer, assignment or licensing of the Company's rights in the United States to either Sumavel DosePro or Zohydro ER), or an event of default (which includes the occurrence of a bankruptcy event or other material adverse change in the Company's business), as defined in the Financing Agreement. Upon such a termination by Healthcare Royalty, the Company is obligated to make a payment of a base amount of \$45,000,000, or, if higher, an amount that generates a 17% internal rate of return on the Borrowed Amount as of the date of prepayment, in each case reduced by the Revenue Interest and principal payments received by Healthcare Royalty up to the date of prepayment.

The rights of the Company and Healthcare Royalty to terminate the Financing Agreement early, as well as the change in the Revenue Interest rate from 5% to 5.75% in connection with the early termination of the Astellas Co-Promotion Agreement, meet the definition of an embedded derivative. As a result, the Company carved out these embedded derivatives from the Financing Agreement and determined the fair value of each derivative using various discounted cash flow valuation models taking into account the probability of these events occurring and various scenarios surrounding the potential Revenue Interest payments that would be made if these events occurred (see Note 2). The aggregate fair value of the embedded derivatives as of June 30, 2013 and December 31, 2012 was \$1,554,000 and \$992,000, respectively, and is included in other long-term liabilities.

The Company received aggregate net proceeds of \$29,485,000 from the Financing Agreement (including the purchase of common stock). The discounts, which are being amortized using the effective interest method over the term of the arrangement within interest expense, include the fair value of the common stock warrants issued to Healthcare Royalty of \$790,000 upon the closing of the Financing Agreement, fees payable to Healthcare Royalty in connection with the execution of the arrangement of \$476,000 and the fair value of embedded derivatives of \$605,000 upon the closing of the Financing Agreement. The Company has recognized other income (expense) in relation to the change in the fair value of the Healthcare Royalty common stock warrant of \$41,000 and \$(91,000) for the three months ended June 30, 2013 and 2012, respectively, and \$(35,000) and \$(42,000) for the six months ended June 30, 2013 and 2012, respectively, in the statement of operations and comprehensive loss. The Company has recognized other (expense) income in relation to the change in the fair value of the Healthcare Royalty embedded derivatives of \$(480,000) and \$330,000 for the three months ended June 30, 2013 and 2012, respectively, and \$(562,000) and \$368,000 for the six

months ended June 30, 2013 and 2012, respectively, in the statement of operations and comprehensive loss.

Table of Contents

Term Debt

In June 2008, the Company entered into a Loan and Security Agreement with Oxford and CIT Healthcare LLC (the Oxford Agreement) under which it borrowed \$18,000,000. The obligations under the Oxford Agreement were collateralized by personal property excluding certain intellectual property and all equipment pledged to secure an equipment financing. In July and October 2010, the Company amended and restated the Oxford Agreement, and Oxford and Silicon Valley Bank (SVB) became party to the amended agreement. In June 2011, the Company again amended and restated the amended Oxford/SVB agreement (the Amended Oxford/SVB Agreement), which provided among other things, the addition of intellectual property to the collateral securing the Oxford/SVB loan and the deferral of principal repayment to commence on February 1, 2012.

The Amended Oxford/SVB Agreement consisted of a \$25,000,000 term loan and a \$10,000,000 revolving credit facility. The obligations under the Amended Oxford/SVB Agreement were collateralized by the Company's intellectual property (including among other things, copyrights, patents, patent applications, trademarks, service marks and trade secret rights) and personal property (including, among other things, accounts receivable, equipment, inventory, contract rights, rights to payment of money, license agreements, general intangibles and cash). The \$25,000,000 term loan bore an interest rate of 12.06% per annum. Under the terms of the revolving credit facility, \$10,000,000 was available to be borrowed within a specified percentage of the Company's eligible accounts receivable and inventory balances (as defined in the agreement). Amounts outstanding under the revolving credit facility accrued interest payable monthly at a floating rate per annum equal to the greater of 3.29% above SVB's prime rate or 7.29%. In addition, the Company paid a monthly fee equal to 0.5% per annum of the average unused portion of the revolving credit facility.

On July 30, 2012, the Company exercised its right to terminate the Amended Oxford/SVB Agreement prior to the loan maturity date of January 2, 2014 and repaid \$19,492,000 of outstanding principal and interest under the agreement. In addition to the repayment of all principal and interest outstanding, the Company was also required to make a final payment of \$1,200,000 and a prepayment premium of \$400,000, or 2% of the then outstanding principal. The Company also paid a \$100,000 prepayment premium to terminate the revolving credit facility. As a result of the termination of the Amended Oxford/SVB Agreement, the lenders no longer have a security interest in the Company's intellectual property and personal property.

