

ZOGENIX, INC.
Form 10-Q
May 11, 2015
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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
(State or Other Jurisdiction of
Incorporation or Organization)

20-5300780
(I.R.S. Employer
Identification No.)

12400 High Bluff Drive, Suite 650
San Diego, California
(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. Yes No
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer

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

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

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The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of May 4, 2015 was 153,363,743.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Zogenix, Inc.

Consolidated Balance Sheets

(In Thousands)

	March 31, 2015 (Unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$21,314	\$42,205
Restricted cash	8,500	8,500
Trade accounts receivable, net	1,624	6,078
Inventory	13,102	11,444
Prepaid expenses	3,460	2,048
Other current assets	547	507
Current assets of discontinued operations	6,636	7,196
Total current assets	55,183	77,978
Property and equipment, net	10,276	10,618
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	2,646	2,832
Noncurrent assets of discontinued operations	3,405	2,673
Total assets	\$180,244	\$202,835
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$5,191	\$4,742
Accrued expenses	6,567	6,016
Accrued compensation	1,657	3,157
Common stock warrant liabilities	4,683	5,093
Revolving credit facility	2,565	1,450
Long-term debt, current portion	1,881	—
Deferred revenue	1,031	1,472
Current liabilities of discontinued operations	21,397	22,307
Total current liabilities	44,972	44,237
Note payable	2,549	2,461
Long term debt	17,447	19,242
Deferred revenue, less current portion	7,345	7,063
Contingent purchase consideration	52,000	53,000
Deferred income taxes	20,500	20,500
Other long-term liabilities	1,138	1,053
Stockholders' equity:		
Common stock, \$0.001 par value; 200,000 shares authorized at March 31, 2015 and December 31, 2014; 153,365 and 153,363 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	153	153
Additional paid-in capital	458,661	456,786
Accumulated deficit	(424,521)	(401,660)
Total stockholders' equity	34,293	55,279

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Total liabilities and stockholders' equity	\$ 180,244	\$ 202,835
See accompanying notes.		

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Zogenix, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In Thousands, except Per Share Amounts)

(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Revenue:		
Contract manufacturing revenue	\$4,181	\$—
Net product revenue	—	6,485
Service and other product revenue	433	904
Total revenue	4,614	7,389
Operating expense:		
Cost of contract manufacturing	3,923	—
Cost of goods sold	—	3,333
Royalty expense	72	267
Research and development	5,150	2,541
Selling, general and administrative	6,268	12,528
Change in fair value of contingent consideration	(1,000) —
Total operating expense	14,413	18,669
Loss from operations	(9,799) (11,280
Other income (expense):		
Interest income	5	6
Interest expense	(648) (1,886
Change in fair value of warrant liabilities	410	8,269
Change in fair value of embedded derivatives	—	(14
Other expense	(120) (47
Total other income (expense)	(353) 6,328
Net loss from continuing operations before income taxes	(10,152) (4,952
Provision for income taxes	(13) —
Net loss from continuing operations	(10,165) (4,952
Discontinued operations:		
Loss from discontinued operations, net of applicable tax	(12,696) (15,980
Net loss	\$ (22,861) \$ (20,932
Basic net loss per share:		
Continuing operations	\$ (0.07) \$ (0.04
Discontinued operations	\$ (0.08) \$ (0.11
Total	\$ (0.15) \$ (0.15
Diluted net loss per share:		
Continuing operations	\$ (0.07) \$ (0.09
Discontinued operations	\$ (0.08) \$ (0.11
Total	\$ (0.15) \$ (0.20
Weighted average shares outstanding, basic	153,362	139,309
Weighted average shares outstanding, diluted	153,362	145,323
Comprehensive loss	\$ (22,861) \$ (20,932
See accompanying notes.		

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Zogenix, Inc.

