ZOGENIX, INC.
Form 10-Q
May 10, 2016
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2016

OR

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

For the transition period from to

Commission file number: 001-34962

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

Delaware	20-5300780
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
5858 Horton Street, #455 Emeryville, California	94608
(Address of Principal Executive Offices)	(Zip Code)

510-550-8300
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes ¨ No

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

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

Large accelerated filer ¨ Accelerated filer x

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

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

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of May 3, 2016 was 24,771,568.

Table of Contents

ZOGENIX, INC.
FORM 10-Q
For the Quarterly Period Ended March 31, 2016
Table of Contents

		Page
PART I. FINANCIAL INFORMATION		
Item 1	Condensed Consolidated Financial Statements:	
	Condensed Consolidated Balance Sheets as of March 31, 2016 and December 31, 2015 (unaudited)	3
	Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2016 and 2015 (unaudited)	4
	Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2016 and 2015 (unaudited)	5
	Notes to the Condensed Consolidated Financial Statements (unaudited)	6
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3	Quantitative and Qualitative Disclosures about Market Risk	23
Item 4	Controls and Procedures	23
PART II. OTHER INFORMATION		
Item 1	Legal Proceedings	24
Item 1A	Risk Factors	24
Item 2	Unregistered Sales of Equity Securities and Use of Proceeds	28
Item 3	Defaults Upon Senior Securities	28
Item 4	Mine Safety Disclosures	28
Item 5	Other Information	28
Item 6	Exhibits	30

Table of Contents

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

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$132,184	$ 155,349
Restricted cash	10,002	10,002
Trade accounts receivable, net	4,904	1,396
Inventory	9,459	12,030
Prepaid expenses and other current assets	6,463	5,518
Current assets of discontinued operations	41	208
Total current assets	163,053	184,503
Property and equipment, net	8,959	9,254
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	5,861	3,331
Total assets	$286,607	$ 305,822
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$3,482	$ 5,290
Accrued expenses	4,259	4,617
Accrued compensation	1,924	3,711
Common stock warrant liabilities	1,669	6,196
Long-term debt, current portion	6,357	6,321
Deferred revenue	661	945
Current liabilities of discontinued operations	2,370	2,906
Total current liabilities	20,722	29,986
Long term debt	14,400	15,899
Deferred revenue, less current portion	5,207	6,139
Contingent purchase consideration	52,300	51,000
Deferred income taxes	18,450	18,450
Other long-term liabilities	1,669	1,588
Stockholders' equity:		
Common stock, $0.001 par value; 50,000 shares authorized at March 31, 2016 and December 31, 2015; 24,772 shares issued and outstanding at March 31, 2016 and December 31, 2015	25	25
Additional paid-in capital	559,739	558,251
Accumulated deficit	(385,905)	(375,516)
Total stockholders' equity	173,859	182,760
Total liabilities and stockholders' equity	$286,607	$ 305,822

See accompanying notes.

3

Table of Contents

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

	Three Months Ended March 31,	
	2016	2015
Revenue:		
Contract manufacturing revenue	$9,206	$4,181
Service and other product revenue	—	433
Total revenue	9,206	4,614
Operating expense:		
Cost of contract manufacturing	7,804	3,923
Royalty expense	71	72
Research and development	7,987	5,150
Selling, general and administrative	6,124	6,268
Change in fair value of contingent consideration	1,300	(1,000)
Total operating expense	23,286	14,413
Loss from operations	(14,080)	(9,799)
Other income (expense):		
Interest expense, net	(598)	(643)
Change in fair value of warrant liabilities	4,527	410
Other expense	(7)	(120)
Total other income (expense)	3,922	(353)
Net loss from continuing operations before income taxes	(10,158)	(10,152)
Income tax expense	(62)	(13)
Net loss from continuing operations	(10,220)	(10,165)
Discontinued operations:		
Net loss from discontinued operations	(169)	(12,696)
Net loss	$(10,389)	$(22,861)
Net loss per share, basic and diluted:		
Continuing operations	$(0.41)	$(0.53)
Discontinued operations	(0.01)	(0.66)
Total	$(0.42)	$(1.19)
Weighted average shares outstanding, basic and diluted	24,772	19,170
Comprehensive loss	$(10,389)	$(22,861)

See accompanying notes.

Table of Contents

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

	Three Months Ended March 31,	
	2016	2015
Operating activities:		
Net loss	$(10,389)	$(22,861)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,488	1,871
Depreciation and amortization	378	393
Amortization of debt issuance costs and non-cash interest charges	257	257
Change in fair value of warrant liabilities	(4,527)	(410)
Change in fair value of contingent purchase consideration	1,300	(1,000)
Changes in operating assets and liabilities:		
Trade accounts receivable	(3,504)	4,207
Inventory	2,586	(450)
Prepaid expenses and other current assets	(851)	(1,853)
Other assets	(2,530)	(621)
Accounts payable and accrued expenses	(4,275)	947
Deferred rent	(23)	(26)
Deferred revenue	(1,326)	(2,401)
Net cash used by operating activities	(21,416)	(21,947)
Investing activities:		
Purchases of property and equipment	(83)	(54)
Net cash used by investing activities	(83)	(54)
Financing activities:		
Proceeds from revolving credit facility	—	1,450
Repayment of revolving credit facility	—	(343)
Repayment of debt	(1,666)	—
Proceeds from exercise of common stock options and warrants	—	3
Net cash (used in) provided by financing activities	(1,666)	1,110
Net decrease in cash and cash equivalents	(23,165)	(20,891)
Cash and cash equivalents at beginning of period	155,349	42,205
Cash and cash equivalents at end of period	$132,184	$21,314

See accompanying notes.

Table of Contents

Zogenix, Inc.
Notes to Condensed Consolidated Financial Statements

1. Organization and Basis of Presentation

Zogenix, Inc. (together with its wholly-owned subsidiary, Zogenix Europe Limited (Zogenix Europe), the Company), is a pharmaceutical company committed to developing and commercializing central nervous system (CNS) therapies that address specific clinical needs for people living with orphan and other CNS disorders who need innovative treatment alternatives to help them improve their daily functioning. The Company's activities are focused on development of two product candidates, ZX008 and Relday, as well as performing contract manufacturing services in accordance with a supply agreement in conjunction with the sale of its Sumavel DosePro business in 2014.

The Company divested its Zohydro ER® business on April 24, 2015 (see Note 4). Zohydro ER activity has been excluded from continuing operations for all periods herein and reported as discontinued operations as a result of the sale.

