ZOGENIX, INC.
Form 10-Q
May 08, 2014
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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 March 31, 2014

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	92130
(Address of Principal Executive Offices)	(Zip Code)
858-259-1165 (Registrant's Telephone Number, Including Area Code)	

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. 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 May 2, 2014 was 139,539,151.

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PART I – FINANCIAL INFORMATION
Item 1. Financial Statements
Zogenix, Inc.
Consolidated Balance Sheets
(In Thousands)

	March 31, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$50,684	$72,021
Trade accounts receivable, net	11,680	6,665
Inventory	14,854	9,936
Prepaid expenses and other current assets	3,767	4,257
Total current assets	80,985	92,879
Property and equipment, net	12,310	13,011
Other assets	6,685	6,614
Total assets	$99,980	$112,504
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$10,569	$4,622
Accrued expenses	18,726	18,865
Accrued compensation	3,789	3,952
Common stock warrant liabilities	22,156	31,341
Long-term debt, current portion	9,579	—
Deferred revenue	5,963	—
Total current liabilities	70,782	58,780
Long-term debt, less current portion	19,313	28,802
Other long-term liabilities	7,466	6,496
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value; 200,000 shares authorized at March 31, 2014 and 2013; 139,539 and 100,809 shares issued and outstanding at March 31, 2014 and 2013, respectively.	140	139
Additional paid-in capital	433,458	428,534
Accumulated deficit	(431,179)	(410,247)
Total stockholders' equity	2,419	18,426
Total liabilities and stockholders' equity	$99,980	$112,504

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 March 31,	
	2014	2013
Revenue:		
Net product revenue	$6,770	$6,893
Service and other revenue	904	88
Total revenue	7,674	6,981
Operating expenses:		
Cost of sales	3,382	4,158
Royalty expense	363	282
Research and development	3,538	3,236
Selling, general and administrative	27,651	14,482
Total operating expenses	34,934	22,158
Loss from operations	(27,260)	(15,177)
Other income (expense):		
Interest income	6	8
Interest expense	(1,886)	(1,613)
Change in fair value of warrant liabilities	8,269	(4,258)
Change in fair value of embedded derivatives	(14)	(81)
Other income (expense)	(47)	66
Total other income (expense)	6,328	(5,878)
Net loss before income taxes	(20,932)	(21,055)
Provision for income taxes	—	—
Net loss	$(20,932)	$(21,055)
Common share data:		
Net loss per share, basic	$(0.15)	$(0.21)
Net loss per share, diluted	$(0.20)	$(0.21)
Weighted average shares outstanding, basic	139,309	100,809
Weighted average shares outstanding, diluted	145,323	100,809
Comprehensive loss	$(20,932)	$(21,055)

See accompanying notes.

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Zogenix, Inc.
Consolidated Statements of Cash Flows
(In Thousands)
(Unaudited)

	Three Months Ended March 31,	
	2014	2013
Operating activities:		
Net loss	$(20,932)	$(21,055)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,507	1,586
Depreciation and amortization	406	479
Amortization of debt issuance costs and non-cash interest	161	133
Change in fair value of warrant liabilities	(8,269)	4,258
Change in fair value of embedded derivatives	14	81
Changes in operating assets and liabilities:		
Trade accounts receivable	(5,015)	(112)
Inventory	(4,918)	223
Prepaid expenses and other current assets	882	(1,027)
Other assets	(534)	421
Accounts payable and accrued expenses	6,911	(61)
Deferred revenue	5,963	—
Net cash used in operating activities	(22,824)	(15,074)
Investing activities:		
Purchases of property and equipment	(15)	(830)
Net cash provided used in investing activities	(15)	(830)
Financing activities:		
Proceeds from exercise of common stock options and warrants	1,502	—
Net cash provided by financing activities	1,502	—
Net decrease in cash and cash equivalents	(21,337)	(15,904)
Cash and cash equivalents at beginning of period	72,021	41,228
Cash and cash equivalents at end of period	$50,684	$25,324
Noncash investing and financing activities:		
Change in purchases of property and equipment in accounts payable	$(310)	$—

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 committed to developing and commercializing therapies that address specific clinical needs for people living with pain-related conditions and central nervous system disorders who need innovative treatment alternatives to help them return to normal daily functioning. On October 25, 2013, the Company received marketing approval from the U.S. Food and Drug Administration (FDA) for Zohydro™ ER (hydrocodone bitartrate) extended-release capsules, the first extended-release oral formulation of hydrocodone without acetaminophen. Zohydro ER is an opioid agonist for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The Company launched Zohydro ER in March 2014.

The Company's 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 FDA that allows for the needle-free, subcutaneous delivery of medication.

The Company was incorporated in the state of Delaware on May 11, 2006 as SJ2 Therapeutics, 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 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.

On April 23, 2014, the Company entered into an asset purchase agreement (Asset Purchase Agreement) with Endo Ventures Bermuda Limited (Endo Ventures Bermuda) and Endo Ventures Limited (Endo Ventures and, together with Endo Ventures Bermuda, the Buyers), pursuant to which, and on the terms and subject to the conditions thereof, among other things, the Company agreed to sell its Sumavel DosePro product line to the Buyers, including the registered trademarks, certain contracts, the New Drug Application (NDA) and other regulatory approvals, the books and records, marketing materials and product data relating to Sumavel DosePro. Under the terms of the Asset Purchase Agreement, the Buyers will pay the Company $85,000,000 in cash upon closing (Closing) of the transaction, $8,500,000 of which will be deposited into escrow to fund potential indemnification claims for a period of 12 months. In addition to the upfront cash payment, the Company is eligible to receive additional cash payments of up to $20,000,000 based on the achievement of pre-determined sales and manufacturing milestones. Furthermore, Endo Ventures will assume responsibility for the Company's royalty obligation to Aradigm Corporation on sales of Sumavel DosePro and assume other liabilities relating to Sumavel DosePro after the Closing. The Company expects the Closing to occur during the second quarter of 2014, subject to the satisfaction of the closing conditions (see Note 7), but there can be no assurance that the Closing will occur on that time frame, or at all.

Management expects operating losses and negative cash flows to continue for at least the next year as the Company continues to incur costs related to the continued development of its product candidates, including an abuse deterrent formulation of Zohydro ER, and commercialization of its approved products. In addition to the Asset Purchase Agreement, management may pursue additional opportunities to raise further capital, if required, through public or private equity offerings, including through 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 Closing under the Asset Purchase Agreement will occur or 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.

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2. Summary of Significant Accounting Policies

Financial Statement Preparation and Use of Estimates

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

In the opinion of management, the accompanying unaudited consolidated financial statements for the periods presented reflect all adjustments, which are normal and recurring, necessary to fairly state the financial position, results of operations and cash flows. These unaudited consolidated financial statements should be read in conjunction with the audited financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013 filed with the SEC on March 7, 2014.

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.

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, accrued compensation and current portion of long-term debt 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 accrued liability for the annual tail payment 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.

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The Company classifies its cash equivalents within Level 1 of the fair value hierarchy because it values its 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 March 31, 2014 and December 31, 2013 are as follows (in thousands):

	Fair Value Measurements at Reporting Date Using			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
At March 31, 2014				
Assets				
Cash equivalents[1]	$46,725	—	—	$46,725
Liabilities				
Common stock warrant liabilities[2]	$—	—	22,156	$22,156
Embedded derivative liabilities[3]	$—	—	247	$247
At December 31, 2013				
Assets				
Cash equivalents[1]	$69,120	—	—	$69,120
Liabilities				
Common stock warrant liabilities[2]	$—	—	31,341	$31,341
Embedded derivative liabilities[3]	$—	—	233	$233

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

(2) Common stock warrant liabilities include liabilities associated with warrants issued in connection with the Company's July 2012 public offering of common stock and warrants (see Note 5) and warrants issued in connection with the Healthcare Royalty financing agreement (see Note 4), which are measured at fair value using the Black-Scholes option pricing valuation model. The assumptions used in the Black-Scholes option pricing valuation model for both common stock warrant liabilities were: (a) a risk-free interest rate based on the rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the remaining contractual term of the warrants; (b) an assumed dividend yield of zero based on the Company’s expectation that it will not pay dividends in the foreseeable future; (c) an expected term based on the remaining contractual term of the warrants; and (d) given the Company’s lack of relevant historical data due to the Company’s limited historical experience, an expected volatility based upon the Company's historical volatility, supplemented with historical volatility of comparable companies whose share prices have been publicly available for a sufficient period of time. The significant unobservable input used in measuring the fair value of the common stock warrant liabilities associated with the Healthcare Royalty financing agreement is the expected volatility. Significant increases in 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 and the timing of such event; and for the valuation scenario in which an extraordinary event occurs that is not an all cash transaction or an event whereby a public acquirer would assume the warrants, (b) an expected volatility rate using

the Company's historical volatility, supplemented with historical volatility of comparable companies, through the projected date of public announcement of an extraordinary transaction, blended with a 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 inputs used in measuring the fair value of the common stock warrant liabilities associated with the July 2012 public offering are the expected volatility and the 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. The decrease in the fair value of the common stock warrant liabilities as of March 31, 2014 was primarily driven by the decrease in the Company's stock price at March 31, 2014 as compared against December 31, 2013 measurement dates.

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(3) Embedded derivatives are 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 interest payments over the term of the Healthcare Royalty 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 of the liability.

