

ZOGENIX, INC.

Form 10-Q

November 08, 2018

falseSeptember 30, 20182018Q3ZGNXZOGENIX, INC.Accelerated

FilerFALSEFALSE0001375151--12-310.0010.00150,00050,00041,9253480841,92534,8080.0010.00110,00010,000

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

---

**FORM 10-Q**

---

(Mark One)

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

**For the quarterly period ended September 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            (I.R.S.  
Jurisdiction of            Employer**

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

**Incorporation  
or  
Organization)**      **Identification  
No.)**

**5858 Horton  
Street, Suite  
455  
Emeryville,  
California**

**94608**

**(Address of  
Principal  
Executive  
Offices)**

**(Zip Code)**

**510-550-8300**

**(Registrant's Telephone Number, Including Area Code)**

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 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            Smaller reporting company     

Emerging growth company     

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 October 31, 2018 was 41,968,019.

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

	Page
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<u>Item 1.</u> <u>Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017</u>	3
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2018 and 2017</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2018 and 2017</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2018 and 2017</u>	6
<u>Notes to the Condensed Consolidated</u>	7

	<u>Financial</u> <u>Statements</u>	
	<u>Management's</u> <u>Discussion and</u> <u>Analysis of</u>	
<u>Item 2.</u>	<u>Financial</u> <u>Condition and</u> <u>Results of</u> <u>Operations</u>	<u>18</u>
	<u>Quantitative and</u> <u>Qualitative</u>	
<u>Item 3.</u>	<u>Disclosures about</u> <u>Market Risk</u>	<u>26</u>
	<u>Controls and</u>	
<u>Item 4.</u>	<u>Procedures</u>	<u>26</u>

**PART II. OTHER**  
**INFORMATION**

<u>Item 1.</u>	<u>Legal</u> <u>Proceedings</u>	<u>27</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>27</u>
	<u>Unregistered</u> <u>Sales of Equity</u> <u>Securities and</u> <u>Use of Proceeds</u>	
<u>Item 2.</u>		<u>27</u>
	<u>Defaults Upon</u>	
<u>Item 3.</u>	<u>Senior Securities</u>	<u>27</u>
	<u>Mine Safety</u>	
<u>Item 4.</u>	<u>Disclosures</u>	<u>27</u>
	<u>Other</u>	
<u>Item 5.</u>	<u>Information</u>	<u>27</u>
<u>Item 6.</u>	<u>Exhibits</u>	<u>28</u>
	<u>Signatures</u>	<u>29</u>

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

(in thousands, except par value)

	September 30, 2018	December 31, 2017
<b>Assets:</b>		
Current assets:		
Cash and cash equivalents	\$ 163,038	\$ 293,503
Marketable securities	376,087	—
Prepaid expenses	6,861	5,994
Other current assets	1,286	5,206
Total current assets	547,272	304,703
Property and equipment, net	244	245
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	3,380	3,931
Total assets	\$ 659,630	\$ 417,613
<b>Liabilities and stockholders' equity:</b>		
Current liabilities:		
Accounts payable	\$ 4,110	\$ 3,356
Accrued clinical trial expenses	10,674	8,657
Accrued compensation	5,039	6,616
Other accrued liabilities	2,413	1,842
Current portion of contingent consideration	32,500	—
Common stock warrant	607	512

## liabilities

Total current liabilities	55,343	20,983
Contingent consideration, net of current portion	47,600	76,900
Deferred income taxes	17,425	17,425
Other long-term liabilities	482	784
Total liabilities	120,850	116,092
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000 shares authorized; none issued and outstanding	—	—
Common stock, \$0.001 par value; 50,000 shares authorized; 41,925 and 34,808 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	42	35
Additional paid-in capital	1,212,305	873,526
Accumulated deficit	(673,521)	(572,040)
Accumulated other comprehensive loss	(46)	—

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

Total stockholders' equity	538,780		301,521
Total liabilities and stockholders' equity		\$ 659,630	\$ 417,613

See accompanying notes to the unaudited condensed consolidated financial statements.

