

ZOGENIX, INC.
Form 10-Q
August 08, 2017
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2017

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, Suite 455	94608
Emeryville, California	
(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. Yes No

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

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

Large accelerated filer Accelerated filer

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

Emerging growth company

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If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. "

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

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of August 2, 2017 was 24,841,080.

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PART I – FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

Zogenix, Inc.

Condensed Consolidated Balance Sheets (Unaudited)

(in thousands, except par value)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$65,761	\$ 91,551
Trade accounts receivable	4,684	12,577
Inventory	2,232	7,047
Prepaid expenses and other current assets	6,137	8,739
Total current assets	78,814	119,914
Property and equipment, net	459	1,710
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	1,995	1,147
Total assets	\$190,002	\$ 231,505
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$1,791	\$ 4,549
Accrued expenses	9,551	6,374
Accrued compensation	2,639	3,652
Common stock warrant liabilities	69	809
Working capital advance note payable, net of discount of \$3,493 and \$3,733 at June 30, 2017 and December 31, 2016, respectively	3,507	3,267
Current portion of long-term debt	3,333	—
Deferred revenue	—	1,245
Current liabilities of discontinued operations	1,093	414
Total current liabilities	21,983	20,310
Long term debt	15,757	18,824
Contingent consideration	53,900	52,800
Deferred income taxes	17,425	17,425
Other long-term liabilities	1,455	1,390
Stockholders' equity:		
Common stock, \$0.001 par value; 50,000 shares authorized; 24,839 and 24,813 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	25	25
Additional paid-in capital	568,995	565,954
Accumulated deficit	(489,538)	(445,223)
Total stockholders' equity	79,482	120,756
Total liabilities and stockholders' equity	\$190,002	\$ 231,505
See accompanying notes to the unaudited condensed consolidated financial statements.		

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Zogenix, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)
(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue:				
Contract manufacturing revenue	\$7,125	\$1,986	\$9,821	\$11,192
Service and other product revenue	—	102	—	102
Total revenue	7,125	2,088	9,821	11,294
Costs and expenses:				
Cost of contract manufacturing	8,242	2,136	10,729	10,011
Research and development	14,850	10,384	28,191	18,371
Selling, general and administrative	5,502	6,844	12,056	12,968
Impairment charges	107	—	920	—
Change in fair value of contingent consideration	500	1,300	1,100	2,600
Total costs and expenses	29,201	20,664	52,996	43,950
Loss from operations	(22,076)	(18,576)	(43,175)	(32,656)
Other income (expense):				
Interest expense, net	(575)	(623)	(1,152)	(1,221)
Change in fair value of common stock warrant liabilities	153	977	740	5,504
Other income (expense)	29	(15)	9	(23)
Total other (expense) income	(393)	339	(403)	4,260
Loss from continuing operations before income taxes	(22,469)	(18,237)	(43,578)	(28,396)
Income tax benefit (expense)	16	(9)	(1)	(71)
Net loss from continuing operations	(22,453)	(18,246)	(43,579)	(28,467)
Net loss from discontinued operations	(555)	(582)	(736)	(751)
Net loss	\$(23,008)	\$(18,828)	\$(44,315)	\$(29,218)
Net loss per share, basic and diluted:				
Continuing operations	\$(0.90)	\$(0.74)	\$(1.76)	\$(1.15)
Discontinued operations	\$(0.03)	\$(0.02)	\$(0.03)	\$(0.03)
Total	\$(0.93)	\$(0.76)	\$(1.79)	\$(1.18)
Weighted average shares outstanding, basic and diluted	24,822	24,777	24,817	24,774
Comprehensive loss	\$(23,008)	\$(18,828)	\$(44,315)	\$(29,218)

See accompanying notes to the unaudited condensed consolidated financial statements.

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Zogenix, Inc.

Condensed Consolidated Statements of Cash Flows (Unaudited)
(in thousands)

	Six Months Ended	
	June 30,	
	2017	2016
Operating activities:		
Net loss	\$(44,315)	\$(29,218)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,804	3,262
Depreciation and amortization	366	694
Amortization of debt issuance costs and debt discount	506	677
Inventory write-down	2,232	—
Asset impairment charges	920	—
Change in fair value of common stock warrant liabilities	(740)	(5,504)
Change in fair value of contingent consideration	1,100	2,600
Changes in operating assets and liabilities:		
Trade accounts receivable	7,893	(712)
Inventory	2,583	186
Prepaid expenses and other current assets	2,602	(2,138)
Other assets	(848)	(1,172)
Accounts payable, accrued expenses and other liabilities	150	(3,911)
Deferred revenue	(1,245)	(1,193)
Net cash used in operating activities	(25,992)	(36,429)
Investing activities:		
Purchases of property and equipment	(35)	(99)
Change in restricted cash related to a previous divestiture	—	10,002
Net cash (used in) provided by investing activities	(35)	9,903
Financing activities:		
Proceeds from term loan	—	2,167
Principal payments on term loan obligation	—	(3,334)
Proceeds from issuance of common stock under employee stock plans	237	141
Net cash provided by (used in) financing activities	237	(1,026)
Net decrease in cash and cash equivalents	(25,790)	(27,552)
Cash and cash equivalents, beginning of the period	91,551	155,349
Cash and cash equivalents, end of the period	\$65,761	\$127,797

See accompanying notes to the unaudited condensed consolidated financial statements.

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Zogenix, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

Note 1 – Organization, Basis of Presentation and Going Concern

Organization

Zogenix, Inc. and its wholly-owned subsidiaries (the “Company”) is a pharmaceutical company committed to developing and commercializing central nervous system (CNS) therapies. The Company’s current primary area of focus is orphan or rare childhood-onset epilepsy disorders and its lead product candidate is ZX008. ZX008 is currently being developed for the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut Syndrome, or LGS. In addition, the Company performed contract manufacturing services under a supply agreement through April 2017 (see Note 5). The Company operates in one business segment—the research, development and commercialization of pharmaceutical products and its headquarters are located in Emeryville, California.

In April 2015, the Company divested its Zohydro ER® business. Zohydro ER activity has been excluded from continuing operations for all periods herein and reported as discontinued operations.

Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of Zogenix, Inc. and its wholly-owned subsidiaries. Intercompany accounts and transactions have been eliminated in consolidation. The condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”) for interim financial reporting. In the opinion of management, the condensed consolidated financial statements reflect all adjustments, which are normal and recurring in nature, necessary for fair financial statement presentation. The results of operations for any interim period are not necessarily indicative of results of operations for any future period. Certain information and footnote disclosures normally included in annual consolidated financial statements prepared in accordance with generally accepted accounting principles in the United States (“GAAP”) have been condensed or omitted. Accordingly, these unaudited interim condensed consolidated financial statements and accompanying notes should be read in conjunction with the consolidated financial statements and related notes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2016 as filed with the SEC on March 9, 2017.

Going Concern

The accompanying condensed consolidated financial statements have been prepared under the assumption that the Company will continue as a going concern. Such assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

Excluding gains from two discrete business divestitures, the Company has incurred recurring net losses and continuing negative cash flows from its operations resulting in an accumulated deficit of \$489.5 million as of June 30, 2017. At June 30, 2017, the Company had cash and cash equivalents of \$65.8 million. Management anticipates further operating losses and negative cash flows from operations for at least the next year as the Company continues to incur costs related to its ongoing Phase 3 clinical trials of ZX008 in North America and the European Union (EU) in Dravet syndrome as well as the planned commencement of a Phase 3 clinical trial in LGS in the second half of 2017.

Additionally, upon acceptance of the Company’s regulatory submissions for ZX008 by the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA), if at all, each a milestone event, the Company will owe milestone payments under an existing agreement in connection with the Company’s prior acquisition of ZX008. Based on the Company’s current operating plans, management believes that the Company’s existing cash and cash equivalents will not be sufficient to meet the Company’s anticipated operating needs beyond the first half of 2018. As a result, management has concluded there is substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the accompanying condensed consolidated financial statements are issued. The accompanying condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty.

The Company’s ability to continue as a going concern is dependent upon its ability to raise additional funding. Management intends to raise additional capital through public or private equity or debt financings and potentially

through collaboration, licensing or other similar arrangements. However, the Company may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if the Company issues equity or debt securities to raise additional funds, its existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of the Company's existing stockholders. If the Company raises additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to its potential products or proprietary technologies, or grant licenses on terms that are not favorable to the Company. Without additional funds, the Company may be forced to delay, scale back or eliminate some of its research and development activities, or other operations

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and potentially delay product development in an effort to provide sufficient funds to continue its operations. If any of these events occur, the Company's ability to achieve the development and commercialization goals could be adversely affected.

Note 2 – Summary of Significant Accounting Policies

Use of Estimates

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.

Accounting Pronouncements Recently Adopted

Accounting Standards Updated ("ASU") 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting changes how companies account for certain aspects of stock-based awards to employees. Under the guidance, entities will no longer record excess tax benefits and certain tax deficiencies in additional paid-in capital. Instead, they will record all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement. In addition, entities will recognize excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. Under current guidance, excess tax benefits are not recognized until the deduction reduces taxes payable. Further, the new guidance allows entities to make an accounting policy election to either estimate forfeitures or recognize forfeitures as they occur. If an election is made, the change to recognize forfeitures as they occur must be adopted using a modified retrospective approach with a cumulative effect adjustment recorded to retained earnings or accumulated deficit.

The Company adopted ASU 2016-09 on January 1, 2017. Upon adoption, the Company recorded a deferred tax asset of \$0.2 million for previously unrecognized excess tax benefits from stock-based compensation, which was fully offset by an equal increase to its valuation allowance resulting in no impact to opening accumulated deficit. In addition and as provided for under this guidance, the Company made an accounting policy election to recognize forfeitures as they occur. The adoption of this aspect of the guidance did not have a material impact on the Company's condensed consolidated financial statements.

ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory simplifies current accounting treatments by requiring entities to measure most inventories at "the lower of cost and net realizable value" rather than using lower of cost or market. This guidance does not apply to inventories measured using the last-in, first-out method or the retail inventory method. The Company adopted ASU 2015-11 on January 1, 2017. The adoption of this new guidance did not have any impact on the Company's condensed consolidated financial statements.

Accounting Pronouncements Issued But Not Yet Effective

ASU 2014-09, Revenue from Contracts with Customers (Topic 606) and subsequent amendments to the initial guidance (collectively, "Topic 606") 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 of Topic 606 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. Topic 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation, among others. This guidance will be effective for the Company beginning January 1, 2018. The guidance permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method). The Company plans to adopt this guidance as of January 1, 2018, using the modified retrospective method. The Company currently generates all its revenue from a manufacturing and supply agreement (the "supply agreement") with Endo International Plc ("Endo") which the Company expects will be terminated before January 1, 2018. The Company is currently assessing the impact of adopting this guidance on its condensed consolidated financial statements and disclosures, including taking into account the anticipated termination of this supply agreement. The Company will continue to monitor any new contracts it enters into with customers for

evaluation under ASU 2014-09.

ASU 2016-02, Leases (Topic 842) requires 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 condensed consolidated financial statements and related disclosures.

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ASU 2017-04, Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. Under the amendments in ASU 2017-04, an entity should recognize an impairment charge for the amount by which the carrying amount of a reporting unit exceeds its fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The updated guidance requires a prospective adoption. ASU 2017-04 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating the timing and impact of adopting this new accounting standard on its condensed consolidated financial statements and related disclosures.

Note 3 – Inventory

Inventory consists of the following (in thousands):

	June 30, 2017	December 31, 2016
Raw materials	\$2,232	\$ 4,397
Work in process	—	2,650
Total	\$2,232	\$ 7,047

The Company acquires raw materials needed to manufacture Sumavel DosePro under the Endo supply agreement. Based on negotiations to date with Endo (see Note 5), the Company recorded a \$2.2 million reduction to inventory during the second quarter of 2017 to reflect its current net realizable value. The reduction to inventory was recorded within cost of contract manufacturing on the condensed consolidated statement of operations and comprehensive loss.