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

2. Summary of Significant Accounting Policies

Financial Statement Preparation and Use of Estimates

The unaudited condensed 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 condensed 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 condensed 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, 2015, each as filed with the SEC.

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results may differ from those estimates.

Principles of Consolidation

The unaudited interim condensed consolidated financial statements include the accounts of Zogenix, Inc. and its wholly owned subsidiary Zogenix Europe, 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's functional currency is the U.S. dollar which is the reporting currency of its parent.

Restricted Cash

The Company has restricted cash in escrow as of March 31, 2016 and December 31, 2015 to fund potential indemnification claims for 12 months from the closing date of its sale of the Zohydro ER business in April 2015. The Company received the full amount from escrow in April 2016. The Company classifies this cash flow as investing activities in the condensed consolidated statement of cash flows as the source of the restricted cash is related to the sale of the Zohydro ER 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 condensed 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.

6

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, 2016 and December 31, 2015 are as follows (in thousands):

	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
At March 31, 2016				
Assets				
Cash equivalents[1]	$128,959	—	—	$128,959
Liabilities				
Common stock warrant liabilities[2]	$—	—	1,669	$1,669
Contingent purchase consideration [3]	$—	—	52,300	$52,300
At December 31, 2015				
Assets				
Cash equivalents[1]	$148,588	—	—	$148,588
Liabilities				
Common stock warrant liabilities[2]	$—	—	6,196	$6,196
Contingent purchase consideration [3]	$—	—	51,000	$51,000

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

(2) Common stock warrant liabilities were incurred in connection with the Company's July 2012 public offering of common stock and warrants and with the financing agreement (the Healthcare Royalty financing agreement) entered into with Healthcare Royalty Partners (Healthcare Royalty) (see Note 5), 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) expected volatility based upon the Company's historical volatility. 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 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, 2016 was primarily driven by the decrease in the market price of the Company's common shares at March 31, 2016 as compared against the December 31, 2015 measurement date.

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

The following table provides a reconciliation of assets and liabilities measured at fair value using significant unobservable inputs (Level 3) for the three months ended March 31, 2016 (in thousands):

	Contingent Purchase Consideration	Common Stock Warrant Liabilities
Balance at December 31, 2015	$ 51,000	$ 6,196
Changes in fair value	1,300	(4,527)
Balance at March 31, 2016	$ 52,300	$ 1,669

The changes in fair value of the liabilities shown in the table above are recorded through change in fair value of contingent consideration in operating expense and change in fair value of warrant liabilities in other income (expense) in the condensed consolidated statements of operations and comprehensive loss.

Net Loss per Share

Basic and diluted net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period without consideration for common stock equivalents. Common stock equivalents that could potentially reduce net earnings per common share in the future that were not included in the determination of diluted net loss per common share as their effects were antidilutive are as follows (in thousands):

	Three Months Ended March 31,	
	2016	2015
Options to purchase common stock	6	91
Restricted stock units not yet vested and released	106	—
Warrants to purchase common stock	32	64
Total	144	155

Goodwill and Intangible Assets

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

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable.

Revenue Recognition

The Company recognized revenue from contract manufacturing, service fees earned on collaborative arrangements and the sale of Sumavel DosePro prior to its sale in May 2014. The Company also recognizes revenue from the sale of Zohydro ER, which is included in net loss from discontinued operations in the condensed consolidated statements 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) the Company's price to the buyer is substantially fixed or determinable at the date of sale, (b) the buyer has paid the Company, or the buyer is obligated to pay the Company and the obligation is not contingent on resale of the product, (c) the buyer's obligation to the Company would not be changed in the event of theft or physical destruction or damage of the product, (d) the buyer acquiring the product for resale has economic substance apart from that provided by the Company, (e) the Company does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (f) the amount of future returns can be reasonably estimated. The Company defers recognition of revenue on product shipments of Zohydro ER until the right of return no longer exists, as the Company was not able to reliably estimate expected returns of the product at the time of shipment given the limited sales history of Zohydro ER.

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

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

Contract Manufacturing Revenue

The Company and Endo entered into a supply agreement in connection with the sale of the Sumavel DosePro business to Endo in May 2014. Under the terms of the supply agreement, the Company retains the sole and exclusive right and the obligation to manufacture or supply Sumavel DosePro to Endo. The Company recognizes deferred revenue related to its supply of Sumavel DosePro as contract manufacturing revenue when earned on a "proportional performance" basis as product is delivered. The Company recognizes revenue related to its sale of Sumavel DosePro product, equal to the cost of contract manufacturing plus a low single-digit 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 ending in May 2022. The Company continually evaluates the performance period and adjusts the period of revenue recognition if circumstances change. The Company recognized $800,000 of contract manufacturing revenue in continuing operations during the three months ended March 31, 2016 based on a change in estimated product to be delivered during the remaining term of the supply agreement. The effect of the change in estimated future product delivery reduced net loss per share from

continuing operations and net loss per share, basic and diluted by $0.03 for the three months ended March 31, 2016. In addition, the Company recognized $2,900,000 of contract manufacturing revenue related to a cost of contract manufacturing charge of $2,800,000 for excess capacity and scrap in continuing operations during the three months ended March 31, 2016. There was no effect on net loss per share related to this activity for the three months ended March 31, 2016.

In addition, the Company follows the authoritative accounting guidance when reporting revenue as gross when the Company acts as a principal versus reporting revenue as net when the Company acts as an agent. For transactions in which the Company acts as a principal, has discretion to choose suppliers, bears credit risk and performs a substantive part of the services,

revenue is recorded at the gross amount billed to a customer and costs associated with these reimbursements are reflected as a component of cost of sales for contract manufacturing services.

Product Revenue, Net

The Company sold Sumavel DosePro through May 2014, and sold Zohydro ER through April 2015, in the United States to wholesale pharmaceutical distributors and retail pharmacies, or collectively the Company's customers, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. The Company recognized Sumavel DosePro product sales at the time title transferred to its customer, and reduced product sales for estimated future product returns and sales allowances in the same period the related revenue was recognized. The Company is responsible for all returns of Sumavel DosePro product distributed by the Company prior to the sale of the Sumavel DosePro business up to a maximum per unit amount as specified in the sales agreement.