3

---

**Zogenix, Inc.****Condensed Consolidated Statements of Operations (Unaudited)**

(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Contract manufacturing revenue	\$ —	\$ —	\$ —	\$ 9,821
Costs and expenses:				
Cost of contract manufacturing	—	—	—	10,729
Research and development	27,608	21,178	77,329	49,369
Selling, general and administrative	11,016	6,073	27,663	18,129
Loss on contract termination	—	478	—	478
Asset impairment charges	—	196	—	1,116
Change in fair value of contingent consideration	5,700	10,500	3,200	11,600
Total costs and expenses	44,324	38,425	108,192	91,421
Loss from operations	(44,324)	(38,425)	(108,192)	(81,600)
Other income (expense):				
Interest income	2,133	121	3,995	332
Interest expense	—	(702)	(6)	(2,065)
Loss on extinguishment of debt	—	(3,378)	—	(3,378)
Change in fair value of common stock warrant liabilities	(64)	(380)	(95)	360
Other (expense) income, net	(9)	62	3,015	71



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

Total other income (expense)	2,060	(4,277)	6,909	(4,680)
Loss from continuing operations before income taxes	(42,264)	(42,702)	(101,283)	(86,280)
Income tax benefit	—	42	—	41
Net loss from continuing operations	(42,264)	(42,660)	(101,283)	(86,239)
Loss from discontinued operations, net of taxes	—	(134)	(198)	(870)
Net loss	\$ (42,264)	\$ (42,794)	\$ (101,481)	\$ (87,109)
Net loss per share, basic and diluted:				
Continuing operations	\$ (1.08)	\$ (1.68)	\$ (2.78)	\$ (3.45)
Discontinued operations	—	—	—	(0.03)
Total	\$ (1.08)	\$ (1.68)	\$ (2.78)	\$ (3.48)
Weighted average common shares used in the calculation of basic and diluted net loss per common share	39,242	25,431	36,485	25,024

See accompanying notes to the unaudited condensed consolidated financial statements.

**Zogenix, Inc.****Condensed Consolidated Statements of Comprehensive Loss (Unaudited)**

(in thousands)

	Three Months Ended September 30,			Nine Months Ended September 30,	
	2018	2017	2018	2017	
Net loss	\$ (42,264)	\$ (42,794)	\$ (101,481)	\$	(87,109)
Other comprehensive income (loss):					
Change in unrealized losses on marketable securities, net of tax	(46)	—	(46)	—	
Comprehensive loss	\$ (42,310)	\$ (42,794)	\$ (101,527)	\$	(87,109)

See accompanying notes to the unaudited condensed consolidated financial statements.

5

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

(in thousands)

	Nine Months Ended September 30,	
	2018	2017
Cash flow from operating activities:		
Net loss	\$ (101,481)	\$ (87,109)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	11,952	4,066
Depreciation and amortization	76	408
Amortization of debt issuance costs and debt discount	—	753
Net accretion and amortization of investments in marketable securities	(521)	—
Loss on extinguishment of debt	—	3,378
Inventory write-down	—	2,232
Asset impairment charges	—	1,116
Change in fair value of common stock warrant liabilities	95	(360)
Change in fair value of contingent consideration	3,200	11,600
Changes in operating assets		

and liabilities:

Trade accounts receivable	—	9,356
Inventory	—	2,583
Prepaid expenses and other current assets	1,429	4,996
Other assets	551	(2,413)
Accounts payable, accrued and other liabilities	1,463	4,204
Deferred revenue	—	(1,245)
Net cash used in operating activities	(83,236)	(46,435)
Cash flows from investing activities:		
Purchases of marketable securities	(375,612)	—
Purchases of property and equipment	(75)	(35)
Net cash used in investing activities	(375,687)	(35)
Cash flows from financing activities:		
Proceeds from issuance of common stock under equity incentive plans	6,749	271
Taxes paid related to net share settlement of equity awards	(1,426)	—
Proceeds from issuance of common stock, net of issuance costs	323,135	19,378

Net cash provided by financing activities	328,458	19,649
Net decrease in cash and cash equivalents	(130,465)	(26,821)
Cash and cash equivalents, beginning of the period	293,503	91,551
Cash and cash equivalents, end of the period	\$ 163,038	\$ 64,730
Noncash financing activities:		
Extinguishment of Endo working capital advance note payable through net settlement of balances owed to the Company	\$ —	\$ 7,000

See accompanying notes to the unaudited condensed consolidated financial statements.

