ZOGENIX, INC.
Form 10-Q
August 08, 2013
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

x 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	20-5300780
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
12400 High Bluff Drive, Suite 650 San Diego, California (Address of Principal Executive Offices)	92130 (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. x 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 x 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 x
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 x No

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.

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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.

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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.

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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.

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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

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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):

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	Fair Value Measurements at Reporting Date Using			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
At 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.

(2) Common stock warrant liabilities include liabilities associated with warrants issued in connection with the Company's July 2012 public offering of common stock and warrants (see Note 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.

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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 June 30,		Six Months Ended June 30,	
	2013	2012	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

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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.

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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.

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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

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- 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.

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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.

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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 years	5.0 to 6.1 years	5.0 to 6.1 years	5.0 to 6.1 years
Expected volatility	84.5% to 85.6%	81.5% to 82.8%	84.5% to 87.9%	80.6% to 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.

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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," "an "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparab 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.

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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

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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.

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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

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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

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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, 2103 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

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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.

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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

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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 lenders no longer have a security interest in our intellectual property and personal property (including, among other things, accounts receivable, equipment, inventory, contract rights, rights to payment of money, license agreements, general intangibles and cash).

On July 18, 2011, we closed the Healthcare Royalty financing agreement. Under the terms of the Healthcare Royalty Financing agreement, we borrowed $30.0 million and we are obligated to repay such borrowed amount together with a specified return to Healthcare Royalty, through the payment of tiered royalties ranging from .5% to 5% of our direct product sales, co-promotion revenues and out-license revenues, or collectively, revenue interest, that we may record or receive as a result of worldwide commercialization of our products including Sumavel DosePro, Zohydro ER and other future products. Pursuant to the terms of the Healthcare Royalty financing agreement, our royalty rate increased to 5.75% in April 2012 in connection with the early termination of the Astellas co-promotion agreement.

We are also obligated to make three fixed payments of $10.0 million on (or before at our option) each of January 31, 2015, January 31, 2016 and January 31, 2017.

We have the option to terminate the Healthcare Royalty financing agreement at our election in connection with a change of control of our company, upon the payment of a base amount of $52.5 million, 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 Healthcare Royalty financing agreement at its election in connection with a change of control of our company (which includes the sale, transfer, assignment or licensing of our 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 our business), as defined in the Healthcare Royalty financing agreement. Upon such a termination by Healthcare Royalty, we are obligated to make a payment of a base amount of $45.0 million, 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. Unless terminated earlier as discussed above, the Healthcare Royalty financing agreement terminates on March 31, 2018.

Any requirement that we repay the borrowed amount under the Healthcare Royalty financing agreement, whether as the result of our default under the applicable agreement or otherwise, could have a material adverse effect on our business, results of operations and financial condition.

On March 27, 2013, we entered into a controlled equity offering sales agreement, or sales agreement, with Cantor, as sales agent, to create a controlled equity offering program under which we may, from time to time, sell shares of common stock up to an aggregate offering price of $25.0 million. Sales of the common stock made pursuant to the sales agreement will be made by methods deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act, including sales made directly on the Nasdaq Global Market, on any other existing trading market for the common stock or to or through a market marker under our currently-effective Registration Statement on Form S-3. In addition, Cantor may sell the common stock by any other method permitted by law, including in privately negotiated transactions. We pay Cantor a commission equal to 3% of the gross proceeds from the sale of shares of our common stock under the sales agreement and have agreed to provide Cantor with customary indemnification and contribution rights. We have also agreed to reimburse Cantor for certain specified expenses, including the fees and disbursements of its legal counsel, in an amount not to exceed $50,000. The offering of common stock pursuant to the sales agreement will terminate upon the earlier of (a) the sale of all of the shares of common stock under the sales agreement having an aggregate offering price of $25.0 million and (b) the termination of the sales agreement by us or Cantor as permitted therein. The sales agreement may be terminated by us or Cantor at any time upon 10 days' prior written notice to the other party, or by Cantor at any time in certain circumstances, including the occurrence of a material adverse change in our company. There can be no assurance that Cantor will be

successful in consummating sales of our common stock based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. As of August 7, 2013, we agreed to the issuance of 3.0 million shares of our common stock pursuant to the sales agreement at an average stock price of $1.66 per share, resulting in net proceeds of approximately $4.9 million.

Cash and Cash Equivalents. Cash and cash equivalents totaled $16.1 million and $41.2 million at June 30, 2013 and December 31, 2012, respectively.

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The following table summarizes our cash flows used in operating, investing and financing activities for the six months ended June 30, 2013 and 2012:

	Six Months Ended June 30,	
	2013	2012
	(In Thousands)	
Statement of Cash Flows Data		
Total cash provided by (used in):		
Operating activities	$(24,570)	$(29,466)
Investing activities	(798)	(291)
Financing activities	261	(4,794)
Decrease in cash and cash equivalents	$(25,107)	$(34,551)

Operating Activities: Net cash used in operating activities was $24.6 million and $29.5 million for the six months ended June 30, 2013 and 2012, respectively. Net cash used for the six months ended June 30, 2013 primarily reflects the use of cash for operations, adjusted for non-cash charges including a $3.0 million change in fair value of warrant liabilities and $3.6 million in stock-based compensation (which includes $0.2 million in stock-based compensation from restructuring), offset by a reduction in accounts receivable of $1.5 million primarily due to a greater number of sales in December 2012 compared to June 2013. Significant working capital uses of cash for the six months ended June 30, 2013 includes personnel-related costs, research and development costs (primarily for employee and infrastructure resources), sales and marketing expenses for Sumavel DosePro, and other professional services. Net cash used for the six months ended June 30, 2012 primarily reflects the use of cash for operations, adjusted for non-cash charges including $2.8 million in stock-based compensation, offset by a reduction in commercial inventory of $1.2 million. Significant working capital uses of cash for the six months ended June 30, 2012 includes personnel related costs, research and development costs (primarily for Zohydro ER and Relday), sales and marketing expenses for Sumavel DosePro, and other professional services.

Investing Activities. Net cash used in investing activities was $0.8 million and $0.3 million for the six months ended June 30, 2013 and 2012, respectively. These amounts are the result of the purchase of property and equipment primarily for use in manufacturing Sumavel DosePro.

We expect to incur additional capital expenditures of approximately $0.3 million to $1.2 million in 2013. These planned capital expenditures primarily relate to further investments in our manufacturing operations for Sumavel DosePro and toward enhancing our existing manufacturing technology and equipment.

Financing Activities. Net cash provided by financing activities during the six months ended June 30, 2013 was $0.3 million, which is from the issuance of common stock under our employee stock purchase plan. Net cash used in financing activities was $4.8 million for the six months ended June 30, 2012, which relates to payments of $15.0 million on our borrowings of debt, offset by net proceeds of $9.9 million from our revolving credit facility.

Our sources of liquidity include our cash balances and cash receipts from the sale of Sumavel DosePro. 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. As of June 30, 2013, we had $16.1 million in cash and cash equivalents. Other potential sources of near-term liquidity include (i) equity offerings, including through our controlled equity offering program, debt or other financing, (ii) entering into a commercialization agreement for Zohydro ER, if approved, or a licensing arrangement for Relday, or (iii) leveraging our sales force capacity to promote Migranal or another new product. Successful transition to profitability is dependent upon achieving a level of product revenues adequate to support our cost structure. We will continue to monitor and evaluate our sales progress, the level of our research, development, manufacturing, sales and marketing and general and administrative expenditures and may adjust such expenditures based upon a variety of factors, such as our available cash, our ability to obtain additional cash, the results and progress of our Sumavel DosePro commercialization efforts, results and progress in our clinical program, the time and costs related to clinical trials and regulatory decisions, as well as the U.S. economic environment.

As described above, we have agreed to specified positive and negative covenants under the Healthcare Royalty financing agreement and upon a termination by Healthcare Royalty, we are obligated to make a payment of a base

amount of $45.0 million, 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 payments received by Healthcare Royalty up to the date of prepayment. If we were required to accelerate the payment of these amounts upon a default, we would be required to find an alternate source of capital from which to draw funds and there can be no assurances that we would be able to do so on terms acceptable to us, or at all.

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If we fail to pay amounts owing under the Healthcare Royalty financing agreement when due, if we breach our other covenants or obligations under the agreement, or if other events of default under the agreement occur, Healthcare Royalty would be entitled to demand immediate repayment of all borrowings and other obligations thereunder and to seize and sell the collateral pledged as security under the agreements to satisfy those obligations. If we were to breach our covenants and obligations and we were unable to obtain a waiver or amendment from the lender, we would be required to seek additional equity or debt financing to refinance our obligations under the agreement. Additional debt or equity financing may not be available to us in amounts or on terms we consider acceptable, or at all. In that regard, we have from time to time been required to obtain waivers and amendments under our debt instruments in order to avoid breaches or other defaults. For example, in each of 2012, 2011 and 2010 we were required to obtain amendments or waivers under our credit facilities.