Given the limited sales history of Zohydro ER, the Company was not able to reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company deferred recognition of revenue on Zohydro ER product shipments until the right of return no longer exists, which occurs at the earlier of the time Zohydro ER is dispensed through patient prescriptions or expiration of the right of return. The Company estimates Zohydro ER patient prescriptions dispensed using an analysis of third-party syndicated data. Zohydro ER was launched in March 2014 and, accordingly, the Company did not have a significant history estimating the number of patient prescriptions dispensed. If the Company underestimated or overestimated patient prescriptions dispensed for a given period, adjustments to revenue from discontinued operations may be necessary in future periods. The deferred revenue balance does not have a direct correlation with future revenue recognition as the Company records sales deductions at the time the prescription unit was dispensed. In addition, the costs of Zohydro ER associated with the deferred revenue were recorded as deferred costs, which were included in inventory, until such time the related deferred revenue is recognized. The Company is responsible for returns for product sold prior to the sale of the business on April 24, 2015 and was responsible for rebates, chargebacks, and related fees for product sold until July 8, 2015 per terms of the asset purchase agreement (the Asset Purchase Agreement) the Company entered into with Pernix Ireland Limited and Pernix Therapeutics (collectively, Pernix). Revenue for Zohydro ER is included in discontinued operations in the condensed consolidated statements 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.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (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 of the guidance is permitted on the original effective date of fiscal years beginning after December 15, 2016. The Company is evaluating the transition method, timing and impact of adopting this new accounting standard on its financial statements and related disclosures.

In 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, 2015. The Company adopted the guidance in the first quarter of 2016. The effect of adopting the guidance retrospectively was to decrease amounts previously reported on our consolidated balance sheet at December 31, 2015 for prepaid expenses and other current assets and decrease long term debt, current portion by $93,000 and to decrease other assets and long term debt balances by $72,000. The balances for December 31, 2015 reflected in our condensed consolidated balance sheet in this Form 10-Q reflect these reclassifications.

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

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

In November 2015, the FASB issued guidance simplifying the classification of deferred tax assets and liabilities. The new standard requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. The guidance is effective for interim and annual periods beginning after December 15, 2016 and early adoption is permitted. The Company adopted the guidance in 2015 on a prospective basis. Adoption of this guidance resulted in a reclassification of the Company's net current deferred tax asset and related valuation allowance to the net non-current deferred tax asset as of March 31, 2016 and December 31, 2015. No prior periods were retrospectively adjusted.

In February 2016, the FASB issued guidance by requiring lessees to recognize the lease assets and lease liabilities that arise from both capital and operating leases with lease terms of more than 12 months and to disclose qualitative and quantitative information about lease transactions. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the timing and impact of adopting this new accounting standard on its financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting. The standard will revise accounting for share-based compensation arrangements, including the income tax impact and classification on the statement of cash flows. The standard is effective for annual and interim periods beginning after December 15, 2016. Early adoption is permitted. We are currently evaluating the impact the adoption of this standard will have on our condensed consolidated financial statements.

3. Inventory

Inventory consists of the following (in thousands):

	March 31, 2016	December 31, 2015
Raw materials	$4,433	$ 3,775
Work in process	5,026	8,255
Total	$9,459	$ 12,030

4. Discontinued operations

On March 10, 2015, the Company entered into the Asset Purchase Agreement whereby the Company agreed to sell its Zohydro ER business to Pernix, and on April 24, 2015, the Company completed the sale to Ferrimill Limited, a subsidiary of Pernix, as a substitute purchaser.

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 financial results from the Zohydro ER business and the related assets and liabilities have been presented as discontinued operations in the condensed consolidated financial statements. 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, and 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 in the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2016 and 2015 (in thousands):

Table of Contents

Discontinued operations	Three Months Ended March 31, 2016	2015
Revenues:		
Net product revenue	$334	$5,006
Operating expenses:		
Cost of product sold	15	1,340
Royalty expense	20	418
Research and development	—	4,808
Selling, general and administrative	468	11,136
Total operating expense	503	17,702
Net loss from discontinued operations	$(169)	$(12,696)

The following table summarizes the assets and liabilities of discontinued operations as of March 31, 2016 and December 31, 2015 related to the Zohydro ER business (in thousands):

	March 31, 2016	December 31, 2015
Assets		
Current assets		
Prepaid expenses and other current assets	$41	$ 208
Total current assets of discontinued operations	41	208
Total assets of discontinued operations	$41	$ 208
Liabilities		
Current liabilities		
Accrued expenses	$2,370	$ 2,796
Deferred revenue and other current liabilities	—	110
Total current liabilities of discontinued operations	2,370	2,906
Total liabilities of discontinued operations	$2,370	$ 2,906

There was no stock-based compensation or amortization expense related to discontinued operations for the three months ended March 31, 2016. Total stock-based compensation expense related to discontinued operations was $522,000 and total amortization expense related to discontinued operations was $124,000 for the three months ended March 31, 2015.

5. Common Stock Warrant Liability

In July 2012, in connection with a public offering of common stock and warrants, the Company sold warrants to purchase 1,973,025 shares of common stock (including over-allotment purchase) and at March 31, 2016 of these warrants to purchase 1,901,918 shares of common stock are outstanding. The warrants are exercisable at an exercise price of $20.00 per share and will expire on July 27, 2017, which is five years from the date of issuance. As the warrants contain a cash settlement feature upon the occurrence of certain events that may be outside of the Company's control, the warrants are recorded as a current liability and are marked to market at each reporting period (see Note 2). None of these warrants were exercised during the three months ended March 31, 2016 or the year ended December 31, 2015. The fair value of the warrants outstanding was approximately $1,603,000 and $6,069,000 as of March 31, 2016 and December 31, 2015, respectively.

In July 2011, upon the closing of and in connection with the Healthcare Royalty financing agreement, the Company issued a warrant to Healthcare Royalty exercisable into 28,125 shares of common stock. The warrant is exercisable at $72.00 per share of common stock and has a term of ten years. As the warrant contains covenants where compliance

with such covenants may be outside of the Company's control, the warrant was recorded as a current liability and is marked to market at each reporting date (see Note 2). The fair value of the warrant was approximately $66,000 and $127,000 as of March 31, 2016 and December 31, 2015, respectively.