Note 4 – Fair Value Measurements

The carrying amount of the Company's financial instruments, including cash and cash equivalents, trade accounts receivable, prepaid expenses and other assets, accounts payable, accrued expenses, accrued compensation and the current liabilities of the Company's discontinued operations approximate their fair value due to their short maturities. The carrying amount of the Company's Term Loan approximates fair value, considering level 2 inputs, because it has a variable interest rate. At June 30, 2017 and December 31, 2016, the estimated fair value of the Company's working capital advance note payable approximated its face amount, considering level 2 inputs, due to its impending maturity upon finalization of the termination of the supply agreement with Endo (see Note 5).

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 fair value of cash equivalents was determined based on Level 1 inputs utilizing quoted prices in active markets.

The fair value of the Company's common stock warrant liabilities and contingent consideration liabilities were determined based on Level 3 inputs using valuation models with significant unobservable inputs. Assets and liabilities measured at fair value on a recurring basis at June 30, 2017 and December 31, 2016 were as follows (in thousands):

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	Fair Value Measurements at Reporting Date			
	Using			
	Quoted			
	Prices			
	in	Significant	Significant	Total
	Active	Other	Unobservable	
	Markets	Observable	Inputs	
	for	Inputs	(Level 3)	
	Identical	(Level 2)		
	Assets			
	(Level 1)			
June 30, 2017				
Assets				
Cash equivalents ⁽¹⁾	\$63,003	\$	—\$ —	\$63,003
Liabilities				
Common stock warrant liabilities ⁽²⁾	\$—	\$	—\$ 69	\$69
Contingent consideration liabilities ⁽³⁾	\$—	\$	—\$ 53,900	\$53,900
December 31, 2016				
Assets				
Cash equivalents ⁽¹⁾	\$87,792	\$	—\$ —	\$87,792
Liabilities				
Common stock warrant liabilities ⁽²⁾	\$—	\$	—\$ 809	\$809
Contingent consideration liabilities ⁽³⁾	\$—	\$	—\$ 52,800	\$52,800

(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.

Represents the fair value of common stock warrants outstanding that may require cash settlement under certain circumstances. The Company estimated the fair value of the warrant liabilities using the Black-Scholes valuation model. As of December 31, 2016, common stock warrant liabilities were primarily attributable to warrants sold as part of the Company's July 2012 public offering. The warrants were exercisable into 1,901,918 shares of the Company's common stock at an exercise price of \$20.00 per share and had a contractual term of 5 years from the issuance date. In July 2017, these warrants expired unexercised. As of June 30, 2017, common stock warrant liabilities relate to warrants issued in July 2011 in connection with a debt financing arrangement. The warrants entitle the holder to purchase up to 28,125 shares of common stock at an exercise price of \$72.00 per share. The warrants will expire in July 2021.

(3) In connection with certain acquisition, the Company may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory approval or sales-based milestone events. The Company estimated the fair value of the contingent consideration liabilities on the acquisition date using a probability-weighted income approach, which reflects the probability and timing of future payments. This fair value measurement is based on significant Level 3 inputs such as the anticipated timelines and probability of achieving development, regulatory approval or sales-based milestone events and projected revenues. The resulting probability-weighted cash flows are discounted at risk-adjusted rates. Subsequent to the acquisition date, at each reporting period prior to settlement, the Company revalues these liabilities by performing a review of the assumptions listed above and record increases or decreases in the fair value of these contingent consideration liabilities. In the absence of any significant changes in key assumptions, the quarterly determination of fair values of these contingent consideration liabilities would primarily reflect the passage of time. Significant judgment is used in determining Level 3 inputs and fair value measurements as of the acquisition date and for each subsequent reporting period. Updates to assumptions could have a significant impact on the Company's results of operations in any given period and actual results may differ from estimates. For example, significant increases in the probability of achieving a milestone or projected revenues would result in a significantly higher fair value measurement while

significant decreases in the estimated probability of achieving a milestone or projected revenues would result in a significantly lower fair value measurement. Significant increases in the discount rate or in the anticipated timelines would result in a significantly lower fair value measurement while significant decreases in the discount rate or anticipated timelines would result in a significantly higher fair value measurement. The potential contingent consideration payments required upon achievement of development, regulatory approval and sales-based milestones related to the Company's acquisition of ZX008 range from zero if none of the milestones are achieved to a maximum of \$95.0 million (undiscounted).

There were no transfers between levels during the periods presented.

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The following table provides a reconciliation of liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the three and six months ended June 30, 2017 and 2016 (in thousands):

	March 31, 2017	Change in Fair Value	June 30, 2017	March 31, 2016	Change in Fair Value	June 30, 2016
Contingent consideration liabilities	\$53,400	\$ 500	\$53,900	\$52,300	\$1,300	\$53,600
Common stock warrant liabilities	222	(153)	69	1,669	(977)	692

	December 31, 2016	Change in Fair Value	June 30, 2017	December 31, 2015	Change in Fair Value	June 30, 2016
Contingent consideration liabilities	\$ 52,800	\$1,100	\$53,900	\$ 51,000	\$2,600	\$53,600
Common stock warrant liabilities	809	(740)	69	6,196	(5,504)	692

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

Note 5 – Contract Manufacturing Agreement with Endo and Associated Exit Activities

As part of the divestiture of the Company's Sumavel DosePro business to Endo in May 2014, the Company entered into a supply agreement with Endo for the exclusive right, and contractual obligation, to manufacture and supply Sumavel DosePro to Endo for an initial term of eight years. To support the Company's Sumavel DosePro manufacturing operations, Endo provided the Company with an interest-free working capital advance of \$7.0 million under a promissory note (see Note 6). The working capital advance matures upon termination of the supply agreement.

In January 2017, the Company and Endo entered into a letter agreement acknowledging Endo's decision to have the Company discontinue the manufacturing and supply of the Sumavel DosePro product while the parties finalize termination of the supply agreement. The termination of the manufacturing and supply agreement with Endo has not been finalized. In April 2017, the Company completed fulfillment of the remaining open orders from Endo and all remaining deferred revenue associated with the supply agreement was recognized. The Company currently has no further obligation to supply Endo with additional Sumavel DosePro.