We cannot be certain if, when and to what extent we will generate positive cash flow from operations from the commercialization of our product and, if approved, product candidates. We expect our expenses to be substantial and to increase over the next few years as we continue to grow the Sumavel DosePro brand and continue to advance our Zohydro ER product potentially through commercialization, and as we potentially advance Relday through clinical development.

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, or AOCI, for each component of AOCI and to disclose, for each affected line item in the income statement, the amount of AOCI that has been reclassified into that line item. For AOCI reclassification items that are not reclassified in their entirety into net income, it is acceptable to cross reference that amount to another footnote that provides the required disclosure. The updated guidance became effective for fiscal and interim periods beginning after December 15, 2012. We adopted this guidance on January 1, 2013 and it did not have a material impact on our results of operations.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet activities.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our cash and cash equivalents as of June 30, 2013 consisted of cash and money market funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. The primary objective of our investment activities is to preserve principal. Instruments that meet this objective include commercial paper, money market funds and government and non-government debt securities. Some of the investment securities available-for-sale that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment securities available-for-sale to fluctuate. To minimize this risk, we intend to continue to maintain our portfolio of cash and money market funds. Due to the short-term nature of our investments and our ability to hold them to maturity, we believe that there is no material exposure to interest rate risk.

Foreign Exchange Risk

All of the revenues we have generated to date have been paid in U.S. dollars and we expect that our revenues will continue to be generated primarily in U.S. dollars for at least the next several years. Payments to our material suppliers and contract manufacturers are denominated in the Euro and U.K. pounds sterling, thereby increasing our exposure to exchange rate gains and losses on non-U.S. currency transactions. Foreign currency gains and losses associated with these expenditures have not been significant to date. However, fluctuations in the rate of exchange between the U.S. dollar and these or other foreign currencies could adversely affect our financial results in the future, particularly to the extent we increase production to support Sumavel DosePro sales demands. For the six months ended June 30, 2013, approximately $9.8 million (based on exchange rates as of June 30, 2013) of our materials purchased and contract manufacturing costs were denominated in foreign currencies. We do not currently hedge our foreign currency exchange rate risk. As a result, we are exposed to gains and/or losses as the exchange rate of certain foreign currencies fluctuates. A 10% increase or decrease in the average rate of the Euro or the U.K. pound sterling during the six months ended June 30, 2013 would have resulted in approximately $0.4 million or $0.6 million in gains or losses, respectively. In addition, we maintain funds in foreign bank accounts denominated in the Euro and U.K. pounds sterling, thereby further increasing our exposure to exchange rate gains and losses. We intend to evaluate various options to mitigate the risk of financial exposure from transacting in foreign currencies in the future.

Item 4. Controls and Procedures

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

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

As required by Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2013 at the reasonable assurance level.

Changes in Disclosure Controls and Procedures

There were no changes in our internal control over financial reporting during the fiscal quarter ended June 30, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any legal proceedings.

Item 1A. Risk Factors

There have been no material changes to the risk factors included in “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, other than those set forth below, which should be read in conjunction with the risk factors disclosed therein.

Risks Related to Our Business and Industry

We are at an early stage of commercialization and have a history of significant net losses and negative cash flow from operations. We cannot predict if or when we will become profitable and anticipate that our net losses and negative cash flow from operations will continue for at least the next several years.

We were organized in 2006 and are at an early stage of commercialization. Our business and prospects must be considered in light of the risks and uncertainties frequently encountered by pharmaceutical companies in the early stages of commercialization.

We have generated substantial net losses and negative cash flow from operations since our inception in 2006. For example, for the six months ended June 30, 2013 and the years ended December 31, 2012 and 2011, we incurred net losses of $34.4 million, $47.4 million and $83.9 million, respectively, our net cash used in operating activities was $24.6 million, $52.2 million and $80.5 million, respectively, and, at June 30, 2013, our accumulated deficit was $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 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. Our ability to generate revenues from Sumavel DosePro or any of our product candidates will depend on a number of factors, including, in the case of Sumavel DosePro, the factors described in risk factors below and, in the case of our product candidates, our ability to successfully complete clinical trials, obtain necessary regulatory approvals and negotiate arrangements with third parties to help finance the development of, and market and distribute, any product candidates that receive regulatory approval. In addition, we will be subject to the risk that the marketplace will not accept our products.

Because of the numerous risks and uncertainties associated with our product development and commercialization efforts, we are unable to predict the extent of our future losses or when or if we will become profitable and it is possible we will never become profitable. If we do not increase sales of Sumavel DosePro or successfully commercialize any of our product candidates that may receive regulatory approval, a material adverse effect would likely impact our business, results of operations, financial condition and prospects and could result in our inability to continue operations.

We will require additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. To date, our operations have been primarily financed through the proceeds from the issuance of our common and preferred stock, including the proceeds from our initial public offering completed in November 2010, our follow-on public offerings completed in September 2011 and July 2012, and borrowings under our loan and financing agreements with Healthcare Royalty Partners, or Healthcare Royalty, Oxford Finance LLC, as successor in interest to Oxford Finance Corporation, or Oxford, and Silicon Valley Bank, or SVB. In addition, we have funded our operations through the proceeds from the sales and issuances of our common stock pursuant to the controlled equity offering program that we established on March 27, 2013 with Cantor Fitzgerald & Co., or Cantor, as sales agent, under which we may, from time to time, sell shares of common stock up to an aggregate offering price of $25.0 million. As of August 7, 2013, we agreed to the issuance of 3.0 million shares of our common stock under the controller equity offering program at an average stock issuance price of $1.66 per share, resulting in net proceeds of approximately $4.9 million; however, there can be no assurance that Cantor will be successful in consummating further sales under the program based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. Cantor or we are permitted to terminate the controlled

equity offering sales agreement, or sales agreement, at any time upon 10 days' prior written notice, and Cantor is also permitted to terminate the sales agreement at any time in certain circumstances, including the occurrence of a material adverse change in our company.

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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 funds to finance our operations beyond that point, or possibly earlier, in order to:

- maintain our sales and marketing activities for Sumavel DosePro;
- qualify secondary sources for the manufacturing of Sumavel DosePro;
- fund our operations, fund further development of Zohydro ER, if required, Relday and any other product candidate to support potential regulatory approval of marketing applications; and
- commercialize Zohydro ER or any of our product candidates or any products or product candidates that we may develop, in-license or otherwise acquire, if any of these product candidates receive regulatory approval.

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.

In addition, our estimates of the amount of cash necessary to fund our business and development and commercialization activities may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the commercial success of Sumavel DosePro;
- the timing of regulatory approval, if granted, of Zohydro ER or any other product candidates and the commercial success of any approved products;
- the rate of progress and cost of our clinical trials and other product development programs for Relday and our other product candidates and any other product candidates that we may develop, in-license or acquire;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with Sumavel DosePro, Zohydro ER, Relday and any of our other product candidates;
- the costs and timing of completion of outsourced commercial manufacturing supply arrangements for any product candidate;
- the costs of maintaining and expanding our sales and marketing infrastructure or establishing distribution capabilities;
- the effect of competing technological and market developments; and
- the terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

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.

Until we can generate a sufficient amount of product revenue and cash flow from operations and achieve profitability, we expect to finance future cash needs through public or private equity offerings, including through our controlled equity offering program, debt financings, receivables financings or corporate collaboration and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. 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. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. If we are unable to maintain sufficient financial resources, including by raising additional funds when needed, our business, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern.

We may not be successful in executing our sales and marketing strategy for the ongoing commercialization of Sumavel DosePro. As part of this strategy, we will be dependent on our collaboration with Mallinckrodt to promote Sumavel DosePro primarily to primary care physicians and physicians specializing in internal medicine. If we are unable to successfully execute such strategy, we may not be able to generate significant revenue.

Prior to the launch of Sumavel DosePro in January 2010, we built a commercial sales and marketing organization including sales, marketing, communications, managed markets, trade and distribution functions, which is focused on marketing and selling Sumavel DosePro primarily to physicians, nurses and other healthcare professionals in the United States. In May

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2013, we commenced a restructuring of our workforce, and our field sales force, which was comprised of approximately 80 field sales personnel as of March 31, 2013, was reduced to approximately 55 field sales personnel. Our current sales force will continue to promote Sumavel DosePro primarily to neurologists and other prescribers of migraine medications, including headache clinics and headache specialists in the United States.

To complement our sales force, we entered into a co-exclusive (with us) co-promotion agreement with Mallinckrodt in June 2012, or the Mallinckrodt co-promotion agreement, under which in August 2012 Mallinckrodt began promoting Sumavel DosePro to a mutually agreed prescriber audience in the United States. Mallinckrodt has committed to a minimum number of sales representatives for the initial term of the co-promotion agreement. Although the Mallinckrodt co-promotion agreement stipulates minimum levels of sales effort, we have limited control over the amount and timing of resources that Mallinckrodt dedicates to the promotion of Sumavel DosePro, and we do not hire or manage such resources. The ability to generate revenue from our arrangement with Mallinckrodt depends on Mallinckrodt's efforts in promoting Sumavel DosePro and its ability to achieve broad market acceptance and prescribing of Sumavel DosePro in its targeted physician segment.

