ZOGENIX, INC.
Form 10-Q
August 10, 2015
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2015
OR

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

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

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

Delaware	20-5300780
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
12400 High Bluff Drive, Suite 650 San Diego, California (Address of Principal Executive Offices)	92130 (Zip Code)
858-259-1165 (Registrant's Telephone Number, Including Area Code)	

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

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

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

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of August 3, 2015 was 19,205,228.

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

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	June 30, 2015 (Unaudited)	December 31, 2014 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$77,372	$42,205
Restricted cash	10,000	8,500
Short-term investments	9,062	—
Trade accounts receivable, net	5,954	6,078
Inventory	12,646	11,444
Prepaid expenses and other current assets	4,500	2,555
Current assets of discontinued operations	5,796	7,196
Total current assets	125,330	77,978
Property and equipment, net	9,823	10,618
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	2,579	2,832
Noncurrent assets of discontinued operations	231	2,673
Total assets	$246,697	$202,835
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$4,293	$4,742
Accrued expenses	6,681	6,016
Accrued compensation	1,988	3,157
Accrued income taxes	6,521	—
Common stock warrant liabilities	5,657	5,093
Revolving credit facility	—	1,450
Long-term debt, current portion	3,040	—
Deferred revenue	827	1,472
Current liabilities of discontinued operations	9,990	22,307
Total current liabilities	38,997	44,237
Note payable	2,641	2,461
Long term debt	16,357	19,242
Deferred revenue, less current portion	7,493	7,063
Contingent purchase consideration	51,400	53,000
Deferred income taxes	20,500	20,500
Other long-term liabilities	1,229	1,053
Stockholders' equity:		
Common stock, $0.001 par value; 50,000 shares authorized at June 30, 2015 and December 31, 2014; 19,186 and 19,170 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	19	19
Additional paid-in capital	461,671	456,920
Accumulated other comprehensive loss	(1,552)	—
Accumulated deficit	(352,058)	(401,660)
Total stockholders' equity	108,080	55,279
Total liabilities and stockholders' equity	$246,697	$202,835

See accompanying notes.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenue:				
Contract manufacturing revenue	$6,003	$2,238	$10,184	$2,238
Net product revenue	—	3,355	—	9,840
Service and other product revenue	1,364	1,144	1,797	2,048
Total revenue	7,367	6,737	11,981	14,126
Operating (income) expense:				
Cost of contract manufacturing	5,803	1,935	9,726	1,935
Cost of goods sold	—	1,928	—	5,261
Royalty expense	71	172	143	439
Research and development	6,241	3,162	11,390	5,703
Selling, general and administrative	7,582	9,062	13,851	21,590
Change in fair value of contingent consideration	(600)	—	(1,600)	—
Impairment of long-lived assets	—	838	—	838
Net gain on sale of business	—	(79,980)	—	(79,980)
Total operating (income) expense	19,097	(62,883)	33,510	(44,214)
Income (loss) from operations	(11,730)	69,620	(21,529)	58,340
Other income (expense):				
Interest income	9	6	14	12
Interest expense	(907)	(1,029)	(1,555)	(2,915)
Loss on early extinguishment of debt	—	(1,254)	—	(1,254)
Change in fair value of warrant liabilities	(975)	10,201	(564)	18,470
Change in fair value of embedded derivatives	—	—	—	(14)
Other expense	(39)	(8)	(160)	(55)
Total other income (expense)	(1,912)	7,916	(2,265)	14,244
Net income (loss) from continuing operations before income taxes	(13,642)	77,536	(23,794)	72,584
Benefit for income taxes	6,946	—	6,932	—
Net income (loss) from continuing operations	(6,696)	77,536	(16,862)	72,584
Discontinued operations:				
Income (loss) from discontinued operations	79,160	(14,672)	66,464	(30,651)
Net income	$72,464	$62,864	$49,602	$41,933
Basic net income (loss) per share:[1]				
Continuing operations	$(0.35)	$4.43	$(0.88)	$4.16
Discontinued operations	4.13	(0.84)	3.47	(1.76)
Total	$3.78	$3.59	$2.59	$2.40
Diluted net income (loss) per share:[1]				
Continuing operations	$(0.35)	$4.43	$(0.88)	$3.03
Discontinued operations	4.13	(0.84)	3.47	(1.72)

Total	$3.78	$3.59	$2.59	$1.31
Weighted average shares outstanding, basic	19,176	17,498	19,173	17,454
Weighted average shares outstanding, diluted	19,176	17,498	19,173	17,846

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Statements of Comprehensive Income				
Net income	$72,464	$62,864	$49,602	$41,933
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	(1,552)	—	(1,552)	—
Comprehensive income	$70,912	$62,864	$48,050	$41,933

(1) The sum of net income (loss) per share amounts may not equal the totals due to rounding.

See accompanying notes.

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

	Six Months Ended June 30,	
	2015	2014
Operating activities:		
Net income	$49,602	$41,933
Adjustments to reconcile net income to net cash used in operating activities:		
Stock-based compensation	4,465	5,292
Stock-based compensation, restructuring	153	—
Depreciation and amortization	814	820
Amortization of debt issuance costs and non-cash interest charges	481	287
Accrued income taxes	6,521	—
Loss on early extinguishment of debt	—	1,254
Gain on sale of business	(89,053)	(79,980)
Loss on impairment of long-lived assets	—	838
Change in fair value of warrant liabilities	564	(18,470)
Change in fair value of embedded derivatives	—	14
Change in fair value of contingent purchase consideration	(1,600)	—
Changes in operating assets and liabilities:		
Trade accounts receivable	2,559	745
Inventory	542	(5,720)
Prepaid expenses and other current assets	(3,493)	(9,378)
Other assets	860	(4,995)
Accounts payable and accrued expenses	(9,876)	10,666
Deferred revenue	(5,413)	15,990
Net cash used in operating activities	(42,874)	(40,704)
Investing activities:		
Purchases of property and equipment	(68)	83
Proceeds from sale of business	80,926	89,624
Change in restricted cash from sale of business	(1,500)	(8,500)
Net cash provided by investing activities	79,358	81,207
Financing activities:		
Proceeds of working capital advance	—	7,000
Repayment of revolving credit facility	(1,450)	—
Repayment of debt	—	(40,041)
Proceeds from exercise of common stock options and warrants	7	1,508
Proceeds from issuance of common stock	126	244
Net cash used by financing activities	(1,317)	(31,289)
Net increase in cash and cash equivalents	35,167	9,214
Cash and cash equivalents at beginning of period	42,205	72,021
Cash and cash equivalents at end of period	$77,372	$81,235
Noncash investing and financing activities:		
Deferred financing charges in accounts payable	$294	$—

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 central nervous system disorders who need innovative treatment alternatives to help them return to normal daily functioning. 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.

On May 16, 2014, the Company sold its Sumavel DosePro business to Endo Ventures Bermuda and Endo Ventures Limited (collectively, Endo). In connection with the sale, the Company entered into a supply agreement under which the Company performs contract manufacturing services to provide Sumavel DosePro product exclusively to the purchaser subsequent to the sale.

On April 24, 2015, the Company sold its Zohydro ER business, including the registered patents and trademarks, certain contracts, the new drug application and other regulatory approvals, documentation and authorizations, the books and records, marketing materials and product data relating to Zohydro ER to Ferrimill Limited (Ferrimill), a wholly-owned subsidiary or Pernix Therapeutics, Inc., and received $80,000,000 in cash, $10,000,000 of which was placed in escrow, plus approximately $926,000 for Zohydro ER finished goods inventory acquired by the purchaser. Zohydro ER activity has been excluded from continuing operations for all periods herein and reported as discontinued operations as a result of this sale. See Note 5, Sale of Zohydro ER business, for additional information on the divestiture of the Company's Zohydro ER product line. All prior period Zohydro ER business information herein has been recast to conform to this presentation.

On July 1, 2015, the Company effected a 1-for-8 reverse stock split of its common stock and changed its authorized shares of common stock to 50,000,000. All historical per share information presented herein has been adjusted to reflect the effect of the reverse stock split and change to authorized shares of common stock.

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 products and proceeds from business collaborations and divestitures. As the Company continues to incur operating 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 may continue to need to raise additional cash. These conditions raised substantial doubt about the Company’s ability to continue as a going concern as noted in our consolidated financial statements for the year ended December 31, 2014. 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.

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 except for the sale of the Company's Zohydro ER business described in Note 5 and the restructuring costs described in Note 6 to these consolidated financial statements, 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 the Company's Annual Report on Form 10-K and Form 10-K/A for the fiscal year ended December 31, 2014, each as filed with the SEC. The Company's Annual Report on Form 10-K and Form 10-K/A for the fiscal year ended December 31, 2014 have not been retroactively revised to reflect the sale of Zohydro ER as a discontinued operation or to reflect the

1-for-8 reverse stock split.

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.

Restricted Cash

In connection with its sale of the Zohydro ER business in April 2015, the Company has $10,000,000 of cash in escrow as of June 30, 2015 to fund potential indemnification claims for a period of 12 months from the closing date of the sale.

In connection with its sale of the Sumavel DosePro business in May 2014, the Company had $8,500,000 of cash in escrow as of December 31, 2014 to fund potential indemnification claims for a period of 12 months from the closing date of the sale. The Company received the full amount from escrow in May 2015.

The Company classifies these cash flows as investing activities in the consolidated statement of cash flows as the source of the restricted cash is related to the sales of the Zohydro ER and Sumavel DosePro businesses.

Short-term Investments

Short-term investments consist of shares of Pernix common stock received as partial consideration for the purchase of the Zohydro ER business. The investments are subject to restrictions over disposition, pledging or assignment for six months after the closing date of the Zohydro ER sale as specified in the related asset purchase agreement the Company entered into with Pernix Ireland Limited and Pernix Therapeutics (together with Pernix Ireland Limited, Pernix) dated March 10, 2015 (the Asset Purchase Agreement).

Management has classified these short-term investments as available-for-sale when acquired and evaluates such classification as of each balance sheet date. Short-term investments are carried at fair value, with the unrealized gains and losses, net of tax, reported in other comprehensive loss, a component of stockholders' equity. The Company evaluates its short-term investments to assess whether any unrealized loss position is other than temporarily impaired. Impairment is considered to be other than temporary if it is likely that the Company will sell the investments before the recovery of the cost basis. Realized gains, losses, and declines in value judged to be other than temporary is reported in other income (expense) in the consolidated statements of operations and comprehensive income.

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.

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 short-term investments, common stock warrant liabilities and contingent purchase consideration within Level 3 of the fair value hierarchy because they are valued using valuation models with significant unobservable inputs. Assets and liabilities measured at fair value on a recurring basis at June 30, 2015 and December 31, 2014 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 June 30, 2015				
Assets				
Cash equivalents[1]	$69,208	—	—	$69,208
Short-term investments[2]	$—	—	9,062	$9,062
Liabilities				
Common stock warrant liabilities[3]	$—	—	5,657	$5,657
Contingent purchase consideration [4]	$—	—	51,400	$51,400
At December 31, 2014				
Assets				
Cash equivalents[1]	$8,021	—	—	$8,021
Liabilities				
Common stock warrant liabilities[3]	$—	—	5,093	$5,093
Contingent purchase consideration [4]	$—	—	53,000	$53,000

(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) Short-term investments consist of Pernix Therapeutics common stock which was acquired in conjunction with the sale of the Zohydro ER business in April 2015. The Company ascertains fair value of short-term investments by using quoted prices for Pernix Therapeutics' common stock on a publicly traded market (a Level 1 input) less a lack of marketability discount on the fair value of the investments because there are restrictions on when the Company can trade the securities. The Company considers the inputs used to calculate the lack of marketability discount Level 3 inputs and, as a result, categorized the short-term investments as Level 3. The lack of marketability discount was determined by using an "Average-Strike Put Option Model of the Marketability Discount" to value a hypothetical put option to approximate the reduction in value of the stock until the restriction ends. Inputs used to derive the discount included an estimation of the amount of time that the stock will be held subject to trading restrictions based on contracted lock-up period, expected volatility of the stock over the term of the remaining trading restrictions, and assumed lack of dividends during the restriction period. An increase in any of these inputs would increase the discount for lack of marketability and thereby reduce the overall fair value of the short-term investments. As of June 30, 2015, the gross fair value of short-term investments was $10,000,000, and the lack of marketability discount was $900,000. During the three months ended June 30, 2015, other comprehensive income included unrealized losses of $1,600,000.

(3) Common stock warrant liabilities are associated with warrants issued in connection with the Company's July 2012 public offering of common stock and warrants (see Note 8) and warrants issued in connection with the financing agreement entered into with Healthcare Royalty Partners (Healthcare Royalty), dated June 30, 2011, (the Healthcare Royalty financing agreement), 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 change in the fair value of the common stock warrant liabilities as of June 30, 2015 was primarily driven by the increase in the market price of the Company's common shares at June 30, 2015 as compared against December 31, 2014 measurement dates.

(4) Contingent purchase consideration was measured at fair value using the income approach based on significant unobservable inputs including management's estimates of the probabilities of achieving specific net sales levels and development milestones and appropriate risk adjusted discount rates. Significant changes of either unobservable input could have a significant effect on the calculation of fair value of the contingent purchase consideration liability.

The following table provides a reconciliation of assets and liabilities measured at fair value using significant unobservable inputs (Level 3) for the six months ended June 30, 2015 (in thousands):

	Short-term Investments	Contingent Purchase Consideration	Common Stock Warrant Liabilities
Balance at December 31, 2014	$—	$53,000	$5,093
Additions	10,614	—	—
Changes in fair value	(1,552)	(1,600)	564
Balance at June 30, 2015	$9,062	$51,400	$5,657

The changes in fair value of the short-term investments shown in the table above are recorded through other comprehensive loss on the consolidated balance sheet. The changes in fair value of the liabilities shown in the table above are recorded through change in fair value of contingent consideration in operating expenses and change in fair value of warrant liabilities in other income (expense) in the consolidated statements of operations and comprehensive income.