The following table provides a reconciliation of liabilities measured at fair value using significant observable inputs (Level 3) for the three months ended March 31, 2014 (in thousands):

	Common Stock Warrant Liabilities	Embedded Derivative Liabilities
Balance at December 31, 2013	$31,341	$233
Changes in fair value	(8,269)	14
Exercises	$(916)	$—
Balance at March 31, 2014	$22,156	$247

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, restricted stock units 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.

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

	Three Months Ended March 31,	
	2014	2013
Numerator		
Net loss for basic EPS	$(20,932)	$(21,055)
Effect of dilutive securities:		
Common stock warrants	$(8,269)	$—
Non-employee stock options and restricted stock units	(132)	—
	$(8,401)	$—
Net loss for diluted EPS	$(29,333)	$(21,055)
Denominator		
Weighted average common shares outstanding, basic	139,309	100,809
Effect of dilutive securities:		
Common stock warrants	5,870	—
Non-employee stock options and restricted stock units	144	—
Dilutive potential shares of common stock	6,014	—
Weighted average common shares outstanding, diluted	145,323	100,809
Basic net loss per share	$(0.15)	$(0.21)
Diluted net loss per share	$(0.20)	$(0.21)

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

	Three Months Ended March 31,	
	2014	2013
Common stock options and restricted stock units	11,246	123
Common stock warrants	508	—
	11,754	123

Revenue Recognition

The Company recognizes revenue from the sale of Sumavel DosePro, Zohydro ER and from license fees, milestones and service fees earned on collaborative arrangements. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured. Revenue from sales transactions where the buyer has the right to return the product is recognized at the time of sale only if (a) the Company's price to the buyer is substantially fixed or determinable at the date of sale, (b) the buyer has paid the Company, or the buyer is obligated to pay the Company and the obligation is not contingent on resale of the product, (c) the buyer's obligation to the Company would not be changed in the event of theft or physical destruction or damage of the product, (d) the buyer acquiring the product for resale has economic substance apart from that provided by the Company, (e) the Company does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (f) the amount of future returns can be reasonably estimated. The Company currently defers recognition of revenue on product shipments of Zohydro ER until the right of return no longer exists, as the Company currently cannot reliably estimate expected returns of the product at the time of shipment given the limited sales history of Zohydro ER.

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Product Revenue, Net

The Company sells Sumavel DosePro and Zohydro ER in the United States to wholesale pharmaceutical distributors and retail pharmacies, or collectively the Company's customers, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. The Company recognizes Sumavel DosePro product sales at the time title transfers to its customer, and reduces product sales for estimated future product returns and sales allowances in the same period the related revenue is recognized.

Given the limited sales history of Zohydro ER, the Company cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company defers recognition of revenue on Zohydro ER product shipments until the right of return no longer exists, which occurs at the earlier of the time Zohydro ER is dispensed through patient prescriptions or expiration of the right of return. The Company estimates Zohydro ER patient prescriptions dispensed using an analysis of third-party syndicated data. Zohydro ER was launched in March 2014 and, accordingly, the Company does not have significant history estimating the number of patient prescriptions dispensed. If the Company underestimates or overestimates patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in future periods. The deferred revenue balance does not have a direct correlation with future revenue recognition as the Company will record sales deductions at the time the prescription unit is dispensed.

The Company will continue to recognize Zohydro ER revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until it can reliably estimate product returns, at which time the Company will record a one-time increase in revenue related to the recognition of revenue previously deferred, net of estimated future product returns and sales allowances. In addition, the costs of Zohydro ER associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time the related deferred revenue is recognized.

Product sales allowances for Sumavel DosePro and Zohydro ER include wholesaler and retail pharmacy distribution fees, prompt pay discounts, chargebacks, rebates and patient discount programs, and are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of the Company's agreements with its customers and third-party payors and the levels of inventory within the distribution and retail channels that may result in future rebates or discounts taken. In certain cases, such as patient support programs, the Company recognizes the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, the Company may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. The Company records product sales deductions in the statement of operations at the time product revenue is recognized.

Segment Reporting

Management has determined that the Company operates in one business segment, which is the development and commercialization of pharmaceutical products for people living with pain-related conditions and central nervous system disorders.

Recent Accounting Pronouncements

In April 2014, the Financial Accounting Standards Board issued an accounting update that raises the threshold for disposals to qualify as discontinued operations and allows companies to have significant continuing involvement with and continuing cash flows from or to the discontinued operations. This accounting update also requires additional disclosures for discontinued operations and new disclosures for individually material disposal transactions that do not meet the definition of a discontinued operation. This guidance will be effective for fiscal years beginning after December 15, 2014, with early adoption permitted. The Company does not expect that the adoption of the guidance will have a material impact on the Company's financial statements.

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3. Inventory (in thousands)

	March 31, 2014	December 31, 2013
Raw materials	$2,980	$2,770
Work in process	5,385	6,054
Finished goods	5,659	1,112
Deferred cost of sales	830	—
	$14,854	$9,936

Deferred cost of sales consists of the costs of Zohydro ER associated with the deferred revenue, which are included in inventory, until such time the related deferred revenue is recognized.

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 committed to a minimum number of sales representatives for the initial term of the agreement, which originally ran through June 30, 2014.

In partial consideration of Mallinckrodt's sales efforts, the Company paid Mallinckrodt a service fee on a quarterly basis through January 31, 2014 that represented 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. For the three months ended March 31, 2014 and 2013, the Company incurred $100,000 and $143,000, respectively, in service fee expenses under the Co-Promotion Agreement, excluding the tail-payment expense discussed below.

In January 2014, the Company entered into an amendment to the Co-Promotion Agreement, whereby the Co-Promotion Agreement terminated on January 31, 2014. The Company assumed full responsibility for the commercialization of Sumavel DosePro in February 2014. In connection with the termination of the Co-Promotion Agreement, the Company is required to make a one-time tail payment to Mallinckrodt, calculated as a fixed percentage of net sales from the Mallinckrodt targeted prescriber audience during the 12 month period ending on January 31, 2015. A liability of $559,000 for this estimated tail-payment was recorded as service fee expense in selling, general and administrative expenses in the statement of operations during the three months ended March 31, 2014.

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. The Company's sales team began promoting Migranal to prescribers in August 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 supplies 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. The cost of any additional samples and any promotional materials ordered by the Company will be recognized as selling, general and administrative expenses.

In partial consideration of the Company's sales efforts, Valeant pays 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 the inability of 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.

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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. 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.

The Company recognizes co-promotion fees received under the Valeant Agreement as service revenue in the period in which its promotional activities generate net sales over the Baseline Forecast or Adjusted Baseline Forecast. For the three months ended March 31, 2014, the Company recognized service revenue of $866,000 under the Valeant Agreement.

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.

Following completion of the co-promotion term in March 2012, the Company was required to pay Astellas one tail payment in July 2013 and is required to pay Astellas another tail payment in July 2014, calculated as decreasing fixed percentages (ranging from mid-twenties down to a mid-teen percentage) of net sales in the Astellas Segment during the 12 months ended March 31, 2012. The fair value of the tail payments is being accreted through interest expense through the dates of payment in July 2013 and July 2014. The first tail payment of $2,032,000 was made in July 2013. As of March 31, 2014, the tail payment liability was $1,174,000. The Company recognized $43,000 and $141,000 of related interest expense during the three months ended March 31, 2014 and 2013, respectively.

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:

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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 with Oxford Finance LLC and Silicon Valley Bank. 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 $75,000,000, whichever is sooner. The Company has agreed to specified positive and negative non-financial 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 March 31, 2014 and December 31, 2013 was $247,000 and $233,000, 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 $122,000 and $(76,000) for the three months ended March 31, 2014 and 2013, respectively, in the statement of operations and comprehensive loss. The Company has recognized other expense in relation to the change in the fair value of the embedded derivatives of $14,000 and $81,000 for the three months ended March 31, 2014 and 2013, respectively, in the statement of operations and

comprehensive loss.

5. 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 are exercisable at an exercise price of $2.50 per share and will expire on July 27, 2017, which is five 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

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recorded as a current liability and are marked to market at each reporting period (see Note 2). During the three months ended March 31, 2014 and the year ended December 31, 2013, warrants to purchase 465,250 and 103,500 shares of common stock, respectively, were exercised. The fair value of the warrants outstanding was approximately $21,785,000 and $30,849,000 as of March 31, 2014 and December 31, 2013, 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 ten 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 $371,000 and $492,000 as of March 31, 2014 and December 31, 2013, respectively.

6. 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 months ended March 31, 2014 and 2013 are as follows:

	Three Months Ended March 31,	
	2014	2013
Risk free interest rate	2.0%	0.8% to 1.1%
Expected term	6.0 to 6.1 years	5.0 to 6.1 years
Expected volatility	84.9%	86.8% to 87.9%
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 March 31,	
	2014	2013
Cost of sales	$127	$45
Research and development	357	216
Selling, general and administrative	2,023	1,325
Total	$2,507	$1,586

As of March 31, 2014, there was approximately $20,285,000 of total unrecognized compensation costs related to outstanding employee and board of director stock options and restricted stock units, which is expected to be recognized over a weighted average period of 2.9 years.