We are subject to a number of additional risks associated with our dependence on our co-promotion arrangement with Mallinckrodt, including:

- Mallinckrodt could unsuccessfully devote sufficient resources to the promotion of Sumavel DosePro, including by failing to develop, deploy or expand its sales force as necessary;
- Mallinckrodt could unsuccessfully comply with applicable regulatory guidelines with respect to the promotion of Sumavel DosePro, which could result in administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, and injunctions; and
- disputes regarding the co-promotion agreement that negatively impact or terminate the commercialization efforts of Mallinckrodt may negatively impact or prevent the generation of sufficient revenue or result in significant litigation or arbitration.

Under the terms of the Mallinckrodt co-promotion agreement, Mallinckrodt may terminate the agreement with 60 days' written 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 our 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.

We may terminate the co-promotion agreement with 60 days' notice if Mallinckrodt does not achieve an agreed-upon minimums sales effort. Either party may terminate the 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.

In addition, the initial term of our co-promotion agreement with Mallinckrodt expires on June 30, 2014, subject to extension of additional six month increments by mutual agreement of both parties. We cannot assure you that Mallinckrodt will enter into any extension of the co-promotion agreement or, if it does so, that it will not condition any such extension upon changes in the co-promotion agreement that could have a material adverse effect on us. If Mallinckrodt were to terminate the co-promotion agreement or elect not to extend the agreement upon its expiration, we would lose the efforts of their sales force, and we may be required to make arrangements with another third party to replace Mallinckrodt's sales force, or expand our sales and marketing organization. We may not be able to enter into such arrangements with third parties in a timely manner, on acceptable terms or at all. To the extent that we enter into another co-promotion or other licensing arrangement, our portion of retained product revenues is likely to be lower

than if we directly marketed and sold Sumavel DosePro solely on our own, and a portion of those revenues generated will depend upon the efforts of such third parties similar to our dependence on Mallinckrodt, and these efforts may not be successful. If our co-promotion agreement with Mallinckrodt is terminated and we are unable to find another partner for the promotion of Sumavel DosePro in the primary care segment in the United States, we may not be able to expand our own sales and marketing capabilities or utilize our existing sales force effectively to cover this segment and any such expansion could, in any event, substantially increase our expenses and capital requirements that we might not be able to fund.

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If we are unable to successfully implement our commercialization plans and drive adoption by patients and physicians of Sumavel DosePro through our sales, marketing and commercialization efforts and the efforts of Mallinckrodt, then we will not be able to generate significant revenue which will have a material adverse effect on our business, results of operations, financial condition and prospects.

We depend on wholesale pharmaceutical distributors for retail distribution of Sumavel DosePro, and if we lose any of our significant wholesale pharmaceutical distributors, our business could be harmed.

The majority of our sales of Sumavel DosePro are to wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. Two wholesale pharmaceutical distributors, Cardinal Health, Inc. and McKesson Corporation, individually comprised 34% and 27%, respectively, of our total gross sales of Sumavel DosePro for the six months ended June 30, 2013, which may result in substantial fluctuations in our results of operations from period to period. The loss of any of these wholesale pharmaceutical distributors' accounts or a material reduction in their purchases could have a material adverse effect on our business, results of operations, financial condition and prospects.

In addition, these wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network has undergone, and may continue to undergo, significant consolidation marked by mergers and acquisitions. As a result, a small number of large wholesale distributors control a significant share of the market. Consolidation of drug wholesalers has increased, and may continue to increase, competitive and pricing pressures on pharmaceutical products. In addition, at times, wholesaler purchases may exceed customer demand, resulting in reduced wholesaler purchases in later quarters, which may result in substantial fluctuations in our results of operations from period to period. We cannot assure you that we can manage these pricing pressures or that wholesaler purchases will not decrease as a result of this potential excess buying.

Our sales can be greatly affected by the inventory levels our wholesalers carry. We monitor wholesaler inventory of Sumavel DosePro using a combination of methods. Pursuant to distribution service agreements with our three largest wholesale customers, we receive inventory level reports. For most other wholesalers where we do not receive inventory level reports, however, our estimates of wholesaler inventories may differ significantly from actual inventory levels. Significant differences between actual and estimated inventory levels may result in excessive production (requiring us to hold substantial quantities of unsold inventory), inadequate supplies of products in distribution channels, insufficient product available at the retail level, and unexpected increases or decreases in orders from our wholesalers. These changes may cause our revenues to fluctuate significantly from quarter to quarter, and in some cases may cause our operating results for a particular quarter to be below our expectations or the expectations of securities analysts or investors. If our financial results are below expectations for a particular period, the market price of our common stock may drop significantly.

We are dependent on numerous third parties in our supply chain, all of which are currently single source suppliers, for the commercial supply of Sumavel DosePro and for the clinical supply of Zohydro ER and Relday, and if we experience problems with any of these suppliers, the manufacturing of Sumavel DosePro, Zohydro ER and Relday could be delayed.

While we own most of the specialized equipment used to manufacture critical components of Sumavel DosePro, we do not own or operate manufacturing facilities and currently lack the in-house capability to manufacture Sumavel DosePro, Zohydro ER, Relday or any other product candidates. Our DosePro device and Sumavel DosePro are manufactured by contract manufacturers, component fabricators and secondary service providers. Aseptic fill, finish, assembly and packaging of Sumavel DosePro are performed at Patheon UK Limited, Swindon, United Kingdom, or Patheon, a specialist in the aseptic fill/finish of injectables and other sterile pharmaceutical products. In May 2012, Patheon announced plans to wind down or transfer its commercial production capacity for a number of products at this facility over a period of 24 to 36 months. We have identified alternative suppliers for these services and are currently working on a plan to transfer the manufacturing processes that are presently handled by Patheon to a new supplier in advance of the expected closure date of the Swindon, United Kingdom facility. In addition, Nypro Limited, located in Bray, Ireland, manufactures the actuator assemblies and injection molded components for our DosePro device and Nipro Glass, Germany AG (formerly MGlas AG), located in Münnerstadt, Germany, manufactures the specialized glass capsule (cartridge) that houses the sumatriptan active pharmaceutical ingredient, or API, in our DosePro device.

Each of these manufacturers and each other company that supplies, fabricates or manufactures any component used in our DosePro device is currently the only qualified source of their respective components. We currently rely on Dr. Reddy's Laboratories as the only supplier of sumatriptan API for use in Sumavel DosePro. We also outsource all manufacturing and packaging of the clinical trial materials for Zohydro ER and Relday to third parties. Although we plan to qualify additional manufacturers and suppliers of some of the components used in Sumavel DosePro, there can be no assurance that we will be able to do so and the current manufacturers and suppliers of these components will likely be single source suppliers to us for a significant period of time. Similarly, an affiliate of Alkermes is the exclusive manufacturer of Zohydro ER and Durect is the exclusive manufacturer of the risperidone formulation using Durect's SABER™ controlled-release technology for all Relday clinical trials through Phase 2 and has the option to supply the same formulation for Phase 3 clinical

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trials and, if approved, commercial production. We have restrictions on establishing a second source of supply under our agreement with an affiliate of Alkermes, and we may never be able to establish additional sources of supply for Zohydro ER or Relday's risperidone formulation.

Manufacturers and suppliers are subject to regulatory requirements covering, among other things, manufacturing, testing, quality control and record keeping relating to our product and product candidates, and are subject to ongoing inspections by regulatory agencies. Failure by any of our manufacturers or suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing supply, and increase our costs, while we seek to secure another supplier who meets all regulatory requirements. Accordingly, the loss of any of our current third-party manufacturers or suppliers could have a material adverse effect on our business, results of operations, financial condition and prospects.

Reliance on third-party manufacturers and suppliers entails risks to which we would not be subject if we manufactured Sumavel DosePro or our product candidates ourselves, including:

- reliance on the third parties for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control or the insolvency of any of these third parties or other financial difficulties, labor unrest, natural disasters or other factors adversely affecting their ability to conduct their business; and
- the possibility of termination or non-renewal of the agreements by the third parties, at a time that is costly or inconvenient for us, because of our breach of the manufacturing agreement or based on their own business priorities.

If our contract manufacturers or suppliers are unable to deliver the required commercial quantities of Sumavel DosePro and its various components, the quantities of Zohydro ER, Relday or any of our other product candidates required for our clinical trials and, if approved, for commercial sale, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers or suppliers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and would have to delay or terminate our pre-clinical or clinical trials, and we would lose potential revenue. It may also take a significant period of time to establish an alternative source of supply for our product, product candidates and components and to have any such new source approved by the FDA or any applicable foreign regulatory authorities. Furthermore, any of the above factors could cause the delay or suspension of initiation or completion of clinical trials, regulatory submissions or required approvals of our product candidates, cause us to incur higher costs and could prevent us from commercializing our product candidates successfully.