The Company is also in the process of negotiating the termination of manufacturing and supply agreements for the production of Sumavel DosePro with its third-party suppliers. As of June 30, 2017, other than certain asset retirement obligations totaling \$0.6 million included in current liabilities in the condensed consolidated balance sheets, no amounts were owed to these third-party suppliers under the existing terms of these manufacturing and supply agreements. The Company may incur additional costs when the termination of these agreements with its third-party suppliers are finalized. These costs would be subject to reimbursement from Endo when the termination of the supply agreement is finalized and would not be significant to the condensed consolidated financial statements.

In the fourth quarter of 2016, the Company performed an analysis to estimate cash flows from property and equipment used in the production of Sumavel DosePro. Based on this analysis, the Company determined its fair value exceeded the carrying value by \$6.4 million and recognized an impairment charge for long-lived assets. In the first quarter of 2017, the Company recorded an additional asset impairment charge of \$0.8 million for long-lived manufacturing assets associated with the production of Sumavel DosePro. Based on recent negotiations with Endo for the final reimbursement of costs incurred under the supply agreement, the Company recorded a \$2.2 million reduction to inventory during the second quarter of 2017 to reflect its current net realizable value.

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Note 6 – Debt Obligations

Term Loan

Scheduled maturities of the term loan are as follows (in thousands):

2017 (remaining 6 months)	\$—
2018	8,000
2019	8,000
2020	4,000
Principal balance outstanding	20,000
Less: unamortized debt discount and issuance costs	(910)
Net carrying value of debt	19,090
Less: current portion	(3,333)
Long-term debt	\$15,757

In December 2014, the Company entered into a Loan and Security Agreement (the “Loan Agreement”) with Oxford Finance LLC (“Oxford”) and Silicon Valley Bank (“SVB”) (collectively, the “Lenders”), under which the Company borrowed a \$20.0 million term loan. In addition, the Loan Agreement provided for a revolving credit facility of up to \$4.0 million. The obligations under the Loan Agreement are secured by liens on the Company’s personal property and the Company has agreed to not encumber any of its intellectual property. The Loan Agreement includes a material adverse change clause, which enables the Lenders to require immediate repayment of the outstanding debt if certain subjective acceleration provisions are triggered. The material adverse change clause covers provisions including a material impairment of underlying collateral, change in business operations or condition or material impairment of the Company’s prospects for repayment of any portion of the remaining debt obligation. To date, the Company has not received any notification from the Lenders that it is not in compliance with this clause.

In connection with the Loan Agreement, the Lenders were issued warrants to purchase an aggregate of up to 63,559 shares of the Company’s common stock at a per share exercise price of \$9.44. The warrants are exercisable for 10 years. At the time of issuance, the fair value of the warrants was estimated to be \$0.6 million using the Black-Scholes valuation model and was recorded at issuance as debt discount to the term loan with a corresponding increase to additional paid in capital in the consolidated balance sheet.

The term loan bore interest at an annual rate equal to the greater of (i) 8.75% or (ii) the sum of the prevailing prime rate (as reported by the Wall Street Journal) plus 5.25%. Payments under the loan were interest-only until January 1, 2016, followed by equal monthly payments of principal and interest through the scheduled maturity date of December 1, 2018.

On April 23, 2015, in connection with the sale of the Zohydro ER business, the Company and the Lenders entered into an amendment to the Loan Agreement, which terminated all encumbrances on the Company’s personal property related to its Zohydro ER business.

On June 17, 2016, the Company entered into a second amendment (the “Second Amendment”) to the Loan Agreement with the Lenders. The Second Amendment modified the loan repayment terms to be interest-only from July 1, 2016 to February 1, 2018, followed by equal monthly payments of principal and interest through a new maturity date of July 1, 2020. Under the terms of the Second Amendment, the interest rate applicable to the term loan bears interest at an annual rate equal to the greater of (i) 7.00% or (ii) the sum of the prevailing prime rate (as reported by the Wall Street Journal) plus 3.25%. In addition, the Second Amendment terminated the revolving credit facility previously available under the Loan Agreement. In connection with the Second Amendment, the Company paid (i) the end of term fee of \$1.0 million due under the Loan Agreement as a result of entering into the Second Amendment and (ii) the end of term fee of \$0.1 million with respect to the termination of the revolving credit facility. The Second Amendment also includes an end of term fee of \$1.4 million payable on July 1, 2020, or upon early repayment of the term loan. An early repayment will be subject to a prepayment penalty of \$0.2 million.

The Loan Agreement required the Company to establish a controlled deposit account with SVB containing at least 85% of the Company’s account balances at all financial institutions which can be utilized by the Lenders to satisfy the obligations in the event of default. The Second Amendment permitted the Company to maintain collateral account balances exceeding the greater of (i) \$50.0 million, 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 \$50.0 million, all such balances will be maintained with the Lenders. Other affirmative covenants include, among others, requiring the Company to maintain legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding accounts receivable. Negative covenants include, among others, restrictions on transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions,

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paying dividends or making other distributions, making investments, creating liens, selling assets and consummation of a change in control, in each case subject to certain exceptions. The Company was in compliance with these covenants at June 30, 2017 and December 31, 2016.

Working Capital Advance Note Payable

In connection with entering into the supply agreement for Sumavel DosePro with Endo, Endo provided the Company with an interest-free working capital advance of \$7.0 million, which is evidenced by a promissory note. The note payable is secured by a lien on the Company's Sumavel DosePro raw materials and work in process inventory. There are no covenants related to this working capital advance. The note payable was initially recorded on the balance sheet net of a \$4.7 million debt discount. The debt discount is being amortized as interest expense using the effective interest method over the supply agreement's initial term of eight years as the note payable matures upon termination of the related supply agreement.

As a result of the negotiations regarding the termination of the supply agreement (see Note 5), the note payable has been classified as a current liability as of June 30, 2017 and December 31, 2016 because the extinguishment of the liability is reasonably expected to require the use of existing current assets, including cash and the underlying collateral of Sumavel DosePro inventory. As of June 30, 2017, the carrying value of the note payable of \$3.5 million was presented net of unamortized debt discount. Upon maturity, the face amount of the note payable of \$7.0 million will be due and payable.

Note 7 – Stock-Based Compensation

The Company has adopted certain equity incentive and stock purchase plans as described in the consolidated financial statements and related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016. Upon adopting ASU 2016-09 on January 1, 2017, the Company elected to account for forfeitures as they occur.