As of March 31, 2014, there were 164,000 unvested stock options and 25,000 restricted stock units outstanding to consultants, with approximately $404,000 of related unrecognized compensation expense based on a March 31, 2014 measurement date. These unvested stock options outstanding to consultants are expected to vest over a weighted average period of 2.5 years, and the restricted stock units outstanding to consultants are expected to vest over approximately 0.2 years. In accordance with accounting guidance for stock-based compensation, the Company re-measures the fair value of stock option grants to non-employees at each reporting date and recognizes the related income or expense during their vesting period. The gain recognized from the valuation of stock options and restricted stock units to consultants was $174,000 for the three months ended March 31, 2014 and was immaterial for the three

months ended March 31, 2013. Stock option expense for awards issued to consultants is included in the consolidated statement of operations and comprehensive loss within selling, general and administrative expense.

7. Subsequent Event

On April 23, 2014, the Company entered into the Asset Purchase Agreement with the Buyers, pursuant to which, and on the terms and subject to the conditions thereof, among other things, the Company agreed to sell its Sumavel DosePro product line to the Buyers, including the registered trademarks, certain contracts, the New Drug Application and other regulatory approvals, the books and records, marketing materials and product data relating to Sumavel DosePro.

Under the terms of the Asset Purchase Agreement, the Buyers will pay the Company $85,000,000 in cash upon Closing of the transaction, $8,500,000 of which will be deposited into escrow to fund potential indemnification claims for a period of 12 months. In addition to the upfront cash payment, the Company is eligible to receive additional cash payments of up to $20,000,000 based on the achievement of pre-determined sales and manufacturing milestones. Furthermore, Endo Ventures will assume responsibility for the Company's royalty obligation to Aradigm on sales of Sumavel DosePro and assume other liabilities relating to Sumavel DosePro after the Closing.

The Asset Purchase Agreement contains customary representations, warranties and covenants, including covenants obligating the Company to continue to conduct the Sumavel DosePro business in the ordinary course and to cooperate in seeking regulatory approvals. Upon the Closing, the Company and Endo Ventures Bermuda will enter into a license agreement, pursuant to which the Company will grant Endo Ventures an exclusive, worldwide, royalty-free license to make and have made (subject to the limitations in the license agreement), use and research, develop and commercialize Sumavel DosePro. Also upon the Closing, Endo Ventures will purchase from the Company the finished goods inventory of Sumavel DosePro. The Company and Endo Ventures also will enter into a supply agreement, pursuant to which the Company will continue to manufacture Sumavel DosePro, and Endo Ventures will support Company' s Sumavel DosePro manufacturing operations with a working capital advance of $7,000,000.

The obligation of the Buyers to purchase the Sumavel DosePro product line is subject to the satisfaction or waiver of a number of conditions set forth in the Asset Purchase Agreement, including (i) the accuracy of the representations and warranties and compliance with covenants contained in the Asset Purchase Agreement, (ii) the absence of any permanent injunction, law, regulation, decree or order by any government, court or governmental entity that would make illegal or otherwise prohibit the consummation of the transactions under the Asset Purchase Agreement, (iii) the absence of any actions or proceedings questioning the validity or legality of the transactions under the Asset Purchase Agreement, (iv) the expiration or termination of applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the receipt of any required third party consents, (v) there not having been a material adverse effect with respect to the Company's Sumavel DosePro business, (vi) the delivery to the Buyers of a license agreement, supply agreement, escrow agreement and other transaction documents, and (vii) other customary conditions. The Company expects the Closing to occur during the second quarter of 2014, subject to the satisfaction of the foregoing closing conditions.

In connection with the Closing, the Company is required to extinguish all encumbrances on the assets to be sold to the Buyers, including those previously granted to Healthcare Royalty pursuant to the Financing Agreement. The Company expects to eliminate its existing debt obligation to Healthcare Royalty by paying approximately $40,000,000 to Healthcare Royalty, consistent with the terms of the Financing Agreement.

Either party may terminate the Asset Purchase Agreement if the Closing has not occurred by September 8, 2014, provided that if the party seeking to terminate the Asset Purchase Agreement is then in material breach of its obligations the outside date will be extended until ten business days following the date upon which such breach is cured.

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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:

- the timing and likelihood of closing the pending sale of the Sumavel DosePro product line to affiliates of Endo Health Solutions Inc. and the estimated amounts of payments and the extinguishment of debt obligations in connection therewith;
- 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 and Zohydro ER, including the planned launch of a 4 mg dose of Sumavel DosePro;
- the progress and timing of clinical trials for Relday and our other product candidates;
- adverse side effects or inadequate therapeutic efficacy of Sumavel DosePro or Zohydro ER that could result in product recalls, market withdrawals or product liability claims;
- the safety and efficacy of our product candidates;
- the market potential for migraine treatments, and our ability to compete within that market;
- the market potential for extended-release/long-acting (ER/LA) opioid products, 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;
- the ability to develop an abuse deterrent formulation of Zohydro ER;
- estimates of the capacity of manufacturing and other facilities to support our products and product candidates;
- our ability to ensure adequate and continued supply of Sumavel DosePro and Zohydro ER 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, Zohydro ER or any of our 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®, 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.

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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, its consolidated subsidiary.

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, 2013 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, 2013.

Overview

Background

We are a pharmaceutical company committed to developing and commercializing therapies that address specific clinical needs for people living with pain-related conditions and central nervous system disorders who need innovative treatment alternatives to help them return to normal daily functioning. On October 25, 2013, we received marketing approval from the U.S. Food and Drug Administrations, or FDA, for Zohydro™ ER (hydrocodone bitartrate) extended-release capsules, an opioid agonist, extended-release oral formulation of hydrocodone without acetaminophen, for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Zohydro ER is the first extended-release oral formulation of hydrocodone without acetaminophen. We launched Zohydro ER in March 2014.

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 FDA that allows for the needle-free, subcutaneous delivery of medication.

Sumavel DosePro and Zohydro ER 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. 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 subcutaneous antipsychotic product that allows for once-monthly dosing. In May 2012, we filed an investigational new drug, or IND, application with the FDA. In July 2012, we initiated our first 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 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 at a 100 mg dose of the same formulation. We 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 we believe will provide the required steady-state pharmacokinetic and safety data prior to initiating Phase 3 development studies. We plan to commence this multi-dose clinical trial in the second half of 2014.

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 March 31, 2014, had an accumulated deficit of $431.2 million. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next year primarily as a result of our efforts to commercialize Zohydro ER, the clinical development for Relday, required post-market testing for Zohydro ER, additional development activities with respect to Zohydro ER, including the development of an abuse deterrent formulation of Zohydro ER, and the cost

of the sales and marketing expenses associated with Sumavel DosePro and Zohydro ER. As of March 31, 2014, we had cash and cash equivalents of $50.7 million.

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Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of March 31, 2014, and our projected product revenues from Zohydro ER and Sumavel DosePro, will be sufficient to fund our operations through 2014. In addition to the Asset Purchase Agreement, we may pursue additional opportunities to raise capital, if necessary, through public or private equity offerings, 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, 2013, our independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern.

Recent Developments

On April 23, 2014, we entered into an asset purchase agreement, or the asset purchase agreement, with Endo Ventures Bermuda Limited, or Endo Ventures Bermuda, and Endo Ventures Limited, or Endo Ventures, and, together with Endo Ventures Bermuda, the Buyers, pursuant to which, and on the terms and subject to the conditions thereof, among other things, we have agreed to sell our Sumavel DosePro product line to the Buyers, including the registered trademarks, certain contracts, the New Drug Application, or NDA, and other regulatory approvals, the books and records, marketing materials and product data relating to Sumavel DosePro. Under the terms of the asset purchase agreement, the Buyers will pay us $85.0 million in cash upon closing, or the Closing, of the transaction, $8.5 million of which will be deposited into escrow to fund potential indemnification claims for a period of 12 months. In addition to the upfront cash payment, we are eligible to receive additional cash payments of up to $20.0 million based on the achievement of pre-determined sales and manufacturing milestones. Furthermore, Endo Ventures will assume responsibility for our royalty obligation to Aradigm Corporation on sales of Sumavel DosePro and assume other liabilities relating to Sumavel DosePro after the Closing.

The asset purchase agreement contains customary representations, warranties and covenants, including covenants obligating us to continue to conduct the Sumavel DosePro business in the ordinary course and to cooperate in seeking regulatory approvals. Upon the Closing, we and Endo Ventures Bermuda will enter into a license agreement, pursuant to which we will grant Endo Ventures an exclusive, worldwide, royalty-free license to make and have made (subject to the limitations in the license agreement), use and research, develop and commercialize Sumavel DosePro. Also upon the Closing, Endo Ventures will purchase from us the finished goods inventory of Sumavel DosePro. We will also enter into a supply agreement with Endo Ventures, pursuant to which we will continue to manufacture Sumavel DosePro, and Endo Ventures will support our Sumavel DosePro manufacturing operations with a working capital advance of $7.0 million.

The obligation of the Buyers to purchase the Sumavel DosePro product line is subject to the satisfaction or waiver of a number of conditions set forth in the asset purchase agreement, including (i) the accuracy of the representations and warranties and compliance with covenants contained in the asset purchase agreement, (ii) the absence of any permanent injunction, law, regulation, decree or order by any government, court or governmental entity that would make illegal or otherwise prohibit the consummation of the transactions under the asset purchase agreement, (iii) the absence of any actions or proceedings questioning the validity or legality of the transactions under the asset purchase agreement, (iv) the expiration or termination of applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the receipt of any required third party consents, (v) there not having been a material adverse effect with respect to our Sumavel DosePro business, (vi) the delivery to the Buyers of a license agreement, supply agreement, escrow agreement and other transaction documents, and (vii) other customary conditions. We expect the Closing to occur during the second quarter of 2014, subject to the satisfaction of the foregoing closing conditions, but there can be no assurance that the Closing will occur.