We rely on third parties to perform many necessary services for our commercial products, including services related to the distribution, invoicing, storage and transportation of our products.

We have retained third-party service providers to perform a variety of functions related to the sale and distribution of our products, key aspects of which are out of our direct control. For example, we rely on Cardinal Health 105, Inc. (a/k/a Specialty Pharmaceutical Services) to provide key services related to logistics, warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management, and, as a result, most of our inventory is stored at a single warehouse maintained by the service provider. We also rely on GENCO and Inmar Inc. to process our product returns. We place substantial reliance on these providers as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers are unable to comply with applicable laws and regulations, are unable to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical damage or natural disaster at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we utilize third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market our products could be jeopardized or we could be subject to regulatory sanctions. We do not currently have the internal capacity to perform these important commercial functions, and we may not be able to maintain commercial arrangements for these services on reasonable terms.

Zohydro ER and Relday are subject to extensive regulation, and we cannot give any assurance that they or any of our other product candidates will receive regulatory approval or be successfully commercialized.

We currently are developing Zohydro ER for the treatment of moderate to severe chronic pain and Relday for the treatment of the symptoms of schizophrenia. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products, among other things, are subject to extensive regulation by the FDA, the DEA (in the case of Zohydro ER) and other regulatory authorities in the United States. We are not permitted to market Zohydro ER, Relday or any of our other product candidates in the United States unless and until we receive regulatory approval from the FDA. We cannot

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provide any assurance that we will obtain regulatory approval for Zohydro ER, Relday or any of our other product candidates, or that any such product candidates will be successfully commercialized.

Under the policies agreed to by the FDA under The Prescription Drug User Fee Act, or PDUFA, as renewed by the Food and Drug Administration Safety and Innovation Act, or FDASIA, the FDA is subject to a two-tiered system of review times for new drugs - Standard Review and Priority Review. For certain drugs subject to standard review, such as Zohydro ER, the FDA has a goal to complete its review of the NDA and respond to the applicant within ten months from the date of receipt of an NDA. The FDA assigned a target action date of March 1, 2013 for the Zohydro ER NDA. The review process and the PDUFA target action date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the three months prior to the PDUFA target action date. The FDA's review goals are subject to change, and the duration of the FDA's review may depend on the number and type of other NDAs that are submitted with the FDA around the same time period. 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.

The FDA may also refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. In connection with the acceptance of our NDA for Zohydro ER, the FDA convened an advisory committee on December 7, 2012, which voted 11-2 (with 1 abstention) against the approval of Zohydro ER. The FDA is not bound by the recommendation of the advisory committee and the final decision regarding approval is made by the FDA. However, due to the advisory committee's recommendation against the approval of our NDA, we may not be able to succeed in securing approval for Zohydro ER. Even if we obtain regulatory approval for Zohydro ER, the matters discussed at the advisory committee meetings, and in particular any concerns regarding safety and abuse potential, could limit our ability to successfully commercialize the product candidate.

As part of its review of the NDA, the FDA may inspect the facility or the facilities where the drug is manufactured. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA will issue an action letter, which will be either an approval letter, authorizing commercial marketing of the drug for a specified indication, or a “Complete Response Letter, or CRL” containing the conditions that must be met in order to secure approval of the NDA. These conditions may include deficiencies identified in connection with the FDA's evaluation of the NDA submission or the

clinical and manufacturing procedures and facilities. Until any such conditions or deficiencies have been resolved, the FDA may refuse to approve the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example:

- the FDA may not deem a product candidate safe and effective;
- the FDA may not find the data from pre-clinical studies and clinical trials sufficient to support approval;
- the FDA may require additional pre-clinical studies or clinical trials;
- the FDA may not approve of our third-party manufacturers' processes and facilities; or
- the FDA may change its approval policies or adopt new regulations.

Zohydro ER has undergone Phase 1 pharmacokinetics studies, Phase 2 clinical trials, and a Phase 3 clinical development program. However, some of these studies and trials were conducted by a third party and, accordingly, we did not directly participate in their design or execution. We initiated the Phase 3 clinical development program for Zohydro ER in March 2010 and reported positive results from our pivotal Phase 3 efficacy trial, Study 801, in August 2011 and completed our Phase 3 safety trial, Study 802, in December 2011, which showed Zohydro ER to be safe and generally well tolerated. However, product candidates such as Zohydro ER may not be approved even if they achieve their specified endpoints in clinical trials. The FDA may disagree with our trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the

design for our clinical trials. The FDA may also approve a product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates. Approval may be contingent on a Risk Evaluation and Mitigation Strategy, or REMS, which limits the labeling, distribution or promotion of a drug product.

Relday and any of our other product candidates may not achieve their specified endpoints in clinical trials. We initiated a Phase 1 safety and pharmacokinetic clinical trial for Relday in July 2012 and announced positive single-dose pharmacokinetic results from this trial in January 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

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at a 100 mg dose of the same formulation and announced positive top-line results from the extended Phase 1 clinical trial in May 2013. 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.

We believe that we have planned, designed and completed an adequate Phase 3 clinical trial program for Zohydro ER, and we presented the trial design for our Phase 3 trials to the FDA at our End of Phase 2 meeting in June 2008. Although we believe the FDA has generally agreed with the design of our Phase 3 clinical trial program, the FDA could still determine that it is not satisfied with our plan, the details of our pivotal clinical trial protocols and designs or the results of our studies. In addition, we concluded our pre-NDA meetings with the FDA in December 2011 during which we discussed the non-clinical, clinical and chemistry, manufacturing and controls, or CMC, development of Zohydro ER, and agreed on the submission requirements for the NDA under 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FFDCA. While the FDA has provided us with a written record of our discussions and responses to our questions at our End of Phase 2 meeting and our pre-NDA meetings, such records and responses do not guarantee that the FDA will deem our trial design to be sufficient for the purpose of obtaining marketing approval for Zohydro ER. We did not seek a Special Protocol Assessment from the FDA for our pivotal Phase 3 efficacy study for Zohydro ER (Study 801).

If we are unable to obtain regulatory approval for Zohydro ER, Relday or any other product candidates on the timeline we anticipate, we will not be able to execute our business strategy effectively and our ability to generate additional revenues beyond Sumavel DosePro will be limited, which would have a material adverse impact on our business, results of operations, financial condition and prospects.

Delays in the commencement or completion of any additional testing for Zohydro ER, if required, or clinical testing for Relday, or pre-clinical or clinical testing for any of our other product candidates could result in increased costs to us and delay or limit our ability to pursue regulatory approval for, or generate revenues from, such product candidates.

Clinical trials are very expensive, time consuming and difficult to design and implement. Delays in the commencement or completion of any additional testing for Zohydro ER, if required, or clinical testing for Relday, or pre-clinical or clinical testing for any of our other product candidates could significantly affect our product development costs and business plan. We initiated clinical testing for Relday in patients with schizophrenia in July 2012 and announced positive single-dose pharmacokinetic results from the Phase 1 clinical trial in January 2013. Based on the favorable safety and pharmacokinetic profile demonstrated in the Phase 1 trial, we extended the study to include an additional dose of the same formulation and announced positive top-line results in May 2013. 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. We do not know whether any of our other pre-clinical or clinical trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining regulatory authorization to commence a clinical trial;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, clinical investigators and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, clinical investigators and trial sites;
- manufacturing or obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining institutional review board, or IRB, approval to initiate and conduct a clinical trial at a prospective site;
- identifying, recruiting and training suitable clinical investigators;
- identifying, recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the treatment of pain, migraine or similar indications;
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy, personal issues, or for any other reason they choose, or who are lost to further follow-up;
- uncertainty regarding proper dosing; and
- scheduling conflicts with participating clinicians and clinical institutions.

In addition, if a significant number of patients fail to stay enrolled in any of our current or future clinical trials of Relday or any of our other product candidates and such failure is not adequately accounted for in our trial design and enrollment assumptions, our clinical development program could be delayed. Clinical trials may also be delayed or repeated as a result of ambiguous or negative interim results or unforeseen complications in testing. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors, including:

- failure to design appropriate clinical trial protocols;

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- failure by us, our employees, our CROs or their employees to conduct the clinical trial in accordance with all applicable FDA, DEA or other regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- discovery of serious or unexpected toxicities or side effects experienced by study participants or other unforeseen safety issues;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- lack of effectiveness of any product candidate during clinical trials;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- failure of our CROs or other third-party contractors to comply with all contractual requirements or to perform their services in a timely or acceptable manner;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unfavorable results from on-going clinical trials and pre-clinical studies.

