ZOGENIX, INC.
Form 10-Q
November 06, 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 September 30, 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 (Address of Principal Executive Offices)	92130 (Zip Code)
858-259-1165 (Registrant's Telephone Number, Including Area Code)	

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes ¨ No
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of November 3, 2014 was 153,040,066.

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

	September 30, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$50,527	$72,021
Restricted cash	8,500	—
Trade accounts receivable, net	5,886	6,665
Inventory	19,271	9,936
Prepaid expenses and other current assets	6,406	4,257
Total current assets	90,590	92,879
Property and equipment, net	10,615	13,011
Other assets	5,821	6,614
Total assets	$107,026	$112,504
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$8,177	$4,622
Accrued expenses	12,650	18,865
Accrued compensation	5,206	3,952
Common stock warrant liabilities	4,007	31,341
Deferred revenue	9,303	—
Total current liabilities	39,343	58,780
Note payable	2,375	—
Long term debt	—	28,802
Deferred revenue, less current portion	7,458	—
Other long-term liabilities	315	6,496
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value; 200,000 shares authorized at September 30, 2014 and December 31, 2013; 141,045 and 138,927 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively.	141	139
Additional paid-in capital	438,533	428,534
Accumulated deficit	(381,139)	(410,247)
Total stockholders' equity	57,535	18,426
Total liabilities and stockholders' equity	$107,026	$112,504

See accompanying notes.

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Zogenix, Inc.
Consolidated Statements of Operations and Comprehensive Income (Loss)
(In Thousands, except Per Share Amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue:				
Net product revenue	$4,125	$6,897	$16,675	$22,693
Contract manufacturing revenue	4,225	—	6,463	—
Service and other revenue	447	271	2,494	398
Total revenue	8,797	7,168	25,632	23,091
Operating (income) expense:				
Cost of goods sold	706	5,354	6,463	14,144
Cost of contract manufacturing	3,986	—	5,921	—
Royalty expense	425	281	1,223	901
Research and development	5,289	2,544	12,947	9,358
Selling, general and administrative	19,056	10,011	71,197	36,491
Restructuring	—	—	—	876
Impairment of long-lived assets	—	—	838	—
Net gain on sale of business	—	—	(79,980)	—
Total operating expense	29,462	18,190	18,609	61,770
Income (loss) from operations	(20,665)	(11,022)	7,023	(38,679)
Other income (expense):				
Interest income	6	1	18	12
Interest expense	(84)	(1,587)	(2,999)	(4,795)
Loss on early extinguishment of debt	—	—	(1,254)	—
Change in fair value of warrant liabilities	7,948	215	26,418	(2,780)
Change in fair value of embedded derivatives	—	1,474	(14)	912
Other income (expense)	15	67	(39)	90
Total other income (expense)	7,885	170	22,130	(6,561)
Net income (loss) before income taxes	(12,780)	(10,852)	29,153	(45,240)
Provision for income taxes	(45)	—	(45)	—
Net income (loss)	$(12,825)	$(10,852)	$29,108	$(45,240)
Common share data:				
Net income (loss) per share, basic	$(0.09)	$(0.10)	$0.21	$(0.44)
Net income (loss) per share, diluted	$(0.09)	$(0.10)	$0.02	$(0.44)
Weighted average shares outstanding, basic	141,045	104,682	140,110	102,136
Weighted average shares outstanding, diluted	141,045	104,682	140,474	102,136
Comprehensive income (loss)	$(12,825)	$(10,852)	$29,108	$(45,240)

See accompanying notes.

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

	Nine Months Ended September 30,	
	2014	2013
Operating activities:		
Net income (loss)	$29,108	$(45,240)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	7,334	5,579
Stock-based compensation, restructuring	—	201
Depreciation and amortization	1,227	1,395
Amortization of debt issuance costs and non-cash interest	370	422
Loss on early extinguishment of debt	1,254	—
Net gain on sale of business	(79,980)	—
Loss on impairment of long-lived assets	838	—
Change in fair value of warrant liabilities	(26,418)	2,780
Change in fair value of embedded derivatives	14	(912)
Changes in operating assets and liabilities:		
Trade accounts receivable	779	(518)
Inventory	(9,335)	797
Prepaid expenses and other current assets	(10,595)	482
Other assets	(4,978)	614
Accounts payable and accrued expenses	2,377	205
Restructuring liabilities	—	6
Deferred revenue	16,761	—
Net cash used in operating activities	(71,244)	(34,189)
Investing activities:		
Purchases of property and equipment	(85)	(785)
Proceeds from sale of business	89,624	—
Restricted cash from sale of business	(8,500)	—
Net cash provided by (used in) investing activities	81,039	(785)
Financing activities:		
Proceeds from note payable	7,000	—
Repayment of debt	(40,041)	—
Proceeds from exercise of common stock options and warrants	1,508	—
Proceeds from issuance of common stock	244	11,098
Net cash provided by (used in) financing activities	(31,289)	11,098
Net decrease in cash and cash equivalents	(21,494)	(23,876)
Cash and cash equivalents at beginning of period	72,021	41,228
Cash and cash equivalents at end of period	$50,527	$17,352

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, CII, 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. The Company launched Zohydro ER in March 2014. On September 30, 2014, the Company submitted a supplemental New Drug Application (sNDA) for a modified formulation of Zohydro ER which was has been designed to have abuse deterrent properties. The new capsule formulation contains additional inactive ingredients that are intended to make the product more difficult to abuse by injection and nasal insufflation. The The FDA assigned a Prescription Drug User Free Act, or PDUFA, target action date on the sNDA of January 30, 2015, and, if approved, we anticipate a transition from the currently marketed product to this new capsule formulation of Zohydro ER in the second quarter of 2015.

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. 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, Endo), pursuant to which, and on the terms and subject to the conditions thereof, among other things, the Company agreed to sell its Sumavel DosePro business to Endo, 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. The Asset Purchase Agreement closed on May 16, 2014 (the Closing) and in connection with the Closing, the Company and Endo Ventures also entered into a supply agreement (the Supply Agreement), pursuant to which the Company will retain the sole and exclusive right and the obligation to manufacture, have manufactured, supply or have supplied Sumavel DosePro to Endo Ventures, subject to Endo Venture's right to qualify and maintain a back-up manufacturer. Further, under the Supply Agreement, Endo will support the Company's Sumavel DosePro manufacturing operations with a working capital advance equivalent to the book value of the inventory of materials and unreleased finished goods held by the Company in connection with the manufacture of Sumavel DosePro minus the accounts payable associated with such materials and unreleased finished goods, capped initially at $7,000,000 and subject to annual adjustment. Upon the Closing, and in addition to the working capital advance, Endo paid the Company $85,000,000, $8,500,000 of which was deposited into escrow to fund potential indemnification claims for a period of 12 months, and $4,624,000 for finished goods inventory on hand at Closing. 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 gross margin milestones (see Note 4).

On October 24, 2014, Zogenix Europe Limited (Zogenix Europe), a wholly-owned subsidiary of the Company, acquired Brabant Pharma Limited, a privately-held company organized under the laws of England and Wales (Brabant), pursuant to the terms of a Sale and Purchase Agreement (the Sale and Purchase Agreement), dated October 24, 2014. Brabant owns worldwide development and commercialization rights to Brabafen, low-dose fenfluramine, for the treatment of Dravet syndrome (also known as Severe Myoclonic Epilepsy of Infancy). Dravet syndrome is a rare and catastrophic form of pediatric epilepsy with life threatening consequences for patients and current treatment options are very limited. Brabafen has recently received orphan drug designation in Europe and the United States for the treatment of Dravet syndrome. Under the terms of the Sale and Purchase Agreement, Zogenix

Europe paid consideration of (i) $20,000,000 in cash (plus $8,432,000 which represents the net cash position of Brabant at the closing), of which $2,000,000 was deposited into escrow to fund potential indemnification claims for a period of 6 months, and (ii) 11,995,202 shares of the Company's common stock. Zogenix Europe also committed to paying up to an aggregate amount of $95,000,000 in connection with the achievement of certain milestones for Brabafen, including $50,000,000 in regulatory milestones and $45,000,000 in sales milestones. The Company has agreed to use commercially reasonable efforts (as defined in the Sale and Purchase Agreement) to develop and commercialize Brabafen and to achieve the milestones (see Note 9).

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.

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

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

On November 6, 2014, the Company entered into a controlled equity offering sales agreement with Cantor Fitzgerald & Co., or Cantor, as sales agent, under which the Company can issue and sell shares of its common stock having an aggregate offering price of up to $25,000,000 from time to time through Cantor. Sales of the Company's common stock made pursuant to the controlled equity offering program, if any, will be made on the Nasdaq Global Market under the Company's shelf registration statement on Form S-3 filed on November 6, 2014, following such time as the registration statement is declared effective by the SEC. However, such registration statement cannot be declared effective until such time as the Company has filed certain financial statements from its recent acquisition of Brabant as required by SEC rules, which must be filed within 71 days of the date of the Company's Current Report on Form 8-K filed with the SEC on October 27, 2014. There can be no assurance that Cantor will be successful in consummating sales under the program based on prevailing market conditions or in the quantities or at the prices that the Company deems appropriate.

2. Summary of Significant Accounting Policies

Financial Statement Preparation and Use of Estimates

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

In the opinion of management, the accompanying unaudited consolidated financial statements for the periods presented reflect all adjustments, which are normal and recurring, necessary to fairly state the financial position, results of operations and cash flows. These unaudited consolidated financial statements should be read in conjunction with the audited financial 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.

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Restricted Cash

In connection with its sale of the Sumavel DosePro business in May 2014, the Company has $8,500,000 of cash in escrow as of September 30, 2014 to fund potential indemnification claims for a period of 12 months (see Note 4). The Company classifies the cash flow from this restricted cash as an investing activity in the consolidated statement of cash flows as the source of the restricted cash is related to the sale of the Sumavel DosePro business.

Further, in December 2009, the Company issued a line of credit for $200,000 in connection with an operating lease which was collateralized by a certificate of deposit in the same amount and recorded as restricted cash within other assets on the consolidated balance sheet as of December 31, 2013. This line of credit and certificate of deposit were terminated in February 2014 in connection with a renegotiation of the operating lease.

Fair Value Measurements

The carrying amount of financial instruments consisting of cash, restricted cash, trade accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and accrued compensation included in the Company's consolidated financial statements are reasonable estimates of fair value due to their short maturities. Based on the borrowing rates currently available to the Company for loans with similar terms, management believes the fair value of long-term debt approximates its carrying value. The accrued liability for the annual tail payment due to Astellas Pharma US, Inc. (Astellas) (see Note 5) for the termination of the Company's co-promotion agreement was measured at fair value in December 2011 using a present value technique, which incorporated the Company's own credit risk as measured by the most recent round of debt financing with Healthcare Royalty Partners (Healthcare Royalty) (formerly Cowen Healthcare Royalty Partners II, L.P.).

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

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

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

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

The Company classifies its cash equivalents within Level 1 of the fair value hierarchy because it values 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 September 30, 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 September 30, 2014				
Assets				
Cash equivalents[1]	$46,919	—	—	$46,919
Liabilities				
Common stock warrant liabilities[2]	$—	—	4,007	$4,007
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

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

(2) Common stock warrant liabilities include liabilities associated with warrants issued in connection with the Company's July 2012 public offering of common stock and warrants (see Note 6) and warrants issued in connection with the Healthcare Royalty financing agreement (see Note 6), 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, and (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 September 30, 2014 was primarily driven by the decrease in the Company's stock price at September 30, 2014 as compared against December 31, 2013 measurement dates.

(3) Embedded derivatives were measured at fair value using various discounted cash flow valuation models and were included as a component of other long-term liabilities on the consolidated balance sheet at December 31, 2013. The assumptions used in the discounted cash flow valuation models included: (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 were management’s revenue projections. Significant decreases in these significant inputs would result in a higher fair value measurement of the liability. The embedded derivatives were derecognized in May 2014 as a result of the early extinguishment of the Healthcare Royalty Financing Agreement (see Note 5).

The following table provides a reconciliation of liabilities measured at fair value using significant unobservable inputs (Level 3) for the nine months ended September 30, 2014 (in thousands):

	Common Stock Warrant Liabilities	Embedded Derivative Liabilities

Balance at December 31, 2013	$31,341	$233
Changes in fair value	(26,418)	14
Derecognition of liability	—	(247)
Exercises	$(916)	$—
Balance at September 30, 2014	$4,007	$—

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

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operations and comprehensive income (loss). The derecognition of the embedded derivative liabilities was included in the loss on early extinguishment of debt in non-operating expenses in the consolidated statements of operations and comprehensive income (loss).

Net Income (Loss) per Share

Basic net income (loss) per share is calculated by dividing the net income (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 income (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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Numerator				
Net income (loss), basic	(12,825)	(10,852)	29,108	(45,240)
Effect of dilutive securities:				
Common stock warrants	$—	$—	$(26,418)	$—
Net income (loss), diluted	$(12,825)	$(10,852)	$2,690	$(45,240)
Denominator				
Weighted average common shares outstanding, basic	141,045	104,682	140,110	102,136
Effect of dilutive securities:				
Common stock warrants	—	—	364	—
Weighted average common shares outstanding, diluted	141,045	104,682	140,474	102,136
Basic net income (loss) per share	$(0.09)	$(0.10)	$0.21	$(0.44)
Diluted net income (loss) per share	$(0.09)	$(0.10)	$0.02	$(0.44)

There were 58,000 and 9,909,000 dilutive securities (in common stock equivalent shares), from common stock options, excluded from the calculation of diluted net loss during the three and nine months ended September 30, 2014, respectively, because to include them would be anti-dilutive. There were 1,776,000 dilutive securities (in common stock equivalent shares), from common stock options and restricted stock units, excluded from the calculation of diluted net loss during the three and nine months ended September 30, 2013 because to include them would be anti-dilutive. All common stock warrants disclosed in Note 6 were excluded from the calculation of diluted net loss during the three months ended September 30, 2014 and 2013, and during the nine months ended September 30, 2013, as the exercise price of the warrants was greater than the Company's average stock price during these periods.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. As a result of the sale of its Sumavel DosePro business in May 2014, the Company recorded an impairment charge of $838,000 in the consolidated statement of operations and comprehensive income (loss) during the nine months ended September 30, 2014 related to the disposal of construction in progress that will no longer be placed into service.

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Revenue Recognition

The Company recognizes revenue from the sale of Sumavel DosePro and Zohydro ER, and from contract manufacturing, 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.

Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer. The consideration received is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. The application of the multiple element guidance requires subjective determinations, and requires the Company to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (1) the delivered item(s) has value to the customer on a stand-alone basis and (2) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in the Company's control. In determining the units of accounting, the Company evaluates certain criteria, including whether the deliverables have stand-alone value, based on the consideration of the relevant facts and circumstances for each arrangement. In addition, the Company considers whether the buyer can use the other deliverable(s) for their intended purpose without the receipt of the remaining element(s), whether the value of the deliverable is dependent on the undelivered item(s), and whether there are other vendors that can provide the undelivered element(s).