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 income (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 income (loss) per share when their effect is dilutive.

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

	Three Months Ended June 30,			
	2015		2014	
	Continuing operations	Discontinued operations	Continuing operations	Discontinued operations
Numerator				
Net income (loss), basic	$(6,696)	$79,160	$77,536	$(14,672)
Effect of dilutive securities:				
Common stock warrants	—	—	—	—
Equity awards	—	—	—	—
	—	—	—	—
Net income (loss), diluted	$(6,696)	$79,160	$77,536	$(14,672)
Denominator				
Weighted average common shares outstanding, basic	19,176	19,176	17,498	17,498
Effect of dilutive securities:				
Common stock warrants	—	—	—	—
Equity awards	—	—	—	—
Dilutive potential shares of common stock	—	—	—	—
Weighted average common shares outstanding, diluted	19,176	19,176	17,498	17,498
Basic net income (loss) per share	$(0.35)	$4.13	$4.43	$(0.84)
Diluted net income (loss) per share	$(0.35)	$4.13	$4.43	$(0.84)

	Six Months Ended June 30,			
	2015		2014	
	Continuing operations	Discontinued operations	Continuing operations	Discontinued operations
Numerator				
Net income (loss), basic	$(16,862)	$66,464	$72,584	$(30,651)
Effect of dilutive securities:				
Common stock warrants	—	—	(18,470)	—
Equity awards	—	—	—	—
	—	—	(18,470)	—
Net income (loss), diluted	$(16,862)	$66,464	$54,114	$(30,651)
Denominator				
Weighted average common shares outstanding, basic	19,173	19,173	17,454	17,454
Effect of dilutive securities:				
Common stock warrants	—	—	392	392
Equity awards	—	—	—	—
Dilutive potential shares of common stock	—	—	392	392
Weighted average common shares outstanding, diluted	19,173	19,173	17,846	17,846
Basic net income (loss) per share	$(0.88)	$3.47	$4.16	$(1.76)
Diluted net income (loss) per share	$(0.88)	$3.47	$3.03	$(1.72)

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There were 521,000 and 297,000 dilutive securities (in common stock equivalent shares), from common stock options excluded from the calculation of diluted net income (loss) during the three and six months ended June 30, 2015, respectively, because to include them would be anti-dilutive. There were 1,157,000 and 1,586,000 dilutive securities (in common stock equivalent shares), from common stock options and restricted stock units excluded from the calculation of diluted net income (loss) during the three and six months ended June 30, 2014, respectively, because to include them would be anti-dilutive. All common stock warrants were excluded from the calculation of diluted net income (loss) during the three and six months ended June 30, 2015 and the three months ended June 30, 2014 as the exercise price of the warrants was greater than the Company's average stock price during these periods.

Goodwill and Intangible Assets

Goodwill represents the excess of acquisition cost over the fair value of the net assets of acquired businesses. Goodwill has an indefinite useful life and is not amortized, but instead tested for impairment annually. Intangible assets consist of in-process research and development with an indefinite useful life that is not amortized, but instead tested for impairment until the successful completion and commercialization or abandonment of the associated research and development efforts, at which point the in-process research and development asset is either amortized over its estimated useful life or written-off immediately.

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.

Revenue Recognition

The Company recognized revenue from contract manufacturing, service fees earned on collaborative arrangements and the sale of Sumavel DosePro prior to its sale in May 2014. The Company also recognizes revenue from the sale of Zohydro ER, which is included in net income (loss) from discontinued operations in the consolidated statement of operations and comprehensive income. 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 defers recognition of revenue on product shipments of Zohydro ER until the right of return no longer exists, as the Company was not able to 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.

Contract Manufacturing Revenue

The Company and Endo entered into a supply agreement in connection with the sale of the Sumavel DosePro business to Endo in May 2014. Under the terms of the supply agreement, the Company retains the sole and exclusive right and the obligation to manufacture or supply Sumavel DosePro to Endo. 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.

Product Revenue, Net

The Company sold Sumavel DosePro through May 2014, and sold Zohydro ER through April 2015, 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. The Company is responsible for all returns of Sumavel DosePro product distributed by the Company prior to the sale of the Sumavel DosePro business up to a maximum per unit amount as specified in the sales agreement.

Given the limited sales history of Zohydro ER, the Company was not able to reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company deferred 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 did not have a significant history estimating the number of patient prescriptions dispensed. If the Company underestimated or overestimated patient prescriptions dispensed for a given period, adjustments to revenue from discontinued operations may be necessary in future periods. The deferred revenue balance does not have a direct correlation with future revenue recognition as the Company records sales deductions at the time the prescription unit was dispensed. In addition, the costs of Zohydro ER associated with the deferred revenue were recorded as deferred costs, which were included in inventory, until such time the related deferred revenue is recognized. The Company is responsible for returns, rebates, chargebacks, and related Health Care Reform fees for product sold. Revenue for Zohydro ER is included in discontinued operations in the consolidated statement of operations and comprehensive income.

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 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 was effective for fiscal years beginning after December 15, 2014, with early adoption permitted. The Company adopted the guidance in the first quarter of 2015.

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 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 15, 2017, 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. On July 9, 2015, the FASB deferred the effective date of this standards update to fiscal years beginning after December 15, 2017, with early adoption permitted on the original effective date of fiscal years beginning after December 15, 2016. The Company is evaluating the transition method, timing and impact of adopting this new accounting standard on its financial statements and related disclosures.

In August 2014, the FASB issued guidance which requires management to assess an entity's ability to continue as a going concern and to provide related disclosures in certain circumstances. Under the new guidance, disclosures are required when conditions give rise to substantial doubt about an entity's ability to continue as a going concern within one year from the financial statement issuance date. The guidance is effective for annual periods ending after December 15, 2016, and all annual and interim periods thereafter. Early application is permitted. The Company is evaluating the timing and impact of adopting this new accounting standard on its financial statements and related disclosures and does not expect that the adoption of the guidance will have a material impact on the Company's financial statements.

In April 2015, the FASB issued guidance which requires debt issuance costs related to a recognized debt liability to be presented on the balance sheet as a direct deduction from the debt liability instead of as an asset. The guidance is effective for annual and interim reporting periods beginning on or after December 15, 2016. Early adoption is permitted. The Company is evaluating the timing and impact of adopting this new accounting standard on its financial statements and related disclosures and does not expect that the adoption of the guidance will have a material impact on the Company's financial statements.

In July 2015, the FASB issued guidance which requires that certain inventory, including inventory measured using the first-in-first-out method, be measured at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years.

The Company is currently evaluating the timing and impact of adopting this new accounting standard on its financial statements and related disclosures.

3. Short-term Investments

Short-term investments consist of shares of Pernix Therapeutic Holding Inc. common stock acquired in April 2015 as partial consideration for the purchase of the Zohydro ER business. The investments are subject to restrictions over disposition, pledging or assignment for six months after the closing date of the Zohydro ER sale as specified in the related Asset Purchase Agreement. Amortized cost represents the fair value at the date of acquisition as determined by the publicly traded quoted market value per share less a discount for lack of marketability.

	June 30, 2015		
	Amortized Cost	Gross Unrealized Losses	Estimated Fair Value
Equity securities, available for sale	$10,614	$(1,552)	$9,062

As of June 30, 2015, there was no impairment considered other-than-temporary for the period presented as the Company has the intent and ability to hold the short-term investments for a period of time sufficient to allow for

recovery of the cost basis.

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4. Inventory

Inventory consists of the following (in thousands):

	June 30, 2015	December 31, 2014
Raw materials	$3,773	$3,453
Work in process	8,873	7,991
Total	$12,646	$11,444

5. Sale of Zohydro ER business

On March 10, 2015, the Company entered into the Asset Purchase Agreement whereby the Company agreed to sell its Zohydro ER business to Pernix, and on April 24, 2015, the Company completed the sale to Ferrimill, a subsidiary of Pernix, as a substitute purchaser. The Zohydro ER business divestiture included the registered patents and trademarks, certain contracts, the new drug application and other regulatory approvals, documentation and authorizations, the books and records, marketing materials and product data relating to Zohydro ER.

The Company received consideration of $80,000,000 in cash, $10,000,000 of which has been deposited in escrow to fund potential indemnification claims for a period of 12 months, and $10,614,000 in Pernix common stock. Further, Ferrimill purchased $926,000 of Zohydro ER inventory. The Company also received consideration due based on percentage of purchase discounts received by Ferrimill through June 30, 2015 based on an assigned supply agreement of $2,057,000 which is recorded as current assets of discontinued operations in the consolidated balance sheet at June 30, 2015. The Company has agreed to indemnify the purchaser for certain intellectual property matters up to an aggregate amount of $5,000,000.

In addition to the cash payment paid at closing, the Company is eligible to receive additional cash payments of up to $283,500,000 based on the achievement of pre-determined milestones, including a $12,500,000 payment upon approval by the U.S. Food and Drug Administration of an abuse-deterrent extended-release hydrocodone tablet (currently in development in collaboration with Altus Formulation Inc.) and up to $271,000,000 in potential sales milestones, as well as a percentage of purchase discounts received by Ferrimill based on an assigned supply agreement up to a total of $2,400,000,of which $2,057,000 has been received as of June 30, 2015. The purchaser will assume responsibility for the Company's obligations under the purchased contracts and regulatory approvals, as well as other liabilities associated with the Zohydro ER business arising after the sale date. The Company retained all liabilities and certain assets associated with the Zohydro ER business arising prior to the sale.

The net gain on sale of the Zohydro ER business totaling $75,575,000 was calculated as the difference between the fair value of non-contingent consideration received for the business and the carrying value of the net assets transferred to Ferrimill. The net gain on sale of business may be adjusted in future periods by the contingent consideration based upon the achievement of pre-determined regulatory approval and sales milestones and eligible purchase discounts received by the acquirer.

The following summarizes the gain on sale (in thousands):

Non-contingent consideration received	$93,597
Carrying value of assets transferred to Ferrimill	(2,516)
Transaction costs	(2,028)
Net gain on sale of business before income tax	89,053
Income tax expense (see Note 10)	(13,478)
Net gain on sale of business	$75,575

As a result of the Company's strategic decision to sell the Zohydro ER business and focus on clinical development of ZX008 and Relday, the consolidated statement of operations and comprehensive income for the three and six months ended June 30, 2014 and the consolidated balance sheet as of December 31, 2014 have been retrospectively revised to

reflect the financial results from the Zohydro ER business, and the related assets and liabilities, as discontinued operations. The results of operations from discontinued operations presented below include certain allocations that management believes fairly reflect the utilization of services provided to the Zohydro ER business. The allocations do not include amounts related to general corporate

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administrative expenses or interest expense. Therefore, the results of operations from the Zohydro ER business do not necessarily reflect what the results of operations would have been had the business operated as a stand-alone entity. The following table summarizes the results of discontinued operations for the periods presented the consolidated statements of operations and comprehensive income for the three and six months ended June 30, 2015 and 2014 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
Discontinued operations	2015	2014	2015	2014
Revenues:				
Net product revenue	$4,173	$2,425	$9,179	$2,710
Operating expenses:				
Cost of product sold	612	446	1,952	495
Royalty expense	291	263	708	359
Research and development	1,020	957	5,829	1,954
Selling, general and administrative	3,097	15,431	14,233	30,553
Restructuring expense	568	—	568	—
Gain on sale of business	(89,053)	—	(89,053)	—
Total operating (income) expenses	(83,465)	17,097	(65,763)	33,361
Other income	5,000	—	5,000	—
Net income (loss) from discontinued operations before tax	92,638	(14,672)	79,942	(30,651)
Income tax expense	(13,478)	—	(13,478)	—
Net income (loss) from discontinued operations	$79,160	$(14,672)	$66,464	$(30,651)

The following table summarizes the assets and liabilities of discontinued operations as of June 30, 2015 and December 31, 2014 related to the Zohydro ER business (in thousands):

	June 30, 2015	December 31, 2014
Assets		
Current assets		
Trade accounts receivable	$365	$2,799
Inventory	251	1,995
Prepaid expenses and other current assets	5,180	2,402
Total current assets of discontinued operations	5,796	7,196
Other assets	231	2,673
Total assets of discontinued operations	$6,027	$9,869
Liabilities		
Current liabilities		
Accounts payable	$1,875	$3,781
Accrued expenses	5,814	9,470
Accrued compensation	376	1,933
Deferred revenue	1,925	7,123
Total current liabilities of discontinued operations	9,990	22,307
Total liabilities of discontinued operations	$9,990	$22,307

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Total stock-based compensation related to discontinued operations was $898,000 and $974,000 for the six months ended June 30, 2015 and 2014, respectively. Total amortization expense related to discontinued operations was $166,000 and $209,000 for the six months ended June 30, 2015 and 2014, respectively.

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6. Restructuring

In April 2015, the Company committed to a restructuring plan in conjunction with the sale of the Zohydro ER business in which approximately 100 employees transitioned employment to Pernix. The Company reduced its workforce by an additional 16 employees as a result of the divestiture. The Company recorded charges totaling $568,000 for the three and six months ended June 30, 2015 consisting of one-time termination benefits in connection with the restructuring plan, which are reflected in restructuring expense for the period in net income from discontinued operations on the consolidated statement of operations and comprehensive income.

The following table sets forth activity of the restructuring liability for the six months ended June 30, 2015 (in thousands):

Balance at December 31, 2014	$—
Costs incurred and charged to expense	568
Payments	(521)
Balance at June 30, 2015	$47

The balance of the restructuring liability at June 30, 2015 is included in current liabilities of discontinued operations in the consolidated balance sheet and is anticipated to be fully distributed by September 2015.

7. Co-Promotion, Waiver and Financing Agreements

Valeant Pharmaceuticals North America LLC Co-Promotion Agreement Termination

On June 27, 2013, the Company entered into a co-promotion agreement with Valeant Pharmaceuticals North America LLC (Valeant) to promote Migranal® 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, and Valeant paid the Company a co-promotion fee on a quarterly basis that represented specified percentages of net sales generated by the Company over defined baseline amounts of net sales. The original term of the agreement was through December 31, 2015.