Table of Contents

6. Stock-Based Compensation

The Company uses the Black-Scholes option-pricing model for determining the estimated fair value of stock-based compensation for stock-based awards to employees and the board of directors. The assumptions used in the Black-Scholes option-pricing model for the three months ended March 31, 2016 and 2015 are as follows:

	Three Months Ended March 31,	
	2016	2015
Risk free interest rate	1.4%	1.5%
Expected term	6.0 years	5.8 to 6.1 years
Expected volatility	77.8%	78.5%
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 based on the lack of relevant historical data due to the Company’s limited historical experience. In addition, due to the Company’s limited historical data, the estimated volatility was calculated based upon the Company's historical volatility, supplemented with historical volatility of comparable companies whose share prices are publicly available for a sufficient period of time.

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

	Three Months Ended March 31,	
	2016	2015
Cost of goods sold	$101	$93
Research and development	424	224
Selling, general and administrative	963	1,033
Total	$1,488	$1,350

As of March 31, 2016, there was approximately $13,200,000 of total unrecognized compensation costs related to outstanding employee and board of director stock options which is expected to be recognized over a weighted average period of 2.9 years, and $700,000 of total unrecognized compensation costs related to unvested employee performance stock units which is expected to be recognized over a weighted average period of 1.9 years.

As of March 31, 2016, there were 43,037 unvested stock options and 7,500 unvested restricted stock units outstanding to consultants, with approximately $369,000 of related unrecognized compensation expense based on a March 31, 2016 measurement date. These unvested stock awards outstanding to consultants are expected to vest over a weighted average period of 2.7 years. In accordance with accounting guidance for stock-based compensation, the Company remeasures the fair value of stock option grants to non-employees at each reporting date and recognizes the related income or expense during their vesting period. The income recognized from the revaluation of stock options and restricted stock units to consultants was immaterial for the three months ended March 31, 2016 and 2015. The expense for awards issued to consultants is included in the condensed consolidated statements of operations and comprehensive loss within selling, general and administrative expense.

Table of Contents

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 and Relday;
- 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,, with respect to our product candidates and our ability to demonstrate the safety and efficacy of our product candidates to the satisfaction of the FDA and such other regulatory 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 liability claims;
- estimates of the capacity of manufacturing and other facilities to support our product candidates;
- our and our licensors ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of our product candidates and the ability to operate our business without infringing the intellectual property rights of others;
- our ability to obtain and maintain adequate levels of coverage and reimbursement from third-party payors for any of our product candidates that may be approved for sale, the extent of such coverage and reimbursement and the willingness of third-party payors to pay for our products versus less expensive therapies;
- the impact of healthcare reform laws; and
- projected cash needs and our expected future revenues, operations and expenditures.

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

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

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

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

The interim condensed 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, 2015 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, 2015.

Table of Contents

Overview

Background

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

Our lead product candidate is ZX008, a low-dose fenfluramine for the treatment of seizures associated with Dravet syndrome. Dravet syndrome is a rare and catastrophic form of pediatric epilepsy with life threatening consequences for patients and for which current treatment options are very limited. ZX008 has received orphan drug designation in the United States and Europe for the treatment of Dravet syndrome. In January 2016, we received notification of Fast Track designation from the U.S. Food and Drug Administration, or FDA, for ZX008 for the treatment of Dravet syndrome. We initiated Phase 3 clinical trials in January 2016 in the United States, and we expect top-line results from this trial in the first quarter of 2017. We plan to initiate Phase 3 clinical trials in Europe in the first half of 2016. Additionally, we intend to initiate the enrollment of 90-100 patients, in the third quarter of this year, in our European study of Dravet syndrome patients who are poor responders to a stiripentol treatment regime. We obtained worldwide development and commercialization rights to ZX008 through our acquisition of Zogenix International Limited in October 2014.

We have an additional product candidate in development, Relday™ (risperidone once-monthly long-acting injectable) for the treatment of schizophrenia. Relday is a proprietary, long-acting injectable formulation of risperidone. Risperidone is used to treat the symptoms of schizophrenia and bipolar disorder in adults and teenagers 13 years of age and older. We began enrolling patients in a Phase 1b multi-dose clinical study for Relday in March 2015. On September 30, 2015, we announced positive top-line pharmacokinetic results from the Phase 1b study. We have now initiated efforts with a third-party transaction advisory firm to help secure a global strategic development and commercialization partner for Relday.

We sold our Zohydro ER® business in April 2015 to enable us to focus on development of our CNS product candidates and to enhance our financial strength. Zohydro ER (hydrocodone bitartrate) is an extended-release capsule oral formulation of hydrocodone without acetaminophen.

We sold our Sumavel® DosePro® (sumatriptan injection) Needle-free Delivery System business in May 2014 to Endo International Plc, or Endo. In connection with the sale, we entered into a supply agreement, or the Supply Agreement, pursuant to 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.

Pernix Asset Purchase Agreement

On March 10, 2015, we entered into an asset purchase agreement with Pernix Ireland Limited and Pernix Therapeutics, or collectively, Pernix, whereby we agreed to sell our Zohydro ER business to Pernix, and on April 24, 2015, we completed the sale to Ferrimill Limited, 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 and $10.6 million in Pernix Therapeutics common stock. Further, Ferrimill purchased Zohydro ER inventory from us of $0.9 million and we received consideration for discounts received by Ferrimill based on an assigned supply agreement of $2.4 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 payments received, 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, or Oxford, and Silicon Valley Bank, or SVB, entered into an amendment to the loan and security agreement dated December 30, 2014 which added an affirmative covenant requiring a liquidity ratio of 1.25 to 1 through our receipt of positive data from placebo-controlled trials in the United States and European Union of ZX008 and terminated all encumbrances on our personal property related to its Zohydro ER business. The remaining obligations under the loan and security agreement remain substantially unchanged.

Table of Contents

Endo Ventures Bermuda Limited and Endo Ventures Limited Asset Purchase Agreement

On April 23, 2014, we sold our Sumavel DosePro business to Endo, including the registered trademarks, certain contracts, the NDA, and other regulatory approvals, the books and records, marketing materials and product data relating to Sumavel DosePro pursuant to an asset purchase agreement. Under the terms of the sale, Endo paid us $85.0 million in cash, $8.5 million of which was deposited into escrow and which we received in May 2015. Further, Endo Ventures Limited, or Endo Ventures, purchased from us our finished goods inventory of Sumavel DosePro for $4.6 million. In addition to the upfront cash payment, we are eligible to receive additional cash payments of up to $20.0 million based on the achievement of pre-determined sales and gross margin milestones. Furthermore, Endo Ventures assumed responsibility for our royalty obligation on sales of Sumavel DosePro and assumed other liabilities relating to Sumavel DosePro after the sale.