Consolidated Statements of Cash Flows

(In Thousands)

(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Operating activities:		
Net loss	\$(22,861) \$(20,932
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,871	2,507
Depreciation and amortization	393	406
Amortization of debt issuance costs and non-cash interest charges	257	161
Change in fair value of warrant liabilities	(410) (8,269
Change in fair value of embedded derivatives	—	14
Change in fair value of contingent purchase consideration	(1,000) —
Changes in operating assets and liabilities:		
Trade accounts receivable	4,207	(5,015
Inventory	(450) (4,918
Prepaid expenses and other current assets	(1,853) 882
Other assets	(621) (534
Accounts payable and accrued expenses	947	6,937
Deferred rent	(26) (26
Deferred revenue	(2,401) 5,963
Net cash used in operating activities	(21,947) (22,824
Investing activities:		
Purchases of property and equipment	(54) (15
Net cash used in investing activities	(54) (15
Financing activities:		
Proceeds from revolving credit facility	1,450	—
Repayment of revolving credit facility	(343) —
Proceeds from exercise of common stock options and warrants	3	1,502
Net cash provided by financing activities	1,110	1,502
Net decrease in cash and cash equivalents	(20,891) (21,337
Cash and cash equivalents at beginning of period	42,205	72,021
Cash and cash equivalents at end of period	\$21,314	\$50,684
Noncash investing and financing activities:		
Change in purchases of property and equipment in accounts payable	\$—	\$310
See accompanying notes.		

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Zogenix, Inc.

Notes to Consolidated Financial Statements

1. Organization and Basis of Presentation

Zogenix, Inc. (the Company) is a pharmaceutical company committed to developing and commercializing therapies that address specific clinical needs for people living with 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.

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 losses, successful transition to profitability is dependent upon achieving a level of revenues adequate to support the Company's cost structure. This may not occur and, unless and until it does, the Company will continue to need to raise additional cash. These conditions 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.

Subsequent to the issuance of the Company's annual report for the year ended December 31, 2014 dated March 11, 2015, and the reporting period included in these consolidated financial statements for the three months ended March 31, 2015, the Company sold its Zohydro ER business to Ferrimill Limited (Ferrimill) and received cash proceeds, net of \$10,000,000 placed in escrow, of approximately \$70,000,000, plus approximately \$900,000 for Zohydro ER finished goods inventory acquired by the purchaser. Also, approximately 100 sales and marketing employees transitioned to the purchaser in conjunction with the divestiture.

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.

Recent Developments

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. 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 6, 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.

2. Summary of Significant Accounting Policies

Financial Statement Preparation and Use of Estimates

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

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

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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 Sumavel DosePro business in May 2014, the Company has \$8,500,000 of cash in escrow as of March 31, 2015 and December 31, 2014 to fund potential indemnification claims for a period of 12 months from the closing date of the sale. The Company classifies the cash flow from this restricted cash as an investing activity in the consolidated statement of cash flows as the source of the restricted cash is related to the sale of the Sumavel DosePro business.

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 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 March 31, 2015 and December 31, 2014 are as follows (in thousands):

	Fair Value Measurements at Reporting Date Using			Total
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
At March 31, 2015				
Assets				
Cash equivalents ⁽¹⁾	\$18,125	—	—	\$18,125
Liabilities				
Common stock warrant liabilities ⁽²⁾	\$—	—	4,683	\$4,683
Contingent purchase consideration ⁽³⁾	\$—	—	52,000	\$52,000
At December 31, 2014				
Assets				
Cash equivalents ⁽¹⁾	\$8,021	—	—	\$8,021
Liabilities				

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Common stock warrant liabilities ⁽²⁾	\$—	—	5,093	\$5,093
Contingent purchase consideration ⁽³⁾	\$—	—	53,000	\$53,000

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- (1) Cash equivalents are comprised of money market fund shares and are included as a component of cash and cash equivalents on the consolidated balance sheets.
- Common stock warrant liabilities include liabilities associated with warrants issued in connection with the Company's July 2012 public offering of common stock and warrants (see Note 4) 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 March 31, 2015 was primarily driven by the decrease in the expected term of the warrant at March 31, 2015 as compared against December 31, 2014 measurement dates.
- 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 liabilities measured at fair value using significant unobservable inputs (Level 3) for the three months ended March 31, 2015 (in thousands):

	Contingent Purchase Consideration	Common Stock Warrant Liabilities
Balance at December 31, 2014	\$53,000	\$5,093
Changes in fair value	(1,000) (410
Balance at March 31, 2015	\$52,000	\$4,683

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 loss.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, reduced by weighted average shares subject to repurchase, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method and as-if converted method, as applicable. For purposes of this calculation, stock options, restricted stock units and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