Additionally, changes in applicable regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. All of the above risks will be applicable to Zohydro ER to the extent we are required by the FDA to conduct any additional clinical trials. If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for Zohydro ER, Relday and our other product candidates may be harmed, which may have a material adverse effect on our business, results of operations, financial condition and prospects.

The development and implementation of a REMS for Zohydro ER could cause significant delays in the approval process for Zohydro ER and will add additional layers of regulatory requirements, including the requirement for a Medication Guide and educational requirements for prescribers and patients, which could significantly impact our ability to commercialize Zohydro ER and dramatically reduce its market potential.

The Food and Drug Administration Amendments Act, or FDAAA, added Section 505-1 to the FFDCA. Section 505-1 permits FDA to require a REMS for a drug product to ensure the safe use of the drug. A REMS is a strategic safety program that the FDA requires to ensure that the benefits of a drug outweigh its risks. In determining whether a REMS is necessary, the FDA will consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment and the seriousness of known or potential adverse events. If the FDA determines a REMS is necessary, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health care providers of the drug's risks, limitations on who may prescribe or dispense the drug, requirements that patients enroll in a registry or undergo certain health evaluations or other measures that the FDA deems necessary to assure the safe use of the drug. In addition, the REMS must include a timetable to assess the strategy minimally at 18 months, three years and seven years after the strategy's approval.

In February 2009, the FDA informed opioid analgesic drug manufacturers that it will require a class-wide REMS for all long-acting and sustained-release opioid drug products. The FDA has since initiated efforts to develop a new standardized REMS for these opioid medications to ensure their safe use. In April 2011, the FDA announced that it had finalized the elements of a class-wide REMS for these products. The central component of the opioid REMS program is an education program for prescribers and patients. Specifically, the REMS for these products must include a Medication Guide available for distribution to patients who are dispensed the drug, as well as a number of elements to assure safe use. These elements include training for prescribers who prescribe the drug; information provided to prescribers that prescribers can use to educate patients in the safe use, storage, and disposal of opioids; and information provided to prescribers of the existence of the REMS and the need to successfully complete the necessary training. The FDA expects that the prescriber training required as part of the REMS is to be conducted by accredited, independent continuing education providers, without cost to the healthcare professionals, under unrestricted grants to

accredited continuing education providers funded by the opioid analgesic sponsor. In November 2011, the FDA issued a draft blueprint for this prescriber education that outlines the core messages that the FDA believes should be conveyed to prescribers in a basic two to three hour educational module. This finalized and approved blueprint is available at www.ER-LA-opioidrems.com for use by continuing education providers in developing continuing education courses. Moreover, the extended-release/long-acting opioid analgesic REMS must include a timetable for submission of assessments that shall be no less frequent than 6 months, 12 months, and annually after the REMS is approved to assess the extent to which the elements to assure safe use are meeting the goals of the REMS and whether the goals or elements should be modified. The FDA expects that manufacturers of long-acting and extended-release opioids work together to provide educational materials as part of a class-wide single shared system to reduce the burden of the REMS on the healthcare system.

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An extended-release formulation of hydrocodone, such as Zohydro ER, will be required to have a REMS that contains the elements of the recently-issued class-wide REMS for long-acting and sustained-release opioids. We submitted a REMS at the time of the NDA submission for Zohydro ER. The REMS submission could cause significant delays in the approval process for the Zohydro ER NDA, and the educational requirements and requirements for a Medication Guide for patients could significantly impact our ability to commercialize Zohydro ER and dramatically reduce its market potential.

We may not successfully develop, obtain approval for or commercialize Sumavel DosePro in the European Union or other foreign territories, which may adversely affect our ability to commercialize Sumavel DosePro both inside and outside the United States.

In March 2008, we entered into a licensing and distribution agreement with Desitin pursuant to which we granted Desitin the exclusive right under our intellectual property rights related to Sumavel DosePro to develop, use, distribute, sell, offer for sale, and import Sumavel DosePro and any potential modified versions of Sumavel DosePro in the European Union, Norway, Switzerland and Turkey. In that regard, Desitin is not obligated under the agreement to pursue regulatory approval or commercialization of Sumavel DosePro in any of these countries except for Germany. Desitin submitted a Marketing Authorization Application for Sumavel DosePro to the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)) in Germany, the reference member state, through the Decentralized Procedure in October 2009, following completion of a European pivotal bioequivalence trial comparing needle-free Sumavel DosePro to a traditional needle-based autoinjector, Imigran-Inject, the European brand of Imitrex STATdose. In November 2010, Denmark became the first member of the European Union to approve marketing of Sumavel DosePro in that country. Subsequently, Sumavel DosePro has received marketing approval in Germany, Sweden, the United Kingdom, Norway and France. The marketing authorization for the United Kingdom and Sweden will expire in December of 2013 and the marketing authorization for Norway and France will expire in February 2014. In order to extend the marketing authorization in these countries, we or a commercialization partner, will be required to re-submit a Marketing Authorization Application, which will need to be re-approved. Any additional clinical studies we, or a commercialization partner, may be required to conduct as part of the regulatory approval process may not corroborate the results of the clinical studies we have conducted or may have adverse results or effects on our ability to maintain regulatory approvals in the United States or obtain them in other countries.

On August 5, 2013, we entered into an agreement with Desitin, whereby the licensing and distribution agreement will terminate effective October 1, 2013. Following the termination of the licensing and distribution agreement, we will assume the rights to exclusive development and commercialization of Sumavel DosePro for the European Union, Norway, Switzerland and Turkey. We may not have the internal resources to further develop and obtain regulatory approval for Sumavel DosePro in other foreign territories, or to find another commercialization partner for foreign territories, if deemed necessary. Although we believe that the U.S. market represents the largest commercial opportunity for Sumavel DosePro, we may not develop Sumavel DosePro as fast or generate as large of a market as we would like or as the market may expect which would limit our opportunity to receive revenue from foreign territories. Furthermore, negative developments occurring in foreign territories could have a negative impact on physician and patient impressions of our product in the United States and elsewhere.

Our inability to successfully establish new partnerships with pharmaceutical companies or contract sales organizations to co-promote Sumavel DosePro and any additional product candidates that may receive regulatory approval may impair our ability to effectively market and sell such product candidates.

Major pharmaceutical companies usually employ groups of sales representatives numbering in the thousands to call on the large number of primary care physicians. In connection with the launch of Sumavel DosePro in January 2010 we built a sales and marketing organization to promote Sumavel DosePro in the United States, including a focused sales force, which as of June 30, 2013 was comprised of approximately 55 field sales personnel, primarily targeting neurologists and other prescribers of migraine medications, including headache clinics and headache specialists. In June 2012, in order to maintain and expand the market opportunity for Sumavel DosePro into the broader primary care physician audiences, we entered into a co-exclusive (with us) co-promotion agreement with Mallinckrodt under which in August 2012 Mallinckrodt began promoting Sumavel DosePro to its customer base of prescribers.

In addition, in order to promote any additional product candidates that receive regulatory approval to these broader primary care physician audiences, we will need to expand our sales and marketing personnel and commercial infrastructure and/or establish partnerships with pharmaceutical companies or contract sales organizations to co-promote such additional products. We currently, and on an ongoing basis will have to, compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. We also face competition in our search for collaborators and potential co-promoters. To the extent we rely on additional third parties to co-promote or otherwise commercialize any product and/or product candidates that may receive regulatory approval, we are likely to receive less revenue than if we commercialized these products ourselves. Further, by entering into strategic partnerships or similar arrangements, we may rely in part on such third parties for financial and commercialization resources. Even if we are able to identify suitable partners to assist in the

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commercialization of our product and/or product candidates, they may be unable to devote the resources necessary to realize the full commercial potential of our products. In addition, we may lack the financial and managerial resources to increase the size of our sales and marketing organization to adequately promote and commercialize Sumavel DosePro and any product candidates that may be approved, and any increase in our sales force would result in an increase in our expenses, which could be significant before we generate revenues from any newly approved product candidate. If we are unable to expand our sales and marketing infrastructure or enter into a third-party arrangement, we would not be able to successfully commercialize any approved products. Even if we are able to expand our sales and marketing personnel or successfully establish partnership arrangements, such sales force and marketing teams may not be successful in commercializing our products, which would adversely affect our ability to generate revenue for such products, which will have a material adverse effect on our business, results of operations, financial condition and prospects.

We recently experienced a reduction in force and may need to increase the size of our organization in the near future, in which case we could experience difficulties in managing and financing such growth.

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.