In connection with the Closing, we are required to extinguish all encumbrances on the assets to be sold to the Buyers, including those previously granted to Healthcare Royalty Partners, or Healthcare Royalty, pursuant to the Financing Agreement, dated June 30, 2011, with Healthcare Royalty, or the Healthcare Royalty financing agreement. We expect

to eliminate our existing debt obligation to Healthcare Royalty by paying approximately $40.0 million to Healthcare Royalty, consistent with the terms of the Healthcare Royalty financing agreement.

Either party may terminate the asset purchase agreement if the Closing has not occurred by September 8, 2014, provided that if the party seeking to terminate the Asset Purchase Agreement is then in material breach of its obligations the outside date will be extended until ten business days following the date upon which such breach is cured.

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Mallinckrodt LLC Co-Promotion Agreement

In June 2012, we entered into a co-promotion agreement with Mallinckrodt LLC. Under the terms of the co-promotion agreement, Mallinckrodt was granted a co-exclusive right (with us) to promote Sumavel DosePro in the United States. Mallinckrodt's sales team began selling Sumavel DosePro in August 2012. The initial term of the agreement was to run through June 30, 2014. In January 2014, we entered into an amendment to the co-promotion agreement, whereby the agreement terminated on January 31, 2014. We assumed full responsibility for the commercialization of Sumavel DosePro in February 2014.

In partial consideration of Mallinckrodt's sales efforts, we paid Mallinckrodt a service fee on a quarterly basis through January 31, 2014 that represented a specified fixed percentage of net sales of prescriptions generated from Mallinckrodt's prescriber audience over a baseline amount of net sales. In addition, in connection with the termination of the co-promotion agreement, we are required to make a one-time tail payment to Mallinckrodt, calculated as a fixed percentage of net sales from the Mallinckrodt targeted prescriber audience during the 12-month period ending on January 31, 2015. A liability of $0.6 million for this estimated tail-payment was recorded as service fee expense during the first quarter of 2014. For the three months ended March 31, 2014 and 2013, we incurred service fee expenses of $0.1 million and $0.1 million, respectively, excluding the tail-payment expense.

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. Our sales team began promoting Migranal to prescribers in August 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 supplies 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. The cost of any additional samples and any promotional materials ordered by us will be recognized as selling, general and administrative expenses.

In partial consideration of our sales efforts, Valeant pays 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, or the Baseline Forecast and 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 our inability to comply with our material obligations under the Valeant agreement, Valeant will be required to pay us an additional tail payment calculated as a fixed percentage of our net sales over the Baseline Forecast (or Adjusted Baseline Forecast) during the first full six months following the last day of the term. For the three months ended March 31, 2014, we recognized service revenue of $0.9 million under the Valeant agreement.

Critical Accounting Policies and Estimates

Revenue Recognition

We recognize revenue from the sale of Sumavel DosePro, Zohydro ER and from license fees, milestones and service fees earned on collaborative arrangements. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured. Revenue from sales transactions where the buyer has the right to return the product is recognized at the time of sale only if (i) our price to the buyer is substantially fixed or determinable at the date of sale, (ii) the buyer has paid us, or the buyer is obligated to pay us and the obligation is not contingent on resale of the product, (iii) the buyer’s obligation to us would not be changed in the event of theft or physical destruction or damage of the product, (iv) the buyer acquiring the product for resale has economic substance apart from that provided by us, (v) we do not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (vi) the amount of future returns can be reasonably estimated. We currently defer recognition of revenue on product shipments of Zohydro ER until the right of return no longer exists, as we currently cannot reliably estimate

expected returns of the product at the time of shipment given the limited sales history of Zohydro ER.

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Product Revenue, Net

We sell Sumavel DosePro and Zohydro ER in the United States to wholesale pharmaceutical distributors and retail pharmacies, or collectively our customers, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. We recognize Sumavel DosePro product sales at the time title transfers to our customer, and reduce product sales for estimated future product returns and sales allowances in the same period the related revenue is recognized.

Given the limited sales history of Zohydro ER, we cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, we defer recognition of revenue on Zohydro ER product shipments until the right of return no longer exists, which occurs at the earlier of the time Zohydro ER is dispensed through patient prescriptions or expiration of the right of return. We estimate Zohydro ER patient prescriptions dispensed using an analysis of third-party syndicated data. Zohydro ER was launched in March 2014 and, accordingly, we do not have significant history estimating the number of patient prescriptions dispensed. If we underestimate or overestimate patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in future periods. The deferred revenue balance does not have a direct correlation with future revenue recognition as the Company will record sales deductions at the time the prescription unit is dispensed.

We will continue to recognize Zohydro ER revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until we can reliably estimate product returns, at which time we will record a one-time increase in revenue related to the recognition of revenue previously deferred, net of estimated future product returns and sales allowances. In addition, the costs of Zohydro ER associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time the related deferred revenue is recognized.

Product sales allowances for Sumavel DosePro and Zohydro ER include wholesaler and retail pharmacy distribution fees, prompt pay discounts, chargebacks, rebates and patient discount programs, and are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with our customers and third-party payors and the levels of inventory within the distribution and retail channels that may result in future rebates or discounts taken. In certain cases, such as patient support programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. We record product sales deductions in the statement of operations at the time product revenue is recognized.

There have been no other significant changes in critical accounting policies during the three months ended March 31, 2014, 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, 2013.

Results of Operations

Comparison of the three months ended March 31, 2014 and 2013

Revenue. Revenue for the three months ended March 31, 2014 and 2013 was $7.7 million and $7.0 million, respectively. Net product revenue for the three months ended March 31, 2014 and 2013 was $6.8 million and $6.9 million, respectively. The aggregate $0.1 million, or 2%, decrease in net product revenue during the three months ended March 31, 2014 compared to 2013 was primarily due to a 20% decrease in Sumavel DosePro unit volume, offset by a 17% increase in the Sumavel DosePro net selling price and the addition of Zohydro ER sales. The decrease in Sumavel DosePro unit volume was primarily caused by a decrease in units in our inventory channel at March 31, 2014 compared to December 31, 2013. The primary driver of the increase in our average net selling price for Sumavel DosePro was a decrease in sales allowances for the three months ended March 31, 2014, as a $1.2 million adjustment for product returns was recorded in the first quarter of 2013.

We currently defer recognition of revenue on product shipments of Zohydro ER to our customers until the right of return no longer exists, which occurs at the earlier of the time Zohydro ER is dispensed through patient prescriptions or expiration of the right of return. As a result of this policy, we had a deferred revenue balance of $6.0 million at March 31, 2014 for Zohydro ER product shipments, which is net of prompt pay discounts and wholesaler distribution fees.

Service and other revenue for the three months ended March 31, 2014 and 2013 was $0.9 million and $0.1 million, respectively. Service and other revenue is primarily comprised of the co-promotion fee that is earned for our Migranal sales efforts under the Valeant Agreement.

Cost of Sales. Cost of sales consists primarily of materials, third-party manufacturing costs, freight and indirect personnel and other overhead costs associated with product sales, as well as write downs for excess, dated or obsolete commercial inventories and production manufacturing variances. The product costs associated with the deferred Zohydro ER product

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revenues are recorded as deferred costs, which are included in inventory, until such time the deferred revenue is recognized. Deferred cost of sales totaled $0.8 million at March 31, 2014.

Cost of sales for the three months ended March 31, 2014 and 2013 was $3.4 million and $4.2 million, respectively. Product gross margin for the three months ended March 31, 2014 and 2013 was 50% and 40%, respectively. The increase in product gross margin for the three months ended March 31, 2014 compared to 2013 was primarily due to a lower cost per Sumavel DosePro unit in the first quarter of 2014 and a lower net selling price in the first quarter of 2013 due to a $1.2 million adjustment for product returns.

Royalty Expense. Royalty expense consists of royalties payable to Aradigm based on net sales of Sumavel DosePro by us or one of our licensees, 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), royalties payable to Alkermes plc based on net sales of Zohydro ER by us, and the amortization of the $2.8 million milestone payment paid by us to Alkermes upon FDA approval of Zohydro ER (which occurred in October 2013). We are required to pay to Aradigm a low single-digit 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. Further, we are required to pay to Alkermes a mid single-digit percentage royalty on net sales of Zohydro ER for an initial royalty term equal to the longer of the expiration of Alkermes' patents covering the product in the United States, or 15 years after commercial launch, if Alkermes does not have patents covering the product in the United States. During the three months ended March 31, 2014 and 2013, we recorded $0.4 million and $0.3 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 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 costs 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 March 31,	
	2014	2013
	(In Thousands)	
Research and development expenses:		
Zohydro	$987	$593
Relday	1,037	755
Sumavel DosePro	97	237
Other[1]	1,417	1,651
Total	$3,538	$3,236

(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 slightly increased by $0.3 million for the three months ended March 31, 2014 compared to the three months ended March 31, 2013, primarily due to increases in development expenses for an abuse deterrent formulation of Zohydro ER and Relday.

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.

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We expect our research and development expenses for the remainder of 2014 to continue to increase over amounts incurred in the same period in 2013 as we prepare for our multi-dose clinical trial for Relday and continue development of an abuse deterrent formulation of Zohydro ER.