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

	Three Months Ended March 31,			
	2015		2014	
	Continuing operations	Discontinued operations	Continuing operations	Discontinued operations
Numerator				
Net loss, basic	\$(10,165)	\$(12,696)	\$(4,952)	\$(15,980)
Effect of dilutive securities:				
Common stock warrants	—	—	(8,269)	—
Non-employee stock options and restricted stock units	—	—	(132)	—
	—	—	(8,401)	—
Net loss, diluted	\$(10,165)	\$(12,696)	\$(13,353)	\$(15,980)
Denominator				
Weighted average common shares outstanding, basic	153,362	153,362	139,309	139,309
Effect of dilutive securities:				
Common stock warrants	—	—	5,870	—
Non-employee stock options and restricted stock units	—	—	144	—
Dilutive potential shares of common stock	—	—	6,014	—
Weighted average common shares outstanding, diluted	153,362	153,362	145,323	139,309
Basic net loss per share	\$(0.07)	\$(0.08)	\$(0.04)	\$(0.11)
Diluted net loss per share	\$(0.07)	\$(0.08)	\$(0.09)	\$(0.11)

There were 730,000 and 11,246,000 dilutive securities (in common stock equivalent shares), from common stock options and restricted stock units excluded from the calculation of diluted net loss during the three months ended March 31, 2015 and 2014, respectively, because to include them would be anti-dilutive. Common stock warrants of 15,724,000 and 508,000 were excluded from the calculation of diluted net loss during the three months ended March 31, 2015 and 2014, respectively, 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 recognized revenue from the sale of Zohydro ER prior to its sale to Ferrimill in April 2015, which is included in net loss from discontinued operations in

the consolidated statement of operations and comprehensive loss. 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

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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. Prior to the divestiture of the Zohydro ER business, the Company deferred recognition of revenue on product shipments of Zohydro ER until the right of return no longer existed, 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

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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, prior to the divestiture of the Zohydro ER business, 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 existed, which occurred at the earlier of the time Zohydro ER was dispensed through patient prescriptions or expiration of the right of return. The Company estimated 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 did not have a direct correlation with future revenue recognition as the Company 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. The Company will be responsible for returns of product sold, rebates and chargebacks for product dispensed and related Health Care Reform fees through the date of the sale of the Zohydro ER business in April 2015. Revenue for Zohydro ER is included in discontinued operations in the consolidated statement of operations and comprehensive loss.

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 has 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. Early adoption is prohibited. The Company is evaluating the transition method, timing and impact of adopting this new accounting standard on its financial statements and related disclosures.

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.

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3. Inventory

Inventory consists of the following (in thousands):

	March 31, 2015	December 31, 2014
Raw materials	\$3,742	\$3,453
Work in process	9,360	7,991
Total	\$13,102	\$11,444

4. Common Stock Warrants

In July 2012, in connection with a public offering of common stock and warrants, the Company sold warrants to purchase 15,784,200 shares of common stock (including over-allotment purchase). The warrants are exercisable at an exercise price of \$2.50 per share and will expire on July 27, 2017, which is five years from the date of issuance. As the warrants contain a cash settlement feature upon the occurrence of certain events that may be outside of the Company's control, the warrants are recorded as a current liability and are marked to market at each reporting period (see Note 2). During the three months ended March 31, 2015, no warrants to purchase shares of common stock were exercised, and during the year ended December 31, 2014, warrants to purchase 465,250 shares of common stock were exercised. The Company recognized \$0 and \$1,163,000 in proceeds from the exercise of warrants during the three months ended March 31, 2015 and during the year ended December 31, 2014, respectively. The fair value of the warrants outstanding was approximately \$4,585,000 and \$4,978,000 as of March 31, 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 225,000 shares of common stock. The warrant is exercisable at \$9.00 per share of common stock and has a term of ten years. As the warrant contains covenants where compliance with such covenants may be outside of the Company's control, the warrant was recorded as a current liability and is marked to market at each reporting date (see Note 2). The fair value of the warrant was approximately \$98,000 and \$115,000 as of March 31, 2015 and December 31, 2014, respectively.

5. Stock-Based Compensation

The Company uses the Black-Scholes option-pricing model for determining the estimated fair value of stock-based compensation for stock-based awards to employees and the board of directors. The assumptions used in the Black-Scholes option-pricing model for the three months ended March 31, 2015 and 2014 are as follows:

	Three Months Ended March 31,	
	2015	2014
Risk free interest rate	1.5%	2.0%
Expected term	5.8 to 6.1 years	6.0 to 6.1 years
Expected volatility	78.5%	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.