In June 2015, the Company and Valeant entered into a Termination and Mutual Release Agreement, whereby the Co-Promotion Agreement terminated on June 12, 2015. In connection with the termination, Valeant made a one-time payment to the Company totaling $500,000, which has been recorded as service and other product revenue in the consolidated statements of operations and comprehensive income for the three months ended June 30, 2015.

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) in 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 Hysingla ER® 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 paid the Company (i) $5,000,000 in November 2014, (ii) was scheduled to pay $5,000,000 on July 1, 2015, and (iii) will pay 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.

The Company recognized the first $5,000,000 payment when received in 2014. The second installment payment, due July 1, 2015, was recognized as other income when received in June 2015, and is reflected in net income from discontinued operations in the consolidated statements of operations and comprehensive income for the three months ended June 30, 2015. The Company will record any future royalties when earned in accordance with terms of the Waiver Agreement.

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Oxford Finance LLC and Silicon Valley Bank Amended Loan and Security Agreement

On April 23, 2015, in connection with the sale of the Zohydro ER business, the Company, Oxford Finance LLC and Silicon Valley Bank entered into an amendment to the loan and security agreement dated December 30, 2014 which added an affirmative covenant requiring a liquidity ratio of 1.25 to 1 through the Company's receipt of positive data from placebo-controlled trials in the United States and European Union of ZX008 and terminated all encumbrances on the Company's personal property related to its Zohydro ER business. The remaining obligations under the loan and security agreement remain substantially unchanged.

8. Common Stock Warrants

In July 2012, in connection with a public offering of common stock and warrants, the Company sold warrants to purchase 1,973,025 shares of common stock (including over-allotment purchase) and at June 30, 2015 warrants to purchase 1,901,931 shares of common stock are outstanding. The warrants are exercisable at an exercise price of $20.00 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 three and six months ended June 30, 2015, no warrants to purchase shares of common stock were exercised, and during the year ended December 31, 2014, warrants to purchase 58,156 shares of common stock were exercised. The Company recognized no proceeds from the exercise of warrants during the three and six months ended June 30, 2015 and $1,163,000 in proceeds from the exercise of warrants during the three and six months ended June 30, 2014. The fair value of the warrants outstanding was approximately $5,538,000 and $4,978,000 as of June 30, 2015 and December 31, 2014, respectively.

In July 2011, upon the closing of and in connection with the Healthcare Royalty financing agreement, the Company issued to Healthcare Royalty a warrant exercisable into 28,125 shares of common stock. The warrant is exercisable at $72.00 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 $119,000 and $115,000 as of June 30, 2015 and December 31, 2014, respectively.

9. Stock-Based Compensation

The Company uses the Black-Scholes option-pricing model for determining the estimated fair value of stock-based compensation for stock-based awards to employees and the board of directors. The assumptions used in the Black-Scholes option-pricing model for the three and six months ended June 30, 2015 and 2014 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Risk free interest rate	1.6% to 1.8%	1.6% to 1.9%	1.5% to 1.8%	1.6% to 2.0%
Expected term	5.1 to 6.1 years	5.1 to 6.1 years	5.1 to 6.1 years	5.1 to 6.1 years
Expected volatility	76.7% to 79.2%	84.2% to 84.7%	76.7% to 79.2%	84.2% to 84.9%
Expected dividend yield	— %	— %	—%	—%

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

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

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Cost of goods sold	$103	$141	$196	$268
Research and development	186	364	409	721
Selling, general and administrative	2,081	1,769	3,115	3,329
Total	$2,370	$2,274	$3,720	$4,318

As of June 30, 2015, there was approximately $8,338,000 of total unrecognized compensation costs related to outstanding employee and board of director stock options, which is expected to be recognized over a weighted average period of 2.4 years.

As of June 30, 2015, there were 207,000 unvested stock options outstanding to consultants, with approximately $262,000 of related unrecognized compensation expense based on a June 30, 2015 measurement date. These unvested stock options outstanding to consultants are expected to vest over a weighted average period of 2.7 years. In accordance with accounting guidance for stock-based compensation, the Company remeasures 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 expense (income) recognized from the valuation of stock options and restricted stock units to consultants was $56,000 and $82,000 for the three and six months ended June 30, 2015, respectively, and ($109,000) and ($150,000) for the three and six months ended June 30, 2014, respectively. Stock option expense for awards issued to consultants is included in the consolidated statement of operations and comprehensive income within selling, general and administrative expense.

10. Income taxes

Intraperiod tax allocation rules require the Company to allocate the provision for income taxes between continuing operations and other categories of earnings, such as discontinued operations. In periods in which the Company has a year-to-date pre-tax loss from continuing operations and pre-tax income in other categories of earnings, such as discontinued operations, the Company must allocate the tax provision to the other categories of earnings, and then record a related tax benefit in continuing operations. During the three months ended June 30, 2015, the Company recognized net income from discontinued operations, and, as a result, recorded income tax expense of $13,478,000, which is included in net income (loss) from discontinued operations in the consolidated statement of operations and comprehensive income. Accordingly, the Company recognized a related income tax benefit of $6,946,000 from continuing operations in the consolidated statement of operations and comprehensive income for the three months ended June 30, 2015. The remaining $6,532,000 income tax benefit to continuing operations will be recorded throughout the remainder of 2015.

11. Subsequent Events

In June 2015, the Company filed an amendment to its Fifth Amended and Restated Certificate of Incorporation to effect a reverse stock split of the Company’s common stock at a ratio of 1-for-8, and a change in the number of authorized shares of the Company’s common stock to 50,000,000 shares, which was approved by the Company's shareholders at the annual meeting held on June 18, 2015. The reverse stock split and change in authorized shares became effective July 1, 2015. Accordingly, all historical per share information presented in these consolidated financial statements as been adjusted to reflect the effect of the reverse stock split and change to authorized shares of common stock.

On July 20, 2015, the Company entered into an amended lease with Emery Station Joint Venture, LLC. The lease amendment extends the term of the original lease to November 30, 2022 and adds 9,916 rentable square feet to the existing 12,118 rentable square feet currently leased by the Company in Emeryville, California. The amendment also contains an option for the Company to expand its space leased from the landlord under certain conditions, as well as a renewal option for an additional five year term upon the expiration date. The lease amendment was effective as of July 16, 2015, and the landlord will deliver possession of the additional space leased within 45 days of the effective

date. Prior to October 1, 2015, the base rent for the Company's existing leased premises remains unchanged from the previous agreement. Following October 1, 2015, the base rent for the existing leased premises will be $39,384 per month. The base rent for the additional premises leased will be $32,227 per month, and the rent for the new premises will be abated for 60 days following the earlier of (a) the date the Company occupies the new premises for the purpose of conducting business and (b) the latter of (i) 21 days after the landlord delivers the new premises and (ii) October 1, 2015. The base rent for both the existing leased premises and additional leased premises will increase 3% on a yearly basis throughout the term, and the Company will pay a portion of common area and pass-through expenses in excess of base year amounts.

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In August 2015, the Company completed a public offering of 5,462,500 shares of its common stock at a public offering price of $18.00 per share, including the over-allotment provision granted to the underwriters of 712,500 shares. The shares were registered pursuant to a registration statement on Form S-3 filed on November 6, 2014. The Company received net proceeds of approximately $92,000,000, after deducting underwriting discounts and commissions and estimated offering-related transaction costs.

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

Forward-Looking Statements

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

- the progress and timing of clinical trials for ZX008, Relday and our other product candidates;
- the safety and efficacy of our product candidates;
- the timing of submissions to, and decisions made by, the U.S. Food and Drug Administration, or FDA , and other regulatory agencies, including foreign regulatory agencies, and demonstrating the safety and efficacy of our product candidates to the satisfaction of the FDA and such other agencies;
- the goals of our development activities and estimates of the potential markets for our product candidates, and our ability to compete within those markets;
- our ability to receive contingent milestone payments from the sale of the Zohydro ER and Sumavel DosePro businesses;
- adverse side effects or inadequate therapeutic efficacy of Zohydro ER that could result in product recalls, market withdrawals or product liability claims;
- estimates of the capacity of manufacturing and other facilities to support our product candidates;
- our and our licensors ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of our 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 any of our product candidates that may be approved for sale, the extent of such coverage and reimbursement and the willingness of third-party payors to pay for our products versus less expensive therapies;
- the impact of healthcare reform legislation; and
- projected cash needs and our expected future revenues, operations and expenditures.

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

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

DosePro®, Relday™ and Zogenix™ 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, 2014 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, 2014. We sold

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our Zohydro® ER business in April 2015, to a wholly-owned subsidiary of Pernix Therapeutics Holdings, Inc., or Pernix, for $80 million in cash, approximately 1.68 million shares of Pernix common stock, plus regulatory and sales milestones of up to $283.5 million. On July 1, 2015, we effected a reverse stock split of our common stock, or the reverse stock split, at an exchange ratio of 1-for-8, and changed the number of authorized shares of our common stock to 50,000,000. The reverse stock split applied to all of our outstanding shares of common stock and therefore did not affect any stockholder's relative ownership percentage.

Our Annual Report on Form 10-K for the year ended December 31, 2014, incorporated herein by reference, is presented without retrospectively reflecting the Zohydro ® ER business as a discontinued operation and without giving effect to the reverse stock split and new number of authorized shares of common stock. Unless otherwise stated, all shares and price per share numbers set forth in this Form 10-Q for periods prior to July 2, 2015 are presented after giving effect to the reverse stock split.

Overview

Background

We are a pharmaceutical company committed to developing and commercializing therapies to address specific clinical needs for people living with central nervous system, or CNS, disorders who need innovative treatment alternatives to help them return to normal daily functioning. Our current areas of focus are epilepsy and schizophrenia.

Our lead product candidate is ZX008, a low-dose fenfluramine for the treatment of Dravet syndrome. Dravet syndrome is a rare and catastrophic form of pediatric epilepsy with life threatening consequences for patients and for which current treatment options are very limited. ZX008 has received orphan drug designation in the United States and Europe for the treatment of Dravet syndrome. We obtained worldwide development and commercialization rights to ZX008 through our acquisition of Brabant Pharma Limited in October 2014. We currently expect to submit an investigational new drug, or IND, application to initiate Phase 3 clinical trials for ZX008 to the U.S. Food and Drug Administration, or the FDA, in August 2015, with Phase 3 clinical trials beginning in the fourth quarter of 2015.

We have an additional product candidate in development, Relday™ (risperidone once-monthly long-acting injectable) for the treatment of schizophrenia. Relday is a proprietary, long-acting injectable formulation of risperidone. Risperidone is used to treat the symptoms of schizophrenia and bipolar disorder in adults and teenagers 13 years of age and older. We began enrolling patients in a Phase 1b multi-dose clinical study for Relday in March 2015 and we plan to initiate worldwide partnering discussions for Relday upon completion of this study.

We launched Zohydro® ER (hydrocodone bitartrate) extended-release capsules, CII, an opioid agonist, extended-release oral formulation of hydrocodone without acetaminophen in March 2014 with our own sales force and had double-digit quarter-over-quarter growth during the launch year. On January 30, 2015, the FDA approved our supplemental New Drug Application, or sNDA, for a modified formulation of Zohydro ER with BeadTek™, which was developed using safe, well-known excipients and proprietary manufacturing processes to create an inactive ingredient that immediately forms a viscous gel when crushed and dissolved in liquids or solvents. On April 24, 2015, we sold our Zohydro ER business to Ferrimill Limited, an Irish corporation and subsidiary of Pernix Therapeutics Holdings Inc.

We have experienced net losses and negative cash flow from operating activities since inception, and as of June 30, 2015, had an accumulated deficit of $352.1 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 progress the clinical development of ZX008 and Relday. As of June 30, 2015, we had cash and cash equivalents of $77.4 million.

In its report on our consolidated financial statements for the year ended December 31, 2014, our independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern. Subsequent to the issuance of our accounting firm's report dated March 11, 2015, we sold our Zohydro ER business and received consideration of $80.0 million in cash, $10.0 million of which has been deposited in escrow to fund potential indemnification claims for a period of 12 months. Also, approximately 100 sales and marketing employees transitioned to Pernix in conjunction with the divestiture. In addition, we raised $92.0 million, after deducting underwriting discounts and commissions and estimated offering-related transaction costs, from a public offering of our common stock in August 2015. As a result, we are currently operating with an improved

cash position and at lower expense levels than previously forecast.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of June 30, 2015, along with our projected manufacturing revenues will be sufficient to fund our operations for at least the next twelve months.

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Recent Developments

On March 10, 2015, we entered into an asset purchase agreement with Pernix Ireland Limited and Pernix Therapeutics, or collectively, Pernix, whereby we agreed to sell our Zohydro ER business to Pernix, and on April 24, 2015, we completed the sale to Ferrimill, an Irish corporation and subsidiary of Pernix, as a substitute purchaser. The Zohydro ER business divested included the registered patents and trademarks, certain contracts, the new drug application, or NDA, and other regulatory approvals, documentation and authorizations, the books and records, marketing materials and product data relating to Zohydro ER. We received consideration of $80.0 million in cash, $10.0 million of which has been deposited in escrow to fund potential indemnification claims for a period of 12 months, and $10.6 million in Pernix common stock. Further, Ferrimill purchased Zohydro ER inventory from us of $0.9 million. We agreed to indemnify the purchaser for certain intellectual property matters up to an aggregate amount of $5.0 million.

In addition to the cash payment paid at closing, we are eligible to receive additional cash payments of up to $283.5 million based on the achievement of pre-determined milestones, including a $12.5 million payment upon approval by the FDA of an abuse-deterrent extended-release hydrocodone tablet (currently in development in collaboration with Altus Formulation Inc.) and up to $271.0 million in potential sales milestones, as well as a percentage of purchase discounts received by Ferrimill based on an assigned supply agreement up to $2.4 million. The purchaser will assume responsibility for our obligations under the purchased contracts and regulatory approvals, as well as other liabilities associated with the Zohydro ER business arising after the sale date.