Selling, General and Administrative Expenses. Selling expenses, which include sales and marketing costs, consists primarily of salaries and benefits of sales and marketing management and sales representatives, marketing and advertising costs, service fees under our co-promotion agreement and sample product costs. 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 increased to $27.7 million for the three months ended March 31, 2014 compared to $14.5 million for the three months ended March 31, 2013. Selling expenses were $20.3 million for the three months ended March 31, 2014 compared to $10.3 million for the three months ended March 31, 2013. General and administrative expenses were $7.4 million for the three months ended March 31, 2014 compared to $4.2 million for the three months ended March 31, 2013. The increase of $13.2 million in selling, general and administrative expenses was due to an increase of $10.0 million in sales and marketing expenses, and an increase of $3.2 million in general and administrative expenses.

- The increase in sales and marketing expenses is primarily the result of an increase in advertising and promotion costs for Zohydro ER, which was launched in March 2014, and an increase in salaries and other benefits, as well as recruiting costs, due to an increase in headcount. The sales and marketing expenses for the three months ended March 31, 2014 also included the costs of a comprehensive training and certification program for our sales representatives in connection with the launch of Zohydro ER.
- The increase in general and administrative expenses is primarily the result of the addition of our medical affairs team, and implementation of the FDA required ER/LA opioids Risk Evaluation and Mitigation Strategy, or REMS, program and our voluntary safe use initiatives for Zohydro ER, as well as an increase in public relations costs.

We expect our sales and marketing expenses throughout the remainder of 2014 to be greater than the same period in 2013 due to the increase in our sales and marketing headcount, and we expect general administrative expenses throughout the remainder of 2014 to be greater than the same period in 2013 due to the addition of our medical affairs team, and increased activity related to the FDA required ER/LA opioids REMS program and our voluntary safe use initiatives for Zohydro ER.

Interest Income. During the three months ended March 31, 2014 and 2013, interest income was $6,000 and $8,000, respectively. The decrease in interest income was primarily driven by a decrease in average cash and cash equivalent balances during the respective periods.

Interest Expense. Interest expense increased to $1.9 million for the three months ended March 31, 2014 compared to $1.6 million for the three months ended March 31, 2013. Interest expense primarily consists of interest expense incurred in connection with the Healthcare Royalty financing agreement, and imputed interest from the two annual tail payments owed to Astellas Pharma US, Inc. related to the termination of our co-promotion agreement on March 31, 2012.

We do not expect a significant change in interest expense over the remainder of 2014 compared to 2013 levels during the same period. However, if Closing occurs for the asset purchase agreement, we expect a significant decrease in interest expense over the remainder of 2014 as our existing debt obligation to Healthcare Royalty will be eliminated.

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 the Healthcare Royalty financing agreement. See Note 5 to our consolidated financial statements.

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 months ended March 31, 2014 and 2013 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.

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Liquidity and Capital Resources

We have experienced net losses and negative cash flow from operations since inception, and as of March 31, 2014, had an accumulated deficit of $431.2 million. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next year primarily as a result of our efforts to commercialize Zohydro ER, the clinical development for Relday, required post-market testing for Zohydro ER, additional development activities with respect to Zohydro ER, including the development of an abuse deterrent formulation of Zohydro ER, and the cost of the sales and marketing expenses associated with Sumavel DosePro and Zohydro ER. As of March 31, 2014, we had cash and cash equivalents of $50.7 million.

On April 23, 2014, we entered into the asset purchase agreement with the Buyers. Under the terms of the asset purchase agreement, the Buyers will pay to us $85.0 million in cash upon the Closing, $8.5 million of which will be deposited into escrow to fund potential indemnification claims for a period of 12 months. Upon the Closing, Endo Ventures will purchase from us the finished goods inventory of Sumavel DosePro. We will also enter into a supply agreement with Endo Ventures, pursuant to which we will continue to manufacture Sumavel DosePro, and Endo Ventures will support our Sumavel DosePro manufacturing operations with a working capital advance of $7.0 million. In connection with the Closing, we expect to eliminate our existing debt facility with Healthcare Royalty by paying approximately $40.0 million to Healthcare Royalty, consistent with the terms of the Healthcare Royalty financing agreement.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of March 31, 2014, and our projected product revenues from Zohydro ER and Sumavel DosePro, will be sufficient to fund our operations through 2014. In addition to the asset purchase agreement, we may pursue additional opportunities to raise capital, if necessary, through public or private equity offerings, 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, 2013, 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 March 31, 2014, we received aggregate net cash proceeds of approximately $419.0 million from the sale of shares of our preferred and common stock, including the following recent financing transactions:

- 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.;
- in 2013, we issued and sold a total of 6,753,104 shares of common stock under our controlled equity offering program (which was terminated in November 2013), resulting in aggregate net proceeds of $10.8 million; and
- in November 2013, we issued and sold a total of 30,666,667 shares of common stock, including shares issued upon the exercise of the underwriters' option to purchase over-allotment shares, in a follow-on public offering, for aggregate net proceeds of $64.5 million.

On July 18, 2011, we closed the Financing Agreement. Under the terms of the 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 Financing Agreement, our royalty rate increased to 5.75% in April 2012 in connection with the early termination of the Astellas co-promotion agreement.

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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, other than in connection with the Closing of the asset purchase 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.

Cash and Cash Equivalents. Cash and cash equivalents totaled $50.7 million and $72.0 million at March 31, 2014 and December 31, 2013, respectively.

The following table summarizes our cash flows used in operating, investing and financing activities for the three months ended March 31, 2014 and 2013:

	Three Months Ended March 31,	
	2014	2013
	(In Thousands)	
Statement of Cash Flows Data:		
Total cash provided by (used in):		
Operating activities	$(22,824)	$(15,074)
Investing activities	(15)	(830)
Financing activities	1,502	—
Decrease in cash and cash equivalents	$(21,337)	$(15,904)

Operating Activities: Net cash used in operating activities was $22.8 million and $15.1 million for the three months ended March 31, 2014 and 2013, respectively. Net cash used for the three months ended March 31, 2014 primarily reflects the use of cash for operations, adjusted for non-cash charges including an $8.3 million change in fair value of warrant liabilities and $2.5 million in stock-based compensation. Significant working capital uses of cash for the three months ended March 31, 2014 include personnel-related costs, research and development costs (primarily for Relday and employee and infrastructure resources), sales and marketing expenses for Sumavel DosePro and Zohydro ER, and other professional services. Net cash used for the three months ended March 31, 2013 primarily reflects the use of cash for operations, adjusted for non-cash charges including a $4.3 million change in fair value of warrant liabilities and $1.6 million in stock-based compensation. Significant working capital uses of cash for the three months ended March 31, 2013 include personnel-related costs, research and development costs (primarily for Relday and employee and infrastructure resources), sales and marketing expenses for Sumavel DosePro, and other professional services.

Investing Activities. Net cash used in investing activities for the three months ended March 31, 2014 and 2013 was $15,000 and $0.8 million, respectively, related to the purchase of property and equipment primarily for use in manufacturing DosePro.

We expect to incur capital expenditures of approximately $0.5 million to $1.0 million in 2014. These planned capital expenditures primarily relate to further investments in our manufacturing operations for DosePro and toward

enhancing our existing manufacturing technology and equipment.

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Financing Activities. Net cash provided by financing activities was $1.5 million for the three months ended March 31, 2014, which relates to the proceeds from the exercise of stock options and warrants. No cash was used in or provided by financing activities during the three months ended March 31, 2013.

Our sources of liquidity include our cash balances and cash receipts from the sale of Sumavel DosePro and Zohydro ER. Through March 31, 2014, we received aggregate net cash proceeds of approximately $419.0 million from the sale of shares of our preferred and common stock. As of March 31, 2014, we had $50.7 million in cash and cash equivalents. Other potential sources of near-term liquidity include (i) the Closing of the asset purchase agreement, (ii) equity, debt or other financing, (iii) entering into a commercialization agreement for Zohydro ER, or a licensing arrangement for Relday, or (iv) further 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 and Zohydro ER 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 non-financial 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.

If we do not 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 Healthcare Royalty financing agreement. Additional debt or equity financing may not be available to us in amounts or on terms we consider acceptable, or at all.

We cannot be certain if, when and to what extent we will generate positive cash flow from operations from the commercialization of our products 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 Zohydro ER and Sumavel DosePro brands and as we potentially advance Relday through clinical development.

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 March 31, 2014 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 three months ended March 31, 2014, approximately $6.6 million (based on exchange rates as of March 31, 2014) 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 in our cash flows 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 three months ended March 31, 2014 would have resulted in approximately $0.2 million or $0.4 million in gains or losses, respectively. 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 March 31, 2014 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 March 31, 2014 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 material 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, 2013, other than those set forth below, which should be read in conjunction with the risk factors disclosed therein.

Risks Related to Our Pending Sale of Sumavel DosePro to Affiliates of Endo Health Solutions Inc.

The announcement and pendency of the sale of our Sumavel DosePro product line to affiliates of Endo Health Solutions Inc., or Endo, could have an adverse effect on our stock price and/or our business, results of operations, financial condition and prospects.

The announcement and pendency of the sale of our Sumavel DosePro product line to Endo pursuant to the asset purchase agreement we entered into on April 23, 2014, or the asset purchase agreement, could disrupt our business in the following ways, among others:

- third parties may determine to delay or defer purchase decisions with regard to Sumavel DosePro or terminate and/or attempt to renegotiate their relationships with us as a result of the pending sale, whether pursuant to the terms of their existing agreements with us or otherwise; and
- the attention of our management may be directed toward the completion of the pending sale and related matters, and their focus may be diverted from the day-to-day business operations of our company, including from other opportunities that might otherwise be beneficial to us.