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

	Three Months Ended March 31,	
	2015	2014
Cost of goods sold	\$93	\$127
Research and development	224	357
Selling, general and administrative	1,033	1,560
Total	\$1,350	\$2,044

As of March 31, 2015, there was approximately \$10,447,000 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 3.0 years.

As of March 31, 2015, there were 233,000 unvested stock options outstanding to consultants, with approximately \$256,000 of related unrecognized compensation expense based on a March 31, 2015 measurement date. These unvested stock options outstanding to consultants are expected to vest over a weighted average period of 2.9 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 income recognized from the valuation of stock options and restricted stock units to consultants was immaterial for the three months ended March 31, 2015 and \$174,000 for the three months ended March 31, 2014. Stock option expense for awards issued to consultants is included in the consolidated statement of operations and comprehensive loss within selling, general and administrative expense.

6. Sale of Zohydro ER business

On March 10, 2015, the Company entered into an asset purchase agreement with Pernix Ireland Limited and Pernix Therapeutics Holdings, Inc., (Pernix Therapeutics, and, together with Pernix Ireland Limited, Pernix) 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 divested 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 \$11,900,000 in Pernix common stock. Further, Ferrimill purchased Zohydro ER inventory of \$900,000. 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. 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 will retain all liabilities associated with the Zohydro ER business arising prior to the sale.

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.

On April 24, 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 plans to reduce its workforce by an additional 16 employees as a result of the divestiture.

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 loss for the three months ended March 31, 2014 and the consolidated balance sheet as of December 31, 2014 have been retrospectively restated to reflect the financial

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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 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 loss for the three months ended March 31, 2015 and 2014 (in thousands):

	Three Months Ended March 31,	
	2015	2014
Discontinued operations		
Revenues:		
Net product revenue	\$5,006	\$285
Operating expenses:		
Cost of product sold	1,340	49
Royalty expense	418	96
Research and development	4,808	997
Selling, general and administrative	11,136	15,123
Total operating expenses	17,702	16,265
Loss from discontinued operations	\$(12,696)	\$(15,980)

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

	March 31,	December 31,
	2015	2014
ASSETS		
Current assets		
Trade accounts receivable	\$3,046	\$2,799
Inventory	787	1,995
Prepaid expenses	1,700	1,767
Other current assets	1,103	635
Total current assets of discontinued operations	6,636	7,196
Other assets	3,405	2,673
Total assets of discontinued operations	\$10,041	\$9,869
LIABILITIES		
Current liabilities		
Accounts payable	\$4,786	\$3,781
Accrued expenses	9,983	9,470
Accrued compensation	1,747	1,933
Deferred revenue	4,881	7,123
Total current liabilities of discontinued operations	21,397	22,307
Total liabilities of discontinued operations	\$21,397	\$22,307

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Total stock-based compensation related to discontinued operations was \$522,000 and \$463,000 for the three months ended March 31, 2015 and 2014, respectively. Total amortization expense related to discontinued operations was \$124,000 and \$85,000 for the three months ended March 31, 2015 and 2014, respectively.

The Company will complete the accounting for this business divestiture, including recording any related gain on sale, during the second quarter of 2015.

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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 products and product candidates and the ability to operate our business without infringing the intellectual property rights of others;
- our ability to obtain and maintain adequate levels of coverage and reimbursement from third-party payors for 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,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “ongoing” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Quarterly Report on Form 10-Q in greater detail under the heading “Item 1A – Risk Factors.” Given these risks, uncertainties and other factors, we urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. We undertake no obligation to revise or update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

DosePro®, 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.

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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.

In October 2014, Zogenix Europe Limited, our wholly-owned subsidiary, acquired Brabant Pharma Limited, or Brabant. With the acquisition, we obtained worldwide development and commercialization rights to a product candidate, 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 Europe and the United States for the treatment of Dravet syndrome. As of March 31, 2015, plans are underway to support the initiation of Phase 3 clinical trials of ZX008 in both Europe and the United States in the third 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 using Durect Corporation's SABER™ controlled-release formulation technology. Risperidone is used to treat the symptoms of schizophrenia and bipolar disorder in adults and teenagers 13 years of age and older. If successfully developed and approved, we believe Relday may be the first subcutaneous antipsychotic product that allows for once-monthly dosing. The development of Relday will first focus on its delivery by conventional needle and syringe in order to allow the administration of different volumes of the same formulation of Relday by a healthcare professional. We anticipate that the introduction of our DosePro needle-free technology for administration of Relday can occur later in development or as part of life cycle management after further work involving formulation development, technology enhancements, and applicable regulatory approvals. We 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. for consideration of \$80.0 million in cash and \$11.9 million in Pernix Therapeutics Holdings Inc.'s common stock, plus potential future regulatory and sales milestones of up to \$283.5 million. Further, Ferrimill purchased Zohydro ER inventory from us of \$0.9 million.