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

In connection with the sale, we were required to extinguish all encumbrances on the assets to be sold to Endo, including those previously granted to Healthcare Royalty Partners, or Healthcare Royalty, pursuant to the financing agreement, dated June 30, 2011, with Healthcare Royalty, or the Healthcare Royalty financing agreement. We eliminated our existing debt obligation to Healthcare Royalty in May 2014 by paying $40.0 million to Healthcare Royalty which was consistent with the terms of the Healthcare Royalty financing agreement.

Critical Accounting Policies and Estimates

We recognize revenue from contract manufacturing, service fees earned on collaborative arrangements and the sale of Sumavel DosePro prior to its sale in May 2014. We also recognize revenue from the sale of Zohydro ER which is included in net loss from discontinued operations in the condensed consolidated statements 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. We defer recognition of revenue on product shipments of Zohydro ER until the right of return no longer exists, as we were not able to reliably estimate expected returns of the product at the time of shipment given the limited sales and return history of Zohydro ER.

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

undelivered element(s).

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

Table of Contents

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 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 our sale of Sumavel DosePro product, equal to the cost of contract manufacturing plus a low single-digit mark-up, upon the transfer of title to Endo. We supply Sumavel DosePro product based on non-cancellable purchase orders. We initially defer revenue for any consideration received in advance of services being performed and product being delivered, and recognize revenue pursuant to the related pattern of performance, based on total product delivered relative to the total estimated product delivery over the minimum eight year term of the Supply Agreement ending in May 2022. We continually evaluate the performance period and will adjust the period of revenue recognition if circumstances change. We recognized $0.8 million of contract manufacturing revenue in continuing operations during the three months ended March 31, 2016 based on a change in estimated product expected to be delivered during the remaining term of the Supply Agreement. The effect of the change in estimated future product delivery reduced net loss per share from continuing operations and net loss per share, basic and diluted by $0.03 for the three months ended March 31, 2016. In addition, the Company recognized $2,900,000 of contract manufacturing revenue related to a cost of contract manufacturing charge of $2,800,000 for excess capacity and scrap in continuing operations during the three months ended March 31, 2016. There was no effect on net loss per share related to this activity for the three months ended March 31, 2016.

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 exists, which occurs at the earlier of the time Zohydro ER was dispensed through patient prescriptions or expiration of the right of return. We estimated Zohydro ER patient prescriptions dispensed using an analysis of third-party syndicated data. Zohydro ER was launched in March 2014 and, accordingly, we did not have a significant history estimating the number of patient prescriptions dispensed. If we underestimated or overestimated patient prescriptions dispensed for a given period, adjustments to revenue from discontinued operations may be necessary in future periods. The deferred revenue balance does not have a direct correlation with future revenue recognition as we recorded sales deductions at the time the prescription unit was dispensed. In addition, the costs of Zohydro ER associated with the deferred revenue were recorded as deferred costs, which were included in inventory, until the time the related deferred revenue was recognized. We are responsible for returns of product sold prior to the sale of the business on April 24, 2015. Zohydro ER activity is included in discontinued operations in the condensed 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.

Table of Contents

There have been no significant changes in critical accounting policies during the three months ended March 31, 2016 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, 2015.

Results of Operations

Comparison of the Three Months Ended March 31, 2016 and 2015

Revenue

	Three Months Ended March 31,			
(Dollars in thousands)	2016	2015	$ change	% change
Contract manufacturing revenue	$9,206	$4,181	$5,025	120.2 %
Service and other product revenue	—	433	(433)	(100.0)%
Total revenue	$9,206	$4,614	$4,592	99.5 %

Contract manufacturing revenue is recognized for Sumavel DosePro finished goods inventory that has been delivered to Endo Ventures Bermuda under the Supply Agreement, and includes a portion of deferred revenue recognized on a proportional performance method. Endo Ventures Bermuda pays us the cost to produce Sumavel DosePro plus a contractual mark-up for Sumavel DosePro product delivered under the terms of our Supply Agreement. The increase in contract manufacturing revenue for the three months ended March 31, 2016 as compared the same period in 2015 was primarily as a result of an increase in costs of contract manufacturing billed to Endo under the terms of our Supply Agreement in 2016 as compared to the same period in 2015 of $4.2 million and recognition of deferred revenue of $0.8 million based upon changes in estimated future production.

Service and other product revenue for the three months ended March 31, 2016 was comprised primarily of co-promotion fees earned for our Migranal ® Nasal Spray sales efforts under our agreement with Valeant Pharmaceuticals North America LLC until it was terminated in June 2015, as well as adjustments to Sumavel DosePro returns reserves subsequent to the sale of the business in May 2014. For the three months ended March 31, 2016, there were no adjustments to Sumavel returns reserves and no service fees earned as the co-promotion agreement was previously terminated. Service and other product revenue for the three months ended March 31, 2015 was comprised primarily of fees generated by Migranal co-promotion activity.

Cost of Contract Manufacturing

	Three Months Ended March 31,			
(Dollars in thousands)	2016	2015	$ change	% change
Cost of contract manufacturing	$7,804	$3,923	$3,881	98.9 %

Costs of contract manufacturing consists primarily of materials, third-party manufacturing costs, freight and indirect personnel and other overhead costs associated with Sumavel DosePro based on units sold to Endo, as well as the effect of changes in reserves for excess, dated or obsolete commercial inventories and production manufacturing variances. It represents the cost of units recognized as contract manufacturing revenues in the period and the impact of underutilized production capacity and other manufacturing variances. The increase in cost of contract manufacturing for the three months ended March 31, 2016 as compared to the same period in 2015 resulted from $2.8 million of charges for excess capacity and scrap and an increase of $1.1 million due to an increase in units delivered under our Supply Agreement with Endo.

Table of Contents

Royalty Expense

(Dollars in thousands)	Three Months Ended March 31, 2016	2015	$ change	% change
Royalty expense	$71	$ 72	$ (1)	(1.4)%

Royalty expense reflects both the amortization of the milestone payment related to technology that we have licensed and immaterial adjustments to previously estimated royalty liabilities based on actual sales results. We expect royalty expense to remain consistent in the near term as we advance our product development plans.

