ZOGENIX, INC.
Form 10-Q
August 09, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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 August 3, 2016 was 24,790,989.

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

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$127,797	$ 155,349
Restricted cash	—	10,002
Trade accounts receivable, net	2,112	1,396
Inventory	11,860	12,030
Prepaid expenses and other current assets	7,750	5,518
Current assets of discontinued operations	—	208
Total current assets	149,519	184,503
Property and equipment, net	8,659	9,254
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	4,502	3,331
Total assets	$271,414	$ 305,822
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$4,139	$ 5,290
Accrued expenses	4,723	4,617
Accrued compensation	2,029	3,711
Common stock warrant liabilities	692	6,196
Long-term debt, current portion	—	6,321
Deferred revenue	1,014	945
Current liabilities of discontinued operations	1,537	2,906
Total current liabilities	14,134	29,986
Long term debt	21,602	15,899
Deferred revenue, less current portion	4,987	6,139
Contingent purchase consideration	53,600	51,000
Deferred income taxes	18,450	18,450
Other long-term liabilities	1,696	1,588
Stockholders' equity:		
Common stock, $0.001 par value; 50,000 shares authorized at June 30, 2016 and December 31, 2015; 24,791 and 24,772 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	25	25
Additional paid-in capital	561,654	558,251
Accumulated deficit	(404,734)	(375,516)
Total stockholders' equity	156,945	182,760
Total liabilities and stockholders' equity	$271,414	$ 305,822

See accompanying notes.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue:				
Contract manufacturing revenue	$1,986	$6,003	$11,192	$10,184
Service and other product revenue	102	1,364	102	1,797
Total revenue	2,088	7,367	11,294	11,981
Operating expense:				
Cost of contract manufacturing	2,061	5,803	9,865	9,726
Royalty expense	75	71	146	143
Research and development	10,384	6,241	18,371	11,390
Selling, general and administrative	6,844	7,582	12,968	13,851
Change in fair value of contingent consideration	1,300	(600)	2,600	(1,600)
Total operating expense	20,664	19,097	43,950	33,510
Loss from operations	(18,576)	(11,730)	(32,656)	(21,529)
Other income (expense):				
Interest expense, net	(623)	(898)	(1,221)	(1,541)
Change in fair value of warrant liabilities	977	(975)	5,504	(564)
Other expense	(15)	(39)	(23)	(160)
Total other income (expense)	339	(1,912)	4,260	(2,265)
Net loss from continuing operations before income taxes	(18,237)	(13,642)	(28,396)	(23,794)
Income tax benefit (expense)	(9)	6,946	(71)	6,932
Net loss from continuing operations	(18,246)	(6,696)	(28,467)	(16,862)
Discontinued operations:				
Net income (loss) from discontinued operations	(582)	79,160	(751)	66,464
Net income (loss)	$(18,828)	$72,464	$(29,218)	$49,602
Net income (loss) per share, basic and diluted:				
Continuing operations	$(0.74)	$(0.35)	$(1.15)	$(0.88)
Discontinued operations	(0.02)	4.13	(0.03)	3.47
Total	$(0.76)	$3.78	$(1.18)	$2.59
Weighted average shares outstanding, basic and diluted	24,777	19,176	24,774	19,173
Statements of Comprehensive Income (Loss)				
Net income (loss)	$(18,828)	$72,464	$(29,218)	$49,602
Other comprehensive income (loss):				
Unrealized loss on available-for-sale securities	—	(1,552)	—	(1,552)
Comprehensive income (loss)	$(18,828)	$70,912	$(29,218)	$48,050

See accompanying notes.