5. Restructuring

In May 2013, the Company commenced a restructuring of its workforce, resulting in a reduction in force of 55 employees across all functional areas of the Company. During the three months ended June 30, 2013, the Company recorded restructuring charges of \$876,000 consisting primarily of employee-related compensation charges. The following table summarizes the components of the restructuring charges for the three and six months ended June 30, 2013 (in thousands):

	Three and Six Months Ended June 30, 2013		
	Accruals	Non-cash items	Total
Employee-related charges	\$ 663	\$ 201	\$ 864
Other restructuring charges	12	—	12
	675	201	\$ 876

The following table sets forth activity in the restructuring liability for the six months ended June 30, 2013, which is primarily comprised of employee severance costs (in thousands):

	Employee severance costs	Other restructuring charges	Total
Balance at December 31, 2012	\$—	\$—	\$—
Accruals	663	12	675
Payments	(519)	(10)	(529)
Balance at June 30, 2013	144	2	\$ 146

The balance of the restructuring liability at June 30, 2013 is anticipated to be fully distributed by the end of 2013.

Table of Contents

6. Common Stock Warrants

In July 2012, in connection with a public offering of common stock and warrants, the Company sold warrants to purchase 15,784,200 shares of common stock (including over-allotment purchase). The warrants will be exercisable beginning on July 27, 2013 at an exercise price of \$2.50 per share and will expire on July 27, 2017, which is 5 years from the date of issuance. As the warrants contain a cash settlement feature upon the occurrence of certain events that may be outside of the Company's control, the warrants are recorded as a current liability and are marked to market at each reporting period (see Note 2). The fair value of the warrants was approximately \$12,268,000 and \$9,308,000 as of June 30, 2013 and December 31, 2012, respectively.

In July 2011, upon the closing of and in connection with the Financing Agreement (see Note 4), the Company issued to Healthcare Royalty a warrant exercisable into 225,000 shares of common stock. The warrant is exercisable at \$9.00 per share of common stock and has a term of 10 years. As the warrant contains covenants where compliance with such covenants may be outside of the Company's control, the warrant was recorded as a current liability and is marked to market at each reporting date (see Note 2). The fair value of the warrant was approximately \$220,000 as of June 30, 2013 and \$185,000 as of December 31, 2012.

In June 2011, and in connection with entering into the Amended Oxford/SVB Agreement (see Note 4), the Company issued to Oxford and SVB warrants exercisable into an aggregate of 26,455 shares of common stock. The warrants are exercisable at \$3.78 per share of common stock and have a term of 7 years. The value of the warrants of approximately \$76,000 was recorded as debt discount and additional paid in capital in the consolidated balance sheet as of December 31, 2011.

7. Stock-Based Compensation

The Company uses the Black-Scholes option-pricing model for determining the estimated fair value of stock-based compensation for stock-based awards to employees and the board of directors. The assumptions used in the Black-Scholes option-pricing model for the three and six months ended June 30, 2013 and 2012 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Risk free interest rate	1.2%	0.7% to 1.0%	0.8% to 1.2%	0.2% to 1.2%
Expected term	5.1 to 6.0	5.0 to	5.0 to 6.1	5.0 to
	years	6.1 years	years	6.1 years
Expected volatility	84.5% to	81.5% to	84.5% to	80.6% to
	85.6%	82.8%	87.9%	82.8%
Expected dividend yield	—	% —	% —	% —

The risk-free interest rate assumption was based on the rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The weighted average expected term of options was calculated using the simplified method as prescribed by accounting guidance for stock-based compensation. This decision was based on the lack of relevant historical data due to the Company's limited historical experience. In addition, due to the Company's limited historical data, the estimated volatility was calculated based upon the Company's historical volatility, supplemented with historical volatility of comparable companies whose share prices are publicly available for a sufficient period of time.

The Company recognized stock-based compensation expense as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Cost of sales	\$63	\$47	\$108	\$76
Research and development	250	236	466	431
Selling, general and administrative	1,465	1,255	2,790	2,287
Restructuring	201	—	201	—
Total	\$1,979	\$1,538	\$3,565	\$2,794

As of June 30, 2013, there was approximately \$15,029,000 of total unrecognized compensation costs related to outstanding options, which is expected to be recognized over a weighted average period of 2.9 years.

Table of Contents

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. These forward looking statements include, but are not limited to, statements about:

- our ability to maintain and increase market demand for, and sales of, Sumavel DosePro;
- our ability to successfully execute our sales and marketing strategy for the commercialization of Sumavel DosePro;
- the progress and timing of clinical trials for Relday and our other product candidates;
- the potential for the FDA to approve the NDA for Zohydro ER despite the advisory committee's recommendation against approval;
- the timing of submissions to, and decisions made by, the FDA and other regulatory agencies, including foreign regulatory agencies, and demonstrating the safety and efficacy of Zohydro ER or any other product candidates to the satisfaction of the FDA and such other agencies;
- adverse side effects or inadequate therapeutic efficacy of Sumavel DosePro that could result in product recalls, market withdrawals or product liability claims;
- the safety and efficacy of Zohydro ER and our other product candidates;
- the market potential for migraine treatments, and our ability to compete within that market;
- the goals of our development activities and estimates of the potential markets for our product candidates, and our ability to compete within those markets;
- estimates of the capacity of manufacturing and other facilities to support our product and product candidates;
- our ability to ensure adequate and continued supply of Sumavel DosePro to successfully meet anticipated market demand;
- our and our licensors ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of our products and product candidates and the ability to operate our business without infringing the intellectual property rights of others;
- our ability to obtain and maintain adequate levels of coverage and reimbursement from third-party payors for Sumavel DosePro or any of our other product candidates that may be approved for sale, the extent of such coverage and reimbursement and the willingness of third-party payors to pay for our products versus less expensive therapies;
- the impact of healthcare reform legislation; and
- projected cash needs and our expected future revenues, operations and expenditures.