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria, as described above, are applied to each of the separate units of accounting in determining the appropriate period or pattern of recognition. The Company determines the estimated selling price for deliverables within each agreement using vendor-specific objective evidence (VSOE) of selling price, if available, third-party evidence (TPE) of selling price if VSOE is not available, or management's best estimate of selling price (BESP) if neither VSOE nor TPE is available. Determining the BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs.

Product Revenue, Net

The Company sells Zohydro ER, and sold Sumavel DosePro through May 2014, 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 recognized Sumavel DosePro product sales at the time title transferred to its customer, and reduced product sales for estimated future product returns and sales allowances in the same period the related revenue was 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 a 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

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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 Zohydro ER and Sumavel DosePro 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.

In connection with the Closing of the Asset Purchase Agreement (APA) in May 2014, whereby Endo acquired the Company's Sumavel DosePro business, Endo purchased the Company's existing finished goods inventory of Sumavel DosePro at standard cost. The Company will be financially responsible for all returns of Sumavel DosePro product distributed by the Company prior to Closing of the APA up to a maximum per unit amount as specified in the agreements. The Company will also be financially responsible for payment of Sumavel DosePro product sales allowances on product distributed by the Company prior to Closing of the APA. Endo will be responsible for payment of all other Sumavel DosePro returns and sales allowances.

Contract Manufacturing Revenue

In connection with the Closing of the APA in May 2014, the Company and Endo Ventures entered into the Supply Agreement, pursuant to which the Company retains the sole and exclusive right and the obligation to manufacture, have manufactured, supply or have supplied Sumavel DosePro to Endo Ventures (see Note 4). The Company recognizes deferred revenue related to its supply of Sumavel DosePro as contract manufacturing revenue when earned on a "proportional performance" basis, as product is delivered. The Company recognizes revenue related to its sale of Sumavel DosePro product, equal to the cost of contract manufacturing plus a 2.5% mark-up, upon the transfer of title to Endo. The Company supplies Sumavel DosePro product based on non-cancellable purchase orders. The Company initially defers revenue for any consideration received in advance of services being performed and product being delivered, and recognizes revenue pursuant to the related pattern of performance, based on total product delivered relative to the total estimated product delivery over the minimum eight year term of the Supply Agreement. The Company continually evaluates the performance period and will adjust the period of revenue recognition if circumstances change.

In addition, the Company follows the authoritative accounting guidance when reporting revenue as gross when the Company acts as a principal versus reporting revenue as net when the Company acts as an agent. For transactions in which the Company acts as a principal, has discretion to choose suppliers, bears credit risk and performs a substantive part of the services, revenue is recorded at the gross amount billed to a customer and costs associated with these reimbursements are reflected as a component of cost of sales for contract manufacturing services.

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 (FASB) 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.

In May 2014, the FASB issued new accounting guidance related to revenue recognition. This new standard will replace all current GAAP guidance on this topic and eliminate all industry-specific guidance. The new revenue recognition standard provides a unified model to determine when and how revenue is recognized. The core principle is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration

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for which the entity expects to be entitled in exchange for those goods or services. This guidance will be effective for fiscal years beginning after December 16, 2016, including interim periods within that reporting period, and can be applied either retrospectively to each period presented or as a cumulative-effect adjustment as of the date of adoption. Early adoption is prohibited. The Company is evaluating the timing and impact of adopting this new accounting standard on its financial statements and related disclosures.

In June 2014, the FASB issued new accounting guidance related to stock compensation. The new standard requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the periods for which the requisite service has already been rendered. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015 and can be applied either prospectively or retrospectively to all awards outstanding as of the beginning of the earliest annual period presented as an adjustment to opening retained earnings. Early adoption is permitted. The Company does not expect that the adoption of the guidance will have a material impact on the Company's financial statements.

In August 2014, the FASB issued new accounting guidance which requires management to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and provide related footnote disclosures. The guidance is effective for annual and interim reporting periods beginning on or after December 15, 2016. Early adoption is permitted. The Company does not expect that the adoption of the guidance will have a material impact on the Company’s financial statements.

3. Inventory (in thousands)

	September 30, 2014	December 31, 2013
Raw materials	$2,183	$2,770
Work in process	10,154	6,054
Finished goods	5,901	1,112
Deferred cost of goods sold	1,033	—
	$19,271	$9,936

Deferred cost of goods sold 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. Sale of Sumavel DosePro Business

Endo Ventures Bermuda Limited and Endo Ventures Limited Asset Purchase Agreement

On May 16, 2014, the Company closed the APA with Endo Ventures Bermuda and Endo Ventures, pursuant to which the Company sold its Sumavel DosePro business to Endo, including the registered trademarks, certain contracts, the NDA and other regulatory approvals, the books and records, marketing materials and product data relating to Sumavel DosePro. Upon Closing of the APA, Endo paid the Company $85,000,000 in cash, $8,500,000 of which was deposited into escrow to fund potential indemnification claims for a period of 12 months, and $4,624,000 in cash for the purchase of Sumavel DosePro finished goods inventory on hand at the Company's standard cost. In addition to the upfront cash payments, the Company is eligible to receive additional cash payments of up to $20,000,000 based on the achievement of pre-determined sales and gross margin milestones.

Furthermore, Endo Ventures assumed responsibility for the Company’s royalty obligation to Aradigm Corporation on sales of Sumavel DosePro.

At the Closing, the Company and Endo Ventures Bermuda entered into a license agreement (License Agreement), pursuant to which the Company granted Endo an exclusive, perpetual, sublicensable, irrevocable (unless terminated as set forth in the License Agreement), fully paid-up, royalty-free license to make and have made, use and research, develop and commercialize Sumavel DosePro throughout the world under a specified subset of the Company's

technology patents. The Company retained all rights to the DosePro technology patents and know-how for use with other products. Either party may terminate the License Agreement in the event of the other party's uncured material breach.

At the Closing, the Company and Endo Ventures entered into the Supply Agreement, pursuant to which the Company will retain the sole and exclusive right and the obligation to manufacture, have manufactured, supply or have supplied Sumavel DosePro to Endo, subject to Endo's right to qualify and maintain a back-up manufacturer. Endo will exclusively purchase all Sumavel DosePro supplied by the Company at the cost of goods sold plus a 2.5% mark-up. The Company will grant Endo a manufacturing license under certain circumstances outlined in the Supply Agreement, if Endo requires the use of a back-up supplier. Representatives from the Company and Endo will participate on a joint supply committee for general oversight and strategic functions regarding the Supply Agreement. Further, under the Supply Agreement, Endo will support the Company's Sumavel DosePro manufacturing operations with an interest-free working capital advance equivalent to the book value of the inventory of materials and unreleased finished goods held by the Company in connection with the manufacture of the Sumavel DosePro minus the accounts payable associated with such materials and unreleased finished goods, capped initially at $7,000,000 and subject to annual adjustment. The working capital advance is evidenced by a promissory note (the Note) and is secured by liens on materials and unreleased finished Sumavel DosePro inventory.

The Supply Agreement may be terminated by either party upon three years' prior written notice, provided that the notice cannot be given prior to the fifth anniversary of the Closing date. Either party may also terminate the Supply Agreement in the following circumstances: (i) if the other party breaches any material term of the agreement and fails to cure such breach within a specified time period following written notice; or (ii) upon the occurrence of certain financial difficulties. Endo Ventures also may terminate the Supply Agreement in the following circumstances: (i) if Sumavel DosePro has been deemed ineffective or unsafe by the applicable governmental authorities; or (ii) if the Company fails to supply to Endo Ventures a minimum quantity of Sumavel DosePro over the course of a six month period which results in Endo Ventures being unable to supply Sumavel DosePro to its trade customers.

Further upon Closing, the Company and Endo Ventures entered into other ancillary agreements associated with the APA, pursuant to which the Company will help facilitate the transfer of the Sumavel DosePro business to Endo Ventures, which Endo Ventures assumed responsibility for as of the Closing date. The services to be provided by the Company include assistance with co-pay/voucher programs, continuation of Zogenix Product Express services, regulatory support and processing of all payment claims made under the Company's National Drug Code. Services provided by the Company will be provided over various time periods specified in the agreements.

The Company accounted for the agreement for the sale of the Sumavel DosePro business as a sale of a business and, as such, was required to estimate the fair value of the business, including the product rights under the APA, DosePro technology license and Sumavel DosePro finished goods inventory on hand at Closing. The Company estimated the fair value of the product rights using an income approach valuation technique through a discounted cash flow method. The assumptions used in the discounted cash flow method included estimated Sumavel DosePro units to be sold in the market based on current demand forecasts, net selling price of Sumavel DosePro based on current market price, working capital needs estimated by management and a discount rate based on a market participant weighted average cost of capital.

The Company estimated the fair value of the DosePro technology license using a relief from royalty valuation method, whereby the presumed royalty savings from owning the license was estimated. The valuation considered royalty rates involving other injection technologies in the current pharmaceutical space.

The Company estimated the fair value of the Sumavel DosePro finished goods inventory on hand at Closing (which was sold to Endo at standard cost) using a market approach reflecting the estimated costs incurred by the Company in performing monitoring and quality control services on inventory supplied to Endo.

The agreements entered into concurrently with the sale of the Sumavel DosePro business, including the License Agreement and Supply Agreement, contain various elements and, as such, are deemed to be an arrangement with multiple deliverables as defined under authoritative accounting guidance (see Note 2). Several non-contingent deliverables were identified within the agreements. The Company identified the contract manufacturing services, manufacturing license, transition services and performance on joint supply committee as separate non-contingent deliverables within the arrangement. The transition services and manufacturing license have standalone value and qualify as separate units of accounting. Performance on the joint supply committee does not have standalone value from the contract manufacturing services, and as such, these two deliverables qualify as one unit of accounting. The non-contingent consideration received from the Endo agreements was allocated to these separate units of accounting,

including the sale of the Sumavel DosePro business, based on their respective fair values, using the relative selling price method.

The Company developed its BESP for each non-contingent deliverable, as VSOE and TPE was not available, in order to allocate the non-contingent arrangement consideration to the three undelivered units of accounting. The Company used a market valuation approach to develop the BESP for contract manufacturing services through the use of market rates available for comparable contract manufacturing services and consideration of internal costs of performing inventory monitoring and

quality control services. Significant increases in the hours necessary to perform inventory monitoring and quality controls services would result in a significant increase in the fair value of the contract manufacturing services.

The Company developed the BESP for the manufacturing license by estimating the total number of hours required to qualify another manufacturer, the hourly rate of internal regulatory and manufacturing employees that are required to qualify another manufacturer and the market rate for estimated cost of travel required to qualify another manufacturer. The Company developed the BESP for the transition services through use of an estimate of the total number of hours required to complete the services and the hourly rate of an internal employee that performs the services, which was compared to hourly market rates for similar consulting services. The Company developed the BESP for performance on the joint supply committee through use of an estimate of the total number of participation hours required on the committee and the hourly rate of the internal employees that participate on the joint supply committee. Significant increases in the estimated number of hours required to qualify another manufacturer, required to perform transition services, or required for performance on the joint supply committee would significantly increase the fair value of these deliverables.

The Company allocated $9,100,000 of the upfront consideration to contract manufacturing services, which includes a discount valued at $4,748,000 related to the interest free working capital advance, and an immaterial amount of the upfront consideration was allocated to the manufacturing license, transition services and performance on the joint supply committee. Revenue associated with each of the undelivered elements will be recognized when the element is delivered.

As of June 30, 2014, the Company determined that the Sumavel DosePro business, which is comprised of the product rights under the APA, DosePro technology license and Sumavel DosePro finished goods inventory purchased at Closing, had been fully delivered, and, therefore representing control of the business obtained by Endo. As such, a gain on sale of business of $79,980,000, net of $660,000 in related transaction costs, was recognized for the sale of the Sumavel DosePro business in the consolidated statement of operations and comprehensive income (loss) for the three and nine months ended September 30, 2014.

Based on the Sumavel DosePro finished goods inventory delivered and the contract manufacturing services performed, as measured using a proportional performance method, during the three and nine months ended September 30, 2014 a total of $4,225,000 and $6,463,000, respectively, was recognized as contract manufacturing revenue in the statement of operations and comprehensive income (loss). An immaterial amount of revenue was recognized for performance of transition services and performance on the joint supply committee during the three and nine months ended September 30, 2014.

As of September 30, 2014, the Company had $8,863,000 remaining in deferred revenue attributed to the Endo arrangement.

The $79,980,000 gain on sale of Sumavel DosePro business was calculated as the difference between the allocated non-contingent consideration amount for the business and the net carrying amount of the assets transferred to Endo. The following sets forth the net assets and calculation of the gain on sale as of Closing (in thousands):

Non-contingent consideration received	$89,624
Imputed interest on working capital advance	4,748
Carrying value of Sumavel DosePro inventory on hand at Closing	(4,624)
Transaction costs	(660)
Deferred revenue associated with undelivered elements	(9,108)
Net gain on sale of business	$79,980

The net gain on sale of business may be adjusted in future periods by the contingent consideration, of up to $20,000,000, based upon the achievement of pre-determined sales and gross margin milestones. Any future adjustment of the net gain on sale of business will be determined through use of the relative selling price method.

Further, as noted above, Endo Ventures provided the Company with an interest-free working capital advance upon Closing. The working capital advance of $7,000,000, which is evidenced by the Note, was recorded as a note payable on the consolidated balance sheet at Closing, net of a $4,748,000 debt discount. The fair value of the debt discount was established using a market approach, including an interest rate reflecting recent term sheets provided to the Company for offerings of debt instruments, interest rates on the Company's most recent debt instruments, and market interest rates on similar debt instruments. The debt discount will be amortized as interest expense using the effective

interest method over the minimum eight year term of the Supply Agreement, as the working capital advance must be repaid upon termination of the Supply Agreement. The Company recognized $83,000 and $123,000 of interest expense during the three and nine months ended September 30, 2014, respectively, related to the working capital advance from Endo.

The sale of the Sumavel DosePro business does not qualify as discontinued operations as the Company will have significant continuing involvement in the business as the exclusive supplier of Sumavel DosePro over the term of the Supply Agreement.

5. Collaboration and Financing Agreements

Daravita Ltd License Agreement

In 2007, the Company entered into a license agreement (the Daravita License Agreement) with Daravita Limited (Daravita), formerly Alkermes Pharma Ireland Limited, which was amended in 2009 and then again on September 12, 2014. Under the terms of the Daravita License Agreement, Daravita granted the Company an exclusive license in the United States and its possessions and territories, with defined sub-license rights to third parties other than certain technological competitors of Daravita, to certain Daravita intellectual property rights related to Zohydro ER. The Daravita License Agreement grants the Company the exclusive right under certain Daravita patents and patent applications to import, use, offer for sale and sell oral controlled-release capsule or tablet formulations of hydrocodone, where hydrocodone is the sole active ingredient, for oral prescriptions in the treatment or relief of pain, pain syndromes or pain associated with medical conditions or procedures in the United States. This right enables the Company to exclusively develop and sell Zohydro ER in the United States. Daravita has retained the exclusive right to take action in the event of infringement or threatened infringement by a third party of Daravita's intellectual property rights under the Daravita License Agreement. The Company has the right to pursue an infringement claim against the alleged infringer should Daravita decline to take or continue an action.