6

---

**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” has been reclassified to present interest income and interest expense separately in the accompanying condensed consolidated statements of operations. 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 \$673.5 million at September 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. See Note 6 for the Company's recent equity offerings.

Until the Company can generate a sufficient amount of revenue to finance its cash requirements, if ever, 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 from those described in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, other than as set forth below.

#### ***Cash Equivalents and Marketable Securities***

The Company considers cash equivalents to be only those investments which are highly liquid, readily convertible to cash and have an original maturity of three months or less at the date of purchase.

The Company invests its excess cash in marketable securities with high credit ratings that are classified as Level 1 and Level 2 within the fair value hierarchy. These marketable securities consists of money market funds and certificate of deposits, securities issued by the U.S. government and its agencies, corporate debt securities and commercial paper, which are all classified as "available-for-sale". The Company considers all available-for-sale securities, including those with maturity dates beyond 12 months, as available to support current operational liquidity needs and, therefore, classifies all securities with maturity dates beyond three months at the date of purchase as current assets on the condensed consolidated balance sheets. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income on the condensed consolidated statements of operations and comprehensive loss. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on marketable securities are included in interest income (expense), net. The cost of securities sold is determined using the specific identification method.

The Company periodically evaluates whether declines in fair values of its marketable securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the marketable security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis. Factors considered include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, other publicly available information that may affect the value of the marketable security, duration and severity of the decline in value, and management's strategy and intentions for holding the marketable security. To date, the Company has not recorded any impairment charges on its marketable securities related to other-than-temporary declines in market value.

#### ***Concentration of Credit Risk***

Cash, cash equivalents and marketable securities are financial instruments that potentially subject the Company to concentration of credit risk. The Company invests its excess cash primarily in money market funds and certificate of deposits, securities issued by the U.S. government and its agencies, corporate debt securities and commercial paper. The Company has established guidelines relative to diversification and maturities to maintain safety and liquidity. The Company has not experienced any credit losses related to these financial instruments and does not believe it is exposed to any significant credit risk related to these instruments.

#### **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

8

---



effective January 1, 2018. The adoption of this ASU 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 adoption of this ASU did not have a material impact on the Company's condensed consolidated financial statements.

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 ASU 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 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.

ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* simplifies the accounting for share-based payment awards issued to nonemployees for goods and services, including fixing the estimated fair value of the stock award at the date of grant. ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The adoption of ASU 2018-07 requires a modified retrospective transition approach, with a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year. ASU 2018-07 is effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company early adopted ASU 2018-07 effective July 1, 2018. The adoption of this ASU did not have a material impact on the Company's condensed consolidated financial statements.

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, Disclosure Update and Simplification. These amendments eliminate, modify, or integrate into other SEC requirements certain disclosure rules. Among the amendments is the requirement to present an analysis of changes in stockholders' equity in the interim financial statements included in quarterly reports on Form 10-Q. The analysis,

which can be presented as a footnote or separate statement, is required for the current and comparative quarter and year-to-date interim periods. The amendments became effective for all filings made on or after November 5, 2018. In light of the anticipated timing of effectiveness of the amendments and expected proximity of effectiveness to the filing date for most filers' quarterly reports, the SEC's Division of Corporate Finance issued a Compliance and Disclosure Interpretation related to Exchange Act Forms, or CDI – Question 105.09, that provides transition guidance related to this disclosure requirement. CDI – Question 105.09 states that the SEC would not object if the filer's first presentation of the changes in shareholders' equity is included in its Form 10-Q for the quarter that begins after the effective date of the amendments. Except for the requirement to provide the annual disclosure

9

---

changes in stockholders' equity for interim periods, which will be included beginning with the Company's quarterly report on Form 10-Q ending March 31, 2019, the Company has adopted all relevant disclosure requirements.

**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 and corresponding liabilities will be recognized in its condensed consolidated balance sheets related to its lease arrangements. The adoption of these standards are 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 ASU on its condensed consolidated financial statements and related disclosures.

ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* modifies the disclosure requirements in Topic 820, Fair Value Measurement, by removing certain disclosure requirements related to the fair value hierarchy, modifying existing disclosure requirements related to measurement uncertainty and adding new disclosure requirements, such as disclosing the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and disclosing the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This ASU is effective for public companies for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year. Early adoption is permitted for any removed or modified disclosures. The Company is currently evaluating the timing and impact of adopting this ASU on its condensed consolidated financial statements and related disclosures.

**Note 3 – Cash, Cash Equivalents and Marketable Securities**

The following table summarizes the amortized cost and fair value of the Company's cash, cash equivalents and marketable securities as of September 30, 2018 (in thousands):



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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
(in thousands)				
Current assets:				
Cash	\$ 4,747	\$ —	\$ —	\$ 4,747
Cash equivalents:				
Commercial paper	58,127	—	—	58,127
Corporate debt securities	1,624	—	—	1,624
Money market funds	97,686	—	—	97,686
Certificate of deposits	854	—	—	854
Total cash equivalents	158,291	—	—	158,291
Total cash and cash equivalents	163,038	—	—	163,038
Marketable securities:				
Commercial paper	174,769	1	(1)	174,769
Corporate debt securities	47,416	—	(30)	47,386
Certificate of deposits	118,775	—	—	118,775
U.S. Treasuries	35,173	—	(16)	35,157
Total marketable securities	376,133	1	(47)	376,087
Total cash, cash equivalents and marketable securities	\$ 539,171	\$ 1	\$ (47)	\$ 539,125

The following table summarizes the cost and fair value of marketable securities based on stated effective maturities as of September 30, 2018 (in thousands):

	Amortized Cost	Fair Value
Due within one year	\$ 345,678	\$ 345,644

Due between one and two years	30,455	30,443
Total	\$ 376,133	\$ 376,087

The Company did not hold any marketable securities as of December 31, 2017.

There have been no significant realized gains or losses on available-for-sale securities for the periods presented. Available-for-sale debt securities that were in a continuous loss position but were not deemed to be other than temporarily impaired were immaterial at September 30, 2018.

See Note 4 for further information regarding the fair value of the Company's financial instruments.

**Note 4 – Fair Value Measurements**

The carrying amount of the Company’s financial instruments, including cash and cash equivalents, other current assets, accounts payable, accrued and other current liabilities 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 following tables summarize assets and liabilities recognized or disclosed at fair value on a recurring basis as of September 30, 2018 and December 31, 2017 (in thousands):

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

	Level 1	Level 2	Level 3	Total
<b><u>September 30, 2018</u></b>				
Assets:				
Cash equivalents:				
Commercial paper	\$ —	\$ 58,127	\$ —	\$ 58,127
Corporate debt securities	—	1,624	—	1,624
Money market funds	97,686	—	—	97,686
Certificate of deposits	—	854	—	854
Marketable securities				
Commercial paper	—	174,769	—	174,769
Corporate debt securities	—	47,386	—	47,386
Certificate of deposits	—	118,775	—	118,775
U.S. Treasuries	—	35,157	—	35,157
Total assets(1)	\$ 97,686	\$ 436,692	\$ —	\$ 534,378
Liabilities:				
Common stock warrant liabilities(2)	\$ —	\$ —	\$ 607	\$ 607
Contingent consideration liabilities(3)	—	—	80,100	80,100
Total liabilities	\$ —	\$ —	\$ 80,707	\$ 80,707

	Level 1	Level 2	Level 3	Total
<b><u>December 31, 2017</u></b>				
Assets:				
Cash equivalents consisting of money market funds(1)				
Total assets	\$ 289,782	\$ —	\$ —	\$ 289,782
Liabilities:				
Common stock warrant liabilities(2)	\$ —	\$ —	\$ 512	\$ 512
Contingent consideration liabilities(3)	—	—	76,900	76,900
Total liabilities	\$ —	\$ —	\$ 77,412	\$ 77,412

(1) Fair value is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs.

(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 September 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

12

---



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 September 30, 2018, the Company has classified \$32.5 million of the total contingent consideration liabilities of \$80.1 million as current liabilities. The classification was based upon the Company's reasonable expectation as to the timing of settlement of certain specified milestones.