The forward-looking statements are contained principally in the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Quarterly Report on Form 10-Q in greater detail under the heading "Item 1A – Risk Factors."

Given these risks, uncertainties and other factors, we urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. We undertake no obligation to revise or update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

DosePro®, Intraject®, Relday™, Sumavel®/Zogenix™ and Zohydro™ ER are our trademarks. All other trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. Use or display by us of other parties' trademarks, trade dress or products is not intended to and does not imply a

relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owner.

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to “Zogenix,” “we,” “us” and “our” refer to Zogenix, Inc., including, as of June 7, 2010, its consolidated subsidiary.

Table of Contents

The interim consolidated financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the consolidated financial statements and notes thereto for the year ended December 31, 2012 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2012.

Overview

Background

We are a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain. Our first commercial product, Sumavel[®] DosePro[®] (sumatriptan injection) Needle-free Delivery System, was launched in January 2010. Sumavel DosePro offers fast-acting, easy-to-use, needle-free subcutaneous administration of sumatriptan for the acute treatment of migraine and cluster headache in a pre-filled, single-use delivery system. Sumavel DosePro is the first drug product approved by the U.S. Food and Drug Administration, or FDA, that allows for the needle-free, subcutaneous delivery of medication. We commercialize Sumavel DosePro through our internal sales and marketing organization and in collaboration with Mallinckrodt LLC, our co-promotion partner.

Our lead product candidate, Zohydro[™]ER (hydrocodone bitartrate, formerly ZX002) is a 12-hour extended-release formulation of hydrocodone without acetaminophen for the treatment of moderate to severe chronic pain requiring around-the-clock opioid therapy. We completed Phase 3 development of Zohydro ER in 2011, and we submitted the New Drug Application, or NDA, for Zohydro ER to the FDA in May 2012. In July 2012, the FDA accepted our NDA as being sufficiently complete for a full review and assigned a Prescription Drug User Fee Act, or PDUFA, target action date of March 1, 2013. In December 2012, an advisory committee convened by the FDA voted 11-2 (with 1 abstention) against the approval of Zohydro ER. The advisory committee provides the FDA with independent expert advice and recommendations; however, the final decision regarding approval is made by the FDA. In February 2013, the FDA informed us that we were unlikely to receive an action letter for our NDA for Zohydro ER by the PDUFA target action date of March 1, 2013. In the beginning of May 2013, the FDA informed us that they are preparing to take action on the Zohydro ER NDA in the summer of 2013. The FDA has not provided a reason for the delay and we have not been informed of any deficiencies in the NDA for Zohydro ER during the review process.

Sumavel DosePro and Zohydro ER, if approved, each have the potential to address significant unmet medical needs and become important and widely-used additions to the treatment options available to patients and physicians in the United States' multi-billion dollar migraine and chronic pain markets, respectively.

We are also developing Relday[™], a proprietary, long-acting injectable formulation of risperidone using Durect Corporation's SABER[™] controlled-release formulation technology through a development and license agreement with Durect, or the Durect License Agreement. Risperidone is used to treat the symptoms of schizophrenia and bipolar disorder in adults and teenagers 13 years of age and older. If successfully developed and approved, we believe Relday may be the first once-monthly, subcutaneous antipsychotic product. In May 2012, we filed an investigational new drug, or IND, application with the FDA. In July 2012, we initiated our first IND clinical trial for Relday. This Phase 1 clinical trial was a single-center, open-label, safety and pharmacokinetic trial of 30 patients with chronic, stable schizophrenia or schizoaffective disorder. We announced positive single-dose pharmacokinetic results from the Phase 1 clinical trial on January 3, 2013. Based on the favorable safety and pharmacokinetic profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase 1 trial, we extended the study to include an additional cohort of 10 patients at a 100 mg dose of the same formulation. We announced positive top-line results from the extended Phase 1 clinical trial on May 2, 2013. The results for the extended Phase 1 clinical trial showed risperidone blood concentrations in the therapeutic range were achieved on the first day of dosing and maintained throughout the one-month period. In addition, dose proportionality has now been established across the full dose range that would be anticipated to be used in clinical practice (50 to 100 mg). The positive results from this study extension position us to begin a multi-dose clinical trial, which would provide the required steady-state pharmacokinetic and safety data prior to initiating Phase 3 development studies, subject to our ability to secure a development and commercialization partner prior to initiation of the multi-dose trial.