Research and Development Expenses

(Dollars in thousands)	Three Months Ended March 31, 2016	2015	$ change	% change
Research and development	$7,987	$5,150	$2,837	55.1 %

Research and development expenses consist of expenses incurred in developing, testing and seeking marketing approval of our product candidates, including license and milestone payments; payments made to third-party clinical research organizations, or CROs, and investigational sites, which conduct our trials on our behalf, and consultants; expenses associated with regulatory submissions, pre-clinical development and clinical trials; payments to third-party manufacturers, which produce our active pharmaceutical ingredient and finished product; personnel related expenses, such as salaries, benefits, travel and other related expenses, including stock-based compensation; and facility, maintenance, depreciation and other related expenses. We expense all research and development costs as incurred.

We utilize CROs, contract laboratories and independent contractors for the conduct of pre-clinical studies and clinical trials. We track third-party costs by type of study being conducted. We recognize the expenses associated with the services provided by CROs based on the percentage of each study completed at the end of each reporting period. We coordinate clinical trials through a number of contracted investigational sites and recognize the associated expense based on a number of factors, including actual and estimated subject enrollment and visits, direct pass-through costs and other clinical site fees.

The table below sets forth information regarding our research and development costs for our major development programs. The period over period changes in our major development programs are explained in the narrative beneath the table.

(Dollars in thousands)	Three Months Ended March 31, 2016	2015
ZX008	$5,292	$1,441
Relday	376	1,945
Other[1]	2,319	1,764
Total	$7,987	$5,150

(1) Other research and development expenses include development costs incurred for other product candidate development, as well as employee and infrastructure resources that are not tracked on a program-by-program basis.

We acquired ZX008 with our acquisition of Zogenix International Limited in October 2014 and have subsequently incurred expenses as we proceed with our Phase 3 clinical trials for ZX008 which commenced in January 2016.

Expenses for Relday decreased for the three months ended March 31, 2016 as compared to the same period in 2015 as we initiated a multi-dose clinical study for Relday in the first quarter of 2015 which concluded later in 2015. We use our employee and infrastructure resources across our product and product candidate development programs. Therefore, we have not tracked salaries, other personnel related expenses, facilities or other related costs to our product development activities on a program-by-program basis.

We expect our research and development expenses for the remainder of 2016 to exceed amounts incurred in the same period in 2015 as we continue to conduct our Phase 3 studies for ZX008.

19

Table of Contents

Selling, General and Administrative Expenses

	Three Months Ended March 31,			
(Dollars in thousands)	2016	2015	$ change	% change
Selling expense	$1,241	$546	$695	127.3 %
General and administrative expense	4,883	5,722	(839)	(14.7)%
Total selling, general and administrative	$6,124	$6,268	$(144)	(2.3)%

Selling expense consist primarily of salaries and benefits of sales and marketing management and market research expenses for product candidates that are in development. 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 also incurred selling expense for Zohydro ER activities which are recorded as discontinued operations for the three months ended March 31, 2015.

Selling expense increased for the three months ended March 31, 2016 from the same period in 2015 due primarily to market research and pre-commercial analysis expenses related to ZX008 of $0.4 million and additional personnel-related marketing costs of $0.2 million. General and administrative expenses decreased primarily due to realignment of our medical affairs department from general and administrative responsibilities for the three months ended March 31 2015 to research and development roles for the three months ended March 31, 2016 following the divestiture of our Zohydro ER business in April 2015.

We anticipate that our selling, general and administrative costs will remain consistent with 2015 levels during 2016.

Change in Fair Value of Contingent Consideration

	Three Months Ended March 31,			
(Dollars in thousands)	2016	2015	$ change	% change
Change in fair value of contingent consideration	$1,300	$(1,000)	$2,300	(230.0)%

The contingent consideration liability results from our acquisition of Zogenix International Limited in October 2014 in connection with the estimated completion of certain future performance milestones related to ZX008. 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 change in fair value of contingent consideration income for the three months ended March 31, 2016 from the same period in 2015 resulted primarily from a decrease in our estimated risk-free adjusted discount rate used in the March 31, 2016 valuation from the rate used at December 31, 2015, as well as a reduction of the estimated time remaining to pay out the liability based on the passage of time from the previous year. The change in fair value of contingent consideration income for the three months ended March 31, 2015 resulted primarily from a change in the expected timing of milestone payments from the previous December 31, 2014 measurement date.

Other Income (Expense)

	Three Months Ended March 31,			
(Dollars in thousands)	2016	2015	$ change	% change
Interest expense, net	$(598)	$(643)	$45	(7.0)%
Change in fair value of warrant liabilities	$4,527	$410	$4,117	1,004.1 %
Other income expense	$(7)	$(120)	$113	(94.2)%
Total other income (expense)	$3,922	$(353)	$4,275	(1,211.0)%

Interest Expense, net. During the three months ended March 31, 2016 and 2015, interest expense was incurred primarily in conjunction with our term loan with Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or SVB.

Table of Contents

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 2 to our condensed consolidated financial statements. The income recorded for the three months ended March 31, 2016 was primarily driven by the decrease in our stock price at March 31, 2016 as compared to the December 31, 2015 measurement date. 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.

We expect this amount to continue to fluctuate in the near term based on changes to our stock price and other valuation inputs.

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

Income Tax Expense

Our income tax expense is primarily due to statutory tax liabilities resulting from our domestic and foreign corporate entities.

Discontinued Operations

During the first quarter of 2015, we reached a decision to sell our Zohydro ER business. On March 10, 2015, we entered into the 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. As a result of our strategic decision to sell the Zohydro ER business and focus on clinical development of ZX008 and Relday, our condensed consolidated statements of operations and comprehensive loss and the condensed consolidated balance sheet reflect the financial results from the Zohydro ER business as discontinued operations for all periods presented. For the three months ended March 31, 2016, activity reflected in the condensed consolidated statements of operations and comprehensive loss consists of product delivered prior to the sale of the business for which revenue and related costs were deferred until the right of return no longer exists in accordance with our revenue recognition policy, as well as legal costs incurred. Activity reflected in the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2015 represents our commercial operations prior to the sale of the Zohydro ER business in April 2015.

Liquidity and Capital Resources

We have experienced net losses and negative cash flow from operations since inception, and as of March 31, 2016, had an accumulated deficit of $385.9 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, 2016, we had cash and cash equivalents of $132.2 million.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of March 31, 2016, along with our projected contract manufacturing revenues will be sufficient to fund our operations for at least the next twelve months. We will need to obtain additional funds to finance our operations beyond that point, or possibly earlier. We intend to raise additional capital, if necessary, through public or private equity offerings, debt financings or through collaborations or partnerships with other companies. If we are unsuccessful in raising additional required funds, we may be required to significantly delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts, or cease operating as a going concern. We also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available.