Valuation of Stock Options

The estimated grant date fair values of the stock options were calculated using the Black-Scholes valuation model, based on the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Risk free interest rate	1.9% to 2.0%	1.2%	1.9% to 2.3%	1.2% to 1.4%
Expected term	5.1 to 6.1 years	6.0 to 6.1 years	5.1 to 6.1 years	6.0 to 6.1 years
Expected volatility	76.0% to 76.3%	78.1%	76.0% to 76.6%	77.8% to 78.1%
Expected dividend yield	—%	—%	—%	—%

During the six months ended June 30, 2017, the Company granted options to purchase approximately 0.9 million shares of common stock with a weighted average grant date fair value of \$7.02.

Restricted Stock Units with a Performance Condition

In March 2017, the Company granted approximately 0.2 million restricted stock units (RSUs) with service and performance-based conditions to employees and executives. The weighted average fair value of RSUs granted was \$10.20 per share. The RSUs vest upon the approval by the FDA of the Company's new drug application for ZX008, provided such approval occurs within five years following the grant date. Due to the uncertainties associated with the FDA approval process, approval is not yet probable, as such term is used for accounting purposes, prior to the occurrence of the event. Accordingly, no compensation expense has been recognized as of June 30, 2017 for these awards.

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Stock-Based Compensation Expense

The following table summarizes the components of total stock-based compensation expense included in the condensed consolidated statements of operations (in thousands):

	Three Months		Six Months	
	Ended June 30,		Ended June 30,	
	2017	2016	2017	2016
Cost of contract manufacturing	\$(6)	\$94	\$71	\$196
Research and development	502	493	1,019	917
Selling, general and administrative	635	1,187	1,714	2,149
Total	\$1,131	\$1,774	\$2,804	\$3,262

Note 8 – Net Loss Per Share

Basic net loss from continuing operations per share is calculated by dividing net loss from continuing operations by the weighted average number of shares outstanding for the period. Diluted net loss from continuing operations per share is calculated by dividing net loss from continuing operations by the weighted average number of shares of common stock and potential dilutive common stock equivalents outstanding during the period if the effect is dilutive. The Company's potentially dilutive shares of common stock include outstanding stock options, restricted stock units and warrants to purchase common stock.

A reconciliation of the numerators and denominators used in computing net loss from continuing operations per share is as follows (in thousands, except per share amounts):

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
Numerator:				
Net loss from continuing operations	\$(22,453)	\$(18,246)	\$(43,579)	\$(28,467)
Denominator:				
Shares used in per share calculation	24,822	24,777	24,817	24,774
Net loss from continuing operations per share, basic and diluted	\$(0.90)	\$(0.74)	\$(1.76)	\$(1.15)

The following table presents the potential shares of common stock outstanding that were excluded from the computation of diluted net loss from continuing operations per share for the periods presented because including them would have been anti-dilutive (in thousands):

	Three Months		Six Months	
	Ended June 30,		Ended June 30,	
	2017	2016	2017	2016
Shares subject to outstanding common stock options	4,020	3,237	3,756	3,036
Shares subject to outstanding restricted stock units	273	108	205	64
Shares subject to outstanding warrants to purchase common stock	1,975	1,975	1,975	1,975
Total	6,268	5,320	5,936	5,075

Note 9 – Subsequent Events

On August 1, 2017, Zogenix and Durect Corporation (“Durect”) entered into an agreement to terminate the development and license agreement related to Relday. Under the terms of the termination agreement, all of the Company's development and commercialization rights related to Relday were returned to Durect and all regulatory filings and development information related to Relday will be assigned and/or transferred to Durect. Upon termination, the

Company has no further obligations to make any potential future milestone payments with respect to Relday. In addition, the termination agreement does not provide the Company with any future royalty entitlements.

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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 of 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;
- the expected termination of the supply agreement with Endo International Plc, or Endo, and the impact on our future revenues; and
- projected cash needs and our expected future revenues, operations and expenditures.

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

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

DosePro® 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 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, 2016 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, 2016.

Overview

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 primary area of focus is

orphan or rare childhood-onset epilepsy disorders.

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We currently own and control worldwide development and commercialization rights to ZX008, our lead product candidate. ZX008 is 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 European Union, or the EU, 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 the FDA, for ZX008 for the treatment of Dravet syndrome. We initiated our Phase 3 clinical trials in North America (Study 1501) in January 2016 and in Europe and Australia in June 2016 (Study 1502). Study 1501 and Study 1502 are each identical randomized, double-blind placebo-controlled studies of ZX008 as adjunctive therapy for patients with uncontrolled seizures who have Dravet syndrome. In January 2017, we announced our plan to report top-line results from Study 1501 and Study 1502 via a merged study analysis approach whereby top-line results from the first approximately 120 subjects randomized into either Study 1501 or 1502 would be reported initially as “Study 1.” In April 2017, we completed enrollment of Study 1 and we currently expect to report top-line results in the third quarter of 2017. In September 2016, we initiated the pharmacokinetic and safety profile portion of Study 1504, a double blind, randomized, two arm pivotal Phase 3 clinical trial of ZX008 in Dravet syndrome patients who are taking stiripentol, valproate and clobazam as part of their baseline standard care. In February 2017, we initiated the safety and efficacy portion of Study 1504, a two-arm study that compares ZX008 versus placebo across the titration and 12-week maintenance periods at multiple sites, which currently includes sites in France, the Netherlands, United States, Canada, Germany, the United Kingdom and Spain.