The development of Relday will first focus on its delivery by conventional needle and syringe in order to allow the administration of different volumes of the same formulation of Relday by a healthcare professional. We anticipate that the introduction of our DosePro needle-free technology for administration of Relday can occur later in development or as part of life cycle management after further work involving formulation development, technology enhancements, and applicable regulatory approvals.

We have experienced net losses and negative cash flow from operating activities since inception, and as of June 30, 2013, had an accumulated deficit of \$363.8 million. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next several years primarily as a result of the expenses incurred in connection with our efforts in

Table of Contents

seeking marketing approval for Zohydro ER, any additional required clinical testing for Zohydro ER, the clinical development for Relday and the cost of the sales and marketing expense associated with Sumavel DosePro, and, if approved, Zohydro ER. As of June 30, 2013, we had cash and cash equivalents of \$16.1 million.

On March 27, 2013, we entered into a controlled equity offering sales agreement with Cantor Fitzgerald & Co., or Cantor, as sales agent, under which we can issue and sell shares of our 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. We did not complete the issuance of any shares of our common stock pursuant to the sales agreement during the three months ended June 30, 2013. Subsequent to June 30, 2013, and through August 7, 2013, we agreed to issue 3.0 million shares of our common stock pursuant to the sales agreement at an average stock issuance price of \$1.66 per share, resulting in net proceeds of approximately \$4.9 million. As of August 7, 2013, we had the capacity to issue up to \$20.0 million in shares of our common stock under the sales agreement. However, there can be no assurance that Cantor will be successful in consummating further sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of June 30, 2013, and our projected product revenues from Sumavel DosePro, will be sufficient to fund our operations into the first quarter of 2014. We will need to obtain additional capital to finance our operations beyond that point, or possibly earlier. Further, if we receive FDA approval of Zohydro ER, we may need to obtain additional capital to finance the commercial launch of Zohydro ER, possibly prior to the first quarter of 2014. We intend to raise additional capital, if necessary, through public or private equity offerings, including through our controlled equity offering program, debt financings, receivables financings or through collaborations or partnerships with other companies. If we are unsuccessful in raising additional required funds, we may be required to significantly delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts, or cease operating as a going concern. We also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available. In its report on our consolidated financial statements for the year ended December 31, 2012, our independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern.

Mallinckrodt Co-Promotion Agreement

In June 2012, we entered into a co-promotion agreement with Mallinckrodt. Under the terms of the co-promotion agreement Mallinckrodt has committed to a minimum number of sales representatives for the initial term of the agreement, which runs through June 30, 2014, and can be extended by mutual agreement of the parties in additional six month increments. We remain responsible for the manufacture, supply and distribution of commercial product for sale in the United States. In addition, we will supply product samples to Mallinckrodt at an agreed upon transfer price and Mallinckrodt will reimburse us for all other promotional materials used.

In partial consideration of Mallinckrodt’s sales efforts, we pay 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, or 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, we 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 twelve months following the last day of the term.

For the three and six months ended June 30, 2013, we incurred service fee expenses of \$0.2 million and \$0.4 million, respectively, under the co-promotion agreement. We did not incur any service fee expenses under the co-promotion agreement during the three and six months ended June 30, 2012.

Astellas Co-Promotion Agreement

We launched the commercial sale of Sumavel DosePro in the United States in January 2010 with our co-promotion partner, Astellas Pharma US, Inc., or Astellas. Under our co-promotion agreement with Astellas that we entered into in July 2009, or the Astellas co-promotion agreement, Astellas primarily promoted Sumavel DosePro to primary care

physicians (including internal medicine, family practice and general practice), OB/GYNs, emergency medicine physicians and urologists, or collectively, the Astellas Segment, in the United States. Our sales force historically promoted Sumavel DosePro primarily to neurologists and other key prescribers of migraine medications, including headache clinics and headache specialists in the United States. We jointly shared in the cost of advertising, marketing and other promotional activities related to the Sumavel DosePro brand and were required to provide minimum levels of sales effort to promote Sumavel DosePro.

Table of Contents

In December 2011, we entered into an amendment to the Astellas co-promotion agreement, whereby the agreement terminated on March 31, 2012. As a result of the agreement termination, and pursuant to a promotion transition plan, beginning in the second quarter of 2012, our field sales force assumed full responsibility from the Astellas sales representatives for the continued marketing of Sumavel DosePro. This promotion transition expanded our focus to include a portion of the high-prescribing primary care physicians previously covered by Astellas under the Astellas co-promotion agreement.

At the inception of the Astellas co-promotion agreement and in exchange for the right to promote Sumavel DosePro, Astellas made a non-refundable up-front payment of \$2.0 million to us and made aggregate additional payments of \$18.0 million to us upon the achievement of a series of milestones. These proceeds were recorded as deferred revenues on our consolidated balance sheet at December 31, 2011, and beginning with the launch of Sumavel DosePro in January 2010, we began recognizing these proceeds as contract revenues over the term of the agreement. Upon amendment of the Astellas co-promotion agreement in December 2011, the remaining deferred proceeds were recognized as contract revenues on a ratable basis over the remaining term of the amended agreement. This acceleration in the recognition of the contract proceeds resulted in the recognition of \$8.5 million of contract revenue during the three months ended March 31, 2012.