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 nine months ended September 30, 2018 and 2017 (in thousands):

	June 30, 2018	Change in Fair Value	September 30, 2018	June 30, 2017	Change in Fair Value	September 30, 2017
Contingent consideration liabilities	\$ 74,400	\$ 5,700	\$ 80,100	\$ 53,900	\$ 10,500	\$ 64,400
Common stock warrant liabilities	543	64	607	69	380	449

  

	December 31, 2017	Change in Fair Value	September 30, 2018	December 31, 2016	Change in Fair Value	September 30, 2017
Contingent consideration liabilities	76,900	\$ 3,200	\$ 80,100	\$ 52,800	\$ 11,600	\$ 64,400
Common stock warrant liabilities	512	95	607	809	(360)	449

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.

There were no transfers between levels during the periods presented. See Note 3 for further information regarding the amortized cost of the Company's financial instruments.

#### **Note 5 – Commitments and Contingencies**

##### **Leases**

The Company has two noncancellable 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 September 30, 2018, net of sublease income, were as follows (in thousands):

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

	Gross Lease Payments	Sublease Income	Net Lease Payments
2018 (remaining 3 months)	\$ 481	\$ (136)	\$ 345
2019	1,955	(576)	1,379
2020	1,234	(148)	1,086
2021	1,004	—	1,004
2022	946	—	946
Total	\$ 5,620	\$ (860)	\$ 4,760

13

---

In October 2018, the Company executed a lease for new headquarters with its current landlord to move to a facility nearby its current headquarters in Emeryville, California. The lease has an initial term that expires on June 30, 2027 and provides for one five-year renewal option. Concurrent with the new lease, the landlord agreed to terminate the Company's existing lease once it completes the move to the new headquarters. The cash expected to be paid for rent over the term of the new lease of eight years is approximately \$15.3 million beginning in June 2019, partially offset by a reduction in the commitments under its existing headquarter lease.

#### **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 6 – Sale of Common Stock**

The Company has an at-the-market offering program (“ATM Program”) 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% of the gross proceeds of the sales price of all common stock sold under the ATM program. The Company and Cantor may each terminate the ATM program at any time upon ten days’ prior notice.

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

In August 2018, the Company completed an underwritten public offering for the sale of 6,000,000 shares of its common stock. Net proceeds raised from the offering were approximately \$292.9 million, after deducting underwriting discounts and commissions and other offering expenses of \$19.1 million.

#### **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, 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.

#### **Performance Stock Options**

In October 2015, the Company granted employees certain performance-based stock options for retention purposes. The stock options would vest upon satisfaction of a specified regulatory milestone within three years of the date of grant. In 2017, management determined the achievement of the performance condition was no longer probable and the cumulative compensation expense previously recognized was reversed. In September 2018, these awards were modified to allow for 90% of such options outstanding at the modification date to vest immediately. The remaining 10% of the awards were canceled in October 2018 since the performance condition was not met. This improbable to probable modification resulted in the calculation and recognition of incremental stock-based compensation expense of \$3.5 million during the third quarter of 2018.

**Equity Incentive Awards Activity*****Stock Options***

The following is a summary of stock option activity for the nine months ended September 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	842	43.13
Exercised	(290)	16.45
Canceled	(59)	26.10
Outstanding at September 30, 2018	3,885	\$ 20.30

***Restricted Stock Units***

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

	Shares (in thousands)	Weighted- Average Fair Value per Share at Grant Date
Outstanding at December 31, 2017	259	\$ 10.43
Granted	146	42.76
Vested	(98)	10.74
Canceled	(8)	29.74
Outstanding at September 30, 2018	299	\$ 25.58

As of September 30, 2018, outstanding restricted stock units included 159,000 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 fair value of the stock options granted or modified during the periods indicated was estimated using the Black-Scholes option pricing model, based on the following assumptions:

Three Months Ended September 30,		Nine Months Ended September 30,	
2018	2017	2018	2017

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

Risk free interest rate	2.8% to 2.9%	1.9% to 2.1%	2.3% to 2.9%	1.9% to 2.3%
Expected term	3.5 to 6.1 years	6.1 years	3.5 to 6.1 years	5.1 to 6.1 years
Expected volatility	79.9% to 83.2%	75.1% to 75.5%	79.9% to 85.2%	75.1% 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.