On April 23, 2015, in connection with the sale of the Zohydro ER business, we, Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or SVB, entered into an amendment to the loan and security agreement dated December 30, 2014 which added an affirmative covenant requiring a liquidity ratio of 1.25 to 1 through our receipt of positive data from placebo-controlled trials in the United States and European Union of ZX008 and terminated all encumbrances on our personal property related to its Zohydro ER business. The remaining obligations under the loan and security agreement remain substantially unchanged.

On April 24, 2015, we committed to a restructuring plan in conjunction with the sale of the Zohydro ER business in which approximately 100 employees transitioned employment to Pernix. We also reduced our workforce by an additional 16 employees as a result of the divestiture. We recorded charges of approximately $0.6 million in discontinued operations related to personnel costs associated with these actions during the three months ended June 30, 2015.

In June 2015, the we filed an amendment to our Fifth Amended and Restated Certificate of Incorporation to effect a reverse stock split of our common stock at a ratio of 1-for-8, and a change in the number of authorized shares of our common stock to 50,000,000 shares, which was approved by our shareholders at our annual meeting held on June 18, 2015. The reverse stock split and change in authorized shares became effective July 1, 2015.

In August 2015, we completed completed a public offering of 5,462,500 shares of our common stock at a public offering price of $18.00 per share, including the over-allotment provision granted to the underwriters of 712,500 shares. We received net proceeds of approximately $92.0 million, after deducting underwriting discounts and commissions and estimated offering-related transaction costs. We may obtain additional financing in the future through the issuance of our common stock in future public offerings, through other equity or debt financings or through collaborations or partnerships with other companies.

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 granted 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 enabled us to exclusively develop and sell Zohydro ER in the United States. On April 24, 2015, we transferred our interest in the License Agreement in conjunction with the sale of our Zohydro ER business to Ferrimill.

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Endo Ventures Bermuda Limited and Endo Ventures Limited Asset Purchase Agreement

On April 23, 2014, we sold 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 pursuant to an asset purchase agreement. Under the terms of the sale, Endo paid us $85.0 million in cash, $8.5 million of which was deposited into escrow and which we received in May 2015. Further, Endo Ventures Limited, or 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 assumed responsibility for our royalty obligation on sales of Sumavel DosePro and assumed other liabilities relating to Sumavel DosePro after the sale.

In addition, we and Endo Ventures Bermuda Limited also entered into a license agreement, pursuant to which we granted Endo Ventures an exclusive, worldwide, royalty-free license for Sumavel DosePro. We also entered into a supply agreement with Endo Ventures, pursuant to which we will continue to manufacture Sumavel DosePro, and Endo Ventures supported our Sumavel DosePro manufacturing operations with a working capital advance of $7.0 million.

In connection with the sale, 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 in May 2014 by paying $40.0 million to Healthcare Royalty which was consistent with the terms of the Healthcare Royalty financing agreement.

Critical Accounting Policies and Estimates

We recognize revenue from contract manufacturing, service fees earned on collaborative arrangements and the sale of Sumavel DosePro prior to its sale in May 2014. We also recognize revenue from the sale of Zohydro ER which is included in net income (loss) from discontinued operations in the consolidated statement of operations and comprehensive income. 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) our price to the buyer is substantially fixed or determinable at the date of sale, (b) the buyer has paid us, or the buyer is obligated to pay us and the obligation is not contingent on resale of the product, (c) the buyer's obligation to us 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 us, (e) we do 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. We defer recognition of revenue on product shipments of Zohydro ER until the right of return no longer exists, as we were not able to reliably estimate expected returns of the product at the time of shipment given the limited sales and return 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. 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).

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.

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Contract Manufacturing Revenue

We and Endo Ventures entered into a supply agreement, or the Supply Agreement, in connection with the sale of the Sumavel DosePro business to Endo in May 2014. Under terms of the supply agreement, we retain the sole and exclusive right and the obligation to manufacture or supply Sumavel DosePro to Endo. 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 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. 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.

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 the 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.

Product Revenue, Net

We sold Sumavel DosePro through May 2014, and sold Zohydro ER until its purchase in April 2015, 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 we reduced product sales for estimated future product returns and sales allowances in the same period the related revenue was recognized. We are responsible for all returns of Sumavel DosePro product distributed by us prior to sale up to a maximum per unit amount as specified in the sale agreement.

Given the limited sales history of Zohydro ER, we could not reliably estimate expected returns of the product at the time of shipment. Accordingly, we deferred 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 was dispensed through patient prescriptions or expiration of the right of return. We estimated Zohydro ER patient prescriptions dispensed using an analysis of third-party syndicated data. Zohydro ER was launched in March 2014 and, accordingly, we did not have a significant history estimating the number of patient prescriptions dispensed. If we underestimated or overestimated patient prescriptions dispensed for a given period, adjustments to revenue from discontinued operations may be necessary in future periods. The deferred revenue balance does not have a direct correlation with future revenue recognition as we recorded sales deductions at the time the prescription unit was dispensed. In addition, the costs of Zohydro ER associated with the deferred revenue were recorded as deferred costs, which were included in inventory, until such time the related deferred revenue was recognized. We are responsible for returns of product sold prior to the sale of the Zohydro ER business in April 2015. Zohydro ER activity is included in discontinued operations in the consolidated financial statements.

Fair Value Measurements

U.S. generally accepted accounting principles, or GAAP, require us to estimate the fair value of certain assets and liabilities as of the date of their acquisition or incurrence, on an ongoing basis, or both. Determining the fair value of an asset or liability, such as our acquired in-process research and development, short-term investments, contingent purchase consideration and warrants for common stock requires the use of accounting estimates and assumptions which are judgmental in nature and could have a significant impact on the determination of the amount of the fair value ascribed to the asset or liability.

There has been no significant changes in critical accounting policies during the six months ended June 30, 2015 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, 2014.

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Results of Operations

Comparison of the Three and Six Months Ended June 30, 2015 and 2014

Revenue

	Three Months Ended June 30,				Six Months Ended June 30,			
(Dollars in thousands)	2015	2014	$ change	% change	2015	2014	$ change	% change
Contract manufacturing revenue	$6,003	$2,238	$3,765	168.2 %	10,184	2,238	$7,946	355.0 %
Net product revenue	—	3,355	(3,355)	(100.0)%	—	9,840	(9,840)	(100.0)%
Service and other product revenue	1,364	1,144	220	19.2 %	1,797	2,048	(251)	(12.3)%
Total revenue	$7,367	$6,737	$630	9.4 %	$11,981	$14,126	$(2,145)	(15.2)%

The increase in contract manufacturing revenue and decrease in net product revenue for the three and six months ended June 30, 2015 as compared to the same periods in 2014 was primarily due to the timing of the sale of the Sumavel DosePro business to Endo in May 2014 and subsequent performance under the related supply agreement. Contract manufacturing revenue increased primarily as a result of additional units delivered during the quarter ended June 30, 2015 as compared to the quarter ended June 30, 2014. Contract manufacturing revenue is recognized for Sumavel DosePro finished goods inventory that has been delivered to Endo Ventures Bermuda under the 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 under the terms of our Supply Agreement.

Service and other product revenue is comprised of a one-time contract termination fee payment related to our Migranal Migranal co-promotion agreement with Valeant Pharmaceuticals of $0.5 million in the quarter ended June 30, 2015, as well as revenue of $0.8 million resulting from lower returns of Sumavel DosePro for the three months ended June 30, 2015. Service and other product revenue is comprised primarily of fees generated by Migranal co-promotion activity for the first quarter of 2015 and three and six months ended June 30, 2014.

Cost of Contract Manufacturing and Cost of Goods Sold

	Three Months Ended June 30,				Six Months Ended June 30,			
(Dollars in thousands)	2015	2014	$ change	% change	2015	2014	$ change	% change
Cost of contract manufacturing	$5,803	$1,935	$3,868	199.9 %	$9,726	$1,935	$7,791	402.6 %
Cost of goods sold	$—	$1,928	$(1,928)	(100.0)%	—	5,261	$(5,261)	(100.0)%

Cost of contract manufacturing and cost of goods sold 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 decline in cost of goods sold and increase in cost of contract manufacturing over these periods is due to the classification of these costs prior to and subsequent to the sale of our Sumavel DosePro business to Endo in May 2014. Overall, the increase in total cost of goods and cost of contract manufacturing was driven primarily by an increase in units sold during the three and six months ended June 30, 2015 as compared to the same periods in 2014.

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Royalty Expense

	Three Months Ended June 30,				Six Months Ended June 30,			
(Dollars in thousands)	2015	2014	$ change	% change	2015	2014	$ change	% change
Royalty expense	71	172	$(101)	(58.7)%	143	439	$(296)	(67.4)%

For the three and six month periods ended June 30, 2014, royalty expense was 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 to Endo, and the amortization of a $4.0 million milestone payment. Endo assumed responsibility for the royalty obligation on sales of Sumavel DosePro subsequent to their purchase of the Sumavel DosePro business. The expense for the three and six month periods ended June 30, 2015 reflects only the amortization of the milestone payment related to technology that we have licensed.

Research and Development Expenses

	Three Months Ended June 30,				Six Months Ended June 30,			
(Dollars in thousands)	2015	2014	$ change	% change	2015	2014	$ change	% change
Research and development	$6,241	$3,162	$3,079	97.4 %	11,390	5,703	$5,687	99.7 %

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 changes in our major development programs are explained in the narrative beneath the table.

	Three Months Ended June 30,		Six Months Ended June 30,	
(Dollars in thousands)	2015	2014	2015	2014
ZX008	$2,366	$—	$3,807	$—
Relday	2,224	1,558	4,169	2,595
Other[(1)]	1,651	1,604	3,414	3,108
Total	$6,241	$3,162	$11,390	$5,703

(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.

We acquired ZX008 in our acquisition of Brabant in October 2014 and incurred expenses in 2015 as we continue to prepare for Phase 3 clinical trials for ZX008. Expenses increased for Relday for the three and six months ended June 30, 2015

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as compared to 2014 as we initiated a multi-dose clinical study for Relday in the first quarter of 2015. 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 2015 to exceed amounts incurred in the same period in 2014 as we prepare for our two Phase 3 studies for ZX008, which we plan to commence in the fourth quarter of 2015, and conduct our multi-dose clinical trial for Relday.

Selling, General and Administrative Expenses

	Three Months Ended June 30,				Six Months Ended June 30,			
(Dollars in thousands)	2015	2014	$ change	% change	2015	2014	$ change	% change
Selling expense	$916	$3,822	$(2,906)	(76.0)%	$1,462	$11,034	$(9,572)	(86.8)%
General and administrative expense	6,666	5,240	1,426	27.2 %	12,389	10,556	1,833	17.4 %
Total selling, general and administrative	$7,582	$9,062	$(1,480)	(16.3)%	$13,851	$21,590	$(7,739)	(35.8)%

Selling expenses, which include sales and marketing costs, consist 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 product sample 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.

We incurred selling expenses for Sumavel DosePro prior to the sale of the business in May 2014. The selling expense in 2015 represents corporate general marketing for product candidates that are in development. We also incurred selling expense for Zohydro ER activities which are recorded as discontinued operations for the three and six months ended June 30, 2015.

The increase in general and administrative expenses is primarily the result of additional professional service fees related to our capital restructuring and one time personnel transition charges incurred during the three months ended June 30, 2015 as compared to the three months ended June 30, 2014. Also, additional professional services were required during the first quarter of 2015 in connection with our 2014 business acquisition and divestiture activities.

We anticipate that our sales and marketing expenses throughout the remainder of 2015 will be considerably lower than the same period in 2014 due to the sale of our Zohydro ER business and related transition of our sales force to Ferrimill in April 2015.

Change in Fair Value of Contingent Consideration

	Three Months Ended June 30,				Six Months Ended June 30,			
(Dollars in thousands)	2015	2014	$ change	% change	2015	2014	$ change	% change
Change in fair value of contingent consideration	$(600)	$—	$(600)	(100.0)%	(1,600)	—	$(1,600)	(100.0)%

The contingent consideration liability results from our acquisition of Brabant in October 2014 in connection with the estimated completion of certain future performance milestones by the sellers. At each reporting period, the remaining estimated liability is determined by applying the income approach which utilizes variable inputs, such as anticipated future cash flows, risk-free adjusted discount rates, and nonperformance risk. This change is reflected in the balance of the estimated fair value of the contingent consideration (income) expense.

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Impairment of Long-lived Assets

Impairment expense of $0.8 million was recorded during the three and six months ended June 30, 2014 as the Company disposed of assets in connection with the sale of the Sumavel DosePro business. There were no impairment charges recorded for the three and six month periods ended June 30, 2015.

Net Gain on Sale of Business

A gain of $80.0 million was recorded during the three and six months ended June 30, 2014 in connection with the sale of our Sumavel DosePro business in May 2014 and was considered a continuing operation due to the ongoing involvement and cash flows with the business after the sale in conjunction with the Supply Agreement. The net gain of $75.6 million on the sale of our Zohydro ER business in 2015 is recorded as a component of net income from discontinued operations.

Benefit for Income Taxes

We are required allocate the provision for income taxes between continuing operations and other categories of earnings, such as discontinued operations. During the three months ended June 30, 2015, we recognized net income from discontinued operations, and, as a result, recorded income tax expense of $13.5 million, which is included in net income (loss) from discontinued operations. Accordingly, we recognized a related income tax benefit of $6.9 million from continuing operations for the three months ended June 30, 2015. The remaining income tax benefit to continuing operations will be recorded throughout the remainder of 2015.