We sold our SUMAVEL® DosePro® (sumatriptan injection) Needle-free Delivery System business in May 2014, to Endo International Plc, or Endo, for \$85.0 million in cash and milestone payments of up to \$20.0 million. In connection with the sale, we entered into a supply agreement, under which we retain the sole and exclusive right and obligation to manufacture Sumavel DosePro for Endo, subject to Endo's right to qualify and maintain a back-up manufacturer.

We have experienced net losses and negative cash flow from operating activities since inception, and as of March 31, 2015, had an accumulated deficit of \$424.5 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 March 31, 2015, we had cash and cash equivalents of \$21.3 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 net cash proceeds, net of \$10.0 million placed in escrow, of approximately \$70.0 million. Also, approximately 100 sales and marketing employees transitioned to Pernix in conjunction with the divestiture. As a result, we are currently operating with an improved cash position and at lower expense levels than

previously forecasted.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of March 31, 2015, along with the proceeds from the sale of our Zohydro ER business in April 2015 and our projected manufacturing and other service 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, including through our controlled equity offering program, debt financings, receivables financings or through collaborations or partnerships with other companies. If we are unsuccessful in raising additional required funds, we may be required to significantly delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts, or cease operating as a going concern.

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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.

Recent Developments

On March 10, 2015, we entered into an asset purchase agreement with Pernix Ireland Limited and Pernix Therapeutics Holdings, Inc., 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 Limited (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 \$11.9 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. 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 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 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, for which we expect to record charges of approximately \$0.5 million related to personnel costs associated with these actions. We also plan to reduce our workforce by an additional 16 employees as a result of the divestiture.

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.

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 to fund potential indemnification claims for a period of 12 months. 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

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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 recognized revenue from the sale of Zohydro ER prior to the divestiture of the Zohydro ER business which is included in net loss from discontinued operations in the consolidated statement of operations and comprehensive loss. 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. Prior to the divestiture of the Zohydro ER business, we deferred recognition of revenue on product shipments of Zohydro ER until the right of return no longer existed, 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.

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

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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 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 existed, which occurred 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 through the date of the business sale 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, 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 have been no significant changes in critical accounting policies during the three months ended March 31, 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.

Results of Operations

Comparison of the three months ended March 31, 2015 and 2014

Revenue

(Dollars in thousands)	Three Months Ended		2014 to 2015		
	March 31, 2015	2014	\$ change	% change	
Contract manufacturing revenue	\$4,181	\$—	\$4,181	100.0	%
Net product revenue	—	6,485	(6,485)	(100.0))%
Service and other product revenue	433	904	(471)	(52.1))%

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Total revenue	\$4,614	\$7,389	\$(2,775)	(37.6)	%
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The 100% increase in contract manufacturing revenue and 100% decrease in net product revenue was primarily due to the sale of the Sumavel DosePro business to Endo in May 2014 and subsequent performance under the related supply agreement. Overall, sales in these categories decreased primarily as a result of a decreased selling price realized under the terms of our Supply Agreement during the quarter ended March 31, 2015 as compared to average selling price realized on our commercial efforts during the quarter ended March 31, 2014. This decrease was partially offset by an increase of 4% in units sold during the quarter ended March 31, 2015 as compared to the same quarter ended March 31, 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.

Service and other revenue for the three months ended March 31, 2015 and 2014 was \$0.4 million and \$0.9 million, respectively. Service and other product revenue is primarily comprised of the co-promotion fee that is earned for our Migranal sales efforts under our agreement with Valeant Pharmaceuticals. The decrease of \$0.5 million or 52.1% for the three months ended March 31, 2015 from the same period in 2014 primarily resulted from lower volume of co-promotion activity.

Cost of Contract Manufacturing and Cost of Goods Sold

(Dollars in thousands)	Three Months Ended March 31,		2014 to 2015		
	2015	2014	\$ change	% change	
Cost of contract manufacturing	\$3,923	\$—	\$3,923	100.0	%
Cost of goods sold	\$—	\$3,333	\$(3,333)	(100.0))%
Product gross margin	—	% 49	%	(100.0))%
Contract manufacturing gross margin	6	% —	%	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. 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.