Under the terms of the amended Astellas co-promotion agreement, we are required to make two annual tail payments to Astellas, estimated as a total of \$5.3 million, calculated as decreasing fixed percentages of net sales in the Astellas Segment in the last 12 months of its active promotion. The present value of such tail payments was recorded as a long-term liability on the amendment date. The first tail payment of \$2.0 million was made in July 2013 and the second tail payment of \$1.1 million as of June 30, 2013, which includes the service fee reduction discussed below, is payable in July 2014. The fair value of each of the tail payments is accreted through interest expense on a monthly basis through the date of payment. There was \$0.1 million and \$0.3 million of related interest expense recognized during the three and six months ended June 30, 2013, respectively.

In consideration for Astellas' performance of its commercial efforts, we were required to pay Astellas a service fee on a quarterly basis that represents a fixed percentage of between 45% and 55% of Sumavel DosePro net sales to the Astellas Segment through the date of termination. Astellas paid us a fixed fee for all sample units they ordered for distribution to their sales force. Amounts received from Astellas for shared marketing costs and sample product are reflected as a reduction of selling, general and administrative expenses, and amounts payable to Astellas for shared marketing expenses and service fees are reflected as selling, general and administrative expenses.

In August 2012, we and Astellas completed a final reconciliation under the terms of the co-promotion agreement and agreed to adjust the service fees paid to Astellas over the term of the co-promotion agreement, resulting in a service fee receivable of \$1.5 million, which will offset the two annual tail payments, and a reduction to the annual tail payment liability of \$0.7 million. The present value of the service fee receivable and tail payment reduction of \$1.9 million was recorded as a reduction in selling, general and administrative expenses during the twelve months ended December 31, 2012, and an offset to the tail payment liability. The fair value of the service fee receivable and tail payment reduction will be accreted through interest expense through the dates of the two tail payments in July 2013 and July 2014.

For the three and six months ended June 30, 2013 and 2012, we recognized shared marketing expense of \$0 and \$0.1 million, and \$0 and \$0.3 million, respectively, under the Astellas co-promotion agreement.

For the three and six months ended June 30, 2013 and 2012, and prior to the final reconciliation of service fees, we incurred \$0 and \$0.1 million, and \$0 and \$1.8 million, respectively, in service fee expenses.

Valeant Co-Promotion Agreement

In June 2013, we entered into a co-promotion agreement, or the Valeant agreement, with Valeant Pharmaceuticals North America LLC, or Valeant. Under the terms of the Valeant agreement, we were granted the exclusive right (with Valeant or any of its affiliates) to promote Migranal® (dihydroergotamine mesylate) Nasal Spray, or Migranal, to a prescriber audience of physicians and other health care practitioners in the United States. Under the Valeant agreement, our sales team will begin selling Migranal to prescribers no later than August 26, 2013. The term of the Valeant agreement will run through December 31, 2015 (unless otherwise terminated), and can be extended by mutual agreement of the parties in additional twelve month increments. Valeant remains responsible for the manufacture,

supply and distribution of Migranal for sale in the United States. In addition, Valeant will supply us with a specified amount of product samples every six months, and we will reimburse Valeant for the cost of additional samples and any promotional materials ordered by us.

In partial consideration of our sales efforts, Valeant will pay us a co-promotion fee on a quarterly basis that represents specified percentages of net sales generated by us over defined baseline amounts of net sales. In addition, upon completion of the co-promotion term, and only if the Valeant agreement is not terminated by Valeant due to a bankruptcy event (as defined in the Valeant agreement) or a material failure by us to comply with our material obligations under the Valeant agreement, Valeant

Table of Contents

will be required to pay us an additional tail payment calculated as a fixed percentage of our net sales over a baseline forecast during the first full six months following the last day of the term.

Critical Accounting Policies and Estimates

There have been no significant changes in critical accounting policies during the six months ended June 30, 2013, as compared to the critical accounting policies described in “Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2012.

Results of Operations

Comparison of the three and six months ended June 30, 2013 to the three and six months ended June 30, 2012 Revenue. We recognize net product sales upon the shipment of product to wholesale pharmaceutical distributors and retail pharmacies. Revenue for the three months ended June 30, 2013 and 2012 was \$8.9 million and \$8.0 million, respectively, and revenue for the six months ended June 30, 2013 and 2012 was \$15.9 million and \$26.4 million, respectively. Net product revenue for the three months ended June 30, 2013 and 2012 was \$8.9 million and \$8.0 million, respectively, and net product revenue for the six months ended June 30, 2013 and 2012 was \$15.9 million and \$17.9 million, respectively.