15

---

**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 September 30,			Nine Months Ended September 30,	
	2018	2017	2018	2017	
Cost of contract manufacturing	\$ —	\$ —	\$ —	\$	71
Research and development	3,275	294	5,018		1,313
Selling, general and administrative	3,706	968	6,934		2,682
Total	\$ 6,981	\$ 1,262	\$ 11,952	\$	4,066

**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 September 30,			Nine Months Ended September 30,	
	2018	2017	2018	2017	
Numerator:					
Net loss from continuing operations	\$ (42,264)	\$ (42,660)	\$ (101,283)	\$	(86,239)
Denominator:					
Shares used in per share calculation	39,242	25,431	36,485		25,024
Net loss from continuing operations per share, basic and diluted	\$ (1.08)	\$ (1.68)	\$ (2.78)	\$	(3.45)

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 September 30,			Nine Months Ended September 30,	
2018	2017	2018	2017	

Shares subject to outstanding common stock options	3,957	4,121	3,752	3,879
Shares subject to outstanding restricted stock units	303	271	287	228
Shares subject to outstanding warrants to purchase common stock	28	1,251	35	1,522
Total	4,288	5,643	4,074	5,629

**Note 9 – 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. In December 2017, the Company filed a claim as an SME for a \$3.0 million refundable cash credit for its 2015 tax year, which was received in July 2018. The Company recorded this amount as a component of other income for the nine months ended September 30, 2018. As of the date hereof, 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.

17

---



## **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 (“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,” “are,” “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, 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 (“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  
18

---

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 (30mg/day maximum), 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 utilizing a dose of ZX008 0.5mg/kg/day (20mg/day maximum). Study 1504, a two-arm study 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, when co-administered with stiripentol regimen (stiripentol, valproate and/or clobazam), 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 without any signs or symptoms of valvulopathy or pulmonary hypertension. We believe we are on track to submit applications for regulatory approvals for ZX008 in the United States and Europe in the first quarter of 2019.

**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. The results of this pilot study of 13 refractory LGS patients were recently published in a peer review journal (*Epilepsia*) and reported an overall 53% median reduction in convulsive seizures, 8 patients (62%) had a  $\geq 50\%$  convulsive seizure reduction and 3 patients (23%) had a  $\geq 75\%$  reduction. In addition, ZX008 was generally well tolerated without any signs or symptoms or echocardiographic findings 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 and drop 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.

19

---

*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 nine months ended September 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 Nine Months Ended September 30, 2018 and 2017******Contract Manufacturing Revenue***

(in thousands)	Three Months Ended September 30,					Nine Months Ended September 30,	
	2018	2017	Change	2018	2017	Change	
Contract manufacturing revenue	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 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 nine months ended September 30, 2018 and no longer have any contracts with customers.



*Cost of Contract Manufacturing*

(in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
Cost of contract manufacturing	\$ —	\$ —	\$ —	\$ —	\$ 10,729	\$ (10,729)

We did not incur contract manufacturing costs during the three and nine months ended September 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 September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
Research and development	\$ 27,608	\$ 21,178	\$ 6,430	\$ 77,329	\$ 49,369	\$ 27,960

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 September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
ZX008	\$ 16,564	\$ 16,520	\$ 44	\$ 52,547	\$ 35,111	\$ 17,436
Other(1)	11,044	4,658	6,386	24,782	14,258	10,524
Total	\$ 27,608	\$ 21,178	\$ 6,430	\$ 77,329	\$ 49,369	\$ 27,960

(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 related to ZX008 remained flat for the three months ended September 30, 2018 compared to the same period in 2017 as a decrease in activity within Study 1504 was offset by an increase in activity within Study 1601, which was initiated in November 2017. Research and development expenses related to ZX008 increased by \$17.4 million for the nine months ended September 30, 2018 compared to the same period in 2017 reflecting the progression and expansion of our clinical trial activities within Study 1504 as well as Study 1601. Other research and development expenses increased by \$6.4 million and \$10.5 million for the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017. The increase was primarily attributable to personnel-related costs from additions to headcount as well as increased stock-based compensation due to modification of stock options.