The decline in cost of goods sold and corresponding 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 months ended March 31, 2015 as compared to the same period in 2014. The decrease in overall gross margin for the three months ended March 31, 2015 as compared to the same period in 2014 resulted from a lower profit margin realized under our Supply Agreement with Endo in 2015 than was previously realized under our commercial sales terms in 2014.

Royalty Expense

(Dollars in thousands)	Three Months Ended March 31,		2014 to 2015		
	2015	2014	\$ change	% change	
Royalty expense	\$72	\$267	\$(195)	(73.0))%

During the three months ended March 31, 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 months ended March 31, 2015 reflects only the amortization of the milestone payment.

Research and Development Expenses

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(Dollars in thousands)	Three Months Ended March 31,		2014 to 2015		
	2015	2014	\$ change	% change	%
Research and development	\$5,150	\$2,541	\$2,609	102.7	%

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

Research and development expenses (in thousands):	Three Months Ended March 31,	
	2015	2014
ZX008	\$1,441	\$—
Relday	1,945	1,037
Other ⁽¹⁾	1,764	1,504
Total	\$5,150	\$2,541

⁽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 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 continue to increase over 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 third quarter of 2015, and conduct our multi-dose clinical trial for Relday, which commenced in February of 2015.

Selling, General and Administrative Expenses

(Dollars in thousands)	Three Months Ended March 31,		2014 to 2015		
	2015	2014	\$ change	% change	%
Selling expense	\$546	\$7,212	\$(6,666)	(92.4))%
General and administrative expense	5,722	5,316	406	7.6	%
Total selling, general and administrative	\$6,268	\$12,528	\$(6,260)	(50.0))%

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

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agreement and sample product costs. General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, accounting, business development, medical affairs and internal support functions. In addition, general and administrative expenses include professional fees for legal, consulting and accounting services.

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 months ended March 31, 2015.

The increase in general and administrative expenses is primarily the result of additional professional service fees incurred during the three months ended March 31, 2015 in conjunction with the sale of our Sumavel DosePro business and the acquisition of Brabant.

Change in fair value of contingent consideration

(Dollars in thousands)	Three Months Ended March 31,		2014 to 2015	
	2015	2014	\$ change	% change
Change in fair value of contingent consideration	\$ (1,000)	\$ —	\$ (1,000)	(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. The balance of the change in fair value of contingent consideration income for the three months ended March 31, 2015 resulted primarily from a decrease in our estimated risk-free adjusted discount rate from the previous December 31, 2014 measurement date.

Other income (expense)

(Dollars in thousands)	Three Months Ended March 31,		2014 to 2015	
	2015	2014	\$ change	% change
Interest income	\$ 5	\$ 6	\$ (1)	(16.7)%
Interest expense	\$ (648)	\$ (1,886)	\$ 1,238	(65.6)%
Change in fair value of warrant liabilities	\$ 410	\$ 8,269	\$ (7,859)	(95.0)%
Change in fair value of embedded derivatives	\$ —	\$ (14)	\$ 14	(100.0)%
Other income (expense)	\$ (120)	\$ (47)	\$ (73)	155.3 %
Total other income (expense)	\$ (353)	\$ 6,328	\$ (6,681)	(105.6)%

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

Interest Expense. During the three months ended March 31, 2015, interest expense was incurred in conjunction with our term loan and revolving line of credit. During the three months ended March 31, 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 months ended March 31, 2015 as compared to the same period in 2014.

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 4 to our consolidated financial statements. The income recorded for the three months ended March 31, 2015 resulted primarily from the shorter remaining term for the potential exercise of the warrants 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 months ended March 31, 2014 was primarily driven by the decrease in our stock price at March 31, 2014 as compared to the December 31, 2013 measurement date.

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Change in Fair Value of Embedded Derivatives. The change in fair value of embedded derivatives relates to a fair value adjustment recorded on the embedded derivatives associated with the Healthcare Royalty financing agreement. 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. The increase in other income (expense) was primarily driven by a higher value of purchases conducted in British pound sterling, offset by a lower average conversion rate, for the three months ended March 31, 2015 as compared to the same period in 2014.