Should they occur, any of these matters could adversely affect our stock price or harm our business, results of operations, financial condition and prospects.

Obtaining required approvals necessary to satisfy the conditions to the completion of the sale of our Sumavel DosePro product line to Endo may delay or prevent completion of the pending sale.

The completion of the sale of our Sumavel DosePro product line to Endo is conditioned upon the expiration or termination of the waiting period under the Hart Scott Rodino Antitrust Improvements Act of 1976, as amended, or the HSR Act. We intend to pursue all required approvals in accordance with the terms of the asset purchase agreement. However, no assurance can be given that the required approvals will be obtained and, even if all such approvals are obtained, no assurance can be given as to the terms, conditions and timing of the approvals or that they will satisfy the terms of the asset purchase agreement.

Inability to complete the sale of our Sumavel DosePro product line could negatively impact our business, financial condition, results of operations or our stock price.

The completion of the sale of our Sumavel DosePro product line is subject to a number of conditions, including, among others, clearance under the HSR Act, the receipt of any required third party consents and there not having been a material adverse effect with respect to the such business, and there can be no assurance that the conditions to the completion of the pending sale will be satisfied. The asset purchase agreement may also be terminated by us and Endo in certain specified circumstances, including, if the sale has not been consummated by September 8, 2014 (subject to a ten-day extension in certain circumstances) due to an inability to satisfy any condition to closing. If the pending sale is not completed, we will be subject to several risks, including:

- the current trading price of our common stock may reflect a market assumption that the sale will be completed;
- we expect to incur substantial transaction costs in connection with the pending sale whether or not it is completed; and
- under the asset purchase agreement, we are subject to certain restrictions on the conduct of our business prior to the completion of the pending sale, which restrictions could adversely affect our ability to realize certain of our business strategies or take advantage of certain business opportunities.

If the pending sale is not completed, these risks may materialize and materially and adversely affect our business, financial condition, results of operations or our stock price.

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Even if we complete the sale of our Sumavel DosePro product line, we may not realize the full economic benefit from such sale.

Pursuant to the asset purchase agreement, in addition to the $85.0 million upfront cash payment, we may receive contingent payments, based on Endo's achievement of pre-determined sales and manufacturing milestones, in an amount up to $20.0 million. Our ability to receive these contingent payments is dependent upon Endo successfully maintaining and increasing market demand for, and sales of, Sumavel DosePro in a manner in which the requisite sales of the product will be achieved and devoting the resources necessary to achieve the manufacturing milestone. In addition, we have agreed to indemnify Endo and its affiliates against losses suffered as a result of our material breach of representations and warranties and our other obligations in the asset purchase agreement and $8.5 million of the upfront cash payment will be deposited into escrow to fund such potential indemnification claims for a period of 12 months following the closing of the sale. We cannot provide any assurance that we will receive all or any portion of the $8.5 million escrow amount or any of the contingent milestone payments.

Risks Related to Our Business and Industry

We 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 year.

We were organized in 2006, began commercialization of Sumavel DosePro in January 2010 and launched the commercial sale of Zohydro ER in the United States in March 2014. Our business and prospects must be considered in light of the risks and uncertainties frequently encountered by pharmaceutical companies commercializing new products.

We have generated substantial net losses and negative cash flow from operations since our inception in 2006. For example, for the three months ended March 31, 2014 and the years ended December 31, 2013 and 2012, we incurred net losses of $20.9 million, $80.9 million and $47.4 million, respectively, our net cash used in operating activities was $22.8 million, $44.9 million and $52.2 million, respectively, and, at March 31, 2014, our accumulated deficit was $431.2 million. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next year primarily as a result of the expenses incurred in connection with to commercialize Zohydro ER, the clinical development for Relday, required post-market testing for Zohydro ER, additional development activities with respect to Zohydro ER, including the development of an abuse deterrent formulation of Zohydro ER, and the cost of the sales and marketing expense associated with Sumavel DosePro and Zohydro ER. Our ability to generate revenues from Sumavel DosePro, Zohydro ER or any of our product candidates will depend on a number of factors including, in the case of Sumavel DosePro and Zohydro ER, the factors described in risk factors below and, in the case of our product candidates, including Relday and an abuse deterrent formulation of Zohydro ER, 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 commercialization and product development 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 Zohydro ER or any of our product candidates that may receive regulatory approval, there would likely be a material adverse effect on our business, results of operations, financial condition and prospects and could result in our inability to continue operations.

If Sumavel DosePro, Zohydro ER, and, if approved, Relday, or any other product candidate for which we receive regulatory approval does not achieve broad market acceptance or coverage by third-party payors, the revenues that we generate will be limited.

The commercial success of Sumavel DosePro, Zohydro ER, and, if approved, Relday, or any other product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our approved products by third-party payors are also necessary for commercial success. The degree of market

acceptance of Sumavel DosePro, Zohydro ER and any product candidates for which we may receive regulatory approval will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- acceptance by physicians and patients of the product as a safe and effective treatment;

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- the relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- limitations or warnings contained in a product's FDA-approved labeling;
- the clinical indications for which a product is approved;
- in the case of Zohydro ER and product candidates that are controlled substances, the U.S. Drug Enforcement Administration, or DEA, scheduling classification;
- availability and perceived advantages of alternative treatments;
- any negative publicity related to our or our competitors' products;
- the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies;
- pricing and cost effectiveness;
- our ability to obtain sufficient third-party payor coverage and reimbursement; and
- the willingness of patients to pay out of pocket in the absence of third-party payor coverage.

For example, while we believe the needle-free nature of our DosePro technology will appeal to patients, some patients may not react favorably to the subcutaneous delivery of drug products by DosePro. Our experience indicates that some patients will experience pain upon injection with the DosePro technology and/or reactions at the site of injection. Any undesirable side effects have the potential to limit market acceptance of our product candidates.

In addition, products used to treat and manage pain, especially in the case of opioids like Zohydro ER, are from time to time subject to negative publicity, including political influences, illegal use, overdoses, abuse, diversion, serious injury and death. For example, in November 2013, eight members of Congress submitted a letter to Department of Health and Human Services Secretary, Kathleen Sebelius, urging reconsideration of the FDA approval of Zohydro ER, and in December 2013, a bipartisan coalition of attorneys general from 29 states and territories submitted a letter to FDA Commissioner, Margaret Hamburg, with the same request. While we do not believe that the FDA will revoke its Zohydro ER approval, and in any event, would have to provide us with notice and opportunity for a hearing first, such negative publicity could negatively affect our ability to market Zohydro ER and any opioid analgesic product candidates for which we may seek approval in the future.

In March 2014, Governor Deval Patrick of the Commonwealth of Massachusetts issued an executive order to ban Zohydro ER in Massachusetts. In response, on April 7, 2014 we filed a lawsuit in the U.S. District Court in Massachusetts requesting the court to grant a temporary restraining order against implementation of Governor Patrick's executive order prohibiting the prescribing and dispensing of Zohydro ER. The lawsuit argued that the executive order was in direct conflict with the authority of the FDA to determine on behalf of the public whether a drug is safe and effective, and to impose the measures necessary to ensure that such drug will be used safely and appropriately. On April 15, 2014, the U.S. District Court in Massachusetts entered a temporary restraining order preventing the implementation of Governor Patrick's order on constitutional grounds. This order became effective on April 22, 2014. While we believe the FDA has the authority to determine on behalf of the public whether a drug is safe and effective, and to impose the measures necessary to ensure that such drug will be used safely and appropriately, we cannot guarantee that Governor Patrick or other state officials will not try to place additional restrictions on the prescription and use of Zohydro ER which could negatively affect our ability to market Zohydro ER.

Moreover, as part of its own initiatives to address the safety risks associated with opioid analgesics, in September 2013, the FDA announced class-wide safety labeling changes, including required new boxed warnings, and new post-market study requirements for all ER/LA opioid analgesics intended to treat pain. Because of the risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death, the FDA determined that these drugs should be reserved for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. In addition, the FDA required the drug companies that make these drugs to conduct further studies and clinical trials to assess the known serious risks of misuse, abuse, increased sensitivity to pain (hyperalgesia), addiction, overdose and death. The scope and design of these required additional studies and clinical trials are under development and the related cost is currently unknown, which could negatively affect our business. The FDA recently announced that it will hold a public meeting to obtain stakeholder input on the design and conduct of the post-marketing requirements for ER/LA opioid analgesic drug products, and we cannot predict how this meeting may affect our post-marketing requirements for

Zohydro ER.

Controlled substances are classified by the DEA as Schedule I through V substances, with Schedule I substances being prohibited for sale in the United States, Schedule II substances considered to present the highest risk of abuse and Schedule V substances being considered to present the lowest relative risk of abuse. Zohydro ER contains hydrocodone, and is regulated as a Schedule II controlled substance, and despite the strict regulations on the marketing, prescribing and dispensing of such substances, illicit use and abuse of hydrocodone is well-documented. Thus, the marketing of Zohydro ER may generate public controversy that may adversely affect market acceptance of Zohydro ER. Due to the concerns regarding abuse of opioids like Zohydro ER, we are developing an abuse deterrent formulation of Zohydro ER.