*Selling, General and Administrative Expenses*

(in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
Selling	\$ 4,200	\$ 648	\$ 3,552	\$ 8,911	\$ 3,071	\$ 5,840
General and administrative	6,816	5,425	1,391	18,752	15,058	3,694
Total selling, general and administrative	\$ 11,016	\$ 6,073	\$ 4,943	\$ 27,663	\$ 18,129	\$ 9,534

21

---



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 \$3.6 million and \$5.8 million for the three and nine months ended September 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 \$1.4 million and \$3.7 million for the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017 and was primarily attributable to personnel-related costs, including stock-based compensation due to incremental expense from modification of stock options.

#### *Loss on Contract Termination*

(in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
Loss on contract termination	\$ —	\$ 478	\$ (478)	\$ —	\$ 478	\$ (478)

For the three and nine months ended September 30, 2017, we entered into a termination agreement of the Supply Agreement with Endo related to Sumavel DosePro. The loss on contract termination represents costs incurred by us to terminate agreements with our third-party manufacturers and suppliers of Sumavel DosePro that were in excess of reimbursements received from Endo for such costs.

#### *Impairment Charges*

(in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
Asset impairment charges	\$ —	\$ 196	\$ (196)	\$ —	\$ 1,116	\$ (1,116)

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

#### *Change in Fair Value of Contingent Consideration*

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Change in fair value of contingent consideration	\$ 5,700	\$ 10,500	\$ 3,200	\$ 11,600

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 the probability of success for achieving regulatory/commercial milestones, 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.

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

For the three and nine months ended September 30, 2018, the estimated fair value of our contingent consideration liabilities increased by \$5.7 million and \$3.2 million, respectively, due to the positive top-line results announced in July 2018 from our second confirmatory Phase 3 study (Study 1504) of ZX008 for the treatment of Dravet syndrome. For the three and nine months ended September 30, 2017, the estimated fair value of our contingent consideration liabilities increased by \$10.5 million and \$11.6 million, respectively, due to the positive top-line results announced in September 2017 from our first Phase 3 trial (Study 1) of ZX008 for the treatment of Dravet syndrome. As a result of the positive top-line data from clinical trials for the reporting periods presented, the probability of success used to calculate the specified milestone payments increased.

22

---

*Other Income (Expense)*

(in thousands)	Three Months Ended September 30,			Nine Months Ended
	2018	2017	2018	September 30, 2017
Other income (expense):				
Interest income	\$ 2,133	\$ 121	\$ 3,995	\$ 332
Interest expense	—	(702)	(6)	(2,065)
Loss on extinguishment of debt	—	(3,378)	—	(3,378)
Change in fair value of common stock warrant liabilities	(64)	(380)	(95)	360
Other income, net	(9)	62	3,015	71
Total other income (expense)	\$ 2,060	\$ (4,277)	\$ 6,909	\$ (4,680)

Total other income for the three months ended September 30, 2018 of \$2.1 million primarily consisted of interest income attributable to higher average cash and investment balances resulting from our recent capital raising activities described below. Total other income for the nine months ended September 30, 2018 of \$6.9 million primarily consisted of interest income and 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 for qualifying expenditures incurred in the 2015 tax year.

Total other expense for the three and nine months ended September 30, 2017 of \$4.3 million and \$4.7 million, respectively, primarily consisted of interest expense recognized under a term loan and its related loss upon early repayment in full.

**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 \$673.5 million at September 30, 2018. 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. To date, the Company has relied primarily on the proceeds from equity offerings to finance its operations. The Company's recent equity offerings include the following transactions.

In the third quarter of 2017, we sold a total of 1,550,880 shares of our common stock under the ATM Program with Cantor resulting in net proceeds of approximately \$19.4 million.

In October 2017, we completed an underwritten public offering for the sale of 7,700,000 shares of our common stock. Net proceeds raised from the offering amounted to approximately \$271.3 million, after deducting underwriting discounts and commissions and other offering expenses.

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

\$1.1 million.

In August 2018, we completed an underwritten public offering for the sale of 6,000,000 shares of our common stock. Net proceeds raised from the offering were approximately \$292.9 million, after deducting underwriting discounts and commissions and other offering expenses of \$19.1 million.