Beginning in first quarter of 2016, we funded an open-label dose-finding twenty-patient investigator initiated study in patients with Lennox-Gastaut Syndrome, or LGS, another rare and catastrophic form of pediatric epilepsy with life threatening consequences for patients and for which current treatment options are very limited. In December 2016, we presented initial data from an interim analysis of the first 13 patients to have completed at least 12 weeks of this Phase 2 open-label, dose-finding clinical trial at the American Epilepsy Society Meeting. These data demonstrated that ZX008 provided clinically meaningful improvement in major motor seizure frequency in patients with severe refractory LGS, with seven out of 13 patients (54%) achieving at least a 50% reduction in the number of major motor seizures, at doses below the 0.8 mg/kg/day maximum. In addition, ZX008 was generally well tolerated, as expected based on our epilepsy program to date. We believe these data indicate that ZX008 has the potential to be a safe and effective adjunctive treatment for LGS. Based on the strength of the LGS data generated, in the first quarter of 2017, we submitted an investigational new drug, or IND, application to the FDA to initiate a Phase 3 program of ZX008 in LGS, which became effective in April 2017. We intend to initiate a Phase 3 program of ZX008 in LGS in the second half of 2017. In February 2017, ZX008 received orphan drug designation for the treatment of LGS in the EU. In June 2017, ZX008 received orphan drug designation for the treatment of LGS in the United States from the FDA.

Relday™ Development and License Agreement Termination

In July 2011, we entered into a development and license agreement with Durect Corporation, or Durect, under which we were granted an exclusive worldwide development and commercialization license to intellectual property related to Relday. Relday is an investigational, proprietary, long-acting formulation of risperidone, an atypical anti-psychotic agent. Under the development and license agreement, we were responsible for the clinical development and commercialization of Relday while Durect was responsible for pre-clinical, formulation and chemistry, manufacturing and controls development. Under the terms of the development and license agreement, we are obligated to use commercially reasonable efforts to fund the development and seek and maintain regulatory approval for Relday and if successful, to pay Durect up to \$103.0 million in total future milestone payments with respect to Relday, subject to and upon the achievement of various development, regulatory, and sales-related milestones.

On August 1, 2017, we and Durect entered into an agreement to terminate the development and license agreement related to Relday. Under the terms of the termination agreement, all of our development and commercialization rights related to Relday were returned to Durect and all our regulatory filings and development information related to Relday will be assigned and/or transferred to Durect. Upon termination, we have no further obligations to make any potential future milestone payments with respect to Relday. In addition, the termination agreement does not provide us with any future royalty entitlements.

Pending Termination of Contract Manufacturing Supply Agreement

Our 2017 revenue is generated from a single contract manufacturing and supply agreement entered into in connection with the divestiture of our Sumavel DosePro business in 2014 to Endo. Under the terms of the supply agreement, we manufacture and supply Sumavel DosePro to Endo for an initial term of eight years. In January 2017, we and Endo entered into a letter agreement acknowledging Endo's decision to have us discontinue the manufacturing and supply of the Sumavel DosePro product while the parties finalize termination of the supply agreement. Negotiations as to the termination of this agreement are ongoing. In April 2017, we completed fulfillment of all open orders to Endo and has no further obligation to supply Endo with additional Sumavel DosePro. We are also in the process of negotiating with our third-party suppliers to terminate agreements under which Sumavel DosePro was manufactured and supplied to us. As of June 30, 2017, no amounts were currently owed to these third-party suppliers as such termination agreements were not yet finalized. We may incur

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additional costs associated with the termination of these agreements. Once the termination agreement is finalized, we will no longer have a source of recurring revenue and expect to have limited to no revenue in the foreseeable future.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in conformity with generally accepted accounting principles in the United States, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates.

We believe that the assumptions and estimates associated with revenue recognition, the impairment assessments related to goodwill, indefinite-lived intangible assets and other long-lived assets, business combinations, discontinued operations, fair value measurements, clinical trials expense accrual and stock-based compensation have the greatest potential impact on our condensed consolidated financial statements. Therefore, we consider these to be our critical accounting policies and estimates.

There have been no significant changes in our critical accounting policies and estimates during the six months ended June 30, 2017, as compared to the critical accounting policies and estimates disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2016.

Recent Accounting Pronouncements

For information with respect to recent accounting pronouncements that are of significance or potential significance to us, see Note 2 of Notes to Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report.

Results of Operations**Comparison of Three and Six Months Ended June 30, 2017 and 2016****Contract Manufacturing Revenue**

	Three Months Ended			Six Months Ended June		
	June 30,			30,		
(in thousands)	2017	2016	Change	2017	2016	Change
Contract manufacturing revenue	\$7,125	\$1,986	\$5,139	\$9,821	\$11,192	\$(1,371)
Service and other product revenue	—	102	(102)	—	102	(102)
Total revenue	\$7,125	\$2,088	\$5,037	\$9,821	\$11,294	\$(1,473)

Our contract manufacturing revenue was solely generated by our supply agreement with Endo. In January 2017, we and Endo entered into a letter agreement acknowledging Endo's decision to have us discontinue the manufacturing and supply of the Sumavel DosePro product under the supply agreement while the parties finalize termination of the supply agreement. Contract manufacturing revenue increased by \$5.1 million for the three months ended June 30, 2017 compared to the same period in 2016 primarily due to more units delivered and the timing of product deliveries. Contract manufacturing revenue decreased by \$1.4 million for the six months ended June 30, 2017 as compared to the same period in 2016. The decrease was primarily attributable to lower cost-reimbursable fixed production costs under the arrangement including facility costs incurred related to our contract manufacturers. In April 2017, we completed fulfillment of the remaining open orders and ceased all manufacturing activities related to Sumavel DosePro. The termination of our supply agreement is currently under negotiation. After the termination of the supply agreement, we will no longer have a source of recurring revenue and expect to have limited to no revenue in the foreseeable future.

Cost of Contract Manufacturing

	Three Months Ended			Six Months Ended June		
	June 30,			30,		
(in thousands)	2017	2016	Change	2017	2016	Change
Cost of contract manufacturing	\$8,242	\$2,136	\$6,106	\$10,729	\$10,011	\$ 718

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Cost of contract manufacturing increased by \$6.1 million for the three months ended June 30, 2017 compared to the same period in 2016 primarily due to more units delivered. In addition, based on negotiations to date with Endo, we recorded a \$2.2 million reduction to inventory during the second quarter of 2017 to reflect its current net realizable value. Cost of contract manufacturing increased by \$0.7 million for the six months ended June 30, 2017 compared to the same period in 2016. The increase was primarily due to the \$2.2 million reduction to inventory as a result of ongoing negotiations with Endo to its net realizable value, partially offset by lower cost-reimbursable fixed production costs under the arrangement.