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

	Six Months Ended June 30,	
	2016	2015
Operating activities:		
Net income (loss)	$(29,218)	$49,602
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	3,262	4,618
Depreciation and amortization	694	814
Amortization of debt issuance costs and non-cash interest charges	677	481
Accrued income taxes	—	6,521
Gain on sale of business	—	(89,053)
Change in fair value of warrant liabilities	(5,504)	564
Change in fair value of contingent purchase consideration	2,600	(1,600)
Changes in operating assets and liabilities:		
Trade accounts receivable	(712)	2,559
Inventory	186	542
Prepaid expenses and other current assets	(2,138)	(3,493)
Other assets	(1,172)	860
Accounts payable and accrued expenses	(3,860)	(9,876)
Deferred rent	(51)	—
Deferred revenue	(1,193)	(5,413)
Net cash used by operating activities	(36,429)	(42,874)
Investing activities:		
Purchases of property and equipment	(99)	(68)
Proceeds from sale of business	—	80,926
Change in restricted cash from sale of business	10,002	(1,500)
Net cash provided by investing activities	9,903	79,358
Financing activities:		
Proceeds of long-term debt	2,167	—
Repayment of revolving credit facility	—	(1,450)
Principal payments on long-term debt	(3,334)	—
Proceeds from exercise of common stock options and warrants	6	7
Proceeds from issuance of common stock, net	135	126
Net cash provided by (used in) financing activities	(1,026)	(1,317)
Net increase (decrease) in cash and cash equivalents	(27,552)	35,167
Cash and cash equivalents at beginning of period	155,349	42,205
Cash and cash equivalents at end of period	$127,797	$77,372
Noncash investing and financing activities:		
Deferred financing charges in accounts payable	$—	$294

See accompanying notes.

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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 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 had restricted cash in escrow as of 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.

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

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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 June 30, 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
June 30, 2016				
Assets				
Cash equivalents[1]	$123,087	—	—	$123,087
Liabilities				
Common stock warrant liabilities[2]	$—	—	692	$692
Contingent purchase consideration [3]	$—	—	53,600	$53,600
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 6), which are measured at fair value using the Black-Scholes option pricing valuation model. The assumptions used in the Black-Scholes option pricing valuation model for both common stock warrant liabilities were: (a) a risk-free interest rate based on the rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the remaining contractual term of the warrants; (b) an assumed dividend yield of zero based on the Company’s expectation that it will not pay dividends in the foreseeable future; (c) an expected term based on the remaining contractual term of the warrants; and (d) 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 June 30, 2016 was primarily driven by the decrease in the market price of the Company's common shares at June 30, 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 six months ended June 30, 2016 (in thousands):

	Contingent Purchase Consideration	Common Stock Warrant Liabilities
Balance at December 31, 2015	$ 51,000	$ 6,196
Changes in fair value	2,600	(5,504)
Balance at June 30, 2016	$ 53,600	$ 692

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 income (loss).

Net Income (Loss) per Share

Basic and diluted net loss per share is calculated by dividing the net income (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 income (loss) per common share as their effects were antidilutive are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Options to purchase common stock	3	521	3	297
Restricted stock units not yet vested and released	107	—	107	—
Warrants to purchase common stock	—	—	—	—
Total	110	521	110	297

Other Comprehensive Income

The Company received shares of Pernix Therapeutics Holdings, Inc. common stock received as partial consideration for the purchase of the Zohydro ER business in April 2015. The Company liquidated all of these investments during the fourth quarter of 2015.

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

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 income (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 deferred 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 $(100,000) and $800,000 of contract manufacturing revenue in continuing operations during the three and six months ended June 30, 2016, respectively, based on changes in estimated product to be delivered during the remaining term of the supply agreement. The effect of the changes in estimated future product delivery increased net loss per share from continuing operations by $0.01 and had no effect on net loss per share for the three months ended June 30, 2016, and decreased both net loss per share from continuing operations and net loss per share by $0.03 for the six months ended June 30, 2016.

In addition, the Company reports 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 income (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, and in April 2016 and May 2016 the FASB issued additional guidance related to revenue recognition. These new

standards 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. The 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 these new accounting standards 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 December 31, 2015 condensed consolidated balance sheet in this Form 10-Q reflects 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 no changes to balances reported at 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 guidance to 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):

	June 30, 2016	December 31, 2015
Raw materials	$4,566	$ 3,775
Work in process	7,294	8,255
Total	$11,860	$ 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.

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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 income (loss) for the three and six months ended June 30, 2016 and 2015 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenues:				
Net product revenue	$(43)	$4,173	$291	$9,179
Operating expense:				
Cost of product sold	—	612	15	1,952
Royalty expense	—	291	17	708
Research and development	—	1,020	—	5,829
Selling, general and administrative	539	3,097	1,010	14,233
Restructuring expense	—	568	—	568
Gain on sale of business	—	(89,053)	—	(89,053)
Total operating (income) expense	539	(83,465)	1,042	(65,763)
Other income	—	5,000	—	5,000
Net income (loss) from discontinued operations before tax	(582)	92,638	(751)	79,942
Income tax expense	—	(13,478)	—	(13,478)
Net income (loss) from discontinued operations	$(582)	$79,160	$(751)	$66,464