Discontinued Operations

During the first quarter of 2015, we reached a decision to sell the 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, with an aggregate cash purchase price of \$80.0 million, \$10.0 million of which has been deposited in escrow to fund potential indemnification claims for a period of 12 months, \$11.9 million in Pernix common stock, plus finished goods inventory of Zohydro ER sold of \$0.9 million, provides us with working capital. We may also receive up to an additional \$283.5 million in potential regulatory and sales milestones, but we cannot anticipate whether the milestones will be achieved.

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 loss and the consolidated balance sheet have been retrospectively revised to reflect the financial results from the Zohydro ER business as discontinued operations.

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Liquidity and Capital Resources

We have experienced net losses and negative cash flow from operations since inception, and as of March 31, 2015, had an accumulated deficit of \$424.5 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. As of March 31, 2015, we had cash and cash equivalents of \$21.3 million.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of March 31, 2015, along with the proceeds from the sale of our Zohydro ER business and our projected contract manufacturing revenues will be sufficient to fund our operations for at least the next twelve months. We may also pursue additional opportunities to raise capital, if necessary, through public or private equity offerings, including through a controlled equity offering program, debt financings, receivables financings or through collaborations or partnerships with other companies.

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 sales and marketing employees transitioned to Pernix in conjunction with the divestiture. As a result, 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 \$21.3 million and \$42.2 million at March 31, 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 three months ended March 31, 2015 and 2014:

	Three Months Ended March 31,	
	2015	2014
	(In Thousands)	
Statement of Cash Flows Data:		
Total cash provided by (used in):		
Operating activities	\$(21,947) \$(22,824
Investing activities	(54) (15
Financing activities	1,110	1,502
Decrease in cash and cash equivalents	\$(20,891) \$(21,337

Operating Activities: Net cash used in operating activities was \$21.9 million and \$22.8 million for the three months ended March 31, 2015 and 2014, respectively. Net cash used for the three months ended March 31, 2015 primarily reflects the use of cash for operations, adjusted for non-cash charges including a \$0.4 million change in fair value of warrant liabilities and \$1.9 million in stock-based compensation. Significant working capital uses of cash for the three months ended March 31, 2015 include personnel-related costs, sales and marketing costs for Zohydro ER, research and development costs (primarily for an abuse deterrent formulation of Zohydro ER, ZX008 and Relday) and other professional services, including legal and accounting services. Significant working capital uses of cash for the three months ended March 31, 2014 include personnel-related costs, research and development costs (primarily for Relday and employee and infrastructure resources, sales and marketing expense for Sumavel DosePro and Zohydro ER, and other professional services.

Investing Activities. Net cash was used by investing activities for the purchase of property and equipment for the three months ended March 31, 2015 and 2014.

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We expect to incur capital expenditures of approximately \$0.6 million in 2015. These planned capital expenditures primarily relate to equipment used in our research and development processes.

Financing Activities. Net cash provided by financing activities was \$1.1 million for the three months ended March 31, 2015, which relates primarily to the net proceeds drawn from our revolving line of credit for the quarter. Net cash provided by financing activities was \$1.5 million for the three months ended March 31, 2014, which relates to the proceeds from the exercise of stock options and warrants.

Our sources of liquidity include our cash balances and cash receipts from contract manufacturing for Sumavel DosePro. Through March 31, 2015, we received aggregate net cash proceeds of approximately \$419.0 million from the sale of shares of our preferred and common stock. As of March 31, 2015, we had \$21.3 million in cash and cash equivalents. Other potential sources of near-term liquidity include (i) proceeds of the sale of our Zohydro ER business, which closed on April 24, 2015, (ii) equity offerings, including through our controlled equity program, debt or other financing, and (iii) 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 stable 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 March 31, 2015 consisted of cash and money market funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. The primary objective of our investment activities is to preserve principal. Instruments that meet this objective include commercial paper, money market funds and government and non-government debt securities. Some of the investment securities available-for-sale that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment securities available-for-sale to fluctuate. To minimize this risk, we intend to continue to maintain our portfolio of cash and money market funds, and due to their short-term nature we believe that there is no material exposure to interest rate risk.

Foreign Exchange Risk

All of the revenues we have generated to date have been paid in U.S. dollars and we expect that our revenues will continue to be generated in U.S. dollars for at least the next several years. Payments to our material suppliers and contract manufacturers are denominated in the Euro and U.K. pounds sterling. 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 foreign currency transaction costs, 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 March 31, 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 March 31, 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, particularly opioid 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 15 Dravet syndrome patients. Based upon feedback from the FDA and the European Medicines Agency, or EMA, we expect to initiate two Phase 3 studies (of 40 to 60 Dravet syndrome patients per study) during the third quarter of 2015 in the United States and Europe, with top-line results potentially available in the first half of 2016. We do not know whether any of our other pre-clinical or clinical trials will begin on time or be completed on schedule, if at all.