We intend to increase our sales force if Zohydro ER is approved by the FDA. Any such increases in our sales force could substantially increase our expenses. We may need to expand our managerial, operational and other resources in order to grow, manage and fund our existing business. Our management and personnel, systems and facilities currently in place may not be adequate to support any future growth, and we may be unable to fund the costs and expenses required to increase our necessary headcount and infrastructure. Our need to effectively manage our operations, any future growth and various projects requires that we:

- manage our internal and external commercialization efforts for Sumavel DosePro effectively while carrying out our contractual obligations to third parties and complying with all applicable laws, rules and regulations;
- manage our internal development efforts for Zohydro ER, Relday and our other product candidates effectively while carrying out our contractual obligations to licensors, collaborators and other third parties and complying with all applicable laws, rules and regulations;
- continue to improve our operational, financial and management controls, reporting systems and procedures; and
- attract and retain sufficient numbers of talented employees.

We may be unable to successfully implement or fund these tasks on a larger scale and, accordingly, may not achieve our commercialization and development goals. In addition, our management may have to divert a disproportionate amount of its attention away from day-to-day activities and towards managing these growth-related activities. Likewise, any increase in our sales force would increase our expenses, perhaps substantially. Our future financial performance and our ability to execute on our business plan will depend, in part, on our ability to effectively manage any future growth and our inability to effectively manage any growth could have a material adverse effect on our business, results of operations, financial condition and prospects.

If we are unable to attract and retain key personnel, we may not be able to manage our business effectively or develop our product candidates or commercialize our product.

Our success depends on our continued ability to attract, retain and motivate highly qualified management and key clinical development, regulatory, sales and marketing and other personnel. 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. In June 2013, we implemented a company-wide retention program pursuant to which restricted stock units were granted to our executives and all other full time personnel; however, this new program may not be effective in retaining our personnel.

We are highly dependent on the development, regulatory, commercial and financial expertise of our senior management team. We may not be able to attract or retain qualified management and scientific and clinical personnel

in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the areas in Southern and Northern California, where we currently operate. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development and commercialization objectives, our ability to raise additional capital and our ability to implement our business strategy. The loss

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of the services of any members of our senior management team, especially our Chief Executive Officer, Roger L. Hawley, and President and Chief Operating Officer, Stephen J. Farr, Ph.D., could negatively impact the commercialization of Sumavel DosePro and could delay or prevent the development and commercialization of any other product candidates, including Zohydro ER or Relday. Further, if we lose any members of our senior management team, we may not be able to find suitable replacements, and our business may be harmed as a result. In addition to the competition for personnel, our locations in California in particular are characterized by a high cost of living. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Although we have employment agreements with each of our executive officers, these agreements are terminable by them at will at any time with or without notice and, therefore, do not provide any assurance that we will be able to retain their services. We do not maintain “key man” insurance policies on the lives of our senior management team or the lives of any of our other employees. In addition, we have clinical advisors who assist us in formulating our clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours. If we are unable to attract and retain key personnel, our business, results of operations, financial condition and prospects will be adversely affected.

Fluctuations in the value of the Euro or U.K. pound sterling could negatively impact our results of operations and increase our costs.

Payments to our material suppliers and contract manufacturers are denominated in the Euro and U.K. pound sterling. Our reporting currency is the U.S. dollar and to date all of the revenues generated by sales of Sumavel DosePro have been in U.S. dollars. For the six months ended June 30, 2013, $9.8 million (based on exchange rates as of June 30, 2013) of our materials purchased and contract manufacturing costs were denominated in foreign currencies. As a result, we are exposed to foreign exchange risk, and our results of operations may be negatively impacted by fluctuations in the exchange rate between the U.S. dollar and the Euro or U.K. pound sterling. A significant appreciation in the Euro or U.K. pound sterling relative to the U.S. dollar will result in higher expenses and cause increases in our net losses. Likewise, to the extent that we generate any revenues denominated in foreign currencies, or become required to make payments in other foreign currencies, fluctuations in the exchange rate between the U.S. dollar and those foreign currencies could also negatively impact our results of operations. We currently have not entered into any foreign currency hedging contracts to reduce the effect of changes in foreign currency exchange rates, and foreign currency hedging is inherently risky and may result in unanticipated losses.

Risks Related to Our Financial Position and Capital Requirements

We have never generated net income or positive cash flow from operations and are dependent upon external sources of financing to fund our business and development.

We launched our only approved product, Sumavel DosePro, in January 2010. Without a long history of sales, we may not accurately predict future sales, and we may never be able to significantly increase these sales, especially in light of our reliance on our new co-promotion partner, Mallinckrodt. We have financed our operations almost exclusively through the proceeds from the issuance of our common and preferred stock, including the proceeds from our initial public offering completed in November 2010, our follow-on public offerings completed in September 2011 and July 2012, and debt, and have incurred losses and negative cash flow from operations in each year since our inception. For example, for the six months ending June 30, 2013 and the years ended December 31, 2012 and 2011, we incurred net losses of $34.4 million, $47.4 million and $83.9 million, respectively, our net cash used in operating activities was $24.6 million, $52.2 million and $80.5 million, respectively, and, at June 30, 2013, our accumulated deficit was $363.8 million. These losses and negative cash flow from operations have had a material adverse effect on our stockholders' equity and working capital. Further, despite the revenues from Sumavel DosePro, we expect our losses to continue for at least the next several years primarily as a result of the expenses incurred in connection with our efforts in seeking marketing approval for Zohydro ER, the potential additional clinical development of 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 a result, we may remain dependent upon external sources of financing to finance our business and the development and commercialization of our approved product and product candidates. To

the extent we need to raise additional capital in the future, we cannot ensure that debt or equity financing will be available to us in amounts, at times or on terms that will be acceptable to us, or at all. Any shortfall in our cash resources could require that we delay or abandon certain development and commercialization activities and could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Our level of indebtedness could adversely affect our ability to raise additional capital to fund our operations, limit our ability to react to changes in the economy or our industry and prevent us from meeting our obligations.

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As of June 30, 2013, we had $30.0 million of outstanding indebtedness under a financing agreement with Healthcare Royalty Partners, or the Healthcare Royalty financing agreement. Our outstanding debt and related debt service obligations could have important adverse consequences to us, including:

- heightening our vulnerability to downturns in our business or our industry or the general economy and restricting us from making improvements or acquisitions, or exploring business opportunities;
- requiring a significant amount of interest payments and fixed payments on our indebtedness, therefore reducing our ability to use our available cash to fund our operations, capital expenditures and future business opportunities;
- limiting our ability to obtain additional financing for working capital, capital expenditures, debt service requirements, acquisitions and general corporate or other purposes;
- limiting our ability to adjust to changing market conditions and placing us at a competitive disadvantage compared to our competitors who have greater capital resources; and
- subjecting us to financial and other restrictive covenants in our debt instruments, the failure with which to comply could result in an event of default under the applicable debt instrument that allows the lender to demand immediate repayment of the related debt.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay product development, sales and marketing, capital and other expenditures, sell assets, seek additional capital or restructure or refinance our indebtedness. These alternative measures may not be successful and may not permit us to meet our scheduled debt service obligations.

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

We will need to raise additional funds through public or private equity offerings, debt financings, receivables financings or corporate collaboration and licensing arrangements. To the extent that we raise additional capital by issuing equity securities, including through our controlled equity offering program, or convertible debt, your ownership interest in us will be diluted. Debt financing typically contains covenants that restrict operating activities. Our obligations under the Healthcare Royalty financing agreement are secured by a security interest in substantially all of our personal property (including, among other things, accounts receivable, equipment, inventory, contract rights or rights to payment of money, license agreements, general intangibles, including all intellectual property, and cash). The security interest will be extinguished once the aggregate payments made by us to Healthcare Royalty equals $75.0 million.

The Healthcare Royalty financing agreement contains provisions which allows Healthcare Royalty to accelerate the debt and seize and sell the collateral if, among other things, we fail to pay interest payments and fixed payments when due or breach our obligations under the agreement or if a material adverse change in our business or any other event of default occurs. Any future debt financing we enter into may involve more onerous covenants that restrict our operations, may be secured by some or all of our assets, and will likely allow the lenders to accelerate the debt and seize and sell any collateral following a default. Our obligations under our outstanding Healthcare Royalty financing agreement or any future debt financing will need to be repaid, which creates additional financial risk for our company, particularly if our business or prevailing financial market conditions are not conducive to paying-off or refinancing our outstanding debt obligations.

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

We may not be able to sell shares of our common stock under our controlled equity offering program with Cantor at times, prices or quantities that we desire, and if such sales do occur, they may result in dilution to our existing stockholders.

On March 27, 2013, we entered into the sales agreement with Cantor. Under the terms of the sales agreement, Cantor will use its commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the Nasdaq Global Market, to sell shares of our common stock

designated by us. However, there can be no assurance that Cantor will be successful in consummating such sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. In addition, we will not be able to make sales of our common stock pursuant to the sales agreement unless certain conditions are met, which include the accuracy of representations and warranties made to Cantor under the sales agreement; compliance with laws; and the continued listing of our stock on the Nasdaq Global Market. In addition, Cantor is permitted to terminate the sales agreement at any time. If we are unable to access funds through sales under the sales agreement, or it is terminated by Cantor, we may be unable to access capital on favorable terms or at all.