Other Income (Expense)

	Three Months Ended June 30,				Six Months Ended June 30,			
(Dollars in thousands)	2015	2014	$ change	% change	2015	2014	$ change	% change
Interest income	$9	$6	$3	50.0 %	$14	$12	$2	16.7 %
Interest expense	$(907)	$(1,029)	$122	(11.9)%	$(1,555)	$(2,915)	$1,360	(46.7)%
Loss on extinguishment of debt	$—	$(1,254)	$1,254	(100.0)%	$—	$(1,254)	$1,254	(100.0)%
Change in fair value of warrant liabilities	$(975)	$10,201	$(11,176)	(109.6)%	$(565)	$18,470	$(19,035)	(103.1)%
Change in fair value of embedded derivatives	$—	$—	$—	— %	$—	$(14)	$14	(100.0)%
Other income (expense)	$(39)	$(8)	$(31)	387.5 %	$(158)	$(55)	$(103)	187.3 %
Total other income (expense)	$(1,912)	$7,916	$(9,828)	(124.2)%	$(2,264)	$14,244	$(16,508)	(115.9)%

Interest Income. Interest income is earned on our cash and cash equivalent balances.

Interest Expense. During the three and six months ended June 30, 2015, interest expense was incurred in conjunction with our term loan and revolving line of credit. During the three and six months ended June 30, 2014, interest expense was incurred primarily in conjunction with our Healthcare Royalty financing agreement, which was terminated on May 16, 2014. Both the average principal balance and applicable interest rate were lower on the loan and revolving line of credit as compared to the Healthcare Royalty financing agreement resulting in a decrease of interest expense for the three and six months ended June 30, 2015 as compared to the same periods in 2014.

Loss on Extinguishment of Debt. The loss on extinguishment of debt of $1.3 million recorded during the three and six months ended June 30, 2014 resulted from the early termination of the Healthcare Royalty financing agreement on May 16, 2014. The loss on early extinguishment of debt consisted of the write-off of unamortized balances of debt discounts, including the derecognition of the embedded derivative liabilities, debt acquisition costs, and accrued interest expenses related to the Healthcare Royalty financing agreement.

Change in Fair Value of Warrant Liabilities. The change in fair value of warrant liabilities results from the periodic remeasurement of the estimated fair value of our warrant liabilities as discussed in Note 8 to our consolidated financial statements. The expense recorded for the three and six months ended June 30, 2015 resulted primarily from an increase in our

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stock price and lower estimated volatility of our stock price from the previous measurement date of December 31, 2014. The income generated from the change in fair value of the common stock warrant liabilities during the three and six months ended June 30, 2014 was primarily driven by the decrease in our stock price at June 30, 2014 as compared to the December 31, 2013 measurement date. The income or expense realized as a change in the valuation will continue to fluctuate based upon changes to inputs used to estimated fair value of our warrant liabilities while the warrants remain outstanding.

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.

Other Income (Expense). Other income (expense) consists primarily of foreign currency transaction gains and losses resulting from transactions conducted in the British pound sterling and Euro.

Discontinued Operations

During the first quarter of 2015, we reached a decision to sell our Zohydro ER business. On March 10, 2015, we entered into an asset purchase agreement with Pernix whereby we agreed to sell our Zohydro ER business to Pernix, and on April 24, 2015, we completed the sale to Ferrimill, a subsidiary of Pernix, as a substitute purchaser.

The sale, including the related gain on the transaction, was reflected in the net income (loss) from discontinued operations for the three and six months ended June 30, 2015, as discussed in Note 5 to our consolidated financial statements. As a result of our strategic decision to sell the Zohydro ER business and focus on clinical development of ZX008 and Relday, our consolidated statements of operations and comprehensive income and the consolidated balance sheet have been retrospectively revised to reflect the financial results from the Zohydro ER business as discontinued operations for all periods presented.

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Liquidity and Capital Resources

We have experienced net losses and negative cash flow from operations since inception, and as of June 30, 2015, had an accumulated deficit of $352.1 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 clinical development for ZX008 and Relday.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of June 30, 2015, along with our projected contract manufacturing revenues will be sufficient to fund our operations for at least the next twelve months. We may pursue additional opportunities to raise capital, if necessary, through public or private equity offerings, debt financings, receivables financings or through collaborations or partnerships with other companies. If we are unsuccessful in raising additional required funds, we may be required to significantly delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts, or cease operating as a going concern. We also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available.

In its report on our consolidated financial statements for the year ended December 31, 2014, 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.

Subsequent to the issuance of our accounting firm's report dated March 11, 2015, we sold our Zohydro ER business and received cash proceeds, net of $10.0 million placed in escrow, of approximately $70.0 million. Also, approximately 100 employees transitioned to Pernix in conjunction with the divestiture. As a result of this sale and the August 2015 public equity offering resulting in net proceeds of approximately $92.0 million, we are currently operating with an improved cash position and at lower expense levels than previously forecast at the time our accounting firm's report was issued.

Cash and cash equivalents totaled $77.4 million and $42.2 million at June 30, 2015 and December 31, 2014, respectively.

The following table summarizes our cash flows provided by (used in) continuing operating, investing and financing activities for the six months ended June 30, 2015 and 2014:

	Six Months Ended June 30,	
	2015	2014
	(In Thousands)	
Statement of Cash Flows Data:		
Total cash provided by (used in):		
Operating activities	$(42,874)	$(40,704)
Investing activities	79,358	81,207
Financing activities	(1,317)	(31,289)
Increase in cash and cash equivalents	$35,167	$9,214

Operating Activities: Net cash used in operating activities was $42.9 million and $40.7 million for the six months ended June 30, 2015 and 2014, respectively. Net cash used for the six months ended June 30, 2015 primarily reflects the use of cash for operations, adjusted for non-cash charges including the $89.1 million pre-tax gain on the sale of our Zohydro ER business, a $6.5 million charge for taxes payable related to the sale of the Zohydro ER business and $4.6 million in stock-based compensation. Significant working capital uses of cash for the six months ended June 30, 2015 include personnel-related costs, research and development costs (primarily for ZX008 and Relday) and other

professional services, including legal and accounting services. Net cash used for the six months ended June 30, 2014 primarily reflects the use of cash for operations, adjusted for non-cash charges including the $80.0 million gain on the sale of our Sumavel DosePro business, an $18.5 million change in fair value of warrant liabilities and $5.3 million in stock-based compensation. Significant working capital uses of cash for the six months ended June 30, 2014 include personnel-related costs, research and development costs (primarily for Relday and employee and infrastructure resources), sales and marketing expenses for Sumavel DosePro, and other professional services, including legal services.

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Investing Activities. Net cash provided by investing activities for the six months ended June 30, 2015 and 2014 was primarily attributable to the proceeds from the sales of our Zohydro ER and Sumavel DosePro businesses, respectively. We expect to incur capital expenditures of less than $1.0 million for the remainder of 2015 related primarily to equipment to be used in our research and development processes.

Financing Activities. Net cash used by financing activities was $1.3 million for the six months ended June 30, 2015, which includes the repayment of our revolving credit facility of $1.4 million offset by proceeds from stock issued under our employee stock purchase plan. Net cash used in financing activities for the six months ended June 30, 2014 consists of 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.

Our sources of liquidity include our cash balances and cash receipts from contract manufacturing for Sumavel DosePro. Through June 30, 2015, we received aggregate net cash proceeds of approximately $419.0 million from the sale of shares of our preferred and common stock, and in August 2015, we completed a public offering of 5,462,500 shares of our common stock and received net proceeds of approximately $92.0 million. As of June 30, 2015, we had $77.4 million in cash and cash equivalents. Other potential sources of near-term liquidity include equity offerings, debt or other financing, and entering into licensing arrangements for ZX008 and/or Relday.

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 the level of our research, development, contract manufacturing and operating 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 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 product candidates, if approved. We expect our expenses to decrease from prior levels due to our recent business divestiture and to remain relatively sta
ble over the next few years as we continue to advance ZX008 and Relday through clinical development.

Off-Balance Sheet Arrangements

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

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our cash and cash equivalents as of June 30, 2015 consisted of cash and money market funds. 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. To minimize this risk, we intend to continue to maintain our portfolio of cash and money market funds, and due to their short-term nature, we believe that there is no material exposure to interest rate risk.

Equity Price Risk

Our short-term investments as of June 30, 2015 consisted of Pernix Therapeutics common stock. These investments are available-for-sale at the conclusion of a six month lock-up period, are actively traded on the Nasdaq Global Market and are subject to risk based on the trading price of the stock. Fluctuations in the market price of publicly traded securities may result from perceived changes in the underlying economic characteristics of the issuer, the relative price of alternative investments, general market conditions and other factors. A change in the prevailing market price of Pernix Therapeutics common stock may cause the value of our short-term investments to fluctuate. Based on the last reported sale price on June 30, 2015 of Pernix Therapeutics common stock on the Nasdaq Global Market, a change of 10% in the market price of Pernix Therapeutics common stock would result in a change to the fair value of our short-term investments by approximately $0.9 million. Because the market price for this investment is subject to ongoing fluctuation, the amount we may eventually realize from a subsequent sale of the investment may differ significantly from the reported amount. This hypothetical increase or decrease will likely be different from what actually occurs in the future, and the impact may differ from that quantified herein.

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 few years. Payments to our material suppliers and contract manufacturers are denominated in the Euro and U.K. pounds sterling. Foreign currency gains and losses associated with these expenditures have not been significant to date. Currently, we do not hedge our foreign currency exchange rate risk, however, substantially all of these purchases are made in connection with our supply agreement with Endo, which reimburses all associated costs, including those paid in foreign currency, plus a 2.5% markup. As a result, we believe the risk of financial exposure from transacting in foreign currencies is adequately mitigated.

Item 4. Controls and Procedures

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

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

As required by Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2015 at the reasonable assurance level.

Changes in Disclosure Controls and Procedures

There were no changes in our internal control over financial reporting during the fiscal quarter ended June 30, 2015 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

There have been no material updates to the legal proceedings as set forth in “Item 3. Legal Proceedings” in our Annual Report on Form 10-K for the year ended December 31, 2014.

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, 2014, 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

Our success depends substantially on our product candidates, ZX008 and Relday. We cannot be certain that any product candidate will receive regulatory approval or be successfully commercialized.

We have only a limited number of product candidates in development, and our business depends substantially on their successful development and commercialization. Following the completion of the sale of our Zohydro ER business in April 2015, we have no drug products approved for sale, and we may not be able to develop marketable drug products in the future. All of our product candidates will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenues from product sales. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, whose regulations differ from country to country.

We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries, and we may never receive such regulatory approvals. Obtaining regulatory approval for a product candidate is a lengthy, expensive and uncertain process, and may not be obtained. Any failure to obtain regulatory approval of any of our product candidates would limit our ability to generate future revenues (and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenue), would potentially harm the development prospects of our product candidates and would have a material and adverse impact on our business.

Even if we successfully obtain regulatory approvals to market our product candidates, our revenues will be dependent, in part, on our ability to commercialize such products as well as the size of the markets in the territories for which we gain regulatory approval. If the markets for our product candidates are not as significant as we estimate, our business and prospects will be harmed.

Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy for ZX008, Relday or any of our other product candidates, which could prevent or significantly delay their regulatory approval.

ZX008, Relday and any of our other product candidates are prone to the risks of failure inherent in drug development. Before obtaining U.S. regulatory approval for the commercial sale of ZX008, Relday or any other product candidate, we must gather substantial evidence from well-controlled clinical trials that demonstrate to the satisfaction of the FDA that the product candidate is safe and effective, and similar regulatory approvals would be necessary to commercialize our product candidates in other countries.

In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products after approval.

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The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of our clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in a delay or failure in obtaining approval or approval for a more limited indication than originally sought. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. If ZX008, Relday or any of our other product candidates are not shown to be safe and effective in clinical trials, the programs could be delayed or terminated, which 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 ZX008, Relday or pre-clinical or clinical testing for any of our other product candidates could result in increased costs to us and delay or limit our ability to pursue regulatory approval for, or generate revenues from, such product candidates.

Clinical trials are very expensive, time consuming and difficult to design and implement. Delays in the commencement or completion of clinical testing for ZX008, Relday or pre-clinical or clinical testing for any of our other product candidates could significantly affect our product development costs and business plan.

The safety and effectiveness of ZX008 has been evaluated in a continuing, long-term, open-label, study in patients with Dravet syndrome. Based upon recent feedback from the FDA, we expect to submit an investigational new drug, or IND, application for ZX008 as an adjunctive treatment in Dravet Syndrome to the FDA in August 2015 to initiate a Phase 3 efficacy and safety study in approximately 100 Dravet syndrome patients during the fourth quarter of 2015 in the United States. We also expect to submit Clinical Trial Applications, or CTAs, for ZX008 to initiate an identical study commencing in the first quarter of 2016 in Europe. Eligible subjects from these two studies will have the option to enter a long-term open label extension protocol. 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.

We initiated clinical testing for Relday in patients with schizophrenia in July 2012 and announced positive single-dose pharmacokinetic results from the Phase 1 clinical trial in January 2013. Based on the favorable safety and pharmacokinetic profile demonstrated in the Phase 1 trial, we extended the study to include an additional dose of the same formulation and announced positive top-line results in May 2013. The results for the extended Phase 1 clinical trial showed risperidone blood concentrations in the therapeutic range were achieved on the first day of dosing and maintained throughout the one-month period. In addition, dose proportionality was demonstrated across the full dose range studied. In March 2015, we began 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.

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 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.

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In addition, if a significant number of patients fail to stay enrolled in any of our current or future clinical trials of ZX008, Relday or any of our other product candidates and such failure is not adequately accounted for in our trial design and enrollment assumptions, our clinical development program could be delayed. Clinical trials may also be delayed or repeated as a result of ambiguous or negative interim results or unforeseen complications in testing. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors, including:

- 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, drug enforcement administration, or 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 ZX008, Relday and our other product candidates may be harmed, which may have a material adverse effect on our business, results of operations, financial condition and prospects.

Fast Track designation for ZX008, if obtained, may not lead to a faster development or review process.