The following table summarizes our cash flows provided by (used in) continuing operating, investing and financing activities for the three months ended March 31, 2016 and 2015:

Table of Contents

	Three Months Ended March 31,	
	2016	2015
	(In Thousands)	
Statement of Cash Flows Data:		
Total cash provided by (used in):		
Operating activities	$(21,416)	$(21,947)
Investing activities	(83)	(54)
Financing activities	(1,666)	1,110
Decrease in cash and cash equivalents	$(23,165)	$(20,891)

Operating Activities: Net cash used for the three months ended March 31, 2016 primarily reflects the use of cash for operations, adjusted for non-cash charges including a $4.5 million change in fair value of warrant liabilities, as well as cash used of $3.5 million related to higher trade accounts receivables balances correlated with an increase in our contract manufacturing revenue, reduction of our accounts payable and accrued expenses by $4.3 million and an increase in long term deposits of $2.5 million related to our ZX008 clinical trials, offset by lower inventory of $2.6 million as compared to the same period in 2015.

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.

Investing Activities. Net cash used in investing activities for the three months ended March 31, 2016 and 2015 was primarily attributable to the purchase of property and equipment.

Financing Activities. Net cash used in financing activities for the three months ended March 31, 2016 represents principal repayment on our term loan with Oxford and SVB. Net cash provided by financing activities for the three months ended March 31, 2015 relates primarily to the net proceeds drawn from our revolving line of credit for the quarter.

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 be substantial and to increase 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.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our cash and cash equivalents as of March 31, 2016 consisted of cash and money market funds. The primary objective of our investment activities is to preserve principal. Instruments that meet this objective include commercial paper, money market funds and government and non-government debt securities. To minimize this risk, we intend to continue to maintain our portfolio of cash and money market funds, and due to their short-term nature, we believe that there is no material exposure to interest rate risk.

Our term loan and revolving line of credit with Oxford and SVB contain adjustable rate interest terms. The term loan bears interest at an annual rate equal to the greater of (i) 8.75% and (ii) the sum of (a) the "prime rate" rate reported in the Wall Street Journal on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 5.25%. Each revolving advance under the credit facility bears interest at an annual rate equal to the sum of (a) the "prime rate" rate reported in the Wall Street Journal on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 4.75%. Based on our outstanding principal balances and historical interest rate volatility, we do not believe an adjustment of 100 basis points would create a material exposure.

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, 2016 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, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

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, 2015.

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, 2015, 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

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 single, continuing, long-term, open-label, study in patients with Dravet syndrome in Belgium. In January 2016 we initiated a Phase 3 clinical trial in North America for ZX008 as an adjunctive treatment of seizures in children with Dravet syndrome. This followed FDA acceptance of our investigational new drug, or IND, application for ZX008 in December 2015. The Phase 3 program for ZX008 includes two randomized, double-blind placebo-controlled studies that will evaluate two dose levels of ZX008 (0.2 mg/kg/day and 0.8 mg/kg/day, up to a maximum daily dose of 30 mg), as well as placebo. We intend to enroll 105 subjects in each of the two studies, with 35 patients in each treatment arm. The first study will be conducted primarily in North America. The other Phase 3 study will be a multi-national study, conducted primarily in western Europe. In addition, a one year, open-label safety study will be offered to eligible subjects who complete one of these trials. Clinical Trial Applications, or CTAs, for ZX008 in Europe and Australia have been submitted to the respective regulatory authorities and we plan to initiate this second study in the first half of 2016. We expect to receive top-line results from the first trial in the first quarter of 2017. However, we may not be able to initiate, identify and enroll sufficient study participants and interpret results on these timeframes, and consequently the completion of our Phase 3 clinical trials may be delayed.

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 assumed therapeutic range were achieved on the first day of dosing and maintained throughout the one-month period. In addition, dose proportionality was demonstrated across the full dose range studied. In March 2015, we began a multi-dose clinical trial, which we believe will provide the required steady-state pharmacokinetic and safety data prior to initiating Phase 3 development studies. On September 30, 2015, we announced positive top-line pharmacokinetic results from our Phase 1b multi-dose clinical trial of Relday. Based on this data, we have initiated efforts to secure a global strategic development and commercialization partner for Relday to support the continued development of Relday. If we are unable to secure such a partner on favorable terms, or at all, we will evaluate the continued development of Relday.

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 clinical research organizations, or CROs, clinical investigators and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, clinical investigators and trial sites;

- manufacturing or obtaining sufficient quantities of a product candidate and placebo 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;

Table of Contents

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

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

Pursuant to the Asset Purchase Agreement with Pernix that we entered into in March 2015, we may receive contingent payments of up to $283.5 million, based on Pernix's achievement of pre-determined milestones. These milestones include 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 cannot provide any assurance that we will receive any of the contingent milestone payments.

Table of Contents

We may never receive regulatory approval or commercialize our product candidates outside of the United States.
We intend to market certain of our product candidates outside of the United States, if approved. For example, ZX008 has received orphan drug designation in Europe, and we plan to initiate a Phase 3 clinical trial in Europe in the first half of 2016 to support a European marketing authorization application. In order to market our products outside of the United States, we, or any potential partner, must obtain separate regulatory approvals in each territory prior to marketing authorization. In order to market our products outside of the United States, we, or any potential partner, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our products. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed in these "Risk Factors" regarding FDA approval in the United States, as well as other risks.
For example, in the European Economic Area (comprised of 28 European Union, or EU, member states plus Iceland, Liechtenstein, and Norway), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of MAs:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency and which is valid throughout the entire territory of the European Economic Area, or EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. Under the Centralized Procedure the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when the authorization of a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Under the accelerated procedure the standard 210-day review period is reduced to 150 days.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

In the EEA, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

In the EEA we can take advantage of the hybrid application pathway of the EU Centralized Procedure, which is similar to the FDA's 505(b)(2) pathway. Hybrid applications may rely in part on the results of pre-clinical tests and clinical trials contained in the authorization dossier of the reference product, but must be supplemented with additional data. In territories where data is not freely available, we or our partners may not have the ability to commercialize our products without negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds. We, or any potential partner, may be unable to obtain rights to the necessary clinical data and may be required to develop our own proprietary safety effectiveness

dossiers. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Inability to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed in these “Risk Factors” regarding FDA approval in the United States. As described above, such effects include the risks that our product candidates may not be approved at all or for all requested indications, which could limit the uses of our product candidates and have an adverse effect on their commercial potential or require costly, post-marketing studies. In addition, we, or any potential partner, may be subject to fines, suspension or withdrawal of regulatory

Table of Contents

approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if we are unable to comply with applicable foreign regulatory requirements.