Under the Daravita License Agreement, the Company paid an upfront fee of $500,000 to Daravita, which was recorded as research and development expense. The Company paid additional milestone payments in the amount of $750,000 to Daravita in August 2011 in connection with the completion of the treatment phase of the Company’s pivotal efficacy Phase 3 clinical trial, Study 801, and $1,000,000 upon submission of the first Zohydro ER NDA to the FDA in May 2012, which were recorded as research and development expense. Lastly, the Company paid a milestone payment of $2,750,000 upon the first NDA approval of Zohydro ER in October 2013, which was recorded as other assets in the consolidated balance sheet and is being amortized over the estimated life of the technology, through November 2019.

In addition, the Company is required to pay a mid single-digit percentage royalty on net sales of the product for an initial royalty term equal to the longer of the expiration of Daravita’s patents covering the product in the United States, or 15 years after commercial launch, if Daravita does not have patents covering the product in the United States. After the initial royalty term, the Daravita License Agreement will continue automatically for three-year rolling periods during which the Company will continue to pay royalties to Daravita on net sales of the product at a reduced low single-digit percentage rate in accordance with the terms of the Daravita License Agreement.

Under the terms of the Daravita License Agreement, the Company and Daravita agreed that, subject to a separate commercial manufacturing and supply agreement entered into by the Company and Daravita in November 2012, Daravita is the exclusive manufacturer and supplier to the Company of Zohydro ER, subject to certain exceptions. Daravita also granted to the Company, in the event that Daravita is unwilling or unable to manufacture or supply commercial product to the Company, a non-exclusive license to make product under Daravita's intellectual property rights. This non-exclusive license also includes the right to sublicense product manufacturing to a third party, other than certain technological competitors of Daravita.

On September 12, 2014, the Company and Daravita entered into a third amendment (Third Amendment) to the Daravita License Agreement. Pursuant to the Third Amendment, the Company may exercise its option to obtain an exclusive license to certain abuse-deterrent technology and know-how from Altus Formulation Inc. (Altus) (pursuant to that certain Development and Option Agreement, dated November 1, 2013, by and between the Company and Altus). Following such exercise and the first commercial sale by the Company, its affiliates or any of its permitted sublicensees of any extended-release formulations of hydrocodone using Altus’ abuse-deterrent technology (Altus Product), Daravita will be entitled to receive from the Company a royalty on net sales of Altus Product through the date that is 15 years following the first commercial sale of the Altus Product in the United States and its possessions and territories. Prior to December 31, 2019, such royalty will be (i) in the mid single-digits if Daravita or an affiliate is the manufacturer of the Altus Product or (ii) in the low twenty-percent-range if Daravita or an affiliate is not the

manufacturer of the Altus Product. After December 31, 2019, such royalty will be in the high single digits, regardless of whether Daravita or an affiliate is the manufacturer. Neither the Company nor Daravita shall be obligated to have Daravita or an affiliate manufacture commercial supplies of Altus Product for the Company. No monetary value was exchanged in connection with the Third Amendment during the three and nine months ended September 30, 2014. Either party may terminate the Daravita License Agreement upon a material, uncured default or certain insolvency events of the other party or upon 12 months written notice prior to the end of the initial royalty term or any additional three-year

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rolling period. The Company may also terminate the Daravita License Agreement, with or without cause, at any point in time upon 12 months' prior written notice, or if the sale of Zohydro ER is prohibited by regulatory authorities.

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), which was originally scheduled to terminate on June 30, 2014. 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.

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. Amounts payable to Mallinckrodt for service fees are reflected as selling, general and administrative expenses. For the three and nine months ended September 30, 2014, the Company incurred $0 and $100,000, respectively, in service fee expenses under the Co-Promotion Agreement, excluding the tail-payment expense discussed below. For the three and nine months ended September 30, 2013, the Company incurred $249,000 and $618,000, respectively, in service fee expenses under the Co-Promotion Agreement.

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. An initial liability of $491,000 for this estimated tail payment was recorded as service fee expense in selling, general and administrative expenses in the statement of operations upon the Co-Promotion Agreement termination in January 2014. This estimated tail payment liability was adjusted based on actual year-to-date net sales through September 30, 2014, which resulted in a credit of $321,000 to service fee expense in selling, general and administrative expenses in the statement of operations during the three and nine months ended September 30, 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 12 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.

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

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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 and nine months ended September 30, 2014, the Company recognized service revenue of $446,000 and $2,427,000, respectively, under the Valeant Agreement. For the three and nine months ended September 30, 2013, the Company recognized service revenue of $232,000 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 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 and the second tail payment of $1,218,000 was made in July 2014. The Company recognized $0 and $40,000 of related interest expense during the three months ended September 30, 2014 and 2013, respectively, and recognized $87,000 and $327,000 of related interest expense during the nine months ended September 30, 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. The Financing Agreement was originally scheduled to terminate on March 31, 2018, but Healthcare Royalty exercised its right to early terminate the Financing Agreement on May 16, 2014, as discussed below.

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 was obligated to pay to Healthcare Royalty:

- 5% to 5.75% of the first $75,000,000 of Revenue Interest recorded (in the case of net product sales) or received (in the case of co-promotion revenues and license fees) by the Company in a calendar year (initially 5% and then 5.75% after the co-promotion agreement with Astellas terminated on March 31, 2012);
- 2.5% of the next $75,000,000 of Revenue Interest recorded (in the case of net product sales) or received (in the case of co-promotion revenues and license fees) by the Company in a calendar year; and

- 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.

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Net sales of Sumavel DosePro outside the United States were only included in the Revenue Interest if such net sales exceeded $10,000,000. The Company was 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.

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's security interest was extinguished upon early termination of the Financing Agreement on May 16, 2014.

The Company had 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 generated 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 had 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.

Healthcare Royalty exercised its option to terminate the Financing Agreement in connection with the Company's sale of the Sumavel DosePro business to Endo on May 16, 2014. Upon termination of the Financing Agreement by Healthcare Royalty, the Company was obligated to make a final payment (Final Payment) of $40,041,000 to Healthcare Royalty, which was an amount that generated a 17% internal rate of return on the Borrowed Amount as of the date of prepayment, reduced by the Revenue Interest and principal payments received by Healthcare Royalty up to the date of Final Payment. The Company no longer has any further payment obligations under the Financing Agreement after the Final Payment was made.

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, met 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 December 31, 2013 was $233,000 and is included in other long-term liabilities. The fair value of the embedded derivatives of $247,000 was derecognized upon termination of the Financing Agreement on May 16, 2014 and is included in the loss on early extinguishment of debt in the statement of operations and comprehensive income (loss) for the nine months ended September 30, 2014.

The Company received aggregate net proceeds of $29,485,000 from the Financing Agreement (including the purchase of common stock). The discounts, which were 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 $125,000 and $397,000 for the three and nine months ended September 30, 2014, respectively, and $(8,000) and $(43,000) for the three and nine months ended September 30, 2013, respectively, in the statement of operations and comprehensive income (loss). The Company has recognized other income in relation to the change in the fair value of the embedded derivatives of $0 and $14,000 for the three and nine months ended September 30, 2014, respectively, and $1,474,000 and $912,000 for the three and nine months ended September 30, 2013, respectively, in the statement of operations and comprehensive income (loss).

Upon early termination of the Financing Agreement on May 16, 2014, and the Company's Final Payment to Healthcare Royalty, the Company determined that the early termination resulted in an extinguishment of the outstanding debt and recognized a loss on early extinguishment of debt of $1,254,000 which was recorded as non-operating expenses in the statement of operations and comprehensive income (loss). The loss on early

extinguishment of debt is related to the write-off of the unamortized balances of the debt discounts (which includes derecognition of the embedded derivative liabilities, as discussed above), debt acquisition costs, and accrued interest expenses related to the Financing Agreement.

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6. Common Stock Warrants

In July 2012, in connection with a public offering of common stock and warrants, the Company sold warrants to purchase 15,784,200 shares of common stock (including over-allotment purchase). The warrants 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 recorded as a current liability and are marked to market at each reporting period (see Note 2). During the nine months ended September 30, 2014, warrants to purchase 465,250 shares of common stock were exercised, and during the year ended December 31, 2013, warrants to purchase 103,500 shares of common stock were exercised. The Company recognized $1,163,000 and $259,000 in proceeds from the exercise of warrants during the nine months ended September 30, 2014 and during the year ended December 31, 2013, respectively. There were no warrants exercised during the three months ended September 30, 2014. The fair value of the warrants outstanding was approximately $3,912,000 and $30,849,000 as of September 30, 2014 and December 31, 2013, respectively.

In July 2011, upon the closing of and in connection with the Financing Agreement (see Note 5), 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 $95,000 and $492,000 as of September 30, 2014 and December 31, 2013, respectively.

7. Operating Lease

On August 5, 2014, the Company entered into a new operating lease (the Lease) for approximately 17,361 rentable square feet of office space located in San Diego, California. The Company intends to use the leased premises as its corporate headquarters, and the new lease is expected to commence on December 1, 2014 upon expiration of the Company's current San Diego office sublease of approximately 13,124 rentable square feet in the same location. The Lease term will expire 64 months after the Lease commencement date with an option to renew the Lease for an additional five years. The initial base rent will be $73,784 per month, with 100% of rent being abated for the second, third, fourth and fifth months of the Lease term and 50% of rent being abated for the sixth month of the Lease term. The base rent will increase approximately 3.25% on a yearly basis throughout the Lease term. The Lease also requires the Company to pay additional rent consisting of a portion of common area and pass-through expenses in excess of base year amounts. The Company will begin to amortize rent expense related to this operating lease using a straight-line method when it gains access to the new leased space, which had not occurred as of September 30, 2014. Further, under the Lease, the landlord will provide up to $382,000 in a tenant improvements allowance to support interior improvements for the rented space. The tenant improvements will be capitalized by the Company as the improvements are made.

8. Stock-Based Compensation

The Company uses the Black-Scholes option-pricing model for determining the estimated fair value of stock-based compensation for stock-based awards to employees and the board of directors. The assumptions used in the Black-Scholes option-pricing model for the three and nine months ended September 30, 2014 and 2013 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Risk free interest rate	2.0%	1.5% to 1.7%	1.6% to 2.0%	0.8% to 1.7%
Expected term	6.1 years	5.1 to 6.0 years	5.1 to 6.1 years	5.0 to 6.1 years
Expected volatility	83.8%	82.8% to 83.9%	83.8% to 84.9%	82.8% 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Cost of goods sold	$101	$119	$369	$227
Research and development	262	316	983	782
Selling, general and administrative	1,679	1,780	5,982	4,570
Restructuring	—	—	—	201
Total	$2,042	$2,215	$7,334	$5,780

As of September 30, 2014, there was approximately $15,079,000 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 2.6 years.

As of September 30, 2014, there were 181,000 unvested stock options outstanding to consultants, with approximately $151,000 of related unrecognized compensation expense based on a September 30, 2014 measurement date. These unvested stock options outstanding to consultants are expected to vest over a weighted average period of 2.2 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 income recognized from the valuation of stock options and restricted stock units to consultants was $80,000 and $230,000 for the three and nine months ended September 30, 2014, respectively, and was immaterial for the three and nine months ended September 30, 2013. Stock option expense for awards issued to consultants is included in the consolidated statement of operations and comprehensive income (loss) within selling, general and administrative expense.

9. Subsequent Events

Brabant Pharma Limited Sales and Purchase Agreement

On October 24, 2014, Zogenix Europe acquired Brabant, pursuant to the terms of the Sale and Purchase Agreement dated October 24, 2014, by and among Zogenix Europe, the Company, Brabant and Anthony Clarke, Richard Stewart, Ann Soenen-Darcis, Jennifer Watson, Reyker Nominees Limited and Aquarius Life Science Limited (collectively, the Sellers). In connection with the consummation of the transactions on October 24, 2014 (the closing) contemplated by the Sale and Purchase Agreement, Zogenix Europe purchased the issued share capital of Brabant from the Sellers (the Acquisition) and the Company agreed to guarantee the obligations, commitments, undertakings and warranties of Zogenix Europe. Brabant owns worldwide development and commercialization rights to Brabafen, low-dose fenfluramine, for the treatment of Dravet syndrome (also known as Severe Myoclonic Epilepsy of Infancy). Dravet syndrome is a rare and catastrophic form of pediatric epilepsy with life threatening consequences for patients and current treatment options are very limited. Brabafen has recently received orphan drug designation in Europe and the United States for the treatment of Dravet syndrome.

Under the terms of the Sale and Purchase Agreement, at the closing Zogenix Europe paid to the Sellers consideration of (i) $20,000,000 in cash (plus $8,432,000 which represents the net cash position of Brabant at the closing), of which $2,000,000 (the escrow amount) will be deposited into escrow to fund potential indemnification claims for a period of 6 months, and (ii) 11,995,202 shares (the Shares) of the Company’s common stock. Zogenix Europe also committed to paying up to an aggregate amount of $95,000,000 in connection with the achievement of certain milestones for Brabafen, including $50,000,000 in regulatory milestones and $45,000,000 in sales milestones. The Company has agreed to use commercially reasonable efforts (as defined in the Sale and Purchase Agreement) to develop and commercialize Brabafen and to achieve the milestones.

In September 2012, Brabant entered into a collaboration and license agreement with the Universities of Antwerp and Leuven in Belgium (the Universities), which was amended and restated in October 2014. Under the terms of the agreement, the Universities granted Brabant an exclusive worldwide license to use the data obtained from the study, as well as certain intellectual property related to fenfluramine for the treatment of Dravet syndrome. Brabant is required

to pay a mid single-digit percentage royalty on net sales of fenfluramine for the treatment of Dravet syndrome or, in the case of a sublicense of fenfluramine for the treatment of Dravet syndrome, a percentage in the mid-twenties of the sub-licensing revenues. The agreement terminates in September 2020; however, upon the commencement of Phase 3 clinical trials of fenfluramine or marketing approval by a regulatory authority, the agreement will be extended until September 2045. The agreement may be

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terminated by the Universities if Brabant: (a) does not use commercially reasonable efforts to (i) develop and commercialize fenfluramine for the treatment of Dravet syndrome or related conditions stemming from infantile epilepsy, or (ii) seek approval of fenfluramine for the treatment of Dravet syndrome in the United States; or (b) if Brabant becomes insolvent, shall make an assignment for the benefit of creditors, or shall have a petition in bankruptcy filed for or against it or for any similar relief has been filed against it. Brabant can terminate the agreement upon specified prior written notice to the Universities.

Both Zogenix Europe and the Sellers agreed to customary warranties and covenants in the Sale and Purchase Agreement. The Sellers agreed to indemnify Zogenix Europe for certain matters, including breaches of warranties and covenants included in the Sale and Purchase Agreement, up to the escrow amount, subject to limited exceptions.

Pursuant to the Sale and Purchase Agreement, the Company has agreed to prepare and file a registration statement on Form S-3 covering the resale of the Shares issued to the Sellers within 90 days of the closing and to use commercially reasonable efforts to cause such registration statement to be declared effective as promptly as practicable following the filing.

The Company will complete its accounting for this business combination during the fourth quarter of 2014.