The following table summarizes the assets and liabilities of discontinued operations as of June 30, 2016 and December 31, 2015 related to the Zohydro ER business (in thousands):

	June 30, 2016	December 31, 2015
Assets		
Current assets		
Prepaid expenses and other current assets	$—	$ 208
Total current assets of discontinued operations	—	208
Total assets of discontinued operations	$—	$ 208
Liabilities		
Current liabilities		
Accounts payable	$ 182	$ —
Accrued expenses	1,355	2,796
Deferred revenue and other current liabilities	—	110
Total current liabilities of discontinued operations	1,537	2,906
Total liabilities of discontinued operations	$ 1,537	$ 2,906

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There was no stock-based compensation or amortization expense related to discontinued operations for the three and six months ended June 30, 2016. Total stock-based compensation expense related to discontinued operations was $898,000 and total amortization expense related to discontinued operations was $166,000 for the six months ended June 30, 2015.

5. Commitments

Amendment of Manufacturing Services Agreement

On April 29, 2016, the Company amended its manufacturing services agreement with Patheon UK Limited to extend the term of the existing agreement. Other terms of the existing agreement remain unchanged. The agreement may be extended further by agreement of both parties for additional terms prior to the expiration of the current term. Future minimum purchase commitments under the amended agreement were $566,000 at June 30, 2016.

Amendment of Loan and Security Agreement

On June 17, 2016, the Company entered into a second amendment to modify the loan and security agreement with Oxford Finance LLC and Silicon Valley Bank dated as of December 30, 2014. Significant terms of the modification included:

- providing the Company with additional term loans in net aggregate principal amount of $3,333,334;
- amending the original repayment schedule of the term loans such that the Company is required to make interest-only payments until February 1, 2018, then equal monthly payments of principal plus interest will be made through the maturity date of the term loans on July 1, 2020;
- amending the interest rate such that the term loans bear interest at an annual rate equal to either (i) 7.00% or (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) 3.25%, whichever is greater;
- removing the revolving line of credit previously available under the original loan and security agreement;
- removing an affirmative covenant requiring the Company to maintain a liquidity ratio of 1.25 to 1 through the Company's receipt of positive data from placebo-controlled trials in the United States and European Union of ZX008; and
- amending a covenant to now permit the Company to maintain collateral account balances exceeding the greater of (i) $50,000,000, or (ii) 50% of the Company's total collateral account balances (other than specifically excluded accounts), with financial institutions other than the lenders; provided that, if the Company's total collateral account balances are below $50,000,000, all such balances will be maintained with the lenders.

In connection with second amendment, the Company paid (i) a final payment of $1,000,000 with respect to the existing term loans, previously due on the earlier to occur of the maturity date of the original loan and security agreement or early repayment of the term loans; (ii) an amendment fee of $25,000 with respect to a previous loan amendment; and (iii) revolving line commitment fees of $64,000 due relative to the termination of the revolving line of credit. Furthermore, the Company agreed to make a final payment of $1,350,000 on the earlier of the maturity date of the amended loan and security agreement or early repayment of the term loans, and to pay a termination fee of $200,000 on the earlier to occur of a change in control or the early termination of the loan and security agreement.

6. 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 June 30, 2016, 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 or six months ended June 30, 2016 or the year ended December 31,

2015. The fair value of the warrants outstanding was approximately $643,000 and $6,069,000 as of June 30, 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

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each reporting date (see Note 2). The fair value of the warrant was approximately $49,000 and $127,000 as of June 30, 2016 and December 31, 2015, respectively.

7. Stock-Based Compensation

The Company uses the Black-Scholes option-pricing model for determining the estimated fair value of stock-based compensation for stock-based awards to employees and the board of directors. The assumptions used in the Black-Scholes option-pricing model for the three and six months ended June 30, 2016 and 2015 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Risk free interest rate	1.2%	1.6% to 1.8%	1.2% to 1.4%	1.5% to 1.8%
Expected term	6.0 to 6.1 years	5.1 to 6.1 years	6.0 to 6.1 years	5.1 to 6.1 years
Expected volatility	78.1%	76.7% to 79.2%	77.8% to 78.1%	76.7% to 79.2%
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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Cost of contract manufacturing	$94	$103	$196	$196
Research and development	493	186	917	409
Selling, general and administrative	1,187	2,081	2,149	3,115
Total	$1,774	$2,370	$3,262	$3,720

As of June 30, 2016, there was approximately $11,651,000 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 2.8 years, and $799,000 of total unrecognized compensation costs related to unvested employee performance stock units which is expected to be recognized over a weighted average period of 1.7 years.