Risks Related to Regulation of our Product and 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 seizures associated with 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, 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 patients with Dravet syndrome at a single academic medical institution in Belgium. In January 2016 we initiated a Phase 3 clinical trial in the United States for ZX008 as an adjunctive treatment of seizures in children with Dravet syndrome. This study initiation followed FDA acceptance of our investigational new drug, or IND, application for ZX008 in December 2015. The Phase 3 program for ZX008

Table of Contents

includes two randomized, double-blind placebo-controlled studies that will include two dose levels of ZX008 (0.2 mg/kg/day and 0.8 mg/kg/day, up to a maximum daily dose of 30 mg), as well as placebo. We intend to enroll 105 subjects in each of the two studies, with 35 patients in each treatment arm. The first study will be conducted primarily in North America. The other study will be a multi-national study, conducted primarily in western Europe. CTAs for ZX008 in Europe and Australia were submitted to the respective regulatory authorities and we plan to initiate this second study in the first half of 2016. We expect to receive top-line results from the first trial in the first quarter of 2017. However, we may not be able to initiate, identify and enroll sufficient study participants and interpret results on these timeframes, and consequently the completion of our Phase 3 clinical trials may be delayed.

We initiated a Phase 1 safety and pharmacokinetic clinical trial for Relday in July 2012 and announced positive single-dose pharmacokinetic results from this trial in January 2013. Based on the favorable safety and pharmacokinetic profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase 1 trial, we extended the study to include an additional cohort of 10 patients at a 100 mg dose of the same formulation and announced positive top-line results from the extended Phase 1 clinical trial in May 2013. The positive results from this study extension positioned us to begin a multi-dose clinical trial, which will provide the required steady-state pharmacokinetic and safety data prior to initiating Phase 3 development studies. We started this multi-dose clinical trial in the first half of 2015 and we announced positive top-line pharmacokinetic data in September 2015. Based on this data, we have initiated efforts to secure a global strategic development and commercialization partner for Relday to support the continued development of Relday. If we are unable to secure such a partner on favorable terms, or at all, we will evaluate the continued development of Relday.

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.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On May 10, 2016, we entered into a Controlled Equity Offering Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., as sales agent, or Cantor, under which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to $25.0 million through Cantor.

Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, Cantor may sell the shares by methods deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act, including sales made directly on the Nasdaq Global Market, on any other existing trading market for the common stock or to or through a market maker. In addition, Cantor may sell the common stock by any other method permitted by law, including in privately negotiated transactions. Subject to the terms and conditions of the Sales Agreement, Cantor will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the Nasdaq Global Market, to sell the shares from time to time, based upon our instructions. Sales of our common stock made pursuant to the controlled equity offering program, if any, will be made under our shelf registration statement on Form S-3 filed on May 10, 2016, following such time as the registration statement is declared effective by the SEC.

28

Table of Contents

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

We will pay Cantor commissions for its services in acting as agent in the sale of common stock. Cantor will be paid a commission in an amount equal to up to 3% of the gross sales price per share sold.

The foregoing description of the Sales Agreement is not complete and is qualified in its entirety by reference to the Sales Agreement, a copy of which is filed as Exhibit 1.2 to our Registration Statement on Form S-3 filed on May 10, 2016 with the SEC and is incorporated herein by reference.

Table of Contents

Item 6. Exhibits
EXHIBIT INDEX

Exhibit Number	Description
3.1(2)	Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.2(5)	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.3(7)	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.4(2)	Amended and Restated Bylaws of the Registrant
4.1(3)	Form of the Registrant's Common Stock Certificate
4.2(1)	Third Amended and Restated Investors' Rights Agreement dated December 2, 2009
4.3(1)	Amendment to Third Amended and Restated Investors' Rights Agreement dated as of July 1, 2010
4.4(4)	Second Amendment to Third Amended and Restated Investors' Rights Agreement dated June 30, 2011
4.5(1)	Warrant dated June 30, 2008 issued by the Registrant to Oxford Finance Corporation
4.6(1)	Transfer of Warrant dated March 24, 2009 from CIT Healthcare LLC to The CIT Group/Equity Investments, Inc.
4.7(4)	Warrant dated July 18, 2011 issued by the Registrant to Healthcare Royalty Partners (formerly Cowen Healthcare Royalty Partners II, L.P.)
4.8(6)	Warrant dated December 30, 2014 issued by the Registrant to Oxford Finance LLC
4.9(6)	Warrant dated December 30, 2014 issued by the Registrant to Silicon Valley Bank
10.1(8)	Sales Agreement, dated May 10, 2016, by and between the Registrant and Cantor Fitzgerald & Co.
10.2#	Independent Director Compensation Policy as amended and restated effective March 8, 2016.
10.3	Amendment #2 to the Manufacturing Services Agreement effective as of April 28, 2016 by and between the Registrant and Patheon UK Limited.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)

32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
101	The following financial statements from the Registrant's Quarterly Report on form 10-Q for the period ended March 31, 2016, formatted in XBRL: (i) Condensed Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Comprehensive Loss, (iii) Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to Condensed Consolidated Financial Statements.

(1) Filed with the Registrant's Registration Statement on Form S-1 on September 3, 2010.
(2) Filed with Amendment No. 2 to the Registrant's Registration Statement on Form S-1 on October 27, 2010.
(3) Filed with Amendment No. 3 to the Registrant's Registration Statement on Form S-1 on November 4, 2010.
(4) Filed with the Registrant's Quarterly Report on Form 10-Q on August 11, 2011.
(5) Filed with the Registrant's Quarterly Report on Form 10-Q on November 8, 2012.
(6) Filed with the Registrant's Current Report on Form 8-K on December 31, 2014.
(7) Filed with the Registrant's Quarterly Report on Form 10-Q on August 10, 2015.
(8) Filed with the Registrant's Registration Statement on Form S-3 on May 10, 2016.

# Indicates management contract or compensatory plan.

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

Table of Contents

SIGNATURES

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

ZOGENIX, INC.

Date: May 10, 2016 By: /s/ Stephen J. Farr
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 10, 2016 By: /s/ Ann D. Rhoads
Executive Vice President, Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)