The aggregate \$0.9 million, or 11.4%, increase in net product revenue during the three months ended June 30, 2013 compared to 2012 was primarily due to an increase in average net selling price of 21%, which was primarily driven by an increase in our whole acquisition cost (WAC) and an additional charge booked in the second quarter of 2012 related to estimated product returns, offset by a decrease in unit volume of 8%. The aggregate \$2.0 million, or 11.1%, decrease in net product revenue during the six months ended June 30, 2013 compared to 2012 was primarily due to a decrease in unit volume of 14%, offset by an increase in our average net selling price of approximately 5%, which was primarily driven by an increase in our WAC. The primary driver of the decrease in unit volume during the six months ended June 30, 2013 compared to 2012 was the resetting of health insurance co-pays and co-insurance at the beginning of 2013, which slowed patient volumes in the first quarter of 2013 to a greater degree than in previous years.

There was no contract revenue recognized for the three months ended June 30, 2013 and 2012. Contract revenue for the six months ended June 30, 2013 and 2012 was \$0 and \$8.5 million, respectively. Contract revenue represents amortization of license fee payments and milestone payments we received in connection with the Astellas co-promotion agreement we entered into in July 2009 and which we began recognizing upon the commencement of sales of Sumavel DosePro in January 2010. In December 2011, we amended the Astellas co-promotion agreement whereby the agreement terminated on March 31, 2012, rather than the initial termination date of June 30, 2013. Based upon this revised termination date, all deferred contract revenue was recognized ratably on an accelerated basis, from the date of the amendment through March 31, 2012.

Cost of Sales. Cost of sales consists primarily of materials, third-party manufacturing costs, freight and indirect personnel and other overhead costs associated with sales of Sumavel DosePro based on units sold to wholesale pharmaceutical distributors and retail pharmacies, as well as reserves for excess, dated or obsolete commercial inventories and production manufacturing variances. It represents the cost of Sumavel DosePro units recognized as net product revenues in the period and the impact of underutilized production capacity and other manufacturing variances. Cost of sales for the three months ended June 30, 2013 and 2012 was \$4.6 million and \$4.2 million, respectively. Cost of sales for the six months ended June 30, 2013 and 2012 was \$8.8 million and \$9.2 million, respectively. Product gross margin for the three months ended June 30, 2013 and 2012 was 48%, and product gross margin was 45% and 48% for the six months ended June 30, 2013 and 2012, respectively. The decrease in product gross margin for the six months ended June 30, 2013 compared to 2012 was primarily due to a higher cost per unit and a decrease in the volume of units sold.

Royalty Expense. Royalty expense consists of royalties payable to Aradigm Corporation based on net sales of Sumavel DosePro by us or one of our licensees and the amortization of the \$4.0 million milestone payment paid by us to Aradigm upon the first commercial sale of Sumavel DosePro in the United States (which occurred in January 2010). We are not required to make any further milestone payments to Aradigm. We are required to pay to Aradigm a 3% royalty on global net sales of Sumavel DosePro, by us or one of our licensees, if any, until the expiration of the

last valid claim of the transferred patents covering the manufacture, use, or sale of the product. During the three months ended June 30, 2013 and 2012, we recorded \$0.3 million in royalty expense, and during the six months ended June 20, 2013 and 2012 we recorded \$0.6 million and \$0.7 million, respectively, in royalty expense.

Research and Development Expenses. Research and development expenses consist of expenses incurred in developing, testing and seeking marketing approval of our product candidates, including: license and milestone payments; payments made

Table of Contents

to third-party clinical research organizations, or CROs, and investigational sites, which conduct our trials on our behalf, and consultants; expenses associated with regulatory submissions, pre-clinical development and clinical trials; payments to third-party manufacturers, which produce our active pharmaceutical ingredient and finished product; personnel related expenses, such as salaries, benefits, travel and other related expenses, including stock-based compensation; and facility, maintenance, depreciation and other related expenses. We expense all research and development costs as incurred.

We utilize CROs, contract laboratories and independent contractors for the conduct of pre-clinical studies and clinical trials. We track third-party costs by type of study being conducted. We recognize the expenses associated with the services provided by CROs based on the percentage of each study completed at the end of each reporting period. We coordinate clinical trials through a number of contracted investigational sites and recognize the associated expense based on a number of factors, including actual and estimated subject enrollment and visits, direct pass-through costs and other clinical site fees.

The table below sets forth information regarding our research and development expenses for our major development programs. The period over period variances for our major development programs are explained in the narrative beneath the table.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Research and development expenses (in thousands):				
Zohydro	\$1,422	\$4,081	\$2,015	\$7,127
Relday	524	751	1,279	2,081
Sumavel DosePro	253	204	491	346
Other ⁽¹⁾	1,378	1,345	3,029	2,791
Total	\$3,577	\$6,381	\$6,814	\$12,345

(1) Other research and development expenses include development costs incurred for the DosePro technology sound enhancement and other product candidate development, as well as employee and infrastructure resources that are not tracked on a program-by-program basis.