As of June 30, 2016, there were 39,195 unvested stock options and 7,500 unvested restricted stock units outstanding to consultants, with approximately $284,000 of related unrecognized compensation expense based on a June 30, 2016 measurement date. These unvested stock awards outstanding to consultants are expected to vest over a weighted average period of 2.5 years. In accordance with accounting guidance for stock-based compensation, the Company remeasures the fair value of stock option grants to non-employees at each reporting date and recognizes the related income or expense during their vesting period. The expense recognized from the revaluation of stock options and restricted stock units to consultants was immaterial for the three and six months ended June 30, 2016 and 2015. The expense for awards issued to consultants is included in the condensed consolidated statements of operations and comprehensive income (loss) within selling, general and administrative expense.

8. Income taxes

Intraperiod tax allocation rules require the Company to allocate the provision for income taxes between continuing operations and other categories of earnings, such as discontinued operations. In periods in which the Company has a year-to-date pre-tax loss from continuing operations and pre-tax income in other categories of earnings, such as discontinued operations, the Company must allocate the tax provision to the other categories of earnings, and then record a related tax benefit in continuing operations. During the three and six months ended June 30, 2016, the Company recognized net losses

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from both continuing and discontinued operations, and therefore no allocation of income tax was required. During the three months ended June 30, 2015, the Company recognized net income from discontinued operations, and, as a result, recorded income tax expense of $13,478,000, which is included in net income (loss) from discontinued operations in the condensed consolidated statement of operations and comprehensive income (loss). Accordingly, the Company recognized a related income tax benefit of $6,946,000 from continuing operations in the condensed consolidated statement of operations and comprehensive income (loss) for the three and six months ended June 30, 2015. The remaining $6,532,000 income tax benefit to continuing operations was recognized throughout the remainder of 2015.

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

Forward-Looking Statements

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

- the progress and timing of clinical trials for ZX008;
- 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.

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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, 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 initiated Phase 3 clinical trials in Europe in June 2016 and we expect top-line results from this trial in the second quarter of 2017. 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 remained substantially unchanged.

On June 17, 2016, we, Oxford and SVB entered into a second amendment to the loan and security agreement dated December 30, 2014 which provided additional net term loan proceeds of $3.3 million, extended the original repayment

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schedule of the term loans such that we are required to make interest-only payments until February 17, 2018, then equal monthly payments of principal plus interest will be made through the maturity date of the term loans on July 1, 2020, reduced the interest rate on the term loans, removed the revolving line of credit previously available, amended the collateral account covenant and removed the liquidity covenant as discussed in the preceding paragraph.

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

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price for deliverables within each agreement using vendor-specific objective evidence, or VSOE, of selling price, if available, third-party evidence, or TPE, of selling price if VSOE is not available, or management's best estimate of selling price, or BESP, if neither VSOE nor TPE is available. Determining the BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, we consider applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs.

Contract Manufacturing Revenue

We and Endo Ventures entered into 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. The Company recognized ($0.1) million and $0.8 million of contract manufacturing revenue in continuing operations during the three and six months ended June 30, 2016, respectively, based on changes in estimated product to be delivered during the remaining term of the supply agreement. The effect of the changes in estimated future product delivery increased net loss per share from continuing operations by $0.01 and had no effect on net loss per share for the three months ended June 30, 2016, and decreased both net loss per share from continuing operations and net loss per share by $0.03 for the six months ended June 30, 2016.

In addition, we report revenue 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.

Fair Value Measurements

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

and could have a significant impact on the determination of the amount of the fair value ascribed to the asset or liability.

There have been no significant changes in critical accounting policies during the three months ended June 30, 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.

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Results of Operations

Comparison of the Three and Six Months ended June 30, 2016 and 2015

Revenue

	Three Months Ended June 30,				Six Months Ended June 30,			
(Dollars in thousands)	2016	2015	$ change	% change	2016	2015	$ change	% change
Contract manufacturing revenue	$1,986	$6,003	$(4,017)	(66.9)%	$11,092	$10,084	$1,008	