Purdue Pharma L.P. Waiver Agreement

On October 29, 2014, the Company entered into a waiver agreement (the Waiver Agreement) with Purdue Pharma L.P. (Purdue) pursuant to which the Company granted a waiver to Purdue of the three-year Hatch-Waxman regulatory exclusivity period with respect to NDA 202880 for Zohydro ER in support of Purdue's single-entity, extended-release hydrocodone product which is the subject of pending NDA 206627 and any single-entity, once-daily hydrocodone successor products or NDAs filed by Purdue (the Purdue Products). In addition, Purdue granted the Company a waiver of the Hatch-Waxman regulatory exclusivity period with respect to Purdue Products in support of our single-entity, twice-a-day hydrocodone product, including Zohydro ER and any successor products with any abuse deterrent properties or labeling claims. Under the terms of the Waiver Agreement, Purdue will pay to the Company (i) $5,000,000 within fifteen (15) days of the date of the Waiver Agreement, (ii) $5,000,000 on July 1, 2015, and (iii) a percentage royalty in the low single-digits on Purdue's net sales of Purdue Product commencing on October 1, 2015 and ending on October 25, 2016, only to the extent such royalty payment by Purdue in the aggregate would exceed $5,000,000 and then only with respect to royalties in excess of such amount.

Teva Letter Agreement

On November 5, 2014, the Company entered into a letter agreement (the Letter Agreement) with Teva Pharmaceuticals USA, Inc. (Teva), under which the Comapny granted Teva a right of reference to certain carcinogenicity data generated by the Company for hydrocodone bitrate for use in connection with Teva's NDA for its extended-release hydrocodone product candidate. Teva is obligated to pay the Company a one-time fee of $3,500,000 within 30 days of the date of the Letter Agreement.

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

Forward-Looking Statements

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

- our ability to successfully execute our sales and marketing strategy for the commercialization of Zohydro ER;
- the potential for the FDA to approve the sNDA for a modified formulation of Zohydro ER that was designed to have abuse deterrent properties;
- the progress and timing of clinical trials for Relday, Brabafen and our other product candidates;
- our ability to receive contingent milestone payments from the sale of the Sumavel DosePro business to Endo Health Solutions, Inc.;
- adverse side effects or inadequate therapeutic efficacy of 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 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 additional formulation of Zohydro ER with abuse deterrent properties;
- 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 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 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.

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

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "Zogenix," "we," "us" and "our" refer to Zogenix, Inc., including, its consolidated subsidiaries.

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. Zohydro ER has the potential to address significant unmet medical needs and become an important and widely-used addition to the treatment options available to patients and physicians in the United States' multi-billion dollar chronic pain market.

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. On April 23, 2014, we entered into an asset purchase agreement, or the APA, with Endo Ventures Bermuda Limited, or Endo Ventures Bermuda, and Endo Ventures Limited, or Endo Ventures and, together with Endo Ventures Bermuda, Endo, pursuant to which, and on the terms and subject to the conditions thereof, among other things, we agreed to sell our Sumavel DosePro business to Endo, 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. The APA closed on May 16, 2014 and, in connection with this closing, we and Endo Ventures also entered into a supply agreement pursuant to which we have retained the sole and exclusive right and the obligation to manufacture, have manufactured, supply or have supplied Sumavel DosePro to Endo Ventures, subject to Endo Venture's right to qualify and maintain a back-up manufacturer.

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 January of 2015.

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

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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 September 30, 2014, had an accumulated deficit of $381.1 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, including introduction of Zohydro ER with abuse deterrent properties to the market, if approved, the clinical development for Relday and Brabafen (our recently acquired product candidate), required post-market testing for Zohydro ER, safe use initiatives for Zohydro ER and additional development activities with respect to Zohydro ER, including the development of multiple formulations of extended-release hydrocodone with abuse deterrent properties. As of September 30, 2014, we had cash and cash equivalents of $50.5 million.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of September 30, 2014, the $8.5 million of the upfront cash payment received from the sale of our Sumavel DosePro business that is included in restricted cash, our projected product revenues from Zohydro ER, the $10.0 million in payments for the waiver granted to Purdue Pharma L.P., or Purdue, due by July 1, 2015, and our projected manufacturing and other service revenues will be sufficient to fund our operations into the thrid quarter of 2015. Our cash and cash equivalents as of September 30, 2014 exclude the $20.0 million cash payment made to the Sellers in connection with our acquisition of Brabant. We may pursue additional opportunities to raise capital, if necessary, through public or private equity offerings, including through our controlled equity offering program, debt financings, receivables financings or through collaborations or partnerships with other companies. If we are unsuccessful in raising additional required funds, we may be required to significantly delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts, or cease operating as a going concern. We also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available. In its report on our consolidated financial statements for the year ended December 31, 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

Brabant Pharma Limited Sales and Purchase Agreement

On October 24, 2014, Zogenix Europe Limited, or Zogenix Europe, our wholly-owned subsidiary, acquired Brabant Pharma Limited, or Brabant, a privately-held company organized under the laws of England and Wales, pursuant to the terms of a Sale and Purchase Agreement, or the Sale and Purchase Agreement, dated October 24, 2014 by and among us, Brabant and Anthony Clarke, Richard Stewart, Ann Soenen-Darcis, Jennifer Watson, Reyker Nominees Limited and Aquarius Life Science Limited (collectively, the Sellers). Brabant owns worldwide development and commercialization rights to Brabafen, low-dose fenfluramine, for the treatment of Dravet syndrome (also known as Severe Myoclonic Epilepsy of Infancy). Dravet syndrome is a rare and catastrophic form of pediatric epilepsy with life threatening consequences for patients and current treatment options are very limited. Brabafen has recently received orphan drug designation in Europe and the United States for the treatment of Dravet syndrome.

Under the terms of the Sale and Purchase Agreement, at the closing we paid to the Sellers consideration of (i) $20.0 million in cash (plus $8.4 million which represents the net cash position of Brabant at the closing), of which $2.0 million (the escrow amount) was deposited into escrow to fund potential indemnification claims for a period of 6 months, and (ii) 11,995,202 shares (the Shares) of our common stock. We also committed to paying up to an aggregate amount of $95.0 million in connection with the achievement of certain milestones for Brabafen, including $50.0 million in regulatory milestones and $45.0 million in sales milestones. We have agreed to use commercially reasonable efforts (as defined in the Sale and Purchase Agreement) to develop and commercialize Brabafen and to achieve the milestones.

The safety and effectiveness of Brabafen has been evaluated in a continuing, long-term, open-label, study in 15 Dravet syndrome patients (the study). The average duration of treatment in the study is currently more than 12 years, with the longest duration of treatment at more than 26 years. More than two-thirds (67%) of patients were seizure free for at least a year after the latest assessment with an average seizure free period of 5.5 years. The majority (87%) of patients

had a greater than 75% reduction in seizure frequency. Brabafen was shown to be well tolerated in the study, and treatment side effects were mild and transient for the entire study treatment period. There were no reports of pulmonary hypertension and there were no deaths. Two patients showed sub-clinical evidence of cardiac valve thickening that was judged to be clinically insignificant following detailed investigation by independent cardiologists. Similar findings spontaneously resolved in a third patient. Based upon feedback from the FDA and the European Medicines Agency, we expect to initiate two Phase 3 studies (of 40 to 60 Dravet

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syndrome patients per study) during the second quarter of 2015 in the United States and Europe, with top-line results potentially available in the first half of 2016.

In September 2012, Brabant entered into a collaboration and license agreement with the Universities of Antwerp and Leuven in Belgium (the Universities), which was amended and restated in October 2014. Under the terms of the agreement, the Universities granted Brabant an exclusive worldwide license to use the data obtained from the study, as well as certain intellectual property related to fenfluramine for the treatment of Dravet syndrome. Brabant is required to pay a mid single-digit percentage royalty on net sales of fenfluramine for the treatment of Dravet syndrome or, in the case of a sublicense of fenfluramine for the treatment of Dravet syndrome, a percentage in the mid-twenties of the sub-licensing revenues. The agreement terminates in September 2020; however, upon the commencement of Phase 3 clinical trials of fenfluramine or marketing approval by a regulatory authority, the agreement will be extended until September 2045. The agreement may be terminated by the Universities if Brabant: (a) does not use commercially reasonable efforts to (i) develop and commercialize fenfluramine for the treatment of Dravet syndrome or related conditions stemming from infantile epilepsy, or (ii) seek approval of fenfluramine for the treatment of Dravet syndrome in the United States; or (b) if Brabant becomes insolvent, shall make an assignment for the benefit of creditors, or shall have a petition in bankruptcy filed for or against it or for any similar relief has been filed against it. Brabant can terminate the agreement upon specified prior written notice to the Universities.

Purdue Pharma L.P. Waiver Agreement

On October 29, 2014, we entered into a waiver agreement with Purdue, pursuant to which we granted a waiver to Purdue of the three-year Hatch-Waxman regulatory exclusivity period with respect to NDA 202880 for Zohydro ER in support of Purdue's single-entity, extended-release hydrocodone product which is the subject of pending NDA 206627 and any single-entity, once-daily hydrocodone successor products or NDAs filed by Purdue, or the Purdue Products. In addition, Purdue granted us a waiver of the Hatch-Waxman regulatory exclusivity period with respect to Purdue Products in support of our single-entity, twice-a-day hydrocodone product, including Zohydro ER and any successor products with any abuse deterrent properties or labeling claims. Under the terms of the Agreement, Purdue will pay to Zogenix (i) $5.0 million within fifteen (15) days of the date of the agreement, (ii) $5.0 million on July 1, 2015, and (iii) a percentage royalty in the low single-digits on Purdue's net sales of Purdue Product commencing on October 1, 2015 and ending on October 25, 2016, only to the extent such royalty payment by Purdue in the aggregate would exceed $5.0 million and then only with respect to royalties in excess of such amount.

Teva Letter Agreement

On November 5, 2014, we entered into a letter agreement with Teva Pharmaceuticals USA, Inc., or Teva, under which we granted Teva a right of reference to certain carcinogenicity data generated by us for hydrocodone bitrate for use in connection with Teva's NDA for its extended-release hydrocodone product candidate. Teva is obligated to pay us a one-time fee of $3.5 million within 30 days of the date of the letter agreement.

Cantor Controlled Equity Offering Sales Agreement

On November 6, 2014, we entered into a controlled equity offering sales agreement with Cantor Fitzgerald & Co., or Cantor, as sales agent, under which we can issue and sell shares of our common stock having an aggregate offering price of up to $25.0 million from time to time through Cantor. The sales of common stock made under the controlled equity offering sales agreement will be made in "at-the-market" offerings as defined in Rule 415 of the Securities Act of 1933, as amended, or the Securities Act. However, there can be no assurance that Cantor will be successful in consummating such sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate.

Daravita Ltd License Agreement

In 2007, we entered into a license agreement, or the License Agreement, with Daravita Limited formerly Alkermes Pharma Ireland Limited, which was amended in 2009 and then again on September 12, 2014. Under the terms of the License Agreement, Daravita granted us an exclusive license in the United States and its possessions and territories, with defined sub-license rights to third parties other than certain technological competitors of Daravita, to certain Daravita intellectual property rights related to Zohydro ER. The License Agreement grants us the exclusive right under certain Daravita patents and patent applications to import, use, offer for sale and sell oral controlled-release capsule or tablet formulations of hydrocodone, where hydrocodone is the sole active ingredient, for oral prescriptions

in the treatment or relief of pain, pain syndromes or pain associated with medical conditions or procedures in the United States. This right enables us to exclusively develop and sell Zohydro ER in the United States.

On September 12, 2014, we entered into a third amendment, or the Third Amendment, to the License Agreement with Daravita. Pursuant to the Third Amendment, we may exercise our option to obtain an exclusive license to certain abuse-

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deterrent technology and know-how from Altus Formulation Inc., or Altus, (pursuant to that certain Development and Option Agreement, dated November 1, 2013, by and between us and Altus). Following such exercise and the first commercial sale by us, our affiliates or any of our permitted sublicensees of any extended-release formulations of hydrocodone using Altus' abuse-deterrent technology, or the Altus Product, Daravita will be entitled to receive from us a royalty on net sales of Altus Product through the date that is 15 years following the first commercial sale of the Altus Product in the United States and its possessions and territories. Prior to December 31, 2019, such royalty will be (i) in the mid single-digits if Daravita or an affiliate is the manufacturer of the Altus Product or (ii) in the low twenty-percent-range if Daravita or an affiliate is not the manufacturer of the Altus Product. After December 31, 2019, such royalty will be in the high single digits, regardless of whether Daravita or an affiliate is the manufacturer. Neither we nor Daravita shall be obligated to have Daravita or an affiliate manufacture commercial supplies of Altus Product for us.

Either party may terminate the License Agreement upon a material, uncured default or certain insolvency events of the other party or upon 12 months written notice prior to the end of the initial royalty term or any additional three-year rolling period. We may also terminate the License Agreement, with or without cause, at any point in time upon 12 months' prior written notice, or if the sale of Zohydro ER is prohibited by regulatory authorities.

Endo Ventures Bermuda Limited and Endo Ventures Limited Asset Purchase Agreement

On April 23, 2014, we entered into the APA with Endo, pursuant to which, and on the terms and subject to the conditions thereof, among other things, we agreed to sell our Sumavel DosePro business to Endo, including the registered trademarks, certain contracts, the NDA and other regulatory approvals, the books and records, marketing materials and product data relating to Sumavel DosePro. Under the terms of the APA, Endo paid us $85.0 million in cash upon closing on May 16, 2014, or the Closing, $8.5 million of which was deposited into escrow to fund potential indemnification claims for a period of 12 months. Further upon the Closing, Endo Ventures purchased from us our finished goods inventory of Sumavel DosePro for $4.6 million. 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 gross margin 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.

Upon the Closing, we and Endo Ventures Bermuda entered into a license agreement, pursuant to which we granted Endo Ventures an exclusive, worldwide, royalty-free license to make and have made, use and research, develop and commercialize Sumavel DosePro. Upon Closing we also entered 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. Lastly upon Closing, we entered into other ancillary agreements with Endo Ventures associated with the APA, pursuant to which we will help facilitate the transfer of the Sumavel DosePro business to Endo Ventures, which Endo Ventures will assume responsibility for as of the Closing date.

In connection with the Closing, we were required to extinguish all encumbrances on the assets to be sold to Endo, 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 eliminated our existing debt obligation to Healthcare Royalty on May 16, 2014 by paying $40.0 million to Healthcare Royalty, consistent with the terms of the Healthcare Royalty financing agreement.

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. An initial liability of $0.5 million for this estimated tail-payment was recorded as service fee expense upon the co-promotion agreement termination in January 2014. This estimated tail payment liability was adjusted based on actual year-to-date net sales through September 30, 2014, which resulted in a credit of $0.3 million to service fee expense during the three and nine months ended September 30, 2014.

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For the three and nine months ended September 30, 2014, we incurred service fee expenses of $0 and $0.1 million, respectively, excluding the tail-payment expense. For the three and nine months ended September 30, 2013, we incurred service fee expenses of $0.2 million and $0.6 million, respectively.

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 and nine months ended September 30, 2014, we recognized service revenue of $0.4 million and $2.4 million, respectively, under the Valeant agreement. For the three and nine months ended September 30, 2013, we recognized service revenue of $0.2 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 contract manufacturing, 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.

Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer. The consideration received is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. The application of the multiple element guidance requires subjective determinations, and requires us to make judgments about the individual deliverables, and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (1) the delivered item(s) has value to the customer on a stand-alone basis and (2) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. In determining the units of accounting, we

evaluate certain criteria, including whether the deliverables have stand-alone value, based on the consideration of the relevant facts and circumstances for each arrangement, such as the commercialization capabilities of the buyer and the availability of the associated expertise in the general marketplace. In addition, we consider whether the buyer can use the other deliverable(s) for their intended purpose without the receipt of the remaining element(s), whether the value of the deliverable is dependent on the undelivered item(s), and whether there are other vendors that can provide the undelivered element(s).

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Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria, as described above, are applied to each of the separate units of accounting in determining the appropriate period or pattern of recognition. We determine the estimated selling price for deliverables within each agreement using vendor-specific objective evidence, or VSOE, of selling price, if available, third-party evidence, or TPE, of selling price if VSOE is not available, or management's best estimate of selling price, or BESP, if neither VSOE nor TPE is available. Determining the BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, we consider applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs.

Product Revenue, Net

We sell Zohydro ER, and sold Sumavel DosePro through May 2014, 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 recognized Sumavel DosePro product sales at the time title transferred to our customer, and reduced product sales for estimated future product returns and sales allowances in the same period the related revenue was 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 we 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 Zohydro ER and Sumavel DosePro 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 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.

In connection with the Closing of the APA in May 2014, whereby Endo acquired our Sumavel DosePro business, Endo purchased our existing finished goods inventory of Sumavel DosePro. We will be financially responsible for all returns of Sumavel DosePro product distributed by us prior to the Closing of the APA up to a maximum per unit amount as specified in the agreements. We will also be financially responsible for payment of Sumavel DosePro product sales allowances on product distributed by us prior to the Closing of the APA. Endo will be responsible for payment of all other Sumavel DosePro returns and sales allowances.

Contract Manufacturing Revenue

In connection with the Closing of the APA in May 2014, we and Endo Ventures entered into the Supply Agreement, pursuant to which we retained the sole and exclusive right and the obligation to manufacture, have manufactured, supply or have supplied Sumavel DosePro to Endo Ventures. We recognize deferred revenue related to our supply of Sumavel DosePro as contract manufacturing revenue when earned on a "proportional performance" basis, as product is delivered. We recognize revenue related to our sale of Sumavel DosePro product, equal to the cost of contract

manufacturing plus a 2.5% mark-up, upon the transfer of title to Endo. We supply Sumavel DosePro product based on non-cancellable purchase orders. We initially defer revenue for any consideration received in advance of services being performed and product being delivered, and recognize revenue pursuant to the related pattern of performance, based on total product delivered relative to the total estimated product delivery over the minimum eight year term of the Supply Agreement. We continually evaluate the performance period and will adjust the period of revenue recognition if circumstances change.

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In addition, we follow the authoritative accounting guidance when reporting revenue as gross when we act as a principal versus reporting revenue as net when we act as an agent. For transactions in which we act as a principal, have discretion to choose suppliers, bear credit risk and perform a substantive part of the services, revenue is recorded at the gross amount billed to a customer and costs associated with these reimbursements are reflected as a component of cost of sales for contract manufacturing services.

There have been no other significant changes in critical accounting policies during the nine months ended September 30, 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 and nine months ended September 30, 2014 and 2013

Revenue. Revenue for the three months ended September 30, 2014 and 2013 was $8.8 million and $7.2 million, respectively. Revenue for the nine months ended September 30, 2014 and 2013 was $25.6 million and $23.1 million, respectively.

Net product revenue for the three months ended September 30, 2014 and 2013 was $4.1 million and $6.9 million, respectively. Net product revenue for the nine months ended September 30, 2014 and 2013 was $16.7 million and $22.7 million, respectively. The aggregate $2.8 million, or 40%, decrease in net product revenue during the three months ended September 30, 2014 compared to 2013, and the aggregate $6.0 million, or 27%, decrease in net product revenue during the nine months ended September 30, 2014 compared to 2013, was primarily due to the decline in Sumavel DosePro sales during the respective periods as we sold our Sumavel DosePro business to Endo in May 2014, offset by our Zohydro ER sales which we launched in March 2014. Further, as we are financially responsible for all returns of Sumavel DosePro product distributed by us prior to the Closing of the APA, up to a maximum per unit amount as specified in the agreements, we increased our product returns reserve by $0.5 million, up to the maximum per unit amount, during the nine months ended September 30, 2014 to account for the increase in net selling price upon sale of the Sumavel DosePro business to Endo.

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 $7.9 million at September 30, 2014 for Zohydro ER product shipments, which is net of prompt pay discounts and wholesaler distribution fees.

Contract manufacturing revenue for the three and nine months ended September 30, 2014 was $4.2 million and $6.5 million, respectively. Contract manufacturing revenue is recognized for Sumavel DosePro finished goods inventory that has been delivered to Endo Ventures Bermuda under the May 2014 Supply Agreement, and includes a portion of deferred revenue recognized on a proportional performance method. Endo Ventures Bermuda pays us the cost to produce Sumavel DosePro plus a 2.5% mark-up for Sumavel DosePro product delivered.

Service and other revenue for the three months ended September 30, 2014 and 2013 was $0.4 million and $0.3 million, respectively. Service and other revenue for the nine months ended September 30, 2014 and 2013 was $2.5 million and $0.4 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 Goods Sold and Cost of Contract Manufacturing. Cost of goods sold and cost of manufacturing services consists primarily of materials, third-party manufacturing costs, freight and indirect personnel and other overhead costs associated with product sales and contract manufacturing, 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 revenues are recorded as deferred costs, which are included in inventory, until such time the deferred revenue is recognized. Deferred cost of goods sold totaled $1.0 million at September 30, 2014.

Cost of goods sold for the three months ended September 30, 2014 and 2013 was $0.7 million and $5.4 million, respectively, and was $6.5 million and $14.1 million for the nine months ended September 30, 2014 and 2013, respectively. The decline in cost of goods sold over these periods is due to the decline in Sumavel DosePro product sold over the respective periods as a result of the sale of our Sumavel DosePro business to Endo in May 2014.

Product gross margin for the three months ended September 30, 2014 and 2013 was 83% and 22%, respectively. The increase in product gross margin for the three months ended September 30, 2014 compared to 2013 was driven by product mix as the only product sold by us during the three months ending September 30, 2014 was Zohydro ER and the only product sold

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by us during the three months ended September 30, 2013 was Sumavel DosePro. Product gross margin for the nine months ended September 30, 2014 and 2013 was 61% and 38%, respectively. The increase in product gross margin for the nine months ended September 30, 2014 compared to 2013 was primarily due to the addition of Zohydro ER sales after our March 2014 product launch, a lower cost per Sumavel DosePro unit in 2014 and a lower net selling price in the first quarter of 2013 due to a $1.2 million adjustment for Sumavel DosePro product returns.

Cost of contract manufacturing for the three and nine months ended September 30, 2014 was $4.0 million and $5.9 million, respectively, related to the Sumavel DosePro product sold to Endo under the May 2014 Supply Agreement. There was no cost of manufacturing revenue for the three and nine months ended September 30, 2013.

Royalty Expense. During the three months ended September 30, 2014 and 2013, we recorded $0.4 million and $0.3 million, respectively, in royalty expense. During the nine months ended September 30, 2014 and 2013, we recorded $1.2 million and $0.9 million, respectively, in royalty expense. Royalty expense consists of (1) royalties payable to Aradigm based on net sales of Sumavel DosePro by us or one of our licensees through May 16, 2014 when we sold our Sumavel DosePro business, (2) 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), (3) royalties payable to Daravita Limited based on net sales of Zohydro ER by us, and (4) the amortization of the $2.8 million milestone payment paid by us to Daravita 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 until the expiration of the last valid claim of the transferred patents covering the manufacture, use, or sale of the product. Endo assumed responsibility for our royalty obligation to Aradigm Corporation on sales of Sumavel DosePro upon the Closing of the APA on May 16, 2014.

Further, we are required to pay to Daravita 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 Daravita’s patents covering the product in the United States, or 15 years after commercial launch, if Daravita does not have patents covering the product in the United States. Further, if we exercise our option to obtain an exclusive license to certain abuse deterrent technology and know-how from Altus, we are required to pay Daravita a mid single-digit to low twenty-percent-range royalty on net sales of any product with extended release formulations of hydrocodone using Altus' abuse-deterrent technology from the first commercial sale in the Unites States through the date that is 15 years following the first commercial sale.

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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development expenses (in thousands):				
Zohydro ER	$2,377	$843	$4,319	$2,858

Relday	1,616	121	4,210	1,400
DosePro	(13)	390	199	881
Other[1]	1,309	1,190	4,219	4,219
Total	$5,289	$2,544	$12,947	$9,358

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(1) Other research and development expenses include development costs incurred for 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 increased by $2.7 million for the three months ended September 30, 2014 compared 2013, and increased by $3.6 million for the nine months ended September 30, 2014 compared to 2013, primarily due to increases in expenses for development of formulations of Zohydro ER with abuse deterrent properties and development expenses for 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.

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, which we plan to commence in January of 2015, continue development of formulations of Zohydro ER with abuse deterrent properties and prepare for our two Phase 3 studies for Brabafen, which we plan to commence in the second quarter of 2015. We filed an sNDA on September 30, 2014 for a next-generation formulation of Zohydro ER designed to make it more difficult to abuse by injection or nasal insufflation. We also continue the development of a formulation of extended-release hydrocodone with abuse deterrent properties using Altus' Intellitab™ drug delivery platform.

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, medical affairs and internal support functions. In addition, general and administrative expenses include professional fees for legal, consulting and accounting services.

Selling, general and administrative expenses increased to $19.1 million for the three months ended September 30, 2014 compared to $10.0 million for the three months ended September 30, 2013. Selling, general and administrative expenses increased to $71.2 million for the nine months ended September 30, 2014 compared to $36.5 million for the nine months ended September 30, 2013.

Selling expenses were $11.8 million and $6.3 million for the three months ended September 30, 2014 and 2013, respectively, and $47.5 million and $24.9 million for the nine months ended September 30, 2014 and 2013, respectively. General and administrative expenses were $7.3 million and $3.7 million for the three months ended September 30, 2014 and 2013, respectively, and $23.7 million and $11.6 million for the nine months ended September 30, 2014 and 2013, respectively.

The increase of $9.1 million in selling, general and administrative expenses for the three months ended September 30, 2014 compared to 2013 was due to an increase of $5.5 million in sales and marketing expenses, and an increase of $3.6 million in general and administrative expenses.

- The increase in sales and marketing expenses is primarily the result of an increase in salaries, other benefits, and other personnel costs, due to an increase in headcount, as well as an increase in advertising and promotion costs for Zohydro ER, which was launched in March 2014, offset by a decrease in advertising and promotion costs due to the sale of the Sumavel DosePro business in May 2014.
- 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 legal, consulting and public relations costs.

The increase of $34.7 million in selling, general and administrative expenses for the nine months ended September 30, 2014 compared to 2013 was due to an increase of $22.6 million in sales and marketing expenses, and an increase of $12.1 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 nine months ended September 30, 2014 also included the costs of a comprehensive training and certification program for our sales

representatives in connection with the launch of Zohydro ER.

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- 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 legal and 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.

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

Impairment of Long-Lived Assets. Impairment expense of $0.8 million was recorded during the nine months ended September 30, 2014, as we disposed of some construction in progress in connection with the sale of the Sumavel DosePro business to Endo in May 2014.

Gain on Sale of Business. A gain on sale of business of $80.0 million, net of $0.6 million in related transaction costs, was recorded during the nine months ended September 30, 2014, in connection with the sale of the Sumavel DosePro business to Endo in May 2014. See Note 4 to our consolidated financial statements.

Interest Income. During the three months ended September 30, 2014 and 2013, interest income was $6,000 and $1,000, respectively, and during the nine months ended September 30, 2014 and 2013, interest income was $18,000 and $12,000, respectively. The increase in interest income was primarily driven by an increase in average cash and cash equivalent balances during the respective periods.

Interest Expense. During the three months ended September 30, 2014 and 2013, interest expense was $84,000 and $1.6 million, respectively, and during the nine months ended September 30, 2014 and 2013, interest expense was $3.0 million and $4.8 million, respectively. Interest expense primarily consists of interest expense incurred in connection with the Healthcare Royalty financing agreement, which was early terminated on May 16, 2014, 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 expect interest expense to decrease over the remainder of 2014 compared to 2013 levels during the same period due to the early termination of the Healthcare Royalty financing agreement on May 16, 2014, offset by imputed interest expense recognized on the note payable to Endo.

Loss on Early Extinguishment of Debt. The loss on extinguishment of debt of $1.3 million recorded during the nine months ended September 30, 2014 resulted from the early termination of the Healthcare Royalty financing agreement on May 16, 2014. The loss on early extinguishment of debt is related to the write-off of the unamortized balances of the debt discounts, including the derecognition of the embedded derivative liabilities, the debt acquisition costs, and accrued interest expenses related to the financing agreement. See Note 5 to our consolidated financial statements.

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 6 to our consolidated financial statements. The income generated from the change in fair value of the common stock warrant liabilities during the three and nine months ended September 30, 2014 was primarily driven by the decrease in our stock price at September 30, 2014 as compared against December 31, 2013 measurement dates.

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. These embedded derivatives were derecognized on May 16, 2014 in connection with the early termination of the Healthcare Royalty financing agreement. See Note 5 to our consolidated financial statements.

Other Income (Expense). Other income (expense) for the three and nine months ended September 30, 2014 and 2013 consists primarily of foreign currency transaction gains and losses.

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Liquidity and Capital Resources

We have experienced net losses and negative cash flow from operations since inception, and as of September 30, 2014, had an accumulated deficit of $381.1 million. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next year as we continue to incur costs related to the commercialization of Zohydro ER, including introduction of Zohydro ER with abuse deterrent properties to the market, if approved, the clinical development for Relday and Brabafen, required post-market testing for Zohydro ER, safe use initiatives for Zohydro ER and additional development activities with respect to Zohydro ER, including the development of multiple formulations of extended-release hydrocodone with abuse deterrent properties. As of September 30, 2014, we had cash and cash equivalents of $50.5 million.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of September 30, 2014, the $8.5 million of the upfront cash payment received from the sale of our Sumavel DosePro business that is included in restricted cash, our projected product revenues from Zohydro ER, the $10.0 million in payments for the waiver granted to Purdue due by July 1, 2015, and our projected manufacturing and other service revenues will be sufficient to fund our operations into the third quarter of 2015. Our cash and cash equivalents as of September 30, 2014 exclude the $20.0 million cash payment made to the Sellers in connection with our acquisition of Brabant. We may pursue additional opportunities to raise capital, if necessary, through public or private equity offerings, including through a controlled equity offering program, debt financings, receivables financings or through collaborations or partnerships with other companies. If 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 September 30, 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 with Healthcare Royalty. Under the terms of the financing agreement, we borrowed $30.0 million and we were obligated to repay such borrowed amount together with a specified return to Healthcare Royalty. Healthcare Royalty exercised its option to terminate the financing agreement in connection with our sale of our Sumavel DosePro business to Endo on May 16, 2014. Upon termination of the financing agreement, we were obligated to make a final payment of $40.0 million to Healthcare Royalty, which was

an amount that generated a 17% internal rate of return on the borrowed amount as of the date of final payment, reduced by the revenue interest and principal payments received by Healthcare Royalty up to the date of final payment.