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As of August 7, 2013, we completed the issuance of 3.0 million shares of our common stock pursuant to the sales agreement, which had a dilutive effect on holdings of our existing stockholders as of August 7, 2013. Should we sell additional shares pursuant to the sales agreement, it will further dilute the holdings of our existing stockholders, and may result in downward pressure on the price of our common stock. If we sell shares under the sales agreement at a time when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.

Even though Sumavel DosePro has received regulatory approval in the United States and a limited number of foreign countries, we, Desitin, or any other potential partners may never receive approval in other countries or commercialize our products anywhere outside of the United States.

In March 2008, we established an exclusive commercial partnership for Sumavel DosePro with Desitin in the European Union, Norway, Switzerland and Turkey, in order to seek to accelerate the development and regulatory approvals in those territories. However, on August 5, 2013, we agreed with Desitin to terminate the licensing and distribution agreement effective October 1, 2013. Following the termination of the licensing and distribution agreement, we will assume the rights to exclusive development and commercialization of Sumavel DosePro for the European Union, Norway, Switzerland and Turkey. We may seek to establish commercial partnerships for Sumavel DosePro in other foreign countries, and we may also seek to establish a new commercial partnership in the European Union, Norway, Switzerland and Turkey. In order to market Sumavel DosePro or any other products outside of the United States, we, or any potential partner, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our products. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed in these “Risk Factors,” and the "Risk Factors" set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, regarding FDA approval in the United States, as well as other risks. For example, legislation analogous to Section 505(b)(2) of the FFDCA in the United States does not exist in other countries. In territories where data is not freely available, we or our partners may not have the ability to commercialize our products without negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds. We, or any potential partner, may be unable to obtain rights to the necessary clinical data and may be required to develop our own proprietary safety effectiveness dossiers. Desitin submitted a Marketing Authorization Application for Sumavel DosePro to the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)) in Germany, the reference member state, through the Decentralized Procedure in October 2009, following completion of a European pivotal bioequivalence trial comparing needle-free Sumavel DosePro to a traditional needle-based autoinjector, Imigran-Inject, the European brand of Imitrex STATdose. However, regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others.

Inability to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed in these “Risk Factors,” and the "Risk Factors" set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, regarding FDA approval in the United States. As described above, such effects include the risks that our product and product candidates may not be approved at all or for all requested indications, which could limit the uses of our product and product candidates and have an adverse effect on their commercial potential or require costly, post-marketing studies. In addition, we, or any potential partner, may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if we are unable to comply with applicable foreign regulatory requirements.

Risks Related to Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our product, Sumavel DosePro, and our product candidates, Zohydro ER and Relday, their respective

components, formulations, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing Sumavel DosePro or our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

We in-license certain intellectual property for Zohydro ER from Alkermes, and certain intellectual property for Relday from Durect. We rely on these licensors to file and prosecute patent applications and maintain patents and otherwise protect

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certain of the intellectual property we license from them. We have not had and do not have primary control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, with respect to our license agreements with Alkermes and Durect, we cannot be certain that such activities by Alkermes and Durect have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Alkermes has retained the first right, but not the obligation, to initiate an infringement proceeding against a third-party infringer of the intellectual property rights that Alkermes has licensed to us, and enforcement of our licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents would also be subject to the control or cooperation of Alkermes. Similarly, Durect has retained the first right, but not the obligation, to initiate an infringement proceeding against a third-party infringer of certain of the intellectual property rights that Durect has licensed to us, and enforcement of certain of our licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents would also be subject to the control or cooperation of Durect. We are not entitled to control the manner in which Alkermes or Durect may defend certain of the intellectual property that is licensed to us and it is possible that their defense activities may be less vigorous than had we conducted the defense ourselves.

Most of our patents related to DosePro were acquired from Aradigm, who acquired those patents from a predecessor owner. Our patents related to Zohydro ER are licensed from Alkermes. Thus, most of our patents, as well as many of our pending patent applications, were not written by us or our attorneys, and we did not have control over the drafting and prosecution of these patents. Further, the former patent owners and our licensors might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. In addition, the former patent owners and Alkermes may not have been completely familiar with U.S. patent law, possibly resulting in inadequate disclosure and/or claims. This could possibly result in findings of invalidity or unenforceability of the patents we own and in-license, patents issuing with reduced claim scope, or in pending applications not issuing as patents.

In addition, as part of the agreement where we acquired patents related to DosePro from Aradigm, Aradigm retained, and we granted to Aradigm, a non-exclusive, worldwide, royalty free license to the acquired patents solely for purposes of the delivery of one or more aerosolized APIs directly into the bronchia or lungs. The agreement with Aradigm also includes a covenant not to compete with us regarding technologies or products for the delivery of one or more APIs via needle free injection. That covenant expired on August 26, 2010, giving Aradigm or its licensees the right to develop and sell other needle-free injection technologies and products.

The patent positions of pharmaceutical, biopharmaceutical and medical device companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States. There have been recent changes regarding how patent laws are interpreted, and both the PTO and Congress have recently proposed radical changes to the patent system. We cannot accurately predict future changes in the interpretation of patent laws or changes to patent laws which might be enacted into law. Those changes may materially affect our patents, our ability to obtain patents and/or the patents and applications of our collaborators and licensors. The patent situation in these fields outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license or third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the pharmaceutical compounds used in Sumavel DosePro and our product candidates but that are not covered by the claims of our patents;
- the APIs in Sumavel DosePro and our current product candidates are, or will soon become, commercially available in generic drug products, and no patent protection will be available without regard to formulation or method of use;
- we or our licensors, as the case may be, may not be able to detect infringement against our in-licensed patents, which may be especially difficult for manufacturing processes or formulation patents;

- we or our licensors, as the case may be, might not have been the first to make the inventions covered by our owned or in-licensed issued patents or pending patent applications;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are dominating patents to Sumavel DosePro or our product candidates of which we are not aware;

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- it is possible that there are prior public disclosures that could invalidate our or our licensors' inventions, as the case may be, or parts of our or their inventions of which we or they are not aware;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our device or product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, or may be narrowed in scope, be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies for which we can obtain patent protection; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully penetrate our target markets could be severely compromised.

If any of our owned or in-licensed patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Likewise, our patents covering certain technology used in our DosePro device are expected to expire on various dates from 2014 through 2026 and the patents licensed to us by Alkermes are expected to expire in 2019. As of June 30, 2013, our patent portfolio included twelve issued U.S. patents, three pending U.S. patent applications, 36 issued foreign patents and two pending foreign patent applications relating to various aspects of Sumavel DosePro and our DosePro technology. Eleven of our U.S. patents relating to our DosePro technology, U.S. Patent Nos. 5,891,086, 5,957,886, 6,135,979, 7,776,007, 7,901,385, 8,267,903, 8,118,771, 8,241,243, 8,241,244, 8,287,489 and 8,343,130 are expected to expire in 2014, 2016, 2017, 2026, 2026, 2023, 2023, 2025, 2022, 2024, and 2022, respectively. U.S. Patent No. 5,891,086 covers a particular actuator mechanism forming a part of the needleless injector device; U.S. Patent No. 5,957,886 claims a needleless injector system using a viscous damping medium; U.S. Patent No. 6,135,979 covers the needleless injector with particular safety mechanisms; U.S. Patent Nos. 7,776,007 and 8,287,489 cover devices with a cap and latch mechanism; U.S. Patent Nos. 7,901,385 and 8,267,903 encompass various embodiments of the casing for enclosing the injection devices; U.S. Patent Nos. 8,118,771, 8,241,243 and 8,241,244 cover a method of reducing breakage of glass capsules; and 8,343,130 covers a method of reducing the propensity to create a shock wave on firing the device as used in the Sumavel DosePro device. Upon the expiration of these patents, we will lose the right to exclude others from practicing these inventions. Additionally, since these ten patents are the only patents currently listed in the FDA Orange Book for Sumavel DosePro, their expiration will mean that we lose certain advantages that come with Orange Book listing of patents. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects. Moreover, if Alkermes or Durect decides not to commence or continue any action relating to the defense of the patents they have licensed to us, they are required to notify us and we have the right to initiate proceedings after receiving their notice. Such proceedings will require the assistance of Alkermes or Durect, as applicable, and we have limited control over the amount or timing of resources Alkermes or Durect devotes on our behalf or the priority they place on enforcing these patent rights.

Risks Relating to the Securities Markets and an Investment in Our Stock

The market price of our common stock has fluctuated and is likely to continue to fluctuate substantially.