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 February 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.

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

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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.

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

As a result of the sale of our Zohydro ER business, 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

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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 product candidates. Epidiolex, which is being developed by GW Pharmaceuticals, has received an orphan designation by the EMA and fast track status by the FDA for the treatment of Dravet syndrome. In October 2014, GW Pharmaceuticals initiated a Phase 2/3 clinical trial for Epidiolex, a cannabanioid drug. Insys Therapeutics has advanced its pharmaceutical cannabanioid 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 is developing 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 and Invega Sustenna marketed by Johnson & Johnson, Zyprexa Relprevv marketed by Eli Lilly & Company, and Abilify Maintena (aripiprazole) 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 as by other pharmaceutical companies such as Alkermes, Endo Health Solutions Inc., Laboratorios Farmaceuticos Rovi SA, Novartis AG, and Reckitt Benckiser Group plc, each of which has announced they are developing long-acting antipsychotic product candidates. In May 2014, Janssen Pharmaceuticals, Inc., announced the submission of sNDAs for once-monthly atypical long-acting antipsychotic Invega Sustenna (paliperidone palmitate) to the FDA for approval to treat schizoaffective disorder as either monotherapy or adjunctive therapy. In May 2015, Indivior PLC announced positive top-line results from its Phase 3 clinical trial of RBP-7000, an investigational drug in development for the treatment of schizophrenia that requires 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.

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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;
- 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 \$8.7 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 March 31, 2015, our accumulated deficit was \$(424.5) 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

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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.

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.

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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 MGlaser AG), located in Műnnerstadt, 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.

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 produce 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.

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We rely on third parties to conduct our pre-clinical 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 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 current good clinical practice, or GCP. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP regulations, the data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional 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 terminate, 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 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.

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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.

In addition, we have agreed to indemnify Endo and its affiliates against losses suffered as a result of our material breach of representations and warranties and our other obligations in the Endo asset purchase agreement, and \$8.5 million of the upfront cash payment has been deposited into escrow to fund such potential indemnification claims for a period of 12 months following the closing of the sale, which period will end in May 2015. We cannot provide any assurance that we will receive all or any portion of the \$8.5 million escrow amount or any of the contingent milestone payments.

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 \$80 million upfront cash payment, 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 the sale, and the value of such stock is subject to change based on fluctuations in the market value of Pernix's common stock.

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 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 April 30, 2015, we employed 70 full-time employees. Of the full-time employees, 20 were engaged in sales and marketing, 8 were engaged in manufacturing operations, 19 were engaged in product development, quality assurance and clinical and regulatory activities and 23 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.

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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.

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.

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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 “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 Zohydro 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.

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.

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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 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. In addition, we may fund our operations through the proceeds from the sales and issuances of our common stock, if any, pursuant to the controlled equity offering program that we established on November 6, 2014 with Cantor Fitzgerald & Co., or Cantor, as sales agent, under which we may, from time to time, sell shares of common stock up to an aggregate offering price of \$25.0 million. Sales of our common stock made pursuant to the controlled equity offering program, if any, will be made on the Nasdaq Global Market under our shelf registration statement on Form S-3 filed on November 6, 2014, which was declared effective on January 20, 2015. There can be no assurance that Cantor will be successful in consummating sales under the program based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. Cantor or we are permitted to terminate the controlled equity offering sales agreement, or sales agreement, at any time upon 10 days' prior written notice, and Cantor is also permitted to terminate the sales agreement at any time in certain circumstances, including the occurrence of a material adverse change in our company.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of March 31, 2015, the upfront cash payment received from the sale of our Zohydro ER business and our projected contract manufacturing and other service 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;

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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.

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.

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.

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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 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 15 Dravet syndrome patients at a single academic medical center site in Belgium. Based upon feedback from the FDA and the EMA we expect to initiate two Phase 3 studies (of 40 to 60 Dravet syndrome patients per study) during the third quarter of 2015 in the United

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States and Europe, with top-line results potentially available in the first half of 2016. 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 with top-line results potentially available in the second half 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.

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 good laboratory practice, or 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

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seize or detain products or require us to initiate a product recall.