Further, upon early termination of the Healthcare Royalty financing agreement, we recognized a loss on early extinguishment of debt of $1.3 million which was recorded as non-operating expenses in our statement of operations and comprehensive income (loss). The loss on early extinguishment of debt is related to the write-off of the unamortized balances

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of the debt discounts, including the derecognition of the embedded derivative liabilities, debt acquisition costs, and accrued interest expenses related to the financing agreement. Healthcare Royalty's security interest in all of our assets was extinguished upon early termination of the financing agreement.

On November 6, 2014, we entered into a controlled equity offering sales agreement, or sales agreement, with Cantor, as sales agent, to create a controlled equity program under which we may, from time to time, sell shares of common stock up to an aggregate offering price of $25.0 million. Sales of our common stock made pursuant to the controlled equity offering program, if any, will be made on the Nasdaq Global Market under our shelf registration statement on Form S-3 filed on November 6, 2014, following such time as the registration statement is declared effective by the SEC. However, such registration statement cannot be declared effective until such time as we have filed certain financial statements from our recent acquisition of Brabant Pharma Limited, or Brabant, or Brabant, as required by SEC rules, which must be filed within 71 days of the date of our Current Report on Form 8-K filed with the SEC on October 27, 2014. There can be no assurance that Cantor will be successful in consummating sales under the program based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. Cantor or we are permitted to terminate the controlled equity offering sales agreement, or sales agreement, at any time upon 10 days' prior written notice, and Cantor is also permitted to terminate the sales agreement at any time in certain circumstances, including the occurrence of a material adverse change in our company.

Cash and Cash Equivalents. Cash and cash equivalents totaled $50.5 million and $72.0 million at September 30, 2014 and December 31, 2013, respectively.

The following table summarizes our cash flows used in operating, investing and financing activities for the nine months ended September 30, 2014 and 2013:

	Nine Months Ended September 30,	
	2014	2013
	(In Thousands)	
Statement of Cash Flows Data:		
Total cash provided by (used in):		
Operating activities	$(71,244)	(34,189)
Investing activities	81,039	(785)
Financing activities	(31,289)	11,098
Decrease in cash and cash equivalents	$(21,494)	$(23,876)

Operating Activities: Net cash used in operating activities was $71.2 million and $34.2 million for the nine months ended September 30, 2014 and 2013, respectively. Net cash used for the nine months ended September 30, 2014 primarily reflects the use of cash for operations, adjusted for non-cash charges including the $80.0 million gain on sale of our Sumavel DosePro business, a $26.4 million change in fair value of warrant liabilities and $7.3 million in stock-based compensation. Significant working capital uses of cash for the nine months ended September 30, 2014 include personnel-related costs, research and development costs (primarily for Relday and formulations of Zohydro ER with abuse deterrent properties), sales and marketing expenses for Zohydro ER and Sumavel DosePro, and other professional services, including legal services. Net cash used for the nine months ended September 30, 2013 primarily reflects the use of cash for operations, adjusted for non-cash charges including a $2.8 million change in fair value of warrant liabilities and $5.8 million in stock-based compensation (which includes $0.2 million in stock-based compensation from restructuring), partially offset by a $0.9 million change in fair value of embedded derivatives. Significant working capital uses of cash for the nine months ended September 30, 2013 include personnel-related costs, research and development costs (primarily for employee and infrastructure resources), sales and marketing expenses for Sumavel DosePro, and other professional services.

Investing Activities. Net cash provided by investing activities for the nine months ended September 30, 2014 was $81.0 million, which is primarily attributable to the proceeds from the sale of our Sumavel DosePro business, including the $85.0 million up-front payment and $4.6 million payment for the Sumavel DosePro finished goods inventory on hand at Closing, offset by $8.5 million of the upfront payment that was deposited into escrow. Net cash used in investing activities for the nine months ended September 30, 2013 was $0.8 million related to the purchase of property and equipment primarily for use in manufacturing DosePro.

We expect to incur capital expenditures of approximately $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 to continue to support the manufacturing and supply agreement with Endo.

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Financing Activities. Net cash used in financing activities was $31.3 million for the nine months ended September 30, 2014, which relates to the $40.0 million repayment of debt for the early extinguishment of our financing agreement with Healthcare Royalty in May 2014, offset by a $7.0 million working capital advance from Endo Ventures pursuant to our May 2014 Supply Agreement, and proceeds from the exercise of stock options and warrants and the issuance of common stock under our employee stock purchase plan. Net cash provided by financing activities was $11.1 million for the nine months ended September 30, 2013, which is primarily from proceeds under our controlled equity offering program (which was terminated in November 2013).

Our sources of liquidity include our cash balances and cash receipts from the sale of Zohydro ER product and contract manufacturing for Sumavel DosePro. Through September 30, 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 September 30, 2014, we had $50.5 million in cash and cash equivalents. Other potential sources of near-term liquidity include (i) equity offerings, including through our controlled equity program, debt or other financing, (ii) entering into a commercialization agreement for Zohydro ER, or a licensing arrangement for Relday, or (iii) 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 Zohydro ER commercialization efforts, results and progress in our clinical programs, the time and costs related to clinical trials and regulatory decisions, as well as the U.S. economic environment.

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 brand and as we potentially advance Relday and Brabafen 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 September 30, 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 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 order demands from Endo Ventures Bermuda Limited. For the nine months ended September 30, 2014, approximately $17.1 million (based on exchange rates as of September 30, 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 nine months ended September 30, 2014 would have resulted in approximately $0.6 million or $1.1 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 September 30, 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 September 30, 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 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 nine months ended September 30, 2014 and the years ended December 31, 2013 and 2012, we incurred net income (loss) of $29.1 million, $(80.9) million and $(47.4) million, respectively, our net cash used in operating activities was $71.2 million, $44.9 million and $52.2 million, respectively, and, at September 30, 2014, our accumulated deficit was $381.1 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 the commercialization of Zohydro ER, including introduction of Zohydro ER with abuse deterrent properties to the market, if approved, the clinical development for Relday and Brabafen (our recently acquired product candidate), required post-market testing for Zohydro ER, safe use initiatives for Zohydro ER and additional development activities with respect to Zohydro ER, including the development of an additional formulation with abuse deterrent properties. Our ability to generate revenues from sales of Zohydro ER, our Sumavel DosePro contract manufacturing services, or any of our product candidates will depend on a number of factors including, in the case of Zohydro ER and Sumavel DosePro contract manufacturing services, the factors described in risk factors below and, in the case of our product candidates, including Relday, Brabafen and multiple formulations of extended-release hydrocodone with abuse deterrent properties, 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 are 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 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 which could result in our inability to continue operations.

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

Our operations have consumed substantial amounts of cash since inception. To date, our operations have been primarily financed through the proceeds from the issuance of our common and preferred stock, including the proceeds from our initial public offering completed in November 2010, our follow-on public offerings completed in September 2011, July 2012 and November 2013, our controlled equity offering program, which was terminated in November 2013, and borrowings under financing agreements. In addition, we may fund our operations through the proceeds from the sales and issuances of our common stock, if any, pursuant to the controlled equity offering program that we established on November 6, 2014 with Cantor Fitzgerald & Co., or Cantor, as sales agent, under which we may, from time to time, sell shares of common stock up to an aggregate offering price of $25.0 million. Sales of our common stock made pursuant to the controlled equity offering program, if any, will be made on the Nasdaq Global Market

under our shelf registration statement on Form S-3 filed on November 6, 2014, following such time as the registration statement is declared effective by the SEC. However, such registration statement cannot be declared effective until such time as we have filed certain financial statements from our recent acquisition of Brabant Pharma Limited, or Brabant, or Brabant, as required by SEC rules, which must be filed within 71 days of the date of our Current Report on Form 8-K filed with the SEC on October 27, 2014. There can be no assurance that Cantor will be successful

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in consummating sales under the program based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. Cantor or we are permitted to terminate the controlled equity offering sales agreement, or sales agreement, at any time upon 10 days' prior written notice, and Cantor is also permitted to terminate the sales agreement at any time in certain circumstances, including the occurrence of a material adverse change in our company.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of September 30, 2014, the $8.5 million of the upfront cash payment received from the sale of our Sumavel DosePro business that is included in restricted cash, our projected product revenues from Zohydro ER, the $10.0 million in payments for the exclusivity waiver granted to Purdue Pharma L.P., or Purdue, due by July 1, 2015, and our projected manufacturing and other service revenues will be sufficient to fund our operations into the third quarter of 2015. Our cash and cash equivalents as of September 30, 2014 exclude the $20.0 million cash payment made to the Sellers in connection with our acquisition of Brabant. We may need to obtain additional funds to finance our operations beyond that point, or possibly earlier, in order to:

- maintain our sales and marketing activities for Zohydro ER;
- fund our operations and fund required post-market testing of Zohydro ER and additional development activities with respect to Zohydro ER, including the development of Zohydro ER with abuse deterrent properties, as well as further development of Relday and Brabafen and development of any other product candidates to support potential regulatory approval; and
- commercialize Zohydro ER with abuse deterrent properties or any of our other product candidates, or any products or product candidates that we may develop, in-license or otherwise acquire, if any such product candidates receive regulatory approval.

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

- the commercial success of Zohydro ER;
- the costs of maintaining our sales and marketing infrastructure or establishing distribution capabilities;
- the timing of regulatory approval, if granted, of Zohydro ER with abuse deterrent properties and any other product candidates and the commercial success of any approved products;
- the rate of progress and cost of our clinical trials and other product development programs for Relday, Brabafen and our other product candidates and any other product candidates that we may develop, in-license or acquire;
- the receipt of contingent payments from the sale of our Sumavel DosePro business, which are based on the achievement of pre-determined sales and gross margin milestones by Endo Health Solutions Inc., or Endo;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with Zohydro ER, our DosePro technology, Relday, Brabafen and any of our other product candidates;
- the costs and timing of completion of outsourced commercial manufacturing supply arrangements for any product candidate;
- the effect of competing technological and market developments; and
- the terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

In its report on our consolidated financial statements for the year ended December 31, 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.

Until we can generate a sufficient amount of product revenue and cash flow from operations and achieve profitability, we expect to finance future cash needs through public or private equity offerings, debt financings, receivables financings or corporate collaboration and licensing arrangements. We cannot be certain that additional funding will be

available on acceptable terms, or at all. If we are unsuccessful in raising additional required funds, we may be required to significantly delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts, or cease operating as a going concern. We also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. If we are unable to maintain sufficient financial resources, including by raising additional funds when needed, our business, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern.

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We are largely dependent on the commercial success of Zohydro ER, and although we have generated revenue from sales of Zohydro ER, it is still early in the commercialization process and we may never significantly increase these sales or become profitable.

Our ability to generate revenues and become profitable will depend in large part on the commercial success of Zohydro ER. We launched the commercial sale of Zohydro ER in the United States in March 2014. The commercial success of Zohydro ER depends on several factors, including our ability to:

- successfully launch and educate prescribers on safe use initiatives for Zohydro ER through our own marketing and sales activities;
- create market demand for Zohydro ER through our own marketing and sales activities, and any other arrangements to promote this product that we may later establish;
- develop and commercialize Zohydro ER with abuse deterrent properties;
- establish and maintain adequate levels of coverage for Zohydro ER from commercial health plans and government health programs, which we refer to collectively as third-party payors, particularly in light of the availability of other branded and generic competitive products;
- maintain compliance with regulatory requirements;
- establish and maintain agreements with wholesalers and distributors on commercially reasonable terms;
- maintain commercial manufacturing arrangements with third-party manufacturers as necessary to meet commercial demand for Zohydro ER and manufacture commercial quantities at acceptable cost levels; and
- successfully maintain intellectual property protection for Zohydro ER.

If we are unable to successfully commercialize Zohydro ER, we may be unable to generate sufficient revenues to grow or sustain our business and we may never become profitable, and our business, financial condition and results of operations will be materially adversely affected.

If Zohydro ER, and, if approved, Zohydro ER with abuse deterrent properties, Relday, Brabafen 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 Zohydro ER, and, if approved, Zohydro ER with abuse deterrent properties, Relday, Brabafen 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 product by third-party payors is also necessary for commercial success. The degree of market acceptance of 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;
- any negative publicity or political action related to our or our competitors' products;
- 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;
- 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, 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 extended-release, or ER, and long-acting, or 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

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clinical trials are under development and the related cost is currently unknown, which could negatively affect our business. The FDA held a public meeting in May 2014 to obtain stakeholder input on the design and conduct of the post-marketing requirements for ER/LA opioid analgesic drug products and will provide feedback on the requirements after consideration of the input obtained during the meeting. We cannot predict how the results of these post-marketing required studies will effect the commercialization of Zohydro ER and future formulations of Zohydro ER with abuse deterrent properties.

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 formulations of Zohydro ER with abuse deterrent properties. We filed a supplemental NDA, or sNDA, on September 30, 2014 for a next-generation formulation of Zohydro ER that is designed to make it more difficult to abuse by injection or nasal administration. The The FDA assigned a Prescription Drug User Free Act, or PDUFA, target action date on the sNDA of January 30, 2015, and, if approved, we anticipate a transition from the currently marketed product to this new capsule formulation of Zohydro ER in the second quarter of 2015.

If approved, this new formulation could be available to prescribers in the first half of 2015. Further, we are targeting an NDA submission for a proprietary tablet formulation of Zohydro ER during the first half of 2016 which incorporates multiple features to maintain the extended-release property of the medication when crushed or chewed, reducing one of the ways in which opioids are abused through oral ingestion, as well other features to address abuse by injection or nasal administration.

Our efforts to educate the medical community and third-party payors on the benefits of Zohydro ER and, if approved, formulations of Zohydro ER with abuse deterrent properties, Relday, Brabafen 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 may not realize the full economic benefit from the sale of our Sumavel DosePro business.

Pursuant to the asset purchase agreement with Endo that we entered into in April 2014, or the asset purchase agreement, in addition to the $89.6 million upfront cash payment, we may receive contingent payments, based on Endo’s achievement of pre-determined sales and gross margin milestones, in an amount up to $20.0 million. Our ability to receive these contingent payments under our supply agreement with Endo is dependent upon Endo successfully maintaining and increasing market demand for, and sales of, Sumavel DosePro.

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 has been 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.

Negative publicity and political action regarding Zohydro ER could delay or impair our ability to market this product, present significant distractions to our management and result in the incurrence of significant costs.