We intend to seek a Fast Track designation for ZX008 in the United States. The Fast Track program is intended to expedite or facilitate the process for reviewing new drug candidates that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended, alone or in combination with one or more drugs, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the drug candidate and the specific indication for which it is being studied. Unique to a Fast Track drug candidate, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA has broad discretion is determining whether to grant a Fast Track designation for a drug. Obtaining a Fast Track designation does not change the standards for product approval, but may expedite the development or approval process. There is no assurance that the FDA will grant such designation. Even if the FDA does grant such designation for ZX008, it may not actually result in faster clinical development or regulatory review or approval. Furthermore, such a designation does not increase the likelihood that ZX008 will receive marketing approval in the United States.

We have limited sales and marketing resources, and we may not be able to effectively market and sell our products.

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As a result of the sale of our Zohydro® ER business in April 2015, we do not currently have an organization for sales, marketing and distribution of pharmaceutical products, and we must build this organization or make arrangements with third parties to perform these functions in order to commercialize any products that we successfully develop and for which we obtain regulatory approvals. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. We will also face competition in our search for collaborators and potential co-promoters. To the extent we may rely on third parties to co-promote or otherwise commercialize any 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 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 establish a sales and marketing organization to adequately promote and commercialize any product candidates that may be approved. The establishment of a 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 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 face intense competition, and if our competitors market and/or develop treatments for Dravet syndrome or psychiatric 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 we do.

If approved for the chronic treatment of Dravet syndrome, ZX008 may compete against other products and product candidates. Diacomit (stiripentol) by Laboratoires Biocodex has been approved and is being commercialized as an adjunctive therapy (in combination with sodium valproate and clobazam) for the treatment of Dravet Syndrome in the European Union, Canada, and Japan; stiripentol, while not yet approved by FDA, is available to patients in the United States via the FDA's Personal Importation Policy. 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. In April 2015, GW Pharmaceuticals initiated a second Phase 3 clinical trial for Epidiolex, a cannabanoid drug. Insys Therapeutics has advanced its pharmaceutical cannabinoid program, which has received orphan drug designation and fast track status by the FDA for use of cannabidiol as a potential treatment for Dravet syndrome. Sage Therapeutics has completed a Phase 1/2 clinical trial for its lead compound SAGE-547, an allosteric modulator of GABA receptors, for the acute treatment of super-refractory status epilepticus, which are acute prolonged seizures that can be associated with Dravet syndrome, as well as other seizure conditions.

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, Invega Sustenna

and Invega Trinza 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, Braeburn Pharmaceuticals, Laboratorios Farmaceuticos Rovi SA, Novartis AG, and Indivior PLC, each of which has announced they are developing long-acting antipsychotic product candidates. In May 2015, Janssen Pharmaceuticals announced that FDA approved Invega Trinza, a three-month long-version of paliperidone

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palmitate, for the treatment of schizophrenia in patients adequately treated with Invega Sustenna for at least four months. Also in May 2015, Indivior PLC announced positive top-line results from its Phase 3 clinical trial of RBP-7000, an investigational drug formulation of risperidone for the treatment of schizophrenia that is intended to require once-monthly dosing.

We expect ZX008, Relday and any of our other product candidates, if approved, 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 or other products that compete with ours, obtain necessary approvals for such products from the FDA, or other agencies, if required, more rapidly than we do 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 an effect on our product prices, market share and results of operations. We may not be able to differentiate any products that we are able to market from those of our competitors, successfully develop or introduce new products that are less costly or offer better results than those of our competitors, or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors. In addition, competitors may seek to develop alternative formulations of our product candidates and/or alternative drug delivery technologies that address our targeted indications.

The commercial opportunity for 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 we are 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 any of our product candidates that are approved, our business, results of operations, financial condition and prospects may be materially adversely affected.

If ZX008, Relday or any other product candidate for which we receive regulatory approval does not achieve broad market acceptance or coverage by third-party payors, the revenues that we generate will be limited.

The commercial success of ZX008, Relday or any other product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our approved product by third-party payors is also necessary for commercial success. The degree of market acceptance of any product candidates for which we may receive regulatory approval will depend on a number of factors, including:

- 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;
- availability and perceived advantages of alternative treatments;

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- 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.

Our efforts to educate the medical community and third-party payors on the benefits of ZX008, Relday or any of our other product candidates for which we obtain marketing approval from the FDA or other regulatory authorities and gain broad market acceptance may require significant resources and may never be successful. If our products do not achieve an adequate level of acceptance by physicians, third-party payors, pharmacists, and patients, we may not generate sufficient revenue from these products to become or remain profitable.

We 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. We sold our Sumavel DosePro business in April 2014 and sold our Zohydro ER business in April 2015. Our business and prospects must be considered in light of the risks and uncertainties frequently encountered by pharmaceutical companies developing and commercializing new products.

We have generated substantial net losses and negative cash flow from operations since our inception in 2006. For example, for the years ended December 31, 2014, 2013 and 2012, we incurred net income (loss) of $8.6 million, $(80.9) million and $(47.4) million, respectively, our net cash used in operating activities was $(80.8) million, $(44.9) million and $(52.2) million, respectively, and, at June 30, 2015, our accumulated deficit was $(352.1) 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 development for ZX008 and Relday. Our ability to generate revenues from our Sumavel DosePro contract manufacturing services or any of our product candidates will depend on a number of factors including, in the case of Sumavel DosePro contract manufacturing services, the factors described in risk factors below and, in the case of our product candidates, including ZX008 and Relday, 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 generate significant sales from 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.

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 ZX008 and commercializing Sumavel DosePro and Zohydro ER. In January 2010, we launched Sumavel DosePro and began generating revenues, and we launched Zohydro ER in March 2014. We sold our Sumavel DosePro business in April 2014 and sold our Zohydro ER business in April 2015. 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.

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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 ZX008 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, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

We are dependent on numerous third parties in our supply chain, all of which are currently single source suppliers, for the commercial supply of Sumavel DosePro and for the clinical supply of ZX008 and Relday, and if we experience problems with any of these suppliers, the manufacturing of Sumavel DosePro, ZX008 and Relday could be delayed.

While we own most of the specialized equipment used to manufacture critical components of Sumavel DosePro, we do not own or operate manufacturing facilities and currently lack the in-house capability to manufacture Sumavel DosePro, ZX008, Relday 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 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 ingredients, 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. We also outsource all manufacturing and packaging of the clinical trial materials for ZX008 and Relday to third parties.

Although we plan to qualify additional manufacturers and suppliers of some of the components used in Sumavel DosePro, there can be no assurance that we will be able to do so and the current manufacturers and suppliers of these components will likely be single source suppliers to us for a significant period of time. Similarly, 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. ZX008, 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 may never be able to establish additional sources of supply for ZX008 or Relday's risperidone formulation.

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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 or our product candidates ourselves, including:

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

If our contract manufacturers or suppliers are unable to provide 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 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.

We rely on third parties to conduct our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We conducted prior clinical trials under agreements with third-party CROs, and we anticipate that we may enter into agreements with third-party CROs in the future regarding ZX008, Relday or any of our other product candidates. We rely heavily on these parties for the execution of our clinical trials and pre-clinical studies, and control only certain aspects of their activities.

Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and regulatory requirements. We and our CROs are required to comply with good clinical practice, or GCP, requirements for clinical studies of our product candidates, and good laboratory practice, or GLP, requirements for certain pre-clinical studies. The FDA enforces these regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable regulations, the data generated in our pre-clinical studies and clinical trials may be deemed unreliable and the FDA may require us to perform additional pre-clinical studies or clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA and similar foreign regulators will determine that any of our clinical trials comply or complied with GCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practice, or cGMP, regulations, and require a large number of test subjects. Our inability to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval

process.

If any of our relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain

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is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate additional revenues could be delayed.

Switching or adding additional CROs can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact 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.

We may not realize the full economic benefit from the sale of our Sumavel DosePro business and Zohydro ER business.

Pursuant to the asset purchase agreement with Endo that we entered into in April 2014, or the Endo 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.
Pursuant to the asset purchase agreement with Pernix that we entered into in March 2015, or the Pernix asset purchase agreement, in addition to the consideration received of $80.0 million in cash, $10.0 million of which has been deposited in escrow to fund potential indemnification claims for a period of 12 months, we also received stock consideration in the amount of 1,682,096 shares of Pernix's common stock. We are not permitted to sell such stock under the Pernix asset purchase agreement for six months from the closing date of the sale, and the value of such stock is subject to change based on fluctuations in the market value of Pernix's common stock. Further, Pernix purchased $0.9 million of Zohydro ER inventory, and we recognized consideration of $2.1 million based on percentage of purchase discounts received by the Pernix based on an assigned supply agreement.

In addition, we may receive contingent payments of up to $283.5 million, based on Pernix's achievement of pre-determined milestones, including a $12.5 million payment upon approval by the FDA of an abuse-deterrent extended-release hydrocodone tablet and up to $271.0 million in potential sales milestones. Our ability to receive these contingent payments is dependent upon Pernix successfully maintaining and increasing market demand for, and sales of, Zohydro ER in a manner in which the requisite sales of the product will be achieved and devoting the resources necessary to achieve the manufacturing milestone.

We have also agreed to indemnify Pernix 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 $10.0 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. In addition, we have agreed to indemnify Pernix for certain indemnification matters up to an aggregate

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amount of $5.0 million. We cannot provide any assurance that we will receive all or any portion of the $10.0 million escrow amount or any of the contingent milestone payments.

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

Our success depends on our continued ability to attract, retain and motivate highly qualified management and key clinical development, regulatory, sales and marketing and other personnel. As of June 30, 2015, we employed 56 full-time employees. Of the full-time employees, 6 were engaged in sales and marketing, 8 were engaged in manufacturing operations, 17 were engaged in product development, quality assurance and clinical and regulatory activities and 25 were engaged in general and administrative activities (including business and corporate development). If we are not able to retain our employee base, we may not be able to effectively manage our business or be successful in commercializing our products.

We are highly dependent on the development, regulatory, commercial and financial expertise of our senior management team. We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the areas in Southern and Northern California, where we currently operate. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development and commercialization objectives, our ability to raise additional capital, our ability to implement our business strategy and our ability to maintain effective internal controls for financial reporting and disclosure controls and procedures as required by the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. The loss of the services of any members of our senior management team, especially our Chief Executive Officer and President, Stephen J. Farr, Ph.D., could delay or prevent the development and commercialization of any of our product candidates, including ZX008 and Relday. Further, if we lose any members of our senior management team, we may not be able to find suitable replacements, and our business may be harmed as a result. In addition to the competition for personnel, our locations in California in particular are characterized by a high cost of living. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

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

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors and consultants are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. For example, we have in the past experienced failures in our information systems and computer servers, which may have been the result of a cyber-attack. These failures resulted in an interruption of our normal business operations and required substantial expenditure of financial and administrative resources to remedy. We cannot be sure that similar failures will not occur in the future. System failures, accidents or security breaches can cause interruptions in our operations, and can result in a material disruption of our commercialization activities, drug development programs and our business operations. The loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval and post-market study compliance efforts and significantly increase our costs to recover or reproduce the data. Similarly, we rely on a large number of third parties to supply components for and manufacture our product candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or

damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of ZX008, Relday or any of our other product candidates could be delayed.

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

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year ended December 31, 2014, $20.4 million (based on exchange rates as of December 31, 2014) of our materials, contract manufacturing costs and other manufacturing-related costs were denominated in foreign currencies. As a result, we are exposed to foreign exchange risk, and our results of operations may be negatively impacted by fluctuations in the exchange rate between the U.S. dollar and the Euro or U.K. pound sterling. A significant appreciation in the Euro or U.K. pound sterling relative to the U.S. dollar will result in higher expenses and cause increases in our net losses. Likewise, to the extent that we generate any revenues denominated in foreign currencies, or become required to make payments in other foreign currencies, fluctuations in the exchange rate between the U.S. dollar and those foreign currencies could also negatively impact our results of operations. We currently have not entered into any foreign currency hedging contracts to reduce the effect of changes in foreign currency exchange rates, and foreign currency hedging is inherently risky and may result in unanticipated losses.

If we are unable to achieve and maintain adequate levels of coverage and reimbursement for 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 any product candidates for which we may receive regulatory approval will 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.

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 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 face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

The commercial use of our products and clinical use of our products and product candidates expose us to the risk of product liability claims. This risk exists even if a product or product candidate is approved for commercial sale by the FDA and manufactured in facilities regulated by the FDA such as the case with Zohydro ER, or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with Zohydro ER or our product candidates could result in injury to a patient or even death. For example, Zohydro ER is an opioid pain reliever that contains hydrocodone, which is a regulated

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"controlled substance" under the Controlled Substances Act of 1970, or CSA, and could result in harm to patients relating to its potential for abuse. Although we no longer sell Zohdryo ER following the sale of the Zohydro ER business in April 2015, we retain all liabilities associated with the Zohydro ER business arising prior to such sale, including possible product liability exposure in connection with sales of Zohydro ER made prior to the sale of the Zohydro ER business. In addition, a liability claim may be brought against us even if our products or product candidates merely appear to have caused an injury.

Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products or product candidates, if approved, among others. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- the inability to commercialize our product candidates;
- decreased demand for our product candidates, if approved;
- impairment of our business reputation;
- product recall or withdrawal from the market;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants; or
- loss of revenues.

We have obtained product liability insurance coverage for commercial product sales and clinical trials with a $20 million per occurrence and annual aggregate coverage limit. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. If we determine that it is prudent to increase our product liability coverage based on sales of Zohydro ER, approval of ZX008 or Relday, or otherwise, we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects, including side effects that are less severe than those of Zohydro ER and our product candidates. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and 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, ZX008 has recently received orphan drug designation in Europe, and we expect to initiate a Phase 3 clinical trial during the first quarter of 2016 in 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 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 (comprised of 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

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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.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending use and disposal. We cannot completely eliminate the risk of contamination, which could cause an interruption of our research and development efforts and business operations, injury to our employees and others, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage.