Research and development expenses decreased by \$2.8 million for the three months ended June 30, 2013 compared to 2012, and decreased by \$5.5 million for the six months ended June 30, 2013 compared to 2012. These decreases were primarily due to a decrease in development expenses for Zohydro ER. Zohydro ER development expenses were greater during the first half of 2012 primarily due to expenses incurred for preparation of the Zohydro ER NDA that we submitted to the FDA in May 2012.

We use our employee and infrastructure resources across our product and product candidate development programs. Therefore, we have not tracked salaries, other personnel related expenses, facilities or other related costs to our product development activities on a program-by-program basis.

We expect our research and development expenses for the remainder of 2013 to continue to decrease over amounts incurred in 2012 as we incurred costs in 2012 related to our Zohydro ER NDA submission and costs related to preparation for and participation in the December 2012 FDA advisory committee meeting for Zohydro ER, which we do not expect to recur in 2013.

Selling, General and Administrative Expenses. Selling expenses, which include sales and marketing costs, consist primarily of salaries and benefits of sales and marketing management and sales representatives, shared marketing and advertising costs and service fees under our Astellas co-promotion agreement prior to its termination in March 2012, service fees under our Mallinckrodt co-promotion agreement, sample product costs, and consulting fees. General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, accounting, business development and internal support functions. In addition, general and administrative expenses include facility costs and professional fees for legal, consulting and accounting services.

Selling, general and administrative expenses decreased slightly to \$12.0 million for the three months ended June 30, 2013 compared to \$12.1 million for the three months ended June 30, 2012. Selling, general and administrative expenses decreased slightly to \$26.5 million for the six months ended June 30, 2013 compared to \$26.7 million for the

six months ended June 30, 2012.

Selling expenses were \$8.3 million and \$18.6 million for the three and six months ended June 30, 2013, respectively, compared to \$8.7 million and \$20.1 million for the three and six months ended June 30, 2012, respectively. General and

21

Table of Contents

administrative expenses were \$3.7 million and \$7.9 million for the three and six months ended June 30, 2013, respectively, compared to \$3.4 million and \$6.6 million for the three and six months ended June 30, 2012, respectively.

The decrease in selling, general and administrative expenses for the three months ended June 30, 2013 compared to 2012 was due to a decrease of \$0.4 million in sales and marketing expenses, offset by an increase of \$0.3 million in general and administrative expenses.

The decrease in sales and marketing expenses is primarily the result of a \$0.7 million decrease in salary and bonus expense, offset by an increase in other marketing and promotional activities.

The increase in general and administrative expenses is primarily the result of an increase in public relations costs and an increase in professional service related costs, such as legal and accounting and advisory services.

The decrease in selling, general and administrative expenses for the six months ended June 30, 2013 was due to a decrease of \$1.5 million in sales and marketing expenses, offset by an increase of \$1.3 million in general and administrative expenses.

The decrease in sales and marketing expenses is primarily the result of a \$1.8 million decrease in co-promote service fees resulting from the termination of the Astellas co-promotion agreement on March 31, 2012, offset by an increase in other marketing and promotional activities.

The increase in general and administrative expenses is primarily the result of an increase in public relations costs and an increase in professional service related costs, such as legal and accounting and advisory services.

We do not expect a significant change in general and administrative expenses throughout the remainder of 2013 as compared to 2012 levels; however, our selling expenses may increase significantly at the end of 2013 if Zohydro ER is approved.

Restructuring Expenses. Restructuring expenses of \$0.9 million were recorded during the three and six months ended June 30, 2013, and consist of the costs incurred in connection with the restructuring of our workforce, which commenced in May 2013. These restructuring expenses primarily consist of cash charges of \$0.7 million in severance costs and \$0.2 million in non-cash stock-based compensation charges.

Interest Income. During the three months ended June 30, 2013 and 2012, interest income was \$3,000 and \$10,000, respectively. During the six months ended June 30, 2013 and 2012, interest income was \$11,000 and \$29,000, respectively. The decrease in interest income during the first half of 2013 compared to the first half of 2012 was primarily due to a decrease in average cash and cash equivalent balances during the respective periods.

Interest Expense. Interest expense consists of interest expense incurred in connection with our financing agreements and certain other arrangements, including the following:

- our \$30.0 million financing agreement, or the Healthcare Royalty financing agreement, with Healthcare Royalty Partners (formerly Cowen Healthcare Royalty Partners II, LP), or Healthcare Royalty;
- our \$10.0 million revolving credit facility with Oxford Finance Corporation, or Oxford, and Silicon Valley Bank, or SVB (terminated in July 2012);
- our \$25.0 million loan and security agreement with Oxford and SVB, or the amended Oxford/SVB loan agreement (terminated in July 2012); and
- imputed interest from the two annual tail payments to Astellas.