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Our efforts to educate the medical community and third-party payors on the benefits of Sumavel DosePro, Zohydro ER and, if approved, Relday or any of our other product candidates for which we obtain marketing approval from the FDA or other regulatory authorities and gain broad market acceptance may require significant resources and may never be successful. If our products do not achieve an adequate level of acceptance by physicians, third-party payors, pharmacists, and patients, we may not generate sufficient revenue from these products to become or remain profitable.

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

The majority of our sales of Sumavel DosePro and Zohydro ER are to wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. Three wholesale pharmaceutical distributors, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation, individually comprised 29.4%, 28.6% and 24.3%, respectively, of our total gross product sales for the quarter ended March 31, 2014. In addition, CVS.com, who purchases from us directly, individually comprised 13.2% of our total gross product sales for the quarter ended March 31, 2014.

Sales to these wholesale pharmaceutical distributors may result in substantial fluctuations in our results of operations from period to period and 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 and Zohydro ER 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 face intense competition, including from generic products, and if our competitors market and/or develop treatments for pain, migraine or psychotic disorders that are marketed more effectively, approved more quickly than our product candidates or demonstrated to be safer or more effective than our products, our commercial opportunities will be reduced or eliminated.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our products or product candidates, including large pharmaceutical companies, smaller pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions, many of which have greater financial resources, sales and marketing capabilities, including larger, well-established sales forces, manufacturing capabilities, experience in obtaining regulatory approvals for product candidates and other resources than us.

Zohydro ER competes against other marketed branded and generic pain therapeutics. Opioid therapeutics generally fall into two classes: codeines, which include oxycodones and hydrocodones, and morphines. Zohydro ER is a

hydrocodone, the most commonly prescribed opioid in the United States, and Zohydro ER competes with therapeutics within both the codeine and morphine classes. These therapeutics include both Schedule II and Schedule III products (meaning that they are considered controlled substances by the DEA) being marketed by companies such as Endo Pharmaceuticals Holdings Inc., Johnson & Johnson, Mallinckrodt Inc., Pfizer, Purdue Pharma L.P., Teva Pharmaceutical Industries Limited and Actavis, Inc. On February 27, 2014, the DEA issued a notice of proposed rulemaking to reschedule hydrocodone combination products from Schedule III to Schedule II, but we cannot predict the timeframe in which the rule may become final and when, if ever, these products will be required to comply with Schedule II requirements. Zohydro ER is already a Schedule II product.

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Zohydro ER will also compete with a significant number of opioid product candidates under development, including abuse deterrent and tamper resistant formulations of currently available opioids, novel opioids and alternative delivery forms of various opioids under development at other pharmaceutical companies, including single-entity extended-release hydrocodone product candidates, which include abuse deterrent and tamper resistant formulations, being developed by Egalet A/S, Pfizer, Purdue Pharma L.P. and Teva Pharmaceutical Industries Limited. In April 2014, Purdue Pharma L.P. announced that it filed an NDA for its extended-release hydrocodone product candidate that is formulated to incorporate abuse deterrent properties. In addition, Teva Pharmaceutical Industries Limited recently announced that it plans to submit an NDA by the end of 2014 for its extended-release hydrocodone product candidate that is also formulated to incorporate abuse deterrent properties. These product candidates, if approved, may present enhanced competition for the current formulation of Zohydro ER.

Zohydro ER may also face competition from non-opioid product candidates including new chemical entities, as well as alternative delivery forms of non-steroidal anti-inflammatory drugs. These new opioid and non-opioid product candidates are being developed by companies such as Acura Pharmaceuticals, Inc., Collegium Pharmaceutical, Inc., Eli Lilly and Company, Elite Pharmaceuticals, Inc., Hospira Inc., Inspirion Delivery Technologies, LLC, Intellipharmaceutics International, Inc., Nektar Therapeutics, Pfizer and QRxPharma Ltd.

Many large, well-capitalized companies offer products in the United States that compete with Sumavel DosePro. Sumavel DosePro currently competes with branded products in the triptan class such as Imitrex and Treximet marketed by GlaxoSmithKline, or GSK, as well as six other branded triptan therapies being sold by AstraZeneca plc, Endo Pharmaceuticals Holdings Inc., Johnson & Johnson, Merck & Co., Inc., and Pfizer Inc. In addition to those migraine therapeutics, there are other marketed non-triptan migraine therapeutics such as Cambia sold by DepoMed, Inc. In addition, Allergan, Inc., is now marketing BOTOX botulinum toxin for the treatment of chronic migraine. We also face competition from generic sumatriptan oral tablets and sumatriptan injection, now marketed in the United States as an authorized generic of the Imitrex STATdose System, or Imitrex STATdose, by Par Pharmaceutical Companies, Inc. In addition, in June 2010, the FDA approved Alsuma (sumatriptan injection), a needle-based autoinjector which was developed and is manufactured and marketed by Pfizer and its subsidiary, Meridian Medical Technologies. Finally, generic injectable sumatriptan in the form of vials and prefilled syringes is available from a number of pharmaceutical companies, and most recently, the FDA granted approval for a needle-based generic sumatriptan auto-injector from Sun Pharmaceutical Industries Limited in June 2011 and from Dr. Reddy's Laboratories Ltd. in January 2014. Although these products may not be directly substituted for Sumavel DosePro, generic versions of sumatriptan injection and alternative autoinjector forms of sumatriptan injection may reduce the future adoption of Sumavel DosePro by third-party payors and consumers, as financial pressure to use generic products may encourage the use of a generic product over Sumavel DosePro. Sumavel DosePro is currently more expensive on a per dose basis than most of the competing branded and all of the generic triptan products for migraine, which may also limit the coverage and reimbursement by third-party payors, which could adversely affect adoption by physicians and patients.

In addition to already marketed therapeutics, we also face competition from product candidates that are or could be under development by many of the above-mentioned entities and others. For example, there are several products for the treatment of migraine under development by large pharmaceutical companies such as GSK, Merck & Co. and Avanir Pharmaceuticals, Inc. In addition, Teva Pharmaceuticals Industries Limited intends to launch its migraine patch, Zecuity, in 2014.

If approved for the treatment of schizophrenia, we anticipate that Relday will compete against other marketed, branded and generic, typical and atypical antipsychotics, including both long-acting injectable and oral products. Currently marketed long-acting injectable atypical antipsychotic products include Risperdal Consta, and Invega Sustenna marketed by Johnson & Johnson, Zyprexa Relprevv marketed by Eli Lilly & Company, and Abilify Maintena (apripiprazole) marketed by Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S. Currently approved and marketed oral atypical antipsychotics include Risperdal (risperidone) and Invega (paliperidone) marketed by Johnson & Johnson, generic risperidone, Zyprexa (olanzapine) marketed by Eli Lilly and Company, Seroquel (quetiapine) marketed by AstraZeneca plc, Abilify (aripiprazole) marketed by BMS/Otsuka Pharmaceutical Co., Ltd., Geodon (ziprasidone) marketed by Pfizer, Fanapt (iloperidone) marketed by Novartis AG, Saphris (asenapine) marketed by

Merck & Co., Latuda (lurasidone) marketed by Dainippon Sumitomo Pharma, and generic clozapine. Finally, in addition to these currently marketed products, we may also face competition from additional long-acting injectable product candidates that could be developed by the large companies listed above, as well and by other pharmaceutical companies such as Alkermes, Endo Health Solutions Inc., Laboratorios Farmaceuticos Rovi SA, Novartis AG, and Reckitt Benckiser Group plc, each of which has announced they are developing long-acting antipsychotic product candidates.

We expect Zohydro ER, Sumavel DosePro and, if approved, Relday and any of our other product candidates to compete on the basis of, among other things, product efficacy and safety, time to market, price, patient reimbursement by third-party payors, extent of adverse side effects and convenience of treatment procedures. One or more of our competitors may develop needle-free injectable products, products to address chronic pain or other products that compete with ours, obtain necessary approvals for such products from the FDA, or other agencies, if required, more rapidly than us or develop alternative products

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or therapies that are safer, more effective and/or more cost effective than any products developed by us. The competition that we will encounter with respect to any of our product candidates that receive the requisite regulatory approval and classification and are marketed will have, and the competition we are currently encountering with Zohydro ER and Sumavel DosePro has had and will continue to have, an effect on our product prices, market share and results of operations. We may not be able to differentiate any products that we are able to market from those of our competitors, successfully develop or introduce new products that are less costly or offer better results than those of our competitors, or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors.