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. 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’s 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. In April 2014, Purdue announced that it filed an NDA for its extended-release hydrocodone product candidate that is formulated to incorporate abuse deterrent properties, which

was accepted by the FDA in July 2014 for a priority review. On October 29, 2014, we entered into a waiver agreement with Purdue, pursuant to which we granted a waiver to Purdue, of the three-year Hatch-Waxman regulatory exclusivity period with respect to NDA 202880 for Zohydro ER in support of the Purdue Products. In addition, Teva Pharmaceutical Industries Limited recently announced that it has initiated a rolling NDA submission which will be completed by the end of 2014 for its extended-release hydrocodone product candidate that is also formulated to incorporate abuse deterrent properties. Approval of these product candidates or any abuse-deterrent formulation of hydrocodone may drive further negative publicity and political action, or even result in the FDA revoking its approval of our NDA for Zohydro ER. While we do not believe that the FDA will revoke its Zohydro ER approval, and, in any event, the FDA would have to provide us with notice and opportunity for a hearing first, the related negative publicity, political influences and actions by our competitors could negatively affect our abil

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ity to market Zohydro ER and any opioid analgesic product candidates for which we may seek approval in the future. If the FDA did revoke its approval of Zohydro ER, our business, results of operations, financial condition and prospects would be materially and adversely affected.

In addition, in March 2014, the Governor of the Commonwealth of Massachusetts issued an executive order to ban Zohydro ER in Massachusetts. In response, in April 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 asserted 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. The U.S. District Court in Massachusetts entered a temporary restraining order preventing the implementation of the Governor's order on constitutional grounds. On July 8, 2014, the U.S. District Court in Massachusetts issued an order upholding the temporary restraining order. 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, and the U.S. District Court in Massachusetts has ruled in our favor, state officials in Massachusetts or elsewhere may nevertheless seek to place additional restrictions on the prescribing and use of Zohydro ER, which could negatively affect our ability to market Zohydro ER.

This negative publicity and political action could also cause a diversion of our management's time and attention, cause us to incur additional significant costs with respect to litigation, marketing or otherwise, and could also result in an increased number of product liability claims, whether or not these claims have a valid basis.

Our short operating history makes it difficult to evaluate our business and prospects.

We commenced our operations on August 25, 2006. Our operations to date have been limited to organizing and staffing our company, scaling up manufacturing operations with our third-party contract manufacturers, building a sales and marketing organization, conducting product development activities for our products and product candidates, in-licensing rights to Zohydro ER and Relday, acquiring rights to Brabafen and commercializing Sumavel DosePro and Zohydro ER. In January 2010, we launched Sumavel DosePro and began generating revenues. We launched Zohydro ER in March 2014 and sold our Sumavel DosePro business in April 2014. Consequently, any predictions about our future performance may not be as accurate as they would be if we had a longer history of developing and commercializing pharmaceutical products.

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

The majority of our sales of Zohydro ER are to wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. Three wholesale pharmaceutical distributors, AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc., individually comprised 41.4%, 29.5% and 20.0%, respectively, of our total ex-factory gross product sales of Zohydro ER for the nine months ended September 30, 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 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

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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 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, Teva Pharmaceutical Industries Limited and Actavis, Inc. On August 22, 2014, the DEA issued a final rule to reschedule hydrocodone combination products from Schedule III to Schedule II. The rescheduling went into effect on October 6, 2014 and requires previously classified Schedule III hydrocodone combination products to comply with more restrictive regulatory requirements under Schedule II classification. Zohydro ER is already a Schedule II product.

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. Purdue's NDA was accepted for priority review in July 2014. On October 29, 2014, we entered into a waiver agreement with Purdue, pusuant to which we granted a waiver to Purdue of the three-year Hatch-Waxman regulatory exclusivity period with respect to NDA 202880 for Zohydro ER in support of the Purdue Products. 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 Zohydro ER brand.

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.

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. In May 2014, Janssen Pharmaceuticals, Inc., announced the submission of sNDAs for once-monthly atypical long-

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acting antipsychotic Invega Sustenna (paliperidone palmitate) to the FDA for approval to treat schizoaffective disorder as either monotherapy or adjunctive therapy.

If approved for the treatment of Dravet syndrome, Brabafen may compete against other product candidates. Epidiolex, which is being developed by GW Pharmaceuticals, has received an orphan designation by the EMA and fast track status by the FDA for the treatment of Dravet syndrome. GW Pharmaceuticals is set to initiate a Phase II/III clinical trial for Epidiolex by the end of the year. Sage Therapeutics is developing its lead compound SAGE-547, an allosteric modulator of GABA receptors, for patients with super-refractory status epilepticus, which are initial prolonged seizures in the developing infant that can be associated with Dravet's syndrome. Further, Insys Therapeutics has advanced its pharmaceutical cannabinoid program, which has received orphan drug designation for use of cannabidiol as a potential treatment for Dravet syndrome.

We expect Zohydro ER and, if approved, Relday, Brabafen 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 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 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 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. On August 13 and September 20, 2014, we received separate notices of paragraph IV certifications from Actavis Laboratories FL, Inc., or Actavis, and from Alvogen Pine Brook, Inc., or Alvogen, respectively, advising us of the filing of Abbreviated New Drug Applications, or ANDAs, with the FDA for a generic version of Zohydro ER. These certification notices allege that the two U.S. patents listed in the FDA's Orange Book for Zohydro ER, each with an expiration date in November 2019, will not be infringed by Actavis' or Alvogen's proposed products, are invalid and/or are unenforceable. On September 3, 2014, Daravita Limited (formerly Alkermes Science One Limited) filed suit in the United States District Court for the District of Delaware against Actavis, and on November 3, 2014, Daravita filed suit in the United States District Court for the District of Deleware against Alvogen. Daravita has licensed rights to Zohydro ER to us, and, under the Zohydro ER license agreement, Daravita has the right to control the enforcement of patents and related proceedings involving Zohydro ER and any prospective generic entrant. We intend to vigorously enforce the intellectual property rights relating to Zohydro ER, but we cannot predict the outcome of these matters or guarantee the outcome of any litigation. The commercial opportunity for Zohydro ER 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 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.

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We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. For example, in October 2014, we completed the acquisition of Brabant, which owns worldwide development and commercialization rights to Brabafen for the treatment of Dravet syndrome. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, the Brabant transaction and any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Although we have been granted three-year Hatch-Waxman exclusivity for Zohydro ER, we have entered into a waiver agreement with Purdue of the three-year Hatch-Waxman regulatory exclusivity period with respect to NDA 202880 for Zohydro ER in support of the Purdue Products and can offer no assurance that such exclusivity will effectively prevent or otherwise limit further competition from other hydrocodone products, either generic or otherwise.

In addition to patent protection, we rely, in part, on Hatch-Waxman marketing exclusivity for the commercialization of Zohydro ER in the United States. Under the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Amendments, newly approved drugs may benefit from certain statutory periods of non-patent marketing exclusivity in the United States. Exclusivity provides the holder of an approved application limited protection from new competition in the marketplace for the innovation represented by its approved drug product.

A three-year period of exclusivity is available for a drug product that contains an active ingredient that has been previously approved and the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the applicant that were essential to approval of the application. Changes to an approved drug product that may qualify for this exclusivity include changes that affect the product's active ingredient(s), strength, dosage form, route of administration, or conditions of use, so long as clinical investigations were essential to approval of the application containing those changes. The exclusivity prevents FDA from approving other applications for the same change for three years from the date of the new product's approval.

While Zohydro ER has been granted three-year Hatch-Waxman exclusivity as the first single-entity hydrocodone product approved for the treatment of chronic pain on the basis of a comprehensive Phase 3 safety and efficacy program, there can be no assurance that such exclusivity will effectively prevent or otherwise limit competition from other hydrocodone products, either generic or otherwise. On October 29, 2014, we entered into a waiver agreement with Purdue, pursuant to which we granted a waiver to Purdue of the three-year Hatch-Waxman regulatory exclusivity period with respect to NDA 202880 for Zohydro ER in support of the Purdue Products. [On [ ],

the FDA approved Purdue'a product Hysingla ER®.] Such competition by the Purdue Products and other hydrocodone products, including other 505(b)(2) applications for different conditions of use or other changes to the hydrocodone products that would not be restricted by the three-year exclusivity, could have a significantly negative impact on our future revenues from Zohydro ER.

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

While we own most of the specialized equipment used to manufacture critical components of Sumavel DosePro, we do not own or operate manufacturing facilities and currently lack the in-house capability to manufacture Sumavel DosePro, Zohydro ER, Relday, Brabafen or any other product candidates. Our DosePro system and Sumavel DosePro are manufactured by contract manufacturers, component fabricators and secondary service providers. Aseptic fill, finish, assembly and packaging of Sumavel DosePro are performed at Patheon UK Limited, Swindon, United Kingdom, or Patheon, a specialist in the aseptic fill/finish of injectables and other sterile pharmaceutical products. In May 2012, Patheon announced plans to wind down or transfer its commercial production capacity for a number of products at this facility over a period of 24 to 36 months. Patheon subsequently notified us that it no longer intends to wind down or transfer its commercial capacity, and as such, at this time we are no longer working to identify alternative suppliers for the services provided to us by Patheon. In addition to Patheon's manufacturing services, Nypro Limited, located in Bray, Ireland, manufactures the actuator assemblies and injection molded components for our DosePro system and Nipro Glass, Germany AG (formerly MGlas AG), located in Münnerstadt, Germany, manufactures the specialized glass capsule (cartridge) that houses the sumatriptan active pharmaceutical ingredient, or API, in our DosePro system. Each of these manufacturers and each other company that supplies, fabricates or manufactures any component used in our DosePro system is currently the only qualified source of their respective components. We currently rely on Dr. Reddy's Laboratories as the only supplier of sumatriptan API for use in Sumavel DosePro. An affiliate of Alkermes, Alkermes Pharma Ireland Limited, or APIL, is the exclusive manufacturer and supplier (subject to certain exceptions) for Zohydro ER. We also outsource all manufacturing and packaging of the clinical trial materials for Relday [and Brabafen] to third parties.

Although we plan to qualify additional manufacturers and suppliers of some of the components used in Sumavel DosePro, there can be no assurance that we will be able to do so and the current manufacturers and suppliers of these components will likely be single source suppliers to us for a significant period of time. Similarly, APIL is the exclusive manufacturer of Zohydro ER and Durect is the exclusive manufacturer of the risperidone formulation using Durect's SABER™ controlled-release technology for all Relday clinical trials through Phase 2 and has the option to supply the same formulation for Phase 3 clinical trials and, if approved, commercial production. Brabafen, if approved, would require a technology transfer to an alternate source to establish commercial supply capabilities, for which there can be no assurance of a successful transfer and validation. We have restrictions on establishing a second source of supply under our agreement with APIL, and we may never be able to establish additional sources of supply for Zohydro ER, Relday's risperidone formulation or Brabafen.

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

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

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

Production capacity to support launch and initial forecast demand for Zohydro ER is installed and has received final packaging qualification. In order to meet future anticipated growth in demand for Zohydro ER, APIL has initiated activities to qualify additional production lines and expand the manufacturing capacity for Zohydro ER. However, if APIL or our other contract manufacturers or suppliers are unable to deliver the required commercial quantities of our products and their various components, the quantities of our product candidates required for our clinical trials and, if approved, for commercial sale, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers or suppliers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and would have to delay or terminate our pre-clinical

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or clinical trials, and we would lose potential revenue. It may also take a significant period of time to establish an alternative source of supply for our products, product candidates and components and to have any such new source approved by the FDA or any applicable foreign regulatory authorities. Furthermore, any of the above factors could cause the delay or suspension of initiation or completion of clinical trials, regulatory submissions or required approvals of our product candidates, cause us to incur higher costs and could prevent us from commercializing our product candidates successfully.

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

Major pharmaceutical companies usually employ groups of sales representatives numbering in the thousands to call on the large number of primary care physicians. Our sales and marketing organization, which as of September 30, 2014 was comprised of approximately 160 personnel, promotes Zohydro ER in the United States, primarily targeting pain specialists. We may seek a co-promotion or other partnering opportunity for Zohydro ER, or may further expand our sales force.

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

Further, we may lack the financial and managerial resources to maintain and potentially increase the size of our sales and marketing organization to adequately promote and commercialize Zohydro ER and any product candidates that may be approved. Any increase in our sales force will result in an increase in our expenses, which could be significant before we generate revenues from any newly approved product candidate. Even though we were able to recently expand our sales and marketing personnel, and may be successful in establishing future partnership arrangements, such sales force and marketing teams may not be successful in commercializing our products, which would adversely affect our ability to generate revenue for such products, and could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may encounter delays in the manufacturing of Sumavel DosePro or fail to generate contract manufacturing revenue if our supply of the components of our DosePro drug delivery system is interrupted.

Our DosePro drug delivery system is sourced, manufactured and assembled by multiple third parties across different geographic locations in Europe, including the United Kingdom, Germany and Ireland. All contract manufacturers and component suppliers have been selected for their specific competencies in the manufacturing processes and materials that make up the DosePro system. The components of DosePro include the actuator subassembly, capsule subassembly and the setting mechanism. The actuator subassembly is comprised of nine individual components which are collectively supplied by six different third-party manufacturers. The capsule subassembly that houses the sterile drug formulation sumatriptan is comprised of five different components also supplied by four third-party manufacturers. Each of these third-party manufacturers is currently the single source of their respective components. If any of these manufacturers is unable to supply its respective component for any reason, including due to violations of the FDA's Quality System Regulation, or QSR, requirements, our ability to manufacture the finished DosePro system will be adversely affected and our ability to meet the distribution requirements for any Sumavel DosePro purchase orders from Endo and the resulting contract manufacturing revenue therefrom will be negatively affected. Accordingly, there can be no assurance that any failure in any part of our supply chain will not have a material adverse effect on our ability to generate contract manufacturing revenue from Sumavel DosePro or our ability to generate

revenue from any potential future DosePro products, which in turn could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

Clinical trials are very expensive, time consuming and difficult to design and implement. Delays in the commencement or completion of clinical testing for Relday or Brabafen or pre-clinical or clinical testing for any of our other product candidates could significantly affect our product development costs and business plan. We initiated clinical testing for Relday in patients

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with schizophrenia in July 2012 and announced positive single-dose pharmacokinetic results from the Phase 1 clinical trial in January 2013. Based on the favorable safety and pharmacokinetic profile demonstrated in the Phase 1 trial, we extended the study to include an additional dose of the same formulation and announced positive top-line results in May 2013. The positive results from this study extension position us to begin a multi-dose clinical trial, which 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 January of 2015. The safety and effectiveness of Brabafen has been evaluated in a continuing, long-term, open-label, study in 15 Dravet syndrome patients. Based upon feedback from the FDA and the European Medicines Agency, we expect to initiate two Phase 3 studies (of 40 to 60 Dravet syndrome patients per study) during the second quarter of 2015 in the United States and Europe, with top-line results potentially available in the first half of 2016. We do not know whether any of our other pre-clinical or clinical trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

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

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

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

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

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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 we have generated have been in U.S. dollars. For the nine months ended September 30, 2014, $17.1 million (based on exchange rates as of September 30, 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.

If we are unable to achieve and maintain adequate levels of coverage and reimbursement for Zohydro ER or any of our other product candidates for which we may receive regulatory approval on reasonable pricing terms, their commercial success may be severely hindered.