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has recently experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Since the commencement of trading in connection with our initial public offering in November 2010, the publicly traded shares of our common stock have themselves experienced significant price and volume fluctuations. During the quarter ended June 30, 2013, the price per share for our common stock on the Nasdaq Global Market has ranged from a low sale price of $1.25 to a high sale price of $1.84. This market volatility is likely to continue. These and

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other factors could reduce the market price of our common stock, regardless of our operating performance. In addition, the trading price of our common stock could change significantly, both over short periods of time and the longer term, due to many factors, including those described elsewhere in this “Risk Factors” section and the following:

- announcements concerning our and Mallinckrodt's commercial progress in promoting and selling Sumavel DosePro, including sales and revenue trends;
- announcements concerning our NDA for Zohydro ER;
- FDA or international regulatory actions, including results and announcements from FDA advisory committee meetings convened with respect to hydrocodone and whether and when we receive regulatory approval for Zohydro ER or any of our other product candidates;
- the development status of Relday or any of our other product candidates, including the results from our clinical trials;
- other regulatory developments, including the FDA's potential grant of regulatory exclusivity to a competitor who receives FDA approval before us for an extended-release hydrocodone product, which could significantly delay our ability to receive approval for Zohydro ER;
- announcements of the introduction of new products by us or our competitors;
- announcements concerning product development results or intellectual property rights of others;
- announcements relating to litigation, intellectual property or our business, and the public's response to press releases or other public announcements by us or third parties;
- variations in the level of expenses related to Zohydro ER, Relday or any of our other product candidates or clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- market conditions or trends in the pharmaceutical sector or the economy as a whole;
- changes in operating performance and stock market valuations of other pharmaceutical companies and price and volume fluctuations in the overall stock market;
- litigation or public concern about the safety of Sumavel DosePro or our product candidates;
- actual and anticipated fluctuations in our quarterly operating results;
- the financial projections we may provide to the public, any changes in these projections or our inability to meet these projections;
- deviations from securities analysts' estimates or the impact of other analyst comments;
- ratings downgrades by any securities analysts who follow our common stock;
- additions or departures of key personnel;
- third-party payor coverage and reimbursement policies;
- developments concerning current or future strategic collaborations, and the timing of payments we may make or receive under these arrangements;
- developments affecting our contract manufacturers, component fabricators and service providers;
- the development and sustainability of an active trading market for our common stock;
- future sales of our common stock by our officers, directors and significant stockholders;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters, security breaches, system failures or responses to these events;
- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

In addition, the stock markets, and in particular the Nasdaq Global Market, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. The realization of any of the above risks or any of a broad range of other risks, including those described in these “Risk Factors” could have a dramatic and material adverse impact on the market price of our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. As of June 30, 2013, we had research coverage by only four securities analysts. If these securities analysts cease coverage of our company, the trading price for our stock would be negatively impacted. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

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Our executive officers and directors and their affiliates will exercise significant control over stockholder voting matters in a manner that may not be in the best interests of all of our stockholders.

Our executive officers and directors and their affiliates together control, as of June 30, 2013, approximately 17% of our outstanding common stock, assuming no exercise of outstanding options or warrants. Two of our non-employee directors are, or are representatives designated by, significant stockholders and two of our directors are executive officers. As a result, these stockholders will collectively be able to significantly influence and may be able to control all matters requiring approval of our stockholders, including the election of directors and approval of significant corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets. The concentration of ownership may delay, prevent or deter a change in control of our company even when such a change may be in the best interests of some stockholders, impede a merger, consolidation, takeover or other business combination involving us, or could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might adversely affect the prevailing market price of our common stock.

In addition, sales of shares beneficially owned by executive officers and directors and their affiliates could be viewed negatively by third parties and have a negative impact on our stock price. Moreover, we cannot assure you as to how these shares will may be distributed and subsequently voted.

Future sales of our common stock or securities convertible or exchangeable for our common stock may depress our stock price.

Persons who were our stockholders prior to the sale of shares in our initial public offering in November 2010 continue to hold a substantial number of shares of our common stock that they are able to sell in the public market, subject in some cases to certain legal restrictions. Significant portions of these shares are held by a small number of stockholders. If these stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. The perception in the market that these sales may occur could also cause the trading price of our common stock to decline. As of June 30, 2013, we had 101,013,904 shares of common stock outstanding. Of these shares, approximately 62,749,900 are freely tradeable, without restriction, in the public market.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act, and, in any event, we have filed a registration statement permitting shares of common stock issued on exercise of options to be freely sold in the public market. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

We have registered under the Securities Act 15,784,200 shares of our common stock issuable upon the exercise of the warrants we issued in July 2012, which warrants became exercisable on July 27, 2013 at an exercise price of $2.50 per share (subject to restrictions on exercise set forth in such warrants), which means that upon exercise of warrants, such shares will be freely tradeable without restriction under the Securities Act, except for shares held by our affiliates. Further, certain holders of shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act, which, if registered, would also become freely tradeable without restriction under the Securities Act, except for shares held by our affiliates. In addition, our directors and executive officers may establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for the purpose of effecting sales of our common stock. Any sales of securities by these stockholders, warrantholders or executive officers and directors, or the perception that those sales may occur, could have a material adverse effect on the trading price of our common stock.

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Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

Not applicable.

Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On August 5, 2013, we agreed with Desitin Arzneimittel GmbH, or Desitin, on termination of the licensing and distribution agreement dated March 14, 2008 between us, or the termination agreement, such termination to be effective October 1, 2013. Under the licensing and distribution agreement, we had licensed to Desitin the exclusive development and commercialization rights to Sumavel DosePro for the European Union, Norway, Switzerland and Turkey. Following the termination of the licensing and distribution agreement, we will assume the rights to exclusive development and commercialization of Sumavel DosePro for the European Union, Norway, Switzerland and Turkey. A complete copy of the termination agreement is filed as Exhibit 10.3 to this Quarterly Report on Form 10-Q and incorporated herein by reference. The foregoing description of the terms of the termination agreement is qualified in its entirety by reference to such exhibit.

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Item 6. Exhibits
EXHIBIT INDEX

Exhibit Number	Description
3.1(2)	Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.2	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.3(2)	Amended and Restated Bylaws of the Registrant
4.1(3)	Form of the Registrant's Common Stock Certificate
4.2(1)	Third Amended and Restated Investors' Rights Agreement dated December 2, 2009
4.3(1)	Amendment to Third Amended and Restated Investors' Rights Agreement dated as of July 1, 2010
4.4(4)	Second Amendment to Third Amended and Restated Investors' Rights Agreement dated June 30, 2011
4.5(1)	Warrant dated March 5, 2007 issued by the Registrant to General Electric Capital Corporation
4.6(1)	Warrant dated June 30, 2008 issued by the Registrant to Oxford Finance Corporation
4.7(1)	Warrant dated June 30, 2008 issued by the Registrant to CIT Healthcare LLC (subsequently transferred to The CIT Group/Equity Investments, Inc.)
4.8(1)	Transfer of Warrant dated March 24, 2009 from CIT Healthcare LLC to The CIT Group/Equity Investments, Inc.
4.9(1)	Warrant dated July 1, 2010 issued by the Registrant to Oxford Finance Corporation
4.10(1)	Warrant dated July 1, 2010 issued by the Registrant to Silicon Valley Bank
4.11(4)	Warrant dated June 30, 2011 issued by the Registrant to Oxford Finance LLC
4.12(4)	Warrant dated June 30, 2011 issued by the Registrant to Silicon Valley Bank
4.13(4)	Warrant dated July 18, 2011 issued by the Registrant to Healthcare Royalty Partners (formerly Cowen Healthcare Royalty Partners II, L.P.)
10.1	Form of Restricted Stock Unit Award Agreement under the 2012 Equity Incentive Award Plan
10.2†	Co-promotion Agreement dated June 27, 2013, by and between the Registrant and Valeant Pharmaceuticals North America LLC

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10.3	Agreement to Termination of Agreements dated August 5, 2013, by and between the Registrant and Desitin Arzneimittel GmbH
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
101	The following financial statements from the Registrant's Quarterly Report on form 10-Q for the period ended June 30, 2013, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Comprehensive Loss, (iii) Consolidated Statements of Cash Flows, and (iv) the Notes to Consolidated Financial Statements.

(1) Filed with the Registrant's Registration Statement on Form S-1 on September 3, 2010.

(2) Filed with Amendment No. 2 to Registrant's Registration Statement on Form S-1 on October 27, 2010.

(3) Filed with Amendment No. 3 to the Registrant's Registration Statement on Form S-1 on November 4, 2010.

(4) Filed with the Registrant's Quarterly Report on Form 10-Q on August 11, 2011.

† Confidential treatment has been requested for portions of this exhibit. These portions have been omitted and filed separately with the Securities and Exchange Commission

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not subject to the liability of that section. These certifications are not to be incorporated by reference into any filing of Zogenix, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ZOGENIX, INC.

Date: August 8, 2013

By: /s/ Roger L. Hawley
Chief Executive Officer
(Principal Executive Officer)

Date: August 8, 2013

By: /s/ Ann D. Rhoads
Executive Vice President, Chief Financial Officer,
Treasurer and Secretary
(Principal Financial and Accounting Officer)