In addition, competitors may seek to develop alternative formulations of our product candidates and/or alternative drug delivery technologies that address our targeted indications. The commercial opportunity for Zohydro ER, Sumavel DosePro and our product candidates could be significantly harmed if competitors are able to develop alternative formulations and/or drug delivery technologies outside the scope of our products. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- research and development resources and experience, including personnel and technology;
- drug development, clinical trial and regulatory resources and experience
- sales and marketing resources and experience;
- manufacturing and distribution resources and experience;
- name recognition; and
- resources, experience and expertise in prosecution and enforcement of intellectual property rights.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit or block us from developing or commercializing our product candidates. Our competitors may also develop drugs that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed or accepted or less costly than ours and may also be more successful than us in manufacturing and marketing their products. If we are unable to compete effectively with the marketed therapeutics of our competitors or if such competitors are successful in developing products that compete with Sumavel DosePro, Zohydro ER or any of our product candidates that are approved, our business, results of operations, financial condition and prospects may be materially 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 and Zohydro ER have been in U.S. dollars. For the three months ended March 31, 2014, $6.6 million (based on exchange rates as of March 31, 2014) of our materials, contract manufacturing costs and other manufacturing-related 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 first approved product, Sumavel DosePro, in January 2010 and our recently approved product, Zohydro ER, in March 2014. Given on our limited sales history for Sumavel DosePro and Zohydro ER, we may not accurately predict future sales, and we may never be able to significantly increase sales. We have financed our operations primarily 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, July 2012 and November 2013, our controlled equity offering program, which was terminated in November 2013, and debt, and have incurred losses and negative cash flow from operations in each year since our inception. For the three months ended March 31, 2014 and the years ended December 31, 2013 and 2012, we incurred net losses of $20.9 million, $80.9 million and $47.4 million, respectively, and

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our cash used in operating activities was $22.8 million, $44.9 million and $52.2 million, respectively. As of March 31, 2014, we had an accumulated deficit of $431.2 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 and Zohydro ER, we expect our losses to continue for at least the next year primarily as a result of the expenses incurred in connection with our efforts to commercialize Zohydro ER, the additional clinical development of Relday, the required post-market testing for Zohydro ER, additional activities with respect to Zohydro ER, including the development of an abuse deterrent formulation of Zohydro ER and the cost of the sales and marketing expense associated with Sumavel DosePro and 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 products 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.

Risks Related to Regulation of our Product and Product Candidates

Annual DEA quotas on the amount of hydrocodone allowed to be produced in the United States and our specific allocation of hydrocodone by the DEA could significantly limit the production or sale of Zohydro ER.

The DEA limits the production and availability of all Schedule II substances through a quota system which includes a national aggregate production quota and individual procurement quotas. Because hydrocodone is subject to the DEA's production and procurement quota scheme, the DEA establishes annually an aggregate production quota for how much hydrocodone may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount of hydrocodone that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. The DEA may adjust individual procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. The DEA requires substantial evidence and documentation of expected legitimate medical and scientific needs before assigning procurement quotas to manufacturers and research organizations. Alkermes, which has licensed us the right to sell Zohydro ER in the United States, was granted sufficient procurement quota of hydrocodone to meet our planned launch requirements through the majority of 2014. Subsequently, a request was made for additional procurement quota to support expected growth through 2014, which was granted by the DEA in April 2014.

We do not know what amounts of hydrocodone other companies manufacturing or developing product candidates containing hydrocodone may request for future years. The DEA, in assessing factors such as medical need, abuse and diversion potential and other policy considerations, may choose to set the aggregate hydrocodone production quota lower than the total amount requested for procurement by the companies. Alkermes is permitted to petition the DEA to increase the annual procurement quota after it is initially established, but there is no guarantee that the DEA would act favorably upon such a petition. Alkermes procurement quota of hydrocodone may not be sufficient to meet any future clinical development needs or commercial demand for Zohydro ER. Any delay or refusal by the DEA in establishing the procurement quota or a reduction in Alkermes procurement quota for hydrocodone or DEA's failure to increase it over time as we anticipate could delay or stop commercial sale of Zohydro ER or cause us not to achieve our expected operating results, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

If we do not comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients’ rights are applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our

business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare,

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Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- federal "sunshine" requirements that require drug manufacturers to report and disclose any "transfer of value" made or distributed to physicians and teaching hospitals, and any investment or ownership interests held by such physicians and their immediate family members. The period between August 1, 2013 and December 31, 2013 was the first reporting period, and manufacturers were required to report aggregate payment data by March 31, 2014, and will be required to report detailed payment data and submit legal attestation to the accuracy of such data during Phase 2 of the program (which begins in May 2014 and extends for at least 30 days). Thereafter, manufacturers must submit reports by the 90th day of each subsequent calendar year;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians, including the tracking and reporting of gifts, compensation and other remuneration to physicians. Certain states mandate implementation of commercial compliance programs to ensure compliance with these laws and impose restrictions on drug manufacturer marketing practices and tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may be found out of compliance of one or more of the requirements.

To the extent that any product we make is sold in a foreign country, we may be subject to similar foreign laws and regulations. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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 depends in large part on obtaining and maintaining patent, trademark and trade secret protection of our products, Sumavel DosePro and Zohydro ER, our current product candidate, Relday, and any future product candidates, 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, Zohydro ER 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.

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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 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 non-infringement, 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 non-infringement, 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, who acquired those patents from a predecessor owner. Thus, most of our patents, as well as many of our pending patent applications, were not written by us or our attorneys, or our licensor or licensors' attorneys, and neither we nor our licensors had 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 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 made significant 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, Zohydro ER and our product candidates but that are not covered by the claims of our patents or our in-licensed patents;

- the active pharmaceutical ingredients (APIs) in Sumavel DosePro, Zohydro ER and Relday 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;

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- 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 our owned or in-licensed U.S. patents or patent applications are not Orange-Book eligible;
- it is possible that there are dominating patents to Sumavel DosePro, Zohydro ER or Relday of which we are not aware;
- 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;
- it is possible that the U.S. government may exercise any of its statutory rights to our owned or in-licensed patents or applications that were developed with government funding;
- 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 system or products or our system 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 administrative 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, state laws in the Unites States vary, and their courts as well as 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 system are expected to expire on various dates from 2014 through 2026 and the patents and patent applications licensed to us by Alkermes are expected to expire in 2019.

As of March 31, 2014, our patent portfolio included 23 issued U.S. patents, 5 pending U.S. patent applications, 55 issued foreign patents and 8 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, and 2024. and 2022, respectively. U.S. Patent No. 5,891,086 covers a particular actuator mechanism forming a part of the needleless injector system; 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 systems 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 systems; U.S. Patent Nos. 8,118,771, 8,241,243 and 8,241,244 cover a method of reducing breakage of glass capsules; 8,491,524 relates to a drug capsule filled with a formulation purged with an inert gas; and 8,343,130 covers a method of reducing the propensity to create a shock wave on firing the system as used in the Sumavel DosePro system. U.S. Patent Nos. 6,902,742 and 6,228,398 relating to Zohydro ER covers a

modified release composition containing hydrocodone and are expected to expire in November 2019. Upon the expiration of these patents, we or Alkermes, as applicable, will lose the right to exclude others from practicing the claimed inventions. Additionally, since these eleven patents are the only patents currently listed in the FDA Orange Book for Sumavel DosePro, or the two patents listed for Zohydro ER, 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.

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The patent rights for Sumavel DosePro do not cover sumatriptan per se. As a result, our market opportunity for this product may be limited by the lack of patent protection for the active ingredient itself.

The active ingredient in Sumavel DosePro is sumatriptan. Patent protection is not available for sumatriptan per se. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredient as Sumavel DosePro so long as the competitors do not infringe on any of our patents.

Third parties may challenge the patents covering Sumavel DosePro, which could result in the invalidation or unenforceability of some or all of the relevant patent claims.

Moreover, if a third party files an abbreviated new drug application, or ANDA, for a generic drug product containing sumatriptan and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that, in the opinion of that third party, the patents listed in the Orange Book for Sumavel DosePro are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the third party's generic drug product. A third party certification that the new product will not infringe the Orange Book-listed patent for Sumavel DosePro, or that such patents are invalid, is called a Paragraph IV patent certification. If the third party submits a Paragraph IV patent certification to the FDA, a notice of the Paragraph IV patent certification must also be sent to us once the third-party's ANDA is accepted for filing by the FDA. A lawsuit may then be initiated to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of the receipt of notice of a Paragraph IV patent certification automatically prevents the FDA from approving the ANDA until the earlier of the expiration of a 30-month period, the expiration of the patents, the entry of a settlement order stating that the patents are invalid or not infringed, a decision in the infringement case that is favorable to the ANDA applicant, or such shorter or longer period as the court may order. If a patent infringement lawsuit is not initiated within the required 45-day period, the third-party's ANDA will not be subject to the 30-month stay.

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 three months ended March 31, 2014, the price per share for our common stock on the Nasdaq Global Market has ranged from a low sale price of $2.66 to a high sale price of $5.19. This market volatility is likely to continue. These and 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 commercial progress in promoting and selling Sumavel DosePro and Zohydro ER, including sales and revenue trends;
- FDA or international regulatory actions and whether and when we receive regulatory approval for any of our product candidates;
- the development status of Relday or any of our other product candidates, including the results from our clinical trials;
- negative publicity, including political actions, related to 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 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, Zohydro ER 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;

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- 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.

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 March 31, 2014, we had 139,539,151 shares of common stock outstanding. Of these shares, approximately 98,877,251 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). As of March 31, 2014, warrants were still outstanding to exercise 15,215,450 shares of this registered common stock, 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.

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

Unregistered Sales of Equity Securities

Not applicable.

Use of Proceeds

Not applicable.

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Item 3. Defaults Upon Senior Securities
Not applicable.
Item 4. Mine Safety Disclosures
Not applicable.
Item 5. Other Information
Not applicable.

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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(5)	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†	Termination and Amendment Agreement effective as of January 31, 2014 by and between the Registrant and Mallinckrodt LLC
10.2†	Amendment No. 1 - Development and Option Agreement dated March 10, 2014 by and between the Registrant and Altus Formulation Inc.

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10.3	Independent Director Compensation Policy as amended and restated effective March 21, 2014
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 March 31, 2014, 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.
(5) Filed with the Registrant's Quarterly Report on Form 10-Q on November 8, 2012.
† 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: May 8, 2014

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

Date: May 8, 2014

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