In connection with the reporting of our financial condition and results of operations, we are required to make estimates and judgments which involve uncertainties, and any significant differences between our estimates and actual results could have an adverse impact on our financial position, results of operations and cash flows.

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP, and do not reflect the presentation of our Zohydro® ER business as a discontinued operation, or the effect of the July 1, 2015 reverse stock split. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. Any significant differences between our actual results and our estimates and assumptions could negatively impact our financial position, results of operations and cash flows.

Changes in accounting standards and their interpretations could adversely affect our operating results.

GAAP are subject to interpretation by the Financial Accounting Standards Board, the American Institute of Certified Public Accountants, the SEC, and various other bodies that promulgate and interpret appropriate accounting principles. These principles and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. A change in these principles or interpretations could have a significant effect on our reported financial results, and could affect the reporting of transactions completed before the announcement of a change.

Risks Related to Our Financial Position and Capital Requirements

We have never generated net income from operations 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 approved product, Zohydro ER, in March 2014 and subsequently sold the business in April 2015. 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. 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 clinical development of ZX008 and Relday. As a result, we

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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 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 future 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.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of June 30, 2015 and our projected contract manufacturing revenues will be sufficient to fund our operations through at least the next 12 months. We may need to obtain additional funds to finance our operations beyond that point, or possibly earlier, in order to:

- fund our operations, including further development of ZX008 and Relday and development of any other product candidates to support potential regulatory approval; and
- commercialize any of our 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 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 rate of progress and cost of our clinical trials and other product development programs for ZX008, Relday and our other product candidates and any other product candidates that we may develop, in-license or acquire;
- the timing of regulatory approval for any of our other product candidates and the commercial success of any approved products;
- 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.;
- the receipt of contingent payments from the sale of our Zohydro ER business, which are based on the achievement of pre-determined regulatory and sales milestones by Pernix;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our DosePro technology, ZX008, Relday and any of our other product candidates;
- the costs of establishing or outsourcing sales, marketing and distribution capabilities, should we elect to do so;
- 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.

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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Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations and liquidity could be materially negatively affected by economic conditions generally, both in the United States and elsewhere around the world. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, our results of operations and liquidity could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may decline. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are not federally insured. If economic instability continues, we cannot provide assurance that we will not experience losses on these investments.

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

We may need to raise additional funds through public or private equity offerings, including through debt financings, receivables or royalty financings or corporate collaboration and licensing arrangements. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership interest in us will be diluted. Debt financing typically contains covenants that restrict operating activities.

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

Our ability to utilize our net operating loss and research and development income tax credit carryforwards may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the IRC, substantial changes in our ownership may limit the amount of net operating loss and research and development income tax credit carryforwards (collectively, tax attributes) that could be utilized annually in the future to offset taxable income, if any. Specifically, this limitation may arise in the event of a cumulative change in ownership of our company of more than 50% within a three-year period as determined under the IRC, which we refer to as an ownership change. Any such annual limitation may significantly reduce the utilization of these tax attributes before they expire. Prior to our initial public offering in November 2010, we performed an IRC Section 382 and 383 analysis and determined that we had one ownership change, which occurred in August 2006 upon the issuance of convertible preferred stock. We performed an additional IRC Section 382 and 383 analysis upon the issuance of common stock in our follow-on public offering in September 2011, and together with the issuance of common stock in our initial public offering and certain other transactions involving our common stock, resulted in an additional ownership change. We had a third ownership change as defined by IRC Sections 382 and 383, which occurred in January 2014. There was no forfeiture in federal and California net operating loss carryforwards or research and development income tax credits as a result of the third ownership change. As a result of these ownership changes, our ability to use our then existing tax attributes to offset future taxable income, if any, was limited. Any future equity financing transactions, private placements and other transactions that occur within the specified three-year period may trigger additional ownership changes, which could further limit our use of such tax attributes. Any such limitations, whether as the result of prior or future offerings of our common stock or sales of common stock by our existing stockholders, could have an adverse effect on our consolidated results of operations in future years.

The terms of our credit facility place restrictions on our operating and financial flexibility.

Effective as of December 30, 2014, we entered into a loan and security agreement, or the credit facility, with Oxford as collateral agent, and the lenders party thereto from time to time, or the lenders, including Oxford and SVB, that is

secured by substantially all of our personal property other than our intellectual property. The outstanding principal balance under the credit facility was $21.5 million at the closing of the loan and security agreement on December 30, 2014. On April 23, 2015, in connection with the sale of our Zohydro ER business pursuant to the Pernix asset purchase agreement, we, Oxford and SVB entered into an amendment, or the loan amendment, to the credit facility. Pursuant to the loan amendment, all encumbrances on our personal property related to the Zohydro ER business under the credit facility were terminated.

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The credit facility includes affirmative and negative covenants applicable to us and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding accounts receivable. The loan amendment added an affirmative covenant requiring us to maintain a liquidity ratio of 1.25 to 1 through our receipt of positive data from placebo-controlled trials in the United States and European Union of ZX008. The negative covenants include, among others, restrictions on our transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and suffering a change in control, in each case subject to certain exceptions.

The credit facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide Oxford, as collateral agent, with the right to exercise remedies against us and the collateral securing the credit facility, including foreclosure against our properties securing the credit facilities, including our cash. These events of default include, among other things, our failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $400,000 and one or more judgments against us in an amount greater than $400,000 individually or in the aggregate.

Our ability to make scheduled payments on or to refinance our indebtedness depends on our future performance and ability to raise additional sources of cash, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. If we desire to refinance our indebtedness, our ability to do so will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Risks Related to Regulation of our Product Candidates

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

We currently are developing ZX008 for the treatment of Dravet syndrome and Relday for the treatment of the symptoms of schizophrenia. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products, among other things, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market ZX008, Relday or any of our other product candidates in the United States unless and until we receive regulatory approval from the FDA. We cannot provide any assurance that we will obtain regulatory approval for any of our product candidates, or that any such product candidates will be successfully commercialized.

Under the policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, as renewed in 2012 by the Food and Drug Administration Safety and Innovation Act, or FDASIA, the FDA is subject to a two-tiered system of review times for new drugs: standard review and priority review. For drugs subject to standard review that do not contain a new molecular entity, such as Relday, the FDA has a goal to complete its review of the NDA and respond to the applicant within ten months from the date of receipt of an NDA. The review process and the PDUFA target action date may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission. The FDA's review goals are subject to change, and the duration of the FDA's review may depend on the number and type of other NDAs that are submitted to the FDA around the same time period.

The FDA may also refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. Although the FDA is not bound by the recommendation of an advisory committee, the matters discussed at the advisory committee meeting, and in particular any concerns regarding safety, could limit our ability to successfully commercialize our product candidates subject to advisory committee review.

As part of its review of an NDA, the FDA may inspect the facility or facilities where the drug is manufactured. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA will issue an

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action letter, which will be either an approval letter, authorizing commercial marketing of the drug for a specified indication, or a Complete Response Letter containing the conditions that must be met in order to secure approval of the NDA. These conditions may include deficiencies identified in connection with the FDA's evaluation of the NDA submission or the clinical and manufacturing procedures and facilities. Until any such conditions or deficiencies have been resolved, the FDA may refuse to approve the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example:

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

Product candidates such as ZX008 and Relday, and any of our other product candidates, may not be approved even if they achieve their specified endpoints in clinical trials. The FDA may disagree with our trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. The FDA may also approve a product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates. Approval may be contingent on a risk evaluation and mitigation strategy, or REMS program, which limits the labeling, distribution or promotion of a drug product.

ZX008, Relday and any of our other product candidates may not achieve their specified endpoints in clinical trials. The safety and effectiveness of ZX008 has been evaluated in a continuing, long-term, open-label, study in patients with Dravet syndrome at a single academic medical institution in Belgium. Based upon feedback from the FDA we expect to submit an IND in the third quarter of 2015 to initiate a Phase 3 efficacy trial for ZX008 and to initiate the Phase 3 study in the fourth quarter of 2015. In addition, we plan to submit CTAs in Europe to initiate an identical Phase 3 efficacy study. Each study will enroll about 100 Dravet syndrome patients. We initiated a Phase 1 safety and pharmacokinetic clinical trial for Relday in July 2012 and announced positive single-dose pharmacokinetic results from this trial in January 2013. Based on the favorable safety and pharmacokinetic profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase 1 trial, we extended the study to include an additional cohort of 10 patients at a 100 mg dose of the same formulation and announced positive top-line results from the extended Phase 1 clinical trial in May 2013. The positive results from this study extension positioned 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 started this multi-dose clinical trial in the first half of 2015 and we expect top-line pharmacokinetic data to be available by the end of the third quarter of 2015.

If we are unable to obtain regulatory approval for ZX008, Relday or any other product candidates on the timeline we anticipate, we may not be able to execute our business strategy effectively and our ability to generate revenues may be limited.

We may not be able to maintain orphan drug designation or obtain or maintain orphan drug exclusivity for ZX008. We have obtained orphan drug designation for ZX008 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. Orphan drug designation in the United States confers certain benefits, including tax incentives and waiver of the applicable application fee upon submission of the product for approval in the rare disease or condition.

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 generally entitled to a period of marketing exclusivity, which precludes the FDA or EMA from approving another marketing application for the same drug to treat the same rare disease or condition for that time period, except in limited circumstances. 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.

The orphan drug exclusivity may not effectively protect the product from competition in the United States because different drugs can be approved for the same condition. Even after an orphan drug is approved and granted exclusivity, the FDA and EMA can subsequently approve the same drug for the same condition during the exclusivity period if the FDA concludes

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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. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Any of our product candidates that receive regulatory approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.

Even after we achieve U.S. regulatory approval for a product, the FDA may still impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product, or the implementation of a REMS program. We may also be subject to ongoing FDA obligations and continued regulatory review with respect to the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for any approved product. These requirements may include submissions of safety and other post-marketing information and reports, establishment registration and drug listing, as well as continued compliance with cGMP for our marketed and investigational products, and with GCP and GLP requirements, which are regulations and guidelines enforced by the FDA for all of our products in clinical and pre-clinical development, and for any clinical trials that we conduct post-approval. To the extent that a product is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

In the case of any product candidates containing controlled substances, we and our contract manufacturers will also be subject to ongoing DEA regulatory obligations, including, among other things, annual registration renewal, security, recordkeeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of our products. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations, QSR requirements for medical device components or similar requirements, if applicable. If we or a regulatory agency discovers previously unknown problems with an approved product, such as adverse events of unanticipated severity or frequency, or problems with the facility where, or processes by which, the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturer or us, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the marketing or manufacturing of a product, suspend or withdraw product approvals or revoke necessary licenses;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;
- impose fines or other civil or criminal penalties;
- suspend any ongoing clinical trials;
- deny or reduce quota allotments for the raw material for commercial production of our controlled substance products;
- delay or refuse to approve pending applications or supplements to approved applications filed by us;
- refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us to initiate a product recall.

In addition, labeling, advertising and promotion of any approved products are subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, a drug may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, although the FDA does not regulate the prescribing practices of physicians. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have

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improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

The FDA's regulations, policies or guidance may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. For example, the FDASIA requires the FDA to issue new guidance describing its policy regarding internet and social media promotion of regulated medical products, and the FDA has since released several draft guidance documents enumerating new regulatory obligations and restrictions with respect to this type of promotion. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our drugs, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

ZX008, Relday and our other product candidates may cause undesirable side effects or have other unexpected properties that could delay or prevent approval or result in post-approval regulatory action.

If we or others identify undesirable side effects, or other previously unknown problems, caused by our products, other products or our product candidates with the same or related active ingredients, during development or after obtaining U.S. regulatory approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may not permit us to initiate our studies or could put them on hold;
- regulatory authorities may not approve, or may withdraw their approval of the product;
- regulatory authorities may require us to recall the product;
- regulatory authorities may add new limitations for distribution and marketing of the product;
- regulatory authorities may require the addition of warnings in the product label or narrowing of the indication in the product label;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way the product is administered or modify the product in some other way;
- we may be required to implement a REMS program;
- the FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

In our ongoing Phase 1b multi-dose clinical trial for Relday with 59 enrolled subjects, there have been three reports of elevated liver enzymes in subjects taking Relday. Increases in hepatic enzymes were noted to affect < 2% of Risperdal Consta subjects in clinical trials for registration. The elevations were considered a serious and unexpected adverse event in one subject. High levels of liver enzymes may indicate liver problems or damage, which may be part of the subjects underlying disease, or an unrelated disease, or it may be related to Relday.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us from achieving or maintaining market acceptance of the affected product, if approved, and could substantially increase the costs of commercializing our product candidates.

Our development strategy for Relday depends upon the FDA’s prior findings of safety and effectiveness of risperidone based on data not developed by us, but which the FDA may rely upon in reviewing any future NDA.

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments added Section 505(b)(2) to the .S. Federal Food, Drug, and Cosmetic Act Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Under this statutory provision, the

FDA may rely, for purposes of approving an NDA, on safety and effectiveness data not developed by the filer of the NDA. We plan to submit an NDA for Relday under Section 505(b)(2), and as such, the NDA will rely, in part, on the FDA's previous findings of safety and effectiveness for risperidone. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product

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candidates, and complications and risks associated with these product candidates, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

Even though we may be able to take advantage of Section 505(b)(2) to support potential U.S. approval for Relday, the FDA may still require us to perform additional studies or measurements to support approval. In addition, the FDA's interpretation and use of Section 505(b)(2) has been controversial and has previously been challenged in court, but without a definitive ruling on the propriety of the FDA's approach. Future challenges, including a direct challenge to the approval of our products and product candidates, may be possible and, if successful, could limit or eliminate our ability to rely on the Section 505(b)(2) pathway for the approval of Relday and our other product candidates. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of Relday and our other product candidates, such as ZX008.