Interest expense was \$1.6 million and \$3.2 million for the three and six months ended June 30, 2013, respectively, compared to \$2.6 million and \$5.3 million for the three and six months ended June 30, 2012, respectively. The decrease in interest expense in the first half of 2013 compared to the first half of 2012 is primarily due to the termination of our amended Oxford/SVB loan agreement in July 2012.

We expect that interest expense throughout the remainder of 2013 will decrease from 2012 interest expense due to the repayment in full and termination of our revolving credit facility and amended Oxford/SVB loan agreement in July 2012.

Change in Fair Value of Warrant Liabilities. The change in fair value of warrant liabilities relates to a fair value adjustment recorded on the warrants to purchase common stock issued in connection with our July 2012 public offering and issued in connection with our Healthcare Royalty financing agreement. See Note 6 to our consolidated financial statements.

Table of Contents

Change in Fair Value of Embedded Derivatives. The change in fair value of embedded derivatives relates to a fair value adjustment recorded on the embedded derivatives associated with the Healthcare Royalty financing agreement. See Note 4 to our consolidated financial statements.

Other Income (Expense). Other income (expense) for the three and six months ended June 30, 2013 and 2012 consists primarily of foreign currency transaction gains and losses.

Provision for Income Tax Expense. Provision for income tax expense is primarily related to the taxable income generated by our wholly-owned subsidiary, Zogenix Europe Limited.

Liquidity and Capital Resources

We have experienced net losses and negative cash flow from operations since inception, and as of June 30, 2013, had an accumulated deficit of \$363.8 million. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next several years primarily as a result of the expenses incurred in connection with efforts in seeking marketing approval for Zohydro ER, the clinical development for Relday, any additional required testing for Zohydro ER, and the cost of the sales and marketing expense associated with Sumavel DosePro, and, if approved, Zohydro ER. As of June 30, 2013, we had cash and cash equivalents of \$16.1 million.

In May 2013, we commenced a restructuring of our workforce, resulting in a reduction in force of approximately 37%, or 55 employees, across all functional areas of our company. We took this step as part of our initiative to extend our cash runway to reach key business milestones that may occur over the remainder of 2013, including gaining FDA approval for our NDA for Zohydro ER, securing a development partner for Relday, and out-licensing our proprietary DosePro needle-free delivery technology.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of June 30, 2013, and our projected product revenues from Sumavel DosePro, will be sufficient to fund our operations into the first quarter of 2014. We will need to obtain additional capital to finance our operations beyond that point, or possibly earlier. Further, if we receive FDA approval of Zohydro ER, we may need to obtain additional capital to finance the commercial launch of Zohydro ER, possibly prior to the first quarter of 2014. We intend to raise additional capital, if necessary, through public or private equity offerings, including through our controlled equity offering program, debt financings, receivables financings or through collaborations or partnerships with other companies. If we are unsuccessful in raising additional required funds, we may be required to significantly delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts, or cease operating as a going concern. We also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available.

In its report on our consolidated financial statements for the year ended December 31, 2012, our independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern. A “going concern” opinion means, in general, that our independent registered public accounting firm has substantial doubt about our ability to continue our operations without continuing infusions of capital from external sources and this opinion could impair our ability to finance our operations through the sale of debt or equity securities or commercial bank loans. Our ability to continue as a going concern depends, in large part, on our ability to generate positive cash flow from operations and obtain additional financing, neither of which is certain. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations and have to liquidate our assets and may receive less than the value at which those assets were carried on our financial statements, and it is likely that investors will lose all or part of their investment.

Since inception, our operations have been financed primarily through equity and debt financings, the issuance of convertible notes and payments received from Astellas under our Astellas co-promotion agreement. Through June 30, 2013, we received aggregate net cash proceeds of approximately \$341.1 million from the sale of shares of our preferred and common stock, including our financing in July 2012. In July 2012, we issued and sold a total of 35,058,300 shares of common stock and warrants to purchase 15,784,200 shares of common stock in a public offering, including the underwriters’ over-allotment purchase, for aggregate net proceeds of \$65.4 million.

On July 30, 2012, we terminated our amended Oxford/SVB loan agreement. The amended Oxford/SVB Agreement consisted of a \$25.0 million term loan and a \$10.0 million revolving credit facility. The obligations under the amended

Oxford/SVB loan agreement were collateralized by our intellectual property (including among other things, copyrights, patents, patent applications, trademarks, service marks and trade secret rights) and personal property (including, among other things, accounts receivable, equipment, inventory, contract rights, rights to payment of money, license agreements, general intangibles and

Table of Contents

cash). The \$25.0 million term loan bore an interest rate of 12.06% per annum. Under the terms of the revolving credit facility, \$10.0 million was available to be borrowed within a specified percentage of our eligible accounts receivable and inventory balances (as defined in the agreement). Amounts outstanding under the revolving credit facility accrued interest payable monthly at a floating rate per annum equal to the greater of 3.29% above SVB's prime rate or 7.29%. In addition, we paid a monthly fee equal to 0.5% per annum of the average unused portion of the revolving credit facility. As a result of the termination of the amended Oxford/SVB loan agreement, the lende