Research and Development Expenses

(in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2017	2016	Change	2017	2016	Change
Research and development	\$14,850	\$10,384	\$4,466	\$28,191	\$18,371	\$9,820

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 clinical 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 utilize contract manufacturing organizations, CROs, contract laboratories and independent contractors to produce product candidate material and for the conduct of our pre-clinical studies and clinical trials. We track third-party costs by program. We recognize the expenses associated with the services provided by CROs based on estimated progress toward completion 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.

(in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2017	2016	Change	2017	2016	Change
ZX008	\$9,398	\$7,754	\$1,644	\$18,591	\$13,046	\$5,545
Other ⁽¹⁾	5,452	2,630	2,822	9,600	5,325	4,275
Total	\$14,850	\$10,384	\$4,466	\$28,191	\$18,371	\$9,820

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

We acquired ZX008 in October 2014 and have since incurred significant expenditures related to conducting clinical trials of ZX008. Research and development expenses for ZX008 increased by \$1.6 million and \$5.5 million for the three and six months ended June 30, 2017, respectively, compared to the same periods in 2016. The increases reflect the progression and expansion of our clinical trial activities related to our Phase 3 development program of ZX008 in Dravet syndrome, which commenced in January 2016.

We expect our research and development expenses for the remainder of 2017 to exceed amounts incurred in comparable periods in 2016 as we continue to advance the Phase 3 development program of ZX008 in Dravet syndrome as well as the planned commencement of a Phase 3 clinical trial in LGS in the second half of 2017.

Selling, General and Administrative Expenses

(in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2017	2016	Change	2017	2016	Change
Selling	\$1,127	\$1,578	\$(451)	\$2,423	\$2,819	\$(396)
General and administrative	4,375	5,266	(891)	9,633	10,149	(516)
Total selling, general and administrative	\$5,502	\$6,844	\$(1,342)	\$12,056	\$12,968	\$(912)

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Selling expense consists 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 and internal support functions. In addition, general and administrative expenses include professional fees for legal, consulting and accounting services.

Selling expense decreased by \$0.5 million and \$0.4 million for the three and six months ended June 30, 2017, respectively, compared to the same periods in 2016. The decreases reflect lower spend on market research activities related to ZX008. General and administrative expense decreased by \$0.9 million and \$0.5 million in the three and six months ended June 30, 2017, respectively, compared to the same periods in 2016. The decreases were primarily attributable to decreases in professional services expenses related to legal, accounting and recruiting services.

We expect our selling, general and administrative expenses in 2017 will remain relatively consistent with 2016 levels.

Impairment Charges

	Three Months Ended June 30,			Six Months Ended June 30,		
(in thousands)	2017	2016	Change	2017	2016	Change
Impairment charges	\$107	\$ —	\$ 107	\$920	\$ —	\$ 920

For the three months ended June 30, 2017, we recorded an impairment charge of \$0.1 million for fixed assets related to Relday, which we no longer have development rights to as a result of a termination agreement entered into on August 1, 2017 with Durect. Included in impairment charges for the six months ended June 30, 2017 was a \$0.8 million write-down of long-lived manufacturing assets associated with the production of Sumavel DosePro recorded in the first quarter of 2017.

Change in Fair Value of Contingent Consideration

	Three Months Ended June 30,			Six Months Ended June 30,		
(in thousands)	2017	2016	Change	2017	2016	Change
Change in fair value of contingent consideration	\$500	\$1,300	\$(800)	\$1,100	\$2,600	\$(1,500)

The contingent consideration liability relates to milestone payments under an existing agreement in connection with our prior acquisition of ZX008. At each reporting period, the estimated fair value of the 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. Any change in the fair value is recorded as contingent consideration (income) expense.

Changes in fair value of contingent consideration for the periods indicated were primarily due to adjustments to the estimated time to payout and discount rates used in calculating the fair value of contingent consideration to reflect market interest rate conditions on the measurement date.

Other Income (Expense)

	Three Months Ended June 30,			Six Months Ended June 30,		
(in thousands)	2017	2016	Change	2017	2016	Change
Other income (expense)	\$(393)	\$339	\$(732)	\$(403)	\$4,260	\$(4,663)

Other income (expense) primarily consists of interest expense, net, changes in fair value of our common stock warrant liabilities and foreign currency gains and losses resulting from transactions denominated in U.K. pounds sterling and euros.

Changes in other income (expense) for the periods indicated were primarily due to the impact of changes in the fair value of our common stock warrant liabilities. During the three and six months ended 2017, the fair value of warrants sold as part of our July 2012 public offering decreased due to our stock price trading significantly below the exercise price and the period to expiration of the warrants becoming shorter. This resulted in income recognized as our liabilities decreased, which was primarily offset by interest expense. In July 2017, these warrants expired unexercised. During the three and six months ended 2016, the fair value of these warrants decreased significantly as a result of a significant decline in our stock price, which contributed to other income, net.

We expect other expense, net to increase for the remainder of 2017, as compared to the same period in 2016, as we will be required to write-off any unamortized discount on our working capital advance from Endo upon maturity (see Note 6 of the

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Notes to Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report). As of June 30, 2017, the unamortized discount was \$3.5 million.

Liquidity and Capital Resources

We have experienced operating net losses and negative cash flow from operations since inception. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next year primarily as a result of the expenses incurred in connection with the clinical development of ZX008 in Dravet syndrome and LGS. Since inception, our operations have been financed primarily through equity and debt financings and proceeds from business divestitures. Excluding gains from two discrete business divestitures, we have incurred recurring net losses and continuing negative cash flows from our operations resulting in an accumulated deficit of \$489.5 million as of June 30, 2017. We held cash and cash equivalents of \$65.8 million as of June 30, 2017. Management anticipates further operating losses and negative cash flows from operations for at least the next year as we continue to incur costs related to ongoing Phase 3 programs in Dravet syndrome in North America and EU for ZX008 as well as the planned commencement of a Phase 3 clinical trial in LGS in the second half of 2017. Additionally, upon acceptance of our regulatory submissions for ZX008 by the FDA or the EMA, if at all, each a milestone event, we will owe milestone payments under an existing agreement in connection with our prior acquisition of ZX008. Based on our current operating plans, we believe that our existing cash and cash equivalents will not be sufficient to meet our anticipated operating needs beyond the first half of 2018. As a result, management has concluded there is substantial doubt about our ability to continue as a going concern within one year after the date that the accompanying financial statements are issued.

We intend to raise additional capital through public or private equity or debt financings and potentially through collaboration, licensing or other similar arrangements. However, we may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. Without additional funds, we may be forced to delay, scale back or eliminate some of our research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue its operations. If any of these events occurs, our ability to achieve the development and commercialization goals could be adversely affected.

The following table presents selected information from our statements of cash flows (in thousands):

	Six Months Ended	
	June 30,	
	2017	2016
Cash and cash equivalents, beginning of the period	\$91,551	\$155,349
Net cash used in operating activities	(25,992)	(36,429)
Net cash (used in) provided by investing activities	(35)	9,903
Net cash provided by (used in) financing activities	237	(1,026)
Net decrease in cash and cash equivalents	(25,790)	(27,552)
Cash and cash equivalents, end of the period	\$65,761	\$127,797

Operating Activities

For the six months ended June 30, 2017, net cash used in operating activities was primarily the result of a net loss of \$44.3 million, offset by non-cash charges of \$7.2 million and a net cash inflow from changes in operating assets and liabilities of \$11.1 million. Non-cash charges primarily consisted of stock-based compensation, inventory write-down and impairment charges for long-lived assets related to our Endo supply agreement, and changes in fair value of mark-to-market warrants and contingent consideration. The increase in cash provided by operating assets and liabilities was primarily attributable to a \$7.9 million decrease in trade accounts receivable as we received payment from Endo for previously delivered product. Cash outflows from changes in operating assets and liabilities include

inventory, accounts payable and accrued expenses due to the timing of inventory receipts and vendor payments. For the six months ended June 30, 2016, net cash used in operating activities was primarily the result of a net loss of \$29.2 million, offset by non-cash charges of \$1.7 million and a net cash outflow from change in operating assets and liabilities of \$8.9 million.

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Investing Activities

For the six months ended June 30, 2017, net cash used in investing activities was minimal. As of April 2017, we have no further obligation to supply Endo with additional Sumavel DosePro. As a result, we expect capital expenditures for the remainder of 2017 to be minimal.

For the six months ended June 30, 2016, net cash provided by investing activities was primarily attributable to \$10.0 million of cash released from an escrow account in connection with the sale of our Zohydro ER business in 2015.

Financing Activities

For the six months ended June 30, 2017, net cash provided by financing activities was due to proceeds from issuance of common stock under employee stock plans.

For the six months ended June 30, 2016, net cash used in financing activities was primarily attributable to principal payments made on our term loan, offset by proceeds from issuance of common stock under employee stock plans and proceeds from our amended term loan with Oxford Finance LLC and Silicon Valley Bank.

Debt Obligations

As of June 30, 2017, we were in compliance with all covenants under our term loan. There are no covenants related to our working capital advance note payable. Our term loan agreement includes a material adverse change clause, which enables the lenders to require immediate repayment of the outstanding debt if certain subjective acceleration provisions are triggered. The material adverse change clause covers provisions including a material impairment of underlying collateral, change in business operations or condition or material impairment of our prospects for repayment of any portion of the remaining debt obligation. To date, we have not received any notification from the Lenders that we are not in compliance with this clause. For a detailed description of our debt obligations, see Note 6 of Notes to Condensed Consolidated Financial Statements included elsewhere in the Quarterly Report.

Contractual Obligations

There were no material changes outside the ordinary course of our business during the six months ended June 30, 2017 to the information regarding our contractual obligations that was disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2016.

Off-Balance Sheet Arrangements

As of June 30, 2017, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There have been no material changes in market risk from the information provided in "Item 7A. Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the year ended December 31, 2016.

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, or the SEC'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 SEC 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

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operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2017 at the reasonable assurance level.

Changes in Disclosure Controls and Procedures

There were no changes in our internal control over financial reporting during the six months ended June 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II – OTHER INFORMATION

Item 1. Legal Proceedings

There have been no material updates to the legal proceedings as set forth in “Item 3. Legal Proceedings” in our Annual Report on Form 10-K for the year ended December 31, 2016.

Item 1A. Risk Factors

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in addition to the risk factors set in our Annual Report on Form 10-K and our other information contained in our public filings with the Securities and Exchange Commission, or SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations. Other than as set forth below, there have been no material changes to the risk factors described in Part 1, Item 1A in our Annual Report on Form 10-K for the year ended December 31, 2016. Our success depends substantially on our only product candidate, ZX008. We cannot be certain that our product candidate will receive regulatory approval or be successfully commercialized.

We have only one product candidate in development, and our business depends substantially on its successful development and commercialization. Following the completion of the sale of our Zohydro ER business in April 2015, we have no drug products approved for sale, and we may not be able to develop marketable drug products in the future. Following the termination of the development and license agreement with Durect in August 2017, our sole product candidate is ZX008. ZX008, our sole product candidate, and any future product candidates, will require additional clinical and pre-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenues from product sales. The research, testing, manufacturing, labeling, approval, sale, marketing, distribution and promotion of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, whose regulations differ from country to country.

We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries, and we may never receive such regulatory approvals. Obtaining regulatory approval for a product candidate is a lengthy, expensive and uncertain process, and may not be successful. Any failure to obtain regulatory approval of ZX008, or failure to obtain such approval for all of the indications and labeling claims we deem desirable, would limit our ability to generate future revenues, would potentially harm the development prospects of our ZX008 and would have a material and adverse impact on our business.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

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Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
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- | | |
|--------|--|
| 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 |
| 31.1 | Certification of Chief Executive Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted) |
| 31.2 | Certification of Chief Financial Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted) |
| 32.1* | Certification of Chief Executive Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted) |
| 32.2* | Certification of Chief Financial Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted) |
| 101 | The following financial statements from the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2017 formatted in XBRL: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to Condensed Consolidated Financial Statements. |

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- (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.

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

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SIGNATURES

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

ZOGENIX, INC.

Date: August 8, 2017 By: /s/ Stephen J. Farr
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 8, 2017 By: /s/ Michael P. Smith
Executive Vice President, Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)