Healthcare reform measures and changes in policies, funding, staffing and leadership at the FDA and other agencies could hinder or prevent the commercial success of any of our product candidates that may be approved by the FDA.

In the United States, there have been a number of legislative and regulatory changes to the healthcare system in ways that could affect our future results of operations and the future results of operations of our customers. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established a new Part D prescription drug benefit, which became effective January 1, 2006. Under the prescription drug benefit, Medicare beneficiaries can obtain prescription drug coverage from private sector plans that are permitted to limit the number of prescription drugs that are covered in each therapeutic category and class on their formularies. If any of our product candidates that are approved by the FDA are not widely included on the formularies of these plans, our ability to market our products to the Medicare population could suffer.

Furthermore, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. In March 2010, the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the PPACA, was signed into law, which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers’ Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing both the volume of sales and manufacturers’ Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
-

new requirements to report certain financial arrangements with physicians and others, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members during each calendar year. Manufacturers were required to begin data collection on August 1, 2013 and report such data to the Centers for Medicare & Medicaid Services, or CMS, by the 90th day of each subsequent calendar year;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;

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- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board which, beginning in 2014, has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Other legislative changes have also been proposed and adopted in the United States since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to market our product candidates, if approved, and generate revenues. In addition, legislation has been introduced in Congress that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the United States, including from countries where the products are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could lead to a decision to decrease our prices to better compete, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from sales of any approved product candidates. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications have fluctuated over the last ten years, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

We may incur liability if our continuing medical or health education programs and/or product promotions are determined, or are perceived, to be inconsistent with regulatory guidelines.

The FDA provides guidelines with respect to appropriate promotion and continuing medical and health education activities. Although we endeavor to follow these guidelines, the FDA or the Office of the Inspector General U.S. Department of Health and Human Services may disagree, and we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management’s attention could be diverted and our reputation could be damaged.

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, 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

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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, in cash or in kind, 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;

- 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;

- 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. Manufacturers are required to report data to the government by the 90th day of each 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 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

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operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Import/export regulations and tariffs may change and increase our costs.

We are subject to risks associated with the regulations relating to the import and export of products and materials. We cannot predict whether the import and/or export of our products will be adversely affected by changes in, or enactment of, new quotas, duties, taxes or other charges or restrictions imposed by any country in the future. Any of these factors could adversely affect our business, results of operations, financial condition and prospects.

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 current product candidates, including ZX008 and Relday, and any future product candidates, their respective components, formulations, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing 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-licensed certain intellectual property for Relday from Durect. We rely on this licensor 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 agreement with Durect, we cannot be certain that such activities by 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. 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 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-licensed 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 of Antwerp and Leuven in Belgium, or the Universities.

Most of our patents related to DosePro were acquired from Aradigm, who acquired those patents from a predecessor owner. Thus, many of our patents, as well as many of our pending patent applications, were not written by us or our attorneys, or our licensor or licensors' attorneys, and neither we nor our licensors had control over the drafting and prosecution of these patents. Further, the former patent owners and our licensors might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. In addition, the former patent owners may not have been completely familiar with U.S. patent law, possibly resulting in inadequate disclosure and/or claims. This could possibly result in findings of invalidity or unenforceability of the patents we own and in-license, patents issuing with reduced claim scope, or in pending applications not issuing as patents.

In addition, as part of the agreement 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 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.

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There are currently no issued patents covering ZX008 and there is no guarantee that any of the pending applications will issue as patents. The API in ZX008 is generic and as such not subject to patent protection. The initial applications covering methods of treatment using ZX008 were acquired by us and not written by our attorneys. Neither we nor our licensors had control over the drafting and initial prosecution of these applications. Further, the counsel previously handling the matter might not have given the same attention to the drafting and prosecution to these applications as we would have if we had been the owners and originators of the applications and had control over the drafting and prosecution. In addition, the former counsel handling the matter may not have been completely familiar with U.S. patent law or the patent law in various countries possibly resulting in inadequate disclosure and/or filing of applications at times which do not meet appropriate priority requirements. All of these factors and others could result in the inability to obtain the issuance of these applications in the United States or elsewhere in the world.

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 our product candidates but that are not covered by the claims of our patents or our in-licensed patents;
- the APIs in ZX008 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 ZX008 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 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

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- the patents of others may have an adverse effect on our business.

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

If any of our owned or in-licensed patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Likewise, our patents covering certain technology used in our DosePro system are expected to expire on various dates from 2015 through 2026.

As of June 30, 2015, our patent portfolio included 23 issued U.S. patents, 4 pending U.S. patent applications, 45 issued foreign patents and 6 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. Upon the expiration of these patents, we 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. 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 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 Durect, and we have limited control over the amount or timing of resources 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 Durect and the Universities impose 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.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our rights to our products and technology.

If we or our collaborators or licensors choose to go to court to stop a third party from using the inventions claimed in our owned or in-licensed patents, that third party may ask the court to rule that the patents are not infringed, invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even

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if we or they, as the case may be, were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we or they, as the case may be, do not have the right to stop others from using the inventions.

There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the third party on the ground that such third-party's activities do not infringe our owned or in-licensed patents. In addition, the U.S. Supreme Court has recently changed some tests regarding granting patents and assessing the validity of patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised standards. Some of our own or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in a reexamination or other post-grant proceeding before the PTO, or during litigation, under the revised criteria which make it more difficult to obtain patents. We are not entitled to control the manner in which Durect may defend certain of the intellectual property that is licensed to us, either in a reexamination or other post-grant proceeding before the PTO, or during the litigation, and it is possible that their defense activities may be less vigorous than had we conducted the defense ourselves.

We may also not be able to detect infringement of our own or in-licensed patents, which may be especially difficult for methods of manufacturing or formulation products. While we intend to take actions reasonably necessary to enforce our patent rights, we depend, in part, on our licensors and collaborators to protect a substantial portion of our proprietary rights. For example, Durect, our licensor, is primarily responsible for the enforcement of certain of the intellectual property rights it licenses to us related to Relday. Under the agreement, Durect has the first right, but not the obligation, to initiate an infringement proceeding against a third-party infringer of those intellectual property rights through the use, marketing, sale or import of a product that is competitive to Relday. If Durect decides not to commence or continue any such action, we have the right, but not the duty, to do so and such enforcement will require the cooperation of Durect. We have limited control over the amount or timing of resources Durect devotes on our behalf or the priority it places on enforcing these patent rights to our advantage.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to ZX008 and Relday. As the medical device, biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our products or product candidates infringe the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of medical devices, drugs, products or their methods of use. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our products, product candidates, technology or methods.

In addition, there may be issued patents of third parties of which we are currently unaware, that are infringed or are alleged to be infringed by our product candidate or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent

application on inventions similar to those owned or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference proceeding declared by the PTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such proceedings may be decided against us if the other party had independently arrived at the same or similar invention prior to our own or, if applicable, our licensor's invention, resulting in a loss of our U.S. patent position with respect to such inventions. In addition, if another party has reason to assert a substantial new question of patentability against any of our claims in our owned and in-licensed U.S. patents, the third party can request that the PTO reexamine the patent claims, which may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential infringement claims, interference and reexamination proceedings, we may become a party to patent opposition proceedings in the European Patent Office, Australian Patent Office or other

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jurisdictions where either our patents are challenged, or we are challenging the patents of others. The costs of these proceedings could be substantial, and it is possible that our efforts would be unsuccessful. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents.

If a third-party's patent was found to cover our product candidates, proprietary technologies or their uses, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to commercialize our product candidates or use our proprietary technologies unless we or they obtained a license to the patent. A license may not be available to us or our collaborators on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our products, technologies or methods pending a trial on the merits, which could be years away.

There is a substantial amount of litigation involving patent and other intellectual property rights in the device, biotechnology and pharmaceutical industries generally. If a third party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management’s attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party’s rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner’s attorneys’ fees;
- a court order prohibiting us from selling or licensing the product unless the third party licenses its patent rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on our owned and in-licensed patents are due to be paid to the PTO in several stages over the lifetime of the patents. Future maintenance fees will also need to be paid on other patents which may be issued to us. We have systems in place to remind us to pay these fees, and we employ outside firms to remind us or our in-licensor to pay annuity fees due to foreign patent agencies on our pending foreign patent applications. The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to

enter the market and this circumstance would have a material adverse effect on our business. For the patents and patent applications related to Relday, Durect is obligated to maintain certain of our in-licensed patents on a worldwide basis, using commercially reasonable efforts, under our license agreement. Should Durect fail to pursue maintenance of certain of those licensed patents and patent applications, Durect is obligated to notify us and, at that time, we will be granted an opportunity to maintain the prosecution and avoid withdrawal, cancellation, expiration or abandonment of those licensed patents and applications.

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

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the device, biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management, which would adversely affect our financial condition.

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 six months ended June 30, 2015, the price per share for our common stock on the Nasdaq Global Market has ranged from a low sale price of $9.36 to a high sale price of $15.68 (which sale prices give effect to the reverse split of our common stock effected on July 1, 2015). 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:

- 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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Our quarterly operating results may fluctuate significantly.

Our quarterly operating results are difficult to predict and may fluctuate significantly from period to period, particularly because the success and costs of our ZX008, Relday and other product candidate development programs are uncertain and therefore our future prospects are uncertain. Our net loss and other operating results will be affected by numerous factors, including:

- the level of underlying demand for any of our product candidates that may receive regulatory approval;
- our ability to control production spending and underutilization of production capacity;
- variations in the level of development and/or regulatory expenses related to ZX008, Relday or other development programs;
- results of clinical trials for ZX008, Relday or any other of our product candidates;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments and legislative changes, including healthcare reform, affecting our product candidates or those of our competitors; and
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

We may become involved in securities class action litigation that could divert management's attention and adversely affect our business and could subject us to significant liabilities.

The stock markets have experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations as well a broad range of other factors, including the realization of any of the risks described in these "Risk Factors," may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies generally experience significant stock price volatility. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

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 December 31, 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.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;

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- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;

- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;

- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than 66 2/3% of all outstanding shares of our voting stock then entitled to vote in the election of directors;

- a requirement of approval of not less than 66 2/3% of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and

- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then- current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

The continued operation and expansion of our business will require substantial funding. Investors seeking cash dividends in the foreseeable future should not purchase our common stock. We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our available cash to fund the development and growth of our business. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any return to stockholders will therefore be limited to the appreciation in the market price of their stock, which may never occur.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to meet compliance obligations.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the Nasdaq Stock Market, or Nasdaq, that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. In addition, on July 21, 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. The requirements of these rules and regulations have increased

and will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place considerable strain on our personnel, systems and resources. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these new compliance initiatives. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

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The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Ensuring that we have adequate internal financial and accounting controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated frequently. In particular, commencing in fiscal 2011, we performed system and process evaluation and testing of our internal controls over financial reporting which allowed management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Our future testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. We expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404. Pursuant to Section 404(c) of the Sarbanes-Oxley Act, our independent registered public accounting firm is required to deliver an attestation report on the effectiveness of our internal control over financial reporting. We currently do not have an internal audit function, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate consolidated financial statements or other reports on a timely basis, could increase our operating costs and could materially

impair our ability to operate our business. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds
Unregistered Sales of Equity Securities
None.
Use of Proceeds
Not applicable.

Item 3. Defaults Upon Senior Securities
None.

Item 4. Mine Safety Disclosures
Not applicable.

Item 5. Other Information
None.

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Item 6. Exhibits
EXHIBIT INDEX

Exhibit Number	Description
2.1†(7)	Amendment to Asset Purchase Agreement, dated April 23, 2015, by and among the Registrant, Pernix Ireland Limited and Pernix Therapeutics Holdings, Inc.
2.2 (7)	Amendment to Asset Purchase Agreement, dated April 23, 2015, by and among Zogenix, Inc., Pernix Ireland
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	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.4(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 June 30, 2008 issued by the Registrant to Oxford Finance Corporation
4.6(1)	Transfer of Warrant dated March 24, 2009 from CIT Healthcare LLC to The CIT Group/Equity Investments, Inc.
4.7(4)	Warrant dated July 18, 2011 issued by the Registrant to Healthcare Royalty Partners (formerly Cowen Healthcare Royalty Partners II, L.P.)
4.8(6)	Warrant dated December 30, 2014 issued by the Registrant to Oxford Finance LLC
4.9(6)	Warrant dated December 30, 2014 issued by the Registrant to Silicon Valley Bank
10.1(7)	First Amendment to Loan and Security Agreement, dated April 23, 2015, by and among the Registrant, Oxford Finance LLC, as collateral agent for the Lenders (as defined therein) and Silicon Valley Bank
10.2 #(8)	General Release of Claims, dated April 23, 2015, by and between the Registrant and Roger L. Hawley

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10.3 #(8)	Annual Incentive Plan as amended and restated effective April 27, 2015
10.4#	Amended and Restated Employment Agreement, dated April 27, 2015, by and between the Registrant and Stephen J. Farr, Ph.D.
10.5#	Employment Agreement, dated June 29, 2015, by and between the Registrant and Gail M. Farfel, Ph.D.
10.6#	Employment Agreement, dated June 29, 2015, by and between the Registrant and Thierry Darcis
10.7#	Independent Director Compensation Policy as amended and restated effective April 23, 2015
10.8	Third Amendment to Office Lease, dated July 20, 2015, by and between the Registrant and Emery Station Joint Venture, LLC
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
101	The following financial statements from the Registrant's Quarterly Report on form 10-Q for the period ended June 30, 2015, 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 the 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 December 31, 2014.
(7) Filed with the Registrant's Current Report on Form 8-K on April 28, 2015.
(8) Filed with the Registrant's Quarterly Report on Form 10-Q on May 11, 2015.

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

# Indicates management contract or compensatory plan.

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

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SIGNATURES

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

ZOGENIX, INC.

Date: August 10, 2015

By: /s/ Stephen J. Farr
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 10, 2015

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