Successful sales of our products depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our products will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. For example, in August 2014, Express Scripts added Zohydro ER to its list of excluded drugs for their National Preferred Drug formulary for 2015. Express Scripts is the largest U.S. pharmacy benefit manager, and the inclusion of Zohydro ER on its list of excluded drugs for their National Preferred Drug formulary may have a negative impact on prescriptions and sales of Zohydro ER.

In addition, regional healthcare authorities and individual hospitals are increasingly using competitive bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This can reduce demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for Zohydro ER or any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may never receive regulatory approval or commercialize our product candidates outside of the United States.

We intend to market certain of our product candidates outside of the United States. For example, Brabafen has recently received orphan drug designation in Europe, and we expect to initiate two Phase 3 studies during the second quarter of 2015 in both the United States and Europe. In order to market our products outside of the United States, we, or any potential partner, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution

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of our products. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed in these "Risk Factors" regarding FDA approval in the United States, as well as other risks. For example, in the European Economic Area, or EEA (comprised of the 27 European Union, or EU, member states plus Iceland, Liechtenstein, and Norway), we can take advantage of the hybrid application pathway of the EU Centralized Procedure, which is similar to the FDA's 505(b)(2) pathway. Hybrid applications may rely in part on the results of pre-clinical tests and clinical trials contained in the authorization dossier of the reference product, but must be supplemented with additional data. In territories where data is not freely available, we or our partners may not have the ability to commercialize our products without negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds. We, or any potential partner, may be unable to obtain rights to the necessary clinical data and may be required to develop our own proprietary safety effectiveness dossiers. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others.

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

Risks Related to 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 subsequently sold the business in April 2014. We launched our recently approved product, Zohydro ER, in March 2014. Given our limited sales history for 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 nine months ended September 30, 2014 and the years ended December 31, 2013 and 2012, we incurred net income (loss) of $29.1 million, $(80.9) million and $(47.4) million, respectively, and our cash used in operating activities was $71.2 million, $44.9 million and $52.2 million, respectively. As of September 30, 2014, we had an accumulated deficit of $381.1 million. These losses and negative cash flow from operations have had a material adverse effect on our stockholders' equity and working capital.

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 the commercialization of Zohydro ER, including introduction of Zohydro ER with abuse deterrent properties to the market, if approved, the clinical development of Relday and Brabafen, required post-market testing for Zohydro ER, safe use initiatives for Zohydro ER and additional development activities with respect to Zohydro ER, including the development of an additional formulation with abuse deterrent properties. As a result, we may remain dependent upon external sources of financing to fund 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.

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

stockholders.

On November 6, 2014, we entered into the sales agreement with Cantor. Sales of our common stock made pursuant to the controlled equity offering program, if any, will be made on the Nasdaq Global Market under our shelf registration statement on Form S-3 filed on November 6, 2014, following such time as the registration statement is declared effective by the SEC. However, such registration statement cannot be declared effective until such time as we have filed certain financial statements from our recent acquisition of Brabant as required by SEC rules, which must be filed within 71 days of the date of our Current Report on Form 8-K filed with the SEC on October 27, 2014. Under the terms of the sales agreement, Cantor will use its commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal laws,

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rules and regulations and the rules of the Nasdaq Global Market, to sell shares of our common stock designated by us. However, there can be no assurance that Cantor will be successful in consummating such sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. In addition, we will not be able to make sales of our common stock pursuant to the sales agreement unless certain conditions are met, which include the effectiveness of the Form S-3; accuracy of representations and warranties made to Cantor under the sales agreement; compliance with laws; and the continued listing of our stock on the Nasdaq Global Market. In addition, Cantor is permitted to terminate the sales agreement at any time. If we are unable to access funds through sales under the sales agreement, or it is terminated by Cantor, we may be unable to access capital on favorable terms or at all.

To the extent that we sell shares pursuant to the sales agreement, it will dilute the holdings of our existing stockholders, and may result in downward pressure on the price of our common stock. If we sell shares under the sales agreement at a time when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.

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. Daravita Limited (formerly Alkermes plc) which has licensed us the right to sell Zohydro ER in the United States, has been granted sufficient procurement quota of hydrocodone by the DEA to support our current demand of Zohydro ER and expected growth through the end of 2015.

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. Daravita 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. Daravita's 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 Daravita’s procurement quota for hydrocodone or the 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.

We may not be able to maintain orphan drug designation or obtain or maintain orphan drug exclusivity for Brabafen.

We have obtained orphan drug designation for Brabafen in the United States and Europe. In the United States, under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or European Medicines Agency, or EMA, from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug

designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

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The orphan drug exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

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, 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;
- 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 began in May 2014 and extends for at least 30 days). Thereafter, manufacturers must submit reports by the 90th day of each subsequent calendar year; and
- 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

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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 product, Zohydro ER, our current product candidates, including Relday and Brabafen, 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 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.

We in-license certain intellectual property for Zohydro ER from Daravita, 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 Daravita and Durect, we cannot be certain that such activities by Daravita 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. Daravita 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 Daravita 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 Daravita. 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 Daravita 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. We also in-license certain data from a continuing, long-term, open-label study in 15 Dravet syndrome patients, as well as certain intellectual property related to fenfluramine for the treatment of Dravet syndrome from the Universities.

On August 13 and September 20, 2014, we received separate notices of paragraph IV certifications from Actavis and from Alvogen, respectively, advising us of the filing of ANDAs with the FDA for a generic version of Zohydro ER. These certification notices allege that the two U.S. patents listed in the FDA’s Orange Book for Zohydro ER, with an expiration date in November 2019, will not be infringed by Actavis' or Alvogen’s proposed products, are invalid and/or are unenforceable. On September 3, 2014, Daravita filed suit in the United States District Court for the District of Delaware against Actavis, and on November 3, 2014, Daravita filed suit in the United States District Court for the District of Delaware against Alvogen. Daravita has licensed rights to Zohydro ER to us, and, under the Zohydro ER license agreement, Daravita has the right to control the enforcement of patents and related proceedings involving Zohydro ER and any prospective generic entrant. We intend to vigorously enforce the intellectual property rights relating to Zohydro ER, but we cannot predict the outcome of these matters or guarantee the outcome of any litigation. An adverse outcome in this litigation could result in one or more generic versions of Zohydro ER being launched in the United States before the expiration of the applicable patents. Since Zohydro ER is currently our only approved product, the introduction of a generic version of Zohydro ER could have a material adverse effect on our business, results of operations, financial condition and prospects.

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 Daravita, 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,

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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 wherein 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 active pharmaceutical ingredients, or 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 U.S. Patent and Trademark Office, or PTO, and Congress have recently made significant changes to the patent system. There have been three U.S. Supreme Court decisions that now show a trend of the Supreme Court which is distinctly negative on patents. The trend of these decisions along with resulting changes in patentability requirements being implemented by the U.S. Patent and Trademark Office could make it increasingly difficult for us to obtain and maintain patents on our products. 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 the same or similar to the pharmaceutical compounds used in Zohydro ER and our product candidates but that are not covered by the claims of our patents or our in-licensed patents;
- the APIs in 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;
- 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 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.

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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 2015 through 2026 and the patents and patent applications licensed to us by Daravita are expected to expire in 2019.

As of September 30, 2014, our patent portfolio included 23 issued U.S. patents, 4 pending U.S. patent applications, 43 issued foreign patents and 7 pending foreign patent applications relating to various aspects of Sumavel DosePro and our DosePro technology. Thirteen of our U.S. patents relating to our DosePro technology, U.S. Patent Nos. 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, 8,343,130, 8,663,158 and 8,715,259 are expected to expire in 2016, 2017, 2026, 2026, 2023, 2023, 2025, 2022, 2024, 2022, 2022 and 2023, respectively. 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, 8,267,903 and 8,715,259 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 and 8,663,158 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 Daravita, as applicable, will lose the right to exclude others from practicing the claimed inventions. Additionally, eleven of these thirteen patents are the only patents currently listed in the FDA Orange Book for Sumavel DosePro. Two patents are listed for Zohydro ER. The expiration of the Orange Book listed patents 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 Daravita 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 Daravita or Durect, as applicable, and we have limited control over the amount or timing of resources Daravita or Durect devotes on our behalf or the priority they place on enforcing these patent rights.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

Our existing licenses with Daravita, Durect and the Universities imposes various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate the license, in which event we would not be able to develop or market the affected products. If we lose such license rights, our business, results of operations, financial condition and prospects may be materially adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer similar consequences.

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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 nine months ended September 30, 2014, the price per share for our common stock on the Nasdaq Global Market has ranged from a low sale price of $1.14 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 Zohydro ER, including sales and revenue trends;
- announcements concerning our sNDA for the formulation of Zohydro ER with abuse deterrent properties;
- FDA or international regulatory actions and whether and when we receive regulatory approval for any of our product candidates;
- negative publicity, including political actions and, potentially, court decisions, related to Zohydro ER;
- announcements of the introduction of new products by us or our competitors, including abuse deterrent formulations of hydrocodone products;
- the development status of Relday, Brabafen or any of our other product candidates, including the results from our clinical trials;
- 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, Brabafen 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 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;
- 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.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. As of September 30, 2014, we had research coverage by only five securities analysts. If these securities analysts cease coverage of our company, the trading price for our stock would be negatively impacted. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

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 September 30, 2014, we had 141,044,864 shares of common stock outstanding. Of these shares, approximately 102,907,400 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 September 30, 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.

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

Unregistered Sales of Equity Securities

Not applicable.

Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Alvogen Paragraph IV Litigation

On Novemer 3, 2014, Daravita filed suit in the United States District Court for the District of Delaware against Alvogen. Daravita has licensed rights to Zohydro ER to us. Under the license agreement with Daravita, Daravita has the right to control the enforcement of patents and related proceedings involving Zohydro ER and any prospective generic entrant.

As previously reported, on September 29, 2014, we received a notice from Alvogen concerning its filing of an ANDA containing a “Paragraph IV” patent certification with the FDA for a generic version of Zohydro ER. The FDA will determine whether Alvogen may be eligible for the 180-day exclusivity period described in 21 U.S.C. § 355(j)(5)(B)(iv).

The lawsuit filed by Daravita alleges that Alvogen has infringed U.S. Patent Nos. 6,228,398, or the ’398 patent, and 6,902,742, or the ’742 patent, by filing its ANDA seeking approval from the FDA to market a generic version of Zohydro ER prior to the expiration of these patents. The ’398 patent and ’742 patent are listed in the FDA’s Orange Book. The patent infringement lawsuit was filed within 45 days of receipt of the notice letter, thereby triggering a stay of FDA approval of the Alvogen ANDA until the earlier of the expiration of a 30-month period, the expiration of the ’398 patent and ’742 patent, the entry of a settlement order or consent decree stating that the ’398 patent and ’742 patent are invalid or not infringed, a decision in the infringement case that is favorable to Alvogen, or such shorter or longer period as the court may order.

Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for Zohydro ER. Specifically, the FDA has granted Zohydro ER three years of regulatory exclusivity, which expires in October 2016.

We and Daravita intend to vigorously enforce the intellectual property rights relating to Zohydro ER to prevent the marketing of infringing generic products prior to the expiration of their patents. The ’398 patent and the ’742 patent each expire November 1, 2019. However, given the unpredictability inherent in litigation, we cannot predict the outcome of this matter or guarantee the outcome of any litigation.

Teva Letter Agreement

On November 5, 2014, we entered into a letter agreement with Teva Pharmaceuticals USA, Inc., or Teva, under which we granted Teva a right of reference to certain carcinogenicity data generated by us for hydrocodone bitrate for use in connection with Teva’s NDA for its extended-release hydrocodone product candidate. Teva is obligated to pay us a one-time fee of $3.5 million within 30 days of the date of the letter agreement. The foregoing description of the letter agreement is not complete and is qualified in its entirety by reference to the letter agreement. We expect to file the letter agreement with our Annual Report on Form 10-K for the year ended December 31, 2014.

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Cantor Controlled Equity Offering Sales Agreement

On November 6, 2014, we entered into a Controlled Equity Offering Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., as sales agent, or Cantor, under which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to $25.0 million through Cantor.

Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, Cantor may sell the shares by methods deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act, including sales made directly on the Nasdaq Global Market, on any other existing trading market for the common stock or to or through a market maker. In addition, Cantor may sell the common stock by any other method permitted by law, including in privately negotiated transactions. Subject to the terms and conditions of the Sales Agreement, Cantor will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the Nasdaq Global Market, to sell the shares from time to time, based upon our instructions. Sales of our common stock made pursuant to the controlled equity offering program, if any, will be made under our shelf registration statement on Form S-3 filed on November 6, 2014, following such time as the registration statement is declared effective by the SEC. However, such registration statement cannot be declared effective until such time as we have filed certain financial statements from our recent acquisition of Brabant as required by SEC rules, which must be filed within 71 days of the date of our Current Report on Form 8-K filed with the SEC on October 27, 2014.

We are not obligated to, and we cannot provide any assurances that we will, make any sales of the shares under the Sales Agreement. The Sales Agreement will terminate upon the earlier of the termination of the Sales Agreement as permitted therein. The Sales Agreement may be terminated by Cantor or us at any time upon 10 days notice to the other party, or by Cantor at any time in certain circumstances, including the occurrence of a material adverse change in us.

We will pay Cantor commissions for its services in acting as agent in the sale of common stock. Cantor will be a commission in an amount equal to 3% of the gross sales price per share sold up to aggregate gross proceeds of $12.5 million, and 2.5% of the gross sales price per share sold on aggregate gross proceeds above $12.5 million.

The foregoing description of the Sales Agreement is not complete and is qualified in its entirety by reference to the Sales Agreement, a copy of which is filed as Exhibit 1.2 to our Registration Statement on Form S-3 filed on November 6, 2014 with the SEC and is incorporated herein by reference.

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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†	Third Amendment to License Agreement, dated as of September 12, 2014, by and between the Registrant and Daravita Limited
10.2†	First Amendment to Commercial Manufacturing and Supply Agreement, dated as of September 12, 2014, by and between the Registrant and Daravita Limited

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10.3†	Amendment No. 2 - Development & Option Agreement, dated as of September 15, 2014, by and between the Registrant and Altus Formulation, Inc.
10.4†	Waiver Agreement between the Registrant and Purdue Pharma L.P. dated October 29, 2014
10.5†	Collaboration and License Agreement, dated as of October 23, 2014, amount The Katholieke Universiteit Leuven, University Hospital Antwerp and Brabant Pharma Limited
10.6	Office Lease, dated as of August 5, 2014, by and between the Registrant and Kilroy Realty, L.P.
10.7(6)	Sale and Purchase Agreement, dated October 24, 2014, by and among Zogenix Inc. Europe, Zogenix Inc., Brabant Pharma Limited and Anthony Clarke, Richard Stewart, Ann Soenen-Darcis, Jennifer Watson, Reyker Nominees Limited and Aquarius Life Science Limited
10.8(7)	Sales Agreement, dated November 6, 2014, by and between the Registrant and Cantor Fitzgerald & Co.
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 September 30, 2014, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Comprehensive Income (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.
(6) Filed with the Registrant's Current Report on Form 8-K on October 27, 2014.
(7) Filed with the Registrant's Registration Statement on Form S-3 on November 6, 2014.
† 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: 11/6/2014

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

Date: 11/6/2014

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