As of September 30, 2018, our cash, cash equivalents and marketable securities totaled \$539.1 million. 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;

23

---

- 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 we can generate a sufficient amount of revenue to finance our cash requirements, if ever, 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):

	Nine Months Ended September 30,	
	2018	2017
Cash and cash equivalents, beginning of the period	\$ 293,503	\$ 91,551
Net cash used in operating activities	(83,236)	(46,435)
Net cash used in investing activities	(375,687)	(35)
Net cash provided by financing activities	328,458	19,649
Net decrease in cash and cash equivalents	(130,465)	(26,821)
Cash and cash equivalents, end of the period	\$ 163,038	\$ 64,730

#### *Operating Activities*

For the nine months ended September 30, 2018, net cash used in operating activities of \$83.2 million was primarily attributable to a net loss of \$101.5 million, plus the net effect of non-cash items of \$14.8 million, primarily from stock-based compensation and changes in the estimated fair value of contingent consideration, and a net cash inflow from changes in operating assets and liabilities of \$3.4 million. Cash inflows from changes in operating assets and

liabilities was primarily attributable to the timing of payments for prepaid and accrued clinical trial costs. For the nine months ended September 30, 2017, net cash used in operating activities consisted of a net loss of \$87.1 million, offset by non-cash charges of \$23.2 million and a net cash inflow from changes in operating assets and liabilities of \$17.5 million.

*Investing Activities*

For the nine months ended September 30, 2018, net cash used in investing activities was attributable to purchases of marketable securities. There were no sales/maturities of marketable securities for the nine months ended September 30, 2018 as our initial investments were made in July 2018.

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

*Financing Activities*

For the nine months ended September 30, 2018, net cash provided by financing activities of \$328.5 million consisted of net proceeds from sales of common stock of \$323.1 million in connection with the equity offerings described above and \$6.7 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 nine months ended September 30, 2017, net cash provided by financing activities was due to proceeds from issuance of common stock under employee equity incentive plans.

**Contractual Obligations**

There were no material changes outside the ordinary course of our business during the nine months ended September 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.

In October 2018, we executed a lease for new headquarters with our current landlord to move to a facility nearby our current headquarters in Emeryville, California. The lease has an initial term that expires on June 30, 2027 and provides for one five-year renewal option. Concurrent with the new lease, the landlord agreed to terminate our existing lease once we complete the move to our new headquarters. The cash expected to be paid for rent over the eight-year term of the new lease is approximately \$15.3 million beginning in June 2019, partially offset by a reduction in the commitments under our existing headquarter lease.

**Off-Balance Sheet Arrangements**

As of September 30, 2018, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

25

---

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

As part of our investment portfolio, we own financial instruments that are sensitive to market risks. The primary objective of our investment activities is to preserve our capital until it is required to fund operations, including our research and development activities.

#### ***Interest Rate Risk***

We place our investments with high quality credit issuers and, by policy, limit the amount of credit exposure to any one issuer. We invest our excess cash primarily in money market funds and certificate of deposits, securities issued by the U.S. government and its agencies, corporate debt securities and commercial paper. These investments are denominated in U.S. Dollars. A portion of our investments consisting of interest-bearing securities are subject to interest rate risk and could decline in value if interest rates fluctuate. The portfolio includes cash equivalents and investments in marketable securities with active secondary or resale markets to ensure portfolio liquidity. Due to the conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk. A 100 basis points change in interest rates would not have a significant impact on the total value of our portfolio. We had no debt outstanding as of September 30, 2018.

#### ***Foreign Exchange Risk***

As a result of our U.K. operations, we face exposure to movements in foreign currency exchange rates, primarily the British Pound Sterling and the Euro against the U.S. Dollar. The current exposures arise primarily from cash and payables and accruals denominated in the British Pound Sterling and the Euro. We have not hedged our foreign currency since the exposure has not been material to our historical operating results. Based on our foreign currency exchange rate exposures at September 30, 2018, a hypothetical 10% adverse fluctuation in the average exchange rate of the Euro or the British Pound Sterling would not have had a material impact on our condensed consolidated financial statements. We will continue to monitor and evaluate our exposure to foreign exchange risk as a result of entering into transactions denominated in currencies other than the U.S. Dollar.

### **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 September 30, 2018 at the reasonable assurance level.

#### **Changes in Disclosure Controls and Procedures**

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



## **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.

#### ***We are exposed to fluctuations in the market values of our investments.***

As of September 30, 2018, our cash, cash equivalents and marketable securities totaled \$539