

ZOGENIX, INC.  
 Form 10-Q  
 August 06, 2018  
Table of Contents

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, 2018

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

Edgar Filing: ZOGENIX, INC. - Form 10-Q

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 July 31, 2018 was 35,826,933.

---

Table of Contents

ZOGENIX, INC.  
FORM 10-Q  
For the Quarterly Period Ended June 30, 2018  
Table of Contents

	Page
<u>PART I. FINANCIAL INFORMATION</u>	
Item 1 <u>Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets as of June 30, 2018 and December 31, 2017</u>	<u>3</u>
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Six Months Ended June 30, 2018 and 2017</u>	<u>4</u>
<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2018 and 2017</u>	<u>5</u>
<u>Notes to the Condensed Consolidated Financial Statements</u>	<u>6</u>
Item 2 <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>15</u>
Item 3 <u>Quantitative and Qualitative Disclosures about Market Risk</u>	<u>21</u>
Item 4 <u>Controls and Procedures</u>	<u>21</u>
<u>PART II. OTHER INFORMATION</u>	
Item 1 <u>Legal Proceedings</u>	<u>23</u>
Item 1A <u>Risk Factors</u>	<u>23</u>
Item 2 <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>23</u>
Item 3 <u>Defaults Upon Senior Securities</u>	<u>23</u>
Item 4 <u>Mine Safety Disclosures</u>	<u>23</u>
Item 5 <u>Other Information</u>	<u>24</u>
Item 6 <u>Exhibits</u>	<u>25</u>
<u>Signatures</u>	<u>26</u>

Table of Contents

## PART I – FINANCIAL INFORMATION

## Item 1. Financial Statements

Zogenix, Inc.

## Condensed Consolidated Balance Sheets (Unaudited)

(in thousands, except par value)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 272,103	\$ 293,503
Prepaid expenses	9,089	5,994
Other current assets	3,933	5,206
Total current assets	285,125	304,703
Property and equipment, net	279	245
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	1,040	3,931
Total assets	\$ 395,178	\$ 417,613
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,434	\$ 3,356
Accrued clinical trial expenses	12,160	8,657
Accrued compensation	3,267	6,616
Other accrued liabilities	2,501	1,842
Contingent consideration, current portion	18,500	—
Common stock warrant liabilities	543	512
Total current liabilities	41,405	20,983
Contingent consideration	55,900	76,900
Deferred income taxes	17,425	17,425
Other long-term liabilities	582	784
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000 shares authorized; none issued and outstanding	—	—
	36	35

Common stock, \$0.001  
par value; 50,000 shares  
authorized; 35,827 and  
34,808 shares issued  
and outstanding at June  
30, 2018 and December  
31, 2017, respectively

Additional paid-in capital	911,087		873,526	
Accumulated deficit	(631,257	)	(572,040	)
Total stockholders' equity	279,866		301,521	
Total liabilities and stockholders' equity	\$	395,178	\$	417,613

See accompanying notes to the unaudited condensed consolidated financial statements.

Table of Contents

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,	
	2018	2017	2018	2017
Contract manufacturing revenue	\$—	\$7,125	\$—	\$9,821
Costs and expenses:				
Cost of contract manufacturing	—	8,242	—	10,729
Research and development	26,741	14,850	49,721	28,191
Selling, general and administrative	8,577	5,502	16,647	12,056
Asset impairment charges	—	107	—	920
Change in fair value of contingent consideration	(2,500 )	500	(2,500 )	1,100
Total costs and expenses	32,818	29,201	63,868	52,996
Loss from operations	(32,818 )	(22,076 )	(63,868 )	(43,175 )
Other income (expense):				
Interest income	1,029	117	1,862	211
Interest expense	—	(692 )	(6 )	(1,363 )
Change in fair value of common stock warrant liabilities	(48 )	153	(31 )	740
Other income, net	2,998	29	3,024	9
Total other income (expense)	3,979	(393 )	4,849	(403 )
Loss from continuing operations before income taxes	(28,839 )	(22,469 )	(59,019 )	(43,578 )
Income tax benefit (expense)	—	16	—	(1 )
Net loss from continuing operations	(28,839 )	(22,453 )	(59,019 )	(43,579 )
Loss from discontinued operations, net of taxes	(198 )	(555 )	(198 )	(736 )
Net loss	\$(29,037)	\$(23,008)	\$(59,217)	\$(44,315)
Net loss per share, basic and diluted:				
Continuing operations	\$(0.82 )	\$(0.90 )	\$(1.68 )	\$(1.76 )
Discontinued operations	\$(0.01 )	\$(0.03 )	\$(0.01 )	\$(0.03 )
Total	\$(0.83 )	\$(0.93 )	\$(1.69 )	\$(1.79 )
Weighted average common shares used in the calculation of basic and diluted net loss per common share	35,355	24,822	35,099	24,817
Comprehensive loss	\$(29,037)	\$(23,008)	\$(59,217)	\$(44,315)

See accompanying notes to the unaudited condensed consolidated financial statements.

Table of Contents

Zogenix, Inc.

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

	Six Months Ended	
	June 30,	
	2018	2017
Operating activities:		
Net loss	\$(59,217 )	\$(44,315)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	4,971	2,804
Depreciation and amortization	50	366
Amortization of debt issuance costs and debt discount	—	506
Inventory write-down	—	2,232
Asset impairment charges	—	920
Change in fair value of common stock warrant liabilities	31	(740 )
Change in fair value of contingent consideration	(2,500 )	1,100
Changes in operating assets and liabilities:		
Trade accounts receivable	—	7,893
Inventory	—	2,583
Prepaid expenses and other current assets	(3,482 )	2,602
Other assets	2,891	(848 )
Accounts payable, accrued and other liabilities	1,689	150
Deferred revenue	—	(1,245 )
Net cash used in operating activities	(55,567 )	(25,992 )
Investing activities:		
Purchases of property and equipment	(84 )	(35 )
Net cash used in investing activities	(84 )	(35 )
Financing activities:		
Proceeds from issuance of common stock under equity incentive plans	5,427	237
Taxes paid related to net share settlement of equity awards	(1,426 )	—
Proceeds from issuance of common stock under an at-the-market offering, net of issuance costs	30,250	—
Net cash provided by financing activities	34,251	237
Net decrease in cash and cash equivalents	(21,400 )	(25,790 )
Cash and cash equivalents, beginning of the period	293,503	91,551
Cash and cash equivalents, end of the period	\$272,103	\$65,761
See accompanying notes to the unaudited condensed consolidated financial statements.		

Table of Contents

Zogenix, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

Note 1 – Organization and Basis of Presentation

Zogenix, Inc., including its wholly-owned subsidiaries (the “Company”), is a pharmaceutical company developing and commercializing innovative central nervous system (“CNS”) therapies for people living with serious and life-threatening rare CNS disorders and medical conditions. The Company’s current primary area of therapeutic focus is rare, or “orphan” 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. The Company operates in one business segment—the research, development and commercialization of pharmaceutical products and its headquarters are located in Emeryville, California.

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. Certain reclassifications have been made to the prior period amounts to conform to the current year presentation. “Accrued clinical trial expenses” and “Other accrued liabilities”, which previously were reported as “Accrued expenses” on the condensed consolidated balance sheet, are now reported as separate line items. Additionally, previously reported “Interest expense, net” have been reclassified to present interest income and interest expense separately in the accompanying condensed consolidated statements of operations and comprehensive loss. 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, 2017, which was filed with the SEC on March 6, 2018.

Future Funding Requirements

Excluding gains from two discrete business divestitures, the Company has incurred significant net losses and negative cash flows from operating activities since inception resulting in an accumulated deficit of \$631.3 million at June 30, 2018. The Company expects to continue to incur significant operating losses and negative cash flows from operations to advance its product candidates through development and commercialization. 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”) and regulatory approval of ZX008 by the FDA or 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. To date, the Company has relied primarily on the proceeds from equity offerings to finance its operations. Until such time, if ever, the Company can generate a sufficient amount of revenue to finance its cash requirements, the Company may need to continue to rely on additional financing to achieve its business objectives. However, if such financing is not available at adequate levels when needed, the Company may be required to significantly delay, scale back or discontinue one or more of the product development programs or commercialization efforts or other aspects of its business plans, and its operating results and financial condition would 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.

Significant Accounting Policies

There have been no material changes to the Company's significant accounting policies during the six months ended June 30, 2018, as compared to the significant accounting policies described in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

Accounting Pronouncements Recently Adopted

Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606) and subsequent amendments to the initial guidance (collectively, "Topic 606") amended the existing accounting standards for revenue recognition. 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. The Company adopted Topic 606 effective January 1, 2018 using the modified retrospective approach. The adoption of Topic 606 did not have a material impact on the Company's condensed consolidated financial statements as the Company does not have any contracts with customers.

ASU 2016-15, Statement of Cash Flows (Topic 230) provides guidance on eight specific cash flow issues, thereby reducing the diversity in practice in how certain transactions are classified in the statement of cash flows. The amendments in this ASU are applied using a retrospective transition method to each period presented. The Company adopted ASU 2016-15 effective January 1, 2018. The adoption of this accounting standards update did not have a material impact on the Company's condensed consolidated financial statements.

ASU 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business narrows the definition of a business and provides additional guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This accounting standards update is required to be applied prospectively to transactions occurring after the date of adoption. The Company adopted ASU 2017-09 effective January 1, 2018. The impact of the adoption on the Company's condensed consolidated financial statements was not material but could impact future acquisitions, if any.

ASU 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting provides guidance on determining changes to the terms and conditions of share-based payment awards and require an entity to apply modification accounting under Topic 718 unless all of the following conditions are met: (1) the fair value of the modified award is the same as the fair value of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification; (2) the vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified; and (3) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The amendments should be applied prospectively to an award modified on or after the adoption date. The Company adopted ASU 2017-09 effective January 1, 2018. The adoption of this accounting standards update did not have a material impact on the Company's condensed consolidated financial statements.

On December 22, 2017, the U.S. federal government enacted the Tax Cuts and Jobs Act ("the Act"). The Tax Act contains, among other things, significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21% for tax years beginning after December 31, 2017, limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, implementing a territorial tax system, and requiring a mandatory one-time tax on U.S. owned undistributed foreign earnings and profits known as the transition tax. In December 2017, SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act ("SAB 118") to address the accounting implications of recently enacted U.S. federal tax reform. SAB 118 allows companies to record provisional amounts during a measurement period not to extend beyond one year of the enactment date to address ongoing guidance and tax interpretations that are expected over the next 12 months. The Company has adopted SAB

118 and currently considers its accounting of the impact of U.S. federal tax reform to be incomplete but continues to make a reasonable estimate of the effects on our existing deferred tax assets. The Company expects to complete the remainder of the analysis within the measurement period in accordance with SAB 118. Adjustments, if any, are

7

---

not expected to impact the condensed consolidated statement of operations and comprehensive loss due to the full valuation allowance on the Company's deferred tax assets.

#### Accounting Pronouncements Issued But Not Yet Effective

ASU 2016-02, Leases (Topic 842) establishes a right-of-use model ("ROU") that requires all lessees to recognize ROU assets and liabilities for leases with a duration greater than one year on the balance sheet as well as provide disclosures with respect to certain qualitative and quantitative information regarding the amount, timing and uncertainty of cash flows arising from leases. Both a ROU asset and liability will initially be measured at the present value of the future minimum lease payments over the lease term. Subsequent measurement, including the presentation of expenses and cash flows, will depend on the classification of the lease as either a finance or an operating lease. Initial costs directly attributable to negotiating and arranging the lease will be included in the asset. The new standard is effective for fiscal years beginning after December 15, 2018, and interim periods therein. Early adoption is permitted. Originally, entities were required to adopt ASU 2016-02 using a modified retrospective approach, which required prior periods to be presented under this new standard with various practical expedients allowed. In July 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-11, Leases (Topic 842): Targeted Improvements, which now allows entities the option of recognizing the cumulative effect of applying the new standard as an adjustment to the opening balance of retained earnings in the year of adoption (January 1, 2019) while continuing to present all prior periods under previous lease accounting guidance. The Company intends to adopt the standard on January 1, 2019 by recognizing a cumulative effect adjustment to the opening balance of retained earnings and utilizing the practical expedient that allows the Company to not reassess whether an expired or existing contract contains a lease, the classification of leases or initial direct costs. The Company is in the process of inventorying and scoping its existing lease contracts. While the Company is currently evaluating the impact of adopting this accounting standard update on its condensed consolidated financial statements and related disclosures, the Company anticipates that ROU assets corresponding liabilities will be recognized in its condensed consolidated balance sheets related to its lease arrangements. The adoption of this accounting standard update is also expected to impact the Company's condensed consolidated financial statement disclosures.

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 accounting standard update on its condensed consolidated financial statements and related disclosures.

#### Note 3 – Fair Value Measurements

The carrying amount of the Company's financial instruments, including cash and cash equivalents, other current assets, accounts payable, accrued expenses and accrued compensation approximate their fair value due to their short maturities.

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, 2018 and December 31, 2017 were as follows (in thousands):



Table of Contents

	Fair Value Measurements at Reporting Date			
	Using			
	Quoted			
	Prices in			
	Significant	Significant		
	Other	Unobservable	Total	
	Observable	Inputs		
	Inputs	(Level 3)		
	(Level 2)			
	Assets			
	(Level 1)			
June 30, 2018				
Assets				
Cash equivalents <sup>(1)</sup>	\$252,894	\$ —	\$ —	\$252,894
Liabilities				
Common stock warrant liabilities <sup>(2)</sup>	\$ —	\$ —	\$ 543	\$543
Contingent consideration liabilities <sup>(3)</sup>	\$ —	\$ —	\$ 74,400	\$74,400
December 31, 2017				
Assets				
Cash equivalents <sup>(1)</sup>	\$289,782	\$ —	\$ —	\$289,782
Liabilities				
Common stock warrant liabilities <sup>(2)</sup>	\$ —	\$ —	\$ 512	\$512
Contingent consideration liabilities <sup>(3)</sup>	\$ —	\$ —	\$ 76,900	\$76,900

(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) 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, 2017 and June 30, 2018, 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 a prior 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 and risk-adjusted interest rates. 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).

As of June 30, 2018, the Company has classified \$18.5 million of the total fair value of its contingent consideration liability based upon the Company's reasonable expectation as to the timing of when the milestone payments associated with the acceptance of the Company's regulatory submissions for ZX008 by the FDA and EMA will be made.

There were no transfers between levels during the periods presented.

Table of Contents

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, 2018 and 2017 (in thousands):

	March 31, 2018	Change in Fair Value	June 30, 2018	March 31, 2017	Change in Fair Value	June 30, 2017
Contingent consideration liabilities	\$76,900	\$(2,500)	\$74,400	\$53,400	\$ 500	\$53,900
Common stock warrant liabilities	495	48	543	222	(153 )	69

  

	December 31, 2017	Change in Fair Value	June 30, 2018	December 31, 2016	Change in Fair Value	June 30, 2017
Contingent consideration liabilities	\$ 76,900	\$(2,500)	\$74,400	\$ 52,800	\$ 1,100	\$53,900
Common stock warrant liabilities	512	31	543	809	(740 )	69

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 4 – Commitments and Contingencies

## Leases

The Company has two noncancelable operating leases consisting of administrative and research and development office space for its Emeryville, California headquarters and former headquarters in San Diego, California that expire in November 2022 and March 2020, respectively. The former headquarters has been subleased to an unrelated third party for the remainder of the Company's original lease term. Future minimum lease payments under our non-cancellable operating leases at June 30, 2018, net of sublease income, were as follows (in thousands):

	Gross Lease Payments	Sublease Income	Net Lease Payments
2018 (remaining 6 months)	\$ 952	\$(258 )	\$ 694
2019	1,955	(576 )	1,379
2020	1,234	(148 )	1,086
2021	1,004	—	1,004
2022	946	—	946
Total	\$ 6,091	\$(982 )	\$ 5,109

## Legal Matters

The Company is not currently involved in any material legal proceedings. The Company may become involved in various legal proceedings and claims that arise in the ordinary course of business. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on its business, results of operations, financial position or cash flows.

## Note 5 – Stockholders' Equity

The Company currently has an at-the-market ("ATM") sales agreement with Cantor Fitzgerald & Co. ("Cantor") as sales agent, pursuant to which the Company may offer and sell, from time to time, through Cantor, shares of its common stock having an aggregate offering price of up to \$75.0 million under a previously filed and effective registration statement on Form S-3 (File No. 333-220759) and a prospectus supplement filed in December 2017. Cantor is entitled to a commission at a fixed commission rate of up to 3.0% of the gross proceeds of the sales price of all common stock sold under the ATM sales agreement. The Company and Cantor may each terminate the ATM sales agreement at any time upon ten days' prior notice.

In the second quarter of 2018, the Company issued a total of 740,417 shares of its common stock under the ATM offering program and received net proceeds of approximately \$30.3 million after deducting \$1.1 million of commissions and other offering expenses.





Table of Contents

## Note 6 – 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, 2017.

In March 2018, our board of directors approved an amendment and restatement of our non-employee director compensation policy, pursuant to which any non-employee director who is first elected to the board of directors is granted an option to purchase 20,000 shares of our common stock on the date of his or her initial election to the board of directors. In addition, on the date of each annual meeting of our stockholders, commencing with the 2018 annual meeting, each non-employee director is eligible to receive an option to purchase 15,000 shares of common stock. Prior to March 2018, under our non-employee director compensation policy, any non-employee director who was first elected to the board of directors was granted an option to purchase 30,000 shares of our common stock on the date of his or her initial election to the board of directors. In addition, on the date of each annual meeting of our stockholders, each non-employee director was eligible to receive an option to purchase 20,000 shares of common stock.

## Equity Incentive Awards Activity

## Stock Options

The following is a summary of stock option activity for the six months ended June 30, 2018 (in thousands, except per share data):

	Shares (in thousands)	Weighted- Average Exercise Price per Share
Outstanding at December 31, 2017	3,392	\$ 14.41
Granted	657	42.14
Exercised	(193 )	17.78
Canceled	(19 )	21.90
Outstanding at June 30, 2018	3,837	\$ 18.95

## Restricted Stock Units

The following is a summary of restricted stock unit activity for the six months ended June 30, 2018 (in thousands, except per share data):

	Shares (in thousands)	Weighted- Average Fair Value per Share at Grant Date
Outstanding as of December 31, 2017	259	\$ 10.43
Granted	131	42.65
Vested	(98 )	10.74
Canceled	(2 )	42.65
Outstanding as of June 30, 2018	290	\$ 24.61

Table of Contents

As of June 30, 2018, outstanding restricted stock units included 162,000 granted in March 2017 with performance-based conditions to employees and executives. The restricted stock units vest upon the approval of the Company's new drug application for ZX008 by the FDA, 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 to date for these performance-based awards.

Valuation of Equity Awards

The estimated grant date fair value of the stock options was estimated using the Black-Scholes option pricing model, based on the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Risk free interest rate	2.6% to 2.9%	1.9% to 2.0%	2.3% to 2.9%	1.9% to 2.3%
Expected term	5.3 to 6.1 years	5.1 to 6.1 years	5.3 to 6.1 years	5.1 to 6.1 years
Expected volatility	80.1% to 83.6%	76.0% to 76.3%	80.1% to 85.2%	76.0% to 76.6%
Expected dividend yield	—%	—%	—%	—%

The fair value of restricted stock units granted is determined based on the price of the Company's common stock on the date of grant.

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 Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Cost of contract manufacturing	\$—	\$(6)	\$—	\$71
Research and development	1,062	502	1,743	1,019
Selling, general and administrative	1,997	635	3,228	1,714
Total	\$3,059	\$1,131	\$4,971	\$2,804

Note 7 – 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Numerator:				
Net loss from continuing operations	\$(28,839)	\$(22,453)	\$(59,019)	\$(43,579)
Denominator:				
Shares used in per share calculation	35,355	24,822	35,099	24,817

Net loss from continuing operations per share, basic and diluted \$(0.82 ) \$(0.90 ) \$(1.68 ) \$(1.76 )

12

---

Table of Contents

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 Ended June 30, 2018		Six Months Ended June 30, 2017	
Shares subject to outstanding common stock options	3,816	4,020	3,648	3,756
Shares subject to outstanding restricted stock units	292	273	279	205
Shares subject to outstanding warrants to purchase common stock	38	1,975	38	1,975
Total	4,146	6,268	3,965	5,936

Table of Contents

Note 8 – United Kingdom (U.K.) Research and Development Incentives

The Company carries out extensive research and development activities that benefit from the U.K.'s small and medium-sized enterprise ("SME") research and development tax credit regime, whereby the Company may either receive an enhanced U.K. tax deduction on its eligible research and development activities or, when an SME entity is in a net operating loss position, elect to surrender net operating losses that arise from its eligible research and development activities in exchange for a cash payment from the U.K. tax authorities. These refundable cash credits, which may be received without regard to actual tax liability, are not subject to accounting for income taxes and have been recorded as a component of other income.

As of December 31, 2017, the Company had filed a claim as an SME for a \$3.0 million refundable cash credit for its 2015 tax year for qualifying research and development activities incurred in that year. The claim was accrued for as a receivable within other current assets at June 30, 2018 based on communication from the U.K. tax authorities in June 2018 and subsequent receipt of the cash in July 2018. The Company has not filed claims for any refundable cash credit for its 2016 or 2017 tax years, nor has it recorded any balances related to claims for these years or for the 2018 tax year, as collectability is deemed not probable or reasonably assured.

Table of Contents

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

Forward-Looking Statements

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

- the progress and timing of clinical trials 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; 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 comparative 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, 2017 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, 2017.

Overview

We are a pharmaceutical company developing and commercializing innovative central nervous system (“CNS”) therapies for people living with serious and life-threatening rare CNS disorders and medical conditions. Our current primary area of therapeutic focus is rare, or “orphan” childhood-onset epilepsy disorders.

We currently own and control worldwide development and commercialization rights to ZX008, our lead Phase 3 product candidate. ZX008 is low-dose fenfluramine for the treatment of seizures associated with two rare and catastrophic forms of childhood-onset epilepsy: Dravet syndrome and Lennox-Gastaut syndrome, or LGS. ZX008 for Patients with Dravet Syndrome

Dravet syndrome is a rare form of pediatric-onset 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 the European

15

---

## Table of Contents

Union (the “EU”) for the treatment of Dravet syndrome. In addition, ZX008 for the treatment of Dravet syndrome received Fast Track designation from the FDA in January 2016 and Breakthrough Therapy designation in February 2018.

### Study 1501 and 1502 (“Study 1”)

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 prospective merged study analysis approach whereby top-line results from the first approximately 120 subjects randomized into either Study 1501 or 1502 would have their study results analyzed and be reported initially as “Study 1”. In April 2017, we completed enrollment of Study 1 and, in September 2017, we announced positive top-line results for the 119 patients included in the Study 1 Phase 3 trial. The Study 1 trial met its primary objective of demonstrating that ZX008, at a dose of 0.8 mg/kg/day, is superior to placebo as adjunctive therapy in the treatment of Dravet syndrome in children and young adults based on change in the frequency of convulsive seizures between the 6-week baseline observation period and the 14-week treatment period ( $p < 0.001$ ). In the trial, ZX008 at a dose of 0.8 mg/kg/day also demonstrated statistically significant improvements versus placebo in all key secondary measures, including the proportion of patients with clinically meaningful reductions in seizure frequency (50% or greater) and longest seizure-free interval. The same analyses comparing a 0.2 mg/kg/day ZX008 dose versus placebo also demonstrated statistically significant improvement compared with placebo. ZX008 was generally well tolerated without any signs or symptoms of valvulopathy or pulmonary hypertension.

### Study 1504

In September 2016, we initiated Part 1 of Study 1504, a two-part, double blind, randomized, two arm pivotal Phase 3 clinical trial of ZX008 in Dravet syndrome patients who are taking stiripentol, valproate and/or clobazam as part of their baseline standard care. Part 1 investigated the pharmacokinetic profile and safety of ZX008 when co-administered with the stiripentol regimen (stiripentol, valproate and/or clobazam). Based on the results of the pharmacokinetic and safety portion of the trial, in February 2017 we initiated the safety and efficacy portion of Study 1504, a two-arm study that compared ZX008 versus placebo across the titration and 12-week maintenance periods at multiple sites, which included sites in France, the Netherlands, United States, Canada, Germany, the United Kingdom and Spain. In January 2018, patient enrollment was completed at 87 patients and randomized between the ZX008-arm ( $n=43$ ) or placebo ( $n=44$ ).

### Announcement of Top-line Clinical Trial Results for Study 1504

On July 12, 2018, we reported positive top-line results from Study 1504. The study results, which are consistent with those reported in Study 1, successfully met the primary objective of demonstrating that ZX008, at a dose of 0.5 mg/kg/day, is superior to placebo as adjunctive therapy in the treatment of Dravet syndrome in children and young adults based on change in the frequency of convulsive seizures between the 6-week baseline observation period and the 15-week treatment period ( $p < 0.001$ ). In the trial, ZX008 at a dose of 0.5 mg/kg/day also demonstrated statistically significant improvements versus placebo in both key secondary measures, the proportion of patients with clinically meaningful reductions in seizure frequency (50% or greater) and longest seizure-free interval. ZX008 was generally well-tolerated in this study, with the adverse events consistent with those observed in Study 1 and the known safety profile of fenfluramine. We believe we are on track to submit applications for regulatory approvals for ZX008 in the United States and Europe in the fourth quarter of 2018.

### ZX008 for Patients with LGS

LGS is another rare, refractory, debilitating pediatric-onset epilepsy with life threatening consequences for patients and for which current treatment options are very limited. Beginning in first quarter of 2016, we funded an open-label, dose-finding, investigator-initiated study of the effectiveness and tolerability of ZX008 as an adjunctive therapy in patients with LGS. 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 clinical trial at the 70<sup>th</sup> Annual Meeting of the American Epilepsy Society. These data demonstrated that ZX008 provided clinically meaningful improvement in major motor seizure frequency in patients with severe refractory LGS, with 7 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 allowed dose. In addition, ZX008 was generally well tolerated without any observed signs or symptoms of valvulopathy or pulmonary hypertension. We believe these data indicate that ZX008 has the potential to be a safe and effective adjunctive treatment of major motor seizures for patients with LGS. Based on the strength of the LGS data generated, in the first quarter of 2017, we submitted an investigational new drug (“IND”) application to the FDA to initiate a Phase 3 program of ZX008 in LGS, which became effective in April 2017. In the first half of 2017, ZX008 received orphan drug designation for the treatment of LGS from the FDA in the United States and the European Medicines Agency (“EMA”) in the EU.

Table of Contents

## Study 1601

In November 2017, we announced the initiation of our multicenter global Phase 3 clinical trial of ZX008 as an adjunctive treatment for seizures in patients with LGS (“Study 1601”). Study 1601 is planned for up to 85 sites in North America, Europe, Asia-Pacific, South America, South Africa and Australia and is divided in two parts. Part 1 is a double-blind, placebo-controlled investigation to assess the safety, tolerability and efficacy of ZX008, low-dose fenfluramine, when added to a patient’s current anti-epileptic therapy. The trial will include two dose levels of ZX008 (0.2 mg/kg/day and 0.8 mg/kg/day, up to a maximum daily dose of 30 mg), as well as placebo. After establishing baseline seizure frequency for 4 weeks, randomized patients will be titrated to their dose over a 2-week titration period, followed by a 12-week fixed dose maintenance period. We are targeting a total of 225 randomized patients (75 per treatment arm) in the trial. The primary endpoint of the clinical trial is change in the number of seizures that result in drops between baseline and the combined titration and maintenance periods at the 0.8 mg/kg/day dose. The key secondary endpoints include change in the number of seizures that result in drops between baseline and the combined titration and maintenance periods at the 0.2 mg/kg/day dose, and the proportion of patients achieving a 50 percent reduction in drop seizures. Part 2 of the clinical trial will be a 12-month open-label extension to evaluate the long-term safety, tolerability and effectiveness of ZX008.

## 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 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 and indefinite-lived intangible assets, estimated fair value of contingent consideration, accrued clinical trial expenses and the related prepaid expenses, stock-based compensation and income taxes have the greatest potential impact on our 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, 2018, 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, 2017.

## Recent Accounting Pronouncements

For information with respect to recent accounting pronouncements that are of significance or potential significance to us, see Note 2 “Summary of Significant Accounting Policies” in the notes to condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

## Results of Operations

## Comparison of Three and Six Months Ended June 30, 2018 and 2017

## Contract Manufacturing Revenue

	Three Months		Six Months Ended	
	Ended June 30,		June 30,	
(in thousands)	2018	Change	2017	Change
Contract manufacturing revenue	\$-7,125	\$(7,125)	\$-9,821	\$(9,821)

Through April 2017, we generated contract manufacturing revenue from supplying Sumavel DosePro to Endo International plc (“Endo”), who purchased our Sumavel DosePro business in May 2014. In September 2017, we and Endo terminated the supply agreement. As a result, we did not generate any contract manufacturing revenue in the three and six months ended June 30, 2018 and no longer have any contracts with customers.

Table of Contents

## Cost of Contract Manufacturing

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Cost of contract manufacturing	\$8,242	\$(8,242)	\$10,729	\$(10,729)

We did not incur contract manufacturing costs during the three and six months ended June 30, 2018 as a result of the aforementioned termination of the supply agreement to manufacture and supply Sumavel DosePro to Endo.

## Research and Development Expenses

(in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2018	2017	Change	2018	2017	Change
Research and development	\$26,741	\$14,850	\$11,891	\$49,721	\$28,191	\$21,530

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 (“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,		
	2018	2017	Change	2018	2017	Change
ZX008	\$19,415	\$9,398	\$10,017	\$35,983	\$18,591	\$17,392
Other <sup>(1)</sup>	7,326	5,452	1,874	13,738	9,600	4,138
Total	\$26,741	\$14,850	\$11,891	\$49,721	\$28,191	\$21,530

(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 increased by \$11.9 million and \$21.5 million for the three and six months ended June 30, 2018, respectively, compared to the same periods in 2017. The increase reflects the progression and expansion of our clinical trial activities related to our ongoing Phase 3 development program of ZX008 in Dravet syndrome. In addition, the increase in the three and six months ended June 30, 2018 was also due to research and development activities for our Phase 3 clinical trial of ZX008 as an adjunctive treatment for seizures in patients with LGS, which was initiated in November 2017.

## Selling, General and Administrative Expenses

(in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2018	2017	Change	2018	2017	Change
Selling	\$2,266	\$1,127	\$1,139	\$4,711	\$2,423	\$2,288
General and administrative	6,311	4,375	1,936	11,936	9,633	2,303
Total selling, general and administrative	\$8,577	\$5,502	\$3,075	\$16,647	\$12,056	\$4,591



Table of Contents

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 increased by \$1.1 million and \$2.3 million for the three and six months ended June 30, 2018, respectively, compared to the same periods in 2017. The increase was primarily attributable to costs incurred for market research and commercialization planning as we prepare for the potential commercialization of ZX008 for Dravet syndrome.

General and administrative expense increased by \$1.9 million and \$2.3 million for the three and six months ended June 30, 2018, respectively, compared to the same periods in 2017 and was primarily attributable to personnel-related costs, including stock-based compensation, due to increases in headcount.

Impairment Charges

	Three Months		Six Months			
	Ended June 30,		Ended June 30,			
(in thousands)	2018	2017	Change	2018	2017	Change
Asset impairment charges	\$—	\$107	\$(107)	\$—	\$920	\$(920)

Asset impairment charges for the three and six months ended June 30, 2017 primarily resulted from the wind down of our contract manufacturing operations.

Change in Fair Value of Contingent Consideration

	Three Months Ended			Six Months Ended June		
	June 30,			30,		
(in thousands)	2018	2017	Change	2018	2017	Change
Change in fair value of contingent consideration	\$(2,500)	\$500	\$(3,000)	\$(2,500)	\$1,100	\$(3,600)

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.

For the three and six months ended June 30, 2018, we recorded a noncash unrealized gain of \$2.5 million to reflect a decrease in the present value of the financial liability resulting from an adjustment to the discount rate used based on current market conditions. For the three and six months ended June 30, 2017, the change in fair value of contingent consideration expense was primarily due to a shorter discount period to reflect the passage of time.

Other Income (Expense)

	Three Months Ended			Six Months Ended June		
	June 30,			30,		
(in thousands)	2018	2017	Change	2018	2017	Change
Other income (expense)	\$3,979	\$(393)	\$4,372	\$4,849	\$(403)	\$5,252

Other income (expense) generally consists of interest income, interest expense, 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.

For the three and six months ended June 30, 2018, the increase in other income compared to the same periods in 2017 was primarily attributable to a \$3.0 million claim for cash payment under the U.K.'s small and medium-sized enterprise and research and development tax credit regime ("SME Regime") for qualifying expenditures incurred in the 2015 tax year. The remainder of the increase was due to an increase in interest income earned from higher cash balances and a decrease in interest expense as we repaid our debt in full in December 2017.

Liquidity and Capital Resources

Excluding gains from two discrete business divestitures, we have incurred significant net losses and negative cash flows from operating activities since inception. We had an accumulated deficit of \$631.3 million at June 30, 2018. To

date, we have

19

---

Table of Contents

relied primarily on the proceeds from equity offerings to finance our operations. We expect to continue to incur significant operating losses and negative cash flows from operations to advance our product candidates through development and commercialization. Additionally, upon acceptance of our regulatory submissions for ZX008 by the FDA or the EMA and regulatory approval of ZX008 by the FDA or 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. We currently do not engage in any revenue-generating activities. We do not know when, or if, we will generate any revenue from product sales and do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize ZX008. As of June 30, 2018, we had cash and cash equivalents of \$272.1 million.

We currently have an at-the-market (“ATM”) sales agreement with Cantor Fitzgerald & Co. (“Cantor”) as sales agent, pursuant to which we may offer and sell, from time to time, through Cantor, shares of our common stock having an aggregate offering price of up to \$75.0 million under our previously filed and effective registration statement on Form S-3 (File No. 333-220759) and a prospectus supplement filed in December 2017. Cantor is entitled to a commission at a fixed commission rate of up to 3.0% of the gross proceeds of the sales price of all common stock sold under the ATM sales agreement. We and Cantor may each terminate the ATM Agreement at any time upon ten days’ prior notice.

In the second quarter of 2018, we issued a total of 740,417 shares of our common stock under the ATM offering program and received net proceeds of approximately \$30.3 million after deducting \$1.1 million of commissions and other offering expenses.

Our principal uses of cash are research and development expenses, selling, general and administrative expenses and other working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of our clinical trials and other product development programs for ZX008 and our other product candidates and any other product candidates that we may develop, in-license or acquire;
- the timing of regulatory approval for any of our other product candidates and the commercial success of any approved products;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with ZX008 and any of our other product candidates;
- the costs of establishing or outsourcing sales, marketing and distribution capabilities, should we elect to do so;
- the costs, terms and timing of completion of outsourced commercial manufacturing supply arrangements for any product candidate; and
- the effect of competing technological and market developments.

Until such time, if ever, as we can generate a sufficient amount of revenue to finance our cash requirements, we may need to continue to rely on additional financing to achieve our business objectives. However, we may not be able to secure such financing in a timely manner or on favorable terms, if at all. If future funds are raised through issuance of equity or debt securities, these 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 at the time we need such funding, 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,	
	2018	2017
Cash and cash equivalents, beginning of the period	\$293,503	\$91,551
Net cash used in operating activities	(55,567 )	(25,992 )
Net cash used in investing activities	(84 )	(35 )

Edgar Filing: ZOGENIX, INC. - Form 10-Q

Net cash provided by financing activities	34,251	237
Net decrease in cash and cash equivalents	(21,400 )	(25,790 )
Cash and cash equivalents, end of the period	\$272,103	\$65,761

Operating Activities

For the six months ended June 30, 2018, net cash used in operating activities of \$55.6 million was primarily attributable to a net loss of \$59.2 million, plus the net effect of non-cash items of \$2.6 million, including stock-based compensation and



Table of Contents

changes in the estimated fair value of contingent consideration, and a net cash inflow from changes in operating assets and liabilities of \$1.1 million. Cash inflows from changes in operating assets and liabilities was attributable to a \$2.9 million decrease in other assets and a \$1.7 million increase in accounts payable, accrued expenses and other liabilities. These changes were primarily attributable to the timing of payments for prepaid and accrued clinical trial costs. Cash outflows from changes in operating assets and liabilities was attributable to a \$3.5 million increase in other current assets, which included a \$3.0 million receivable related to a claim for cash payment under the U.K.'s SME Regime. For the six months ended June 30, 2017, net cash used in operating activities consisted 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.

Investing Activities

For the six months ended June 30, 2018, and 2017, net cash used in investing activities was attributable to purchases of property and equipment.

Financing Activities

For the six months ended June 30, 2018, net cash provided by financing activities of \$34.3 million consisted of net proceeds from sales of common stock of \$30.3 million under an ATM offering described above and \$5.4 million in proceeds received from the issuance of common stock under equity incentive plans. These cash inflows were offset by cash used to remit withholding taxes of \$1.4 million related to the vesting of restricted stock units that were net share-settled by us to cover the required withholding tax.

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.

Contractual Obligations

There were no material changes outside the ordinary course of our business during the six months ended June 30, 2018 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, 2017.

Off-Balance Sheet Arrangements

As of June 30, 2018, 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, 2017.

Item 4. Controls and Procedures

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

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

As required by 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 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, 2018 at the reasonable assurance level.



Table of Contents

Changes in Disclosure Controls and Procedures

There were no changes in our internal control over financial reporting during the six months ended June 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

22

---

Table of Contents

**PART II – OTHER INFORMATION**

**Item 1. Legal Proceedings**

There have been no material updates to the legal proceedings as set forth in “Item 3. Legal Proceedings” in our Annual Report on Form 10-K for the year ended December 31, 2017.

**Item 1A. Risk Factors**

There have been no material changes in our risk factors from those disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2017, other than as set forth below.

Future sales of our common stock or securities convertible or exchangeable for our common stock may depress our stock price.

Persons who were our stockholders prior to the sale of shares in our initial public offering in November 2010 continue to hold a substantial number of shares of our common stock that they are able to sell in the public market, subject in some cases to certain legal restrictions. Significant portions of these shares are held by a small number of stockholders. If these stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. The perception in the market that these sales may occur could also cause the trading price of our common stock to decline. As of June 30, 2018, we had 35.8 million shares of common stock outstanding. The majority of these shares are freely tradeable, without restriction, in the public market.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act, and, in any event, we have filed a registration statement permitting shares of common stock issued on exercise of options to be freely sold in the public market. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Certain of our directors and executive officers have established, or may establish, programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for the purpose of effecting sales of our common stock. Any sales of securities by these stockholders, warrant holders or executive officers and directors, or the perception that those sales may occur, could have a material adverse effect on the trading price of our common stock.

**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.

Table of Contents

Item 5. Other Information

Erle T. Mast, a member of our Board of Directors and chair of our Audit Committee, served as Executive Vice President and Chief Financial Officer of Clovis Oncology, Inc., a public biopharmaceutical company, from its inception in April 2009 until his retirement in March 2016. Earlier this year, Clovis and certain current and/or former officers, including Mr. Mast, received “Wells notices” from the staff of the U.S. Securities and Exchange Commission, or SEC, stating that the staff had made a preliminary determination to recommend that the SEC file an action against Clovis and the officers regarding possible violations of the federal securities laws relating to a regulatory update announcement in November 2015 that the FDA requested additional clinical data on the efficacy and safety of a product under development by Clovis. Clovis recently disclosed that it has reached an agreement in principle with the SEC staff to settle the matter on negligence-based charges. Pursuant to the proposed settlement, without admitting or denying the SEC’s allegations, Clovis has indicated that it would agree to pay a civil penalty, and would stipulate to a standard injunction against future violations of those provisions of the federal securities laws. Mr. Mast has informed us that he has separately reached an agreement in principle with the SEC staff on similar negligence-based allegations, pursuant to which he would neither admit nor deny the SEC’s allegations, pay disgorgement and a civil penalty, and agree to a standard injunction against future violations of those provisions of the federal securities laws. We have also been informed that the proposed settlements do not allege that Clovis or any of its current or former officers, including Mr. Mast, engaged in any intentional fraud or misconduct and do not preclude Mr. Mast from continuing to serve as a director of a public company. The proposed settlements are subject to approval by the SEC and will also require approval by the United States District Court where the settlements are ultimately filed.

Table of Contents

Item 6. Exhibits

EXHIBIT INDEX

Exhibit  
Number Description

- 3.1(2) Fifth Amended and Restated Certificate of Incorporation of the Registrant
- 3.2(5) Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant
- 3.3(6) 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) Warrant dated June 30, 2008 issued by the Registrant to Oxford Finance Corporation
- 4.3(1) Warrant dated June 30, 2008 issued by the Registrant to CIT Healthcare LLC (subsequently transferred to The CIT Group/Equity Investments, Inc.)
- 4.4(1) Transfer of Warrant dated March 24, 2009 from CIT Healthcare LLC to The CIT Group/Equity Investments, Inc.
- 4.5(4) Warrant dated July 18, 2011 issued by the Registrant to Healthcare Royalty Partners (formerly Cowen Healthcare Royalty Partners II, L.P.)
- 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, 2018 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.

(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 12, 2011.

(5) Filed with the Registrant's Quarterly Report on Form 10-Q on November 8, 2012.

(6) Filed with the Registrant's Quarterly Report on Form 10-Q on August 10, 2015.

Edgar Filing: ZOGENIX, INC. - Form 10-Q

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

Table of Contents

SIGNATURES

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

ZOGENIX, INC.

Date: August 6, 2018 By: /s/ Stephen J. Farr  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: August 6, 2018 By: /s/ Michael P. Smith  
Executive Vice President, Chief Financial Officer, Treasurer and Secretary  
(Principal Financial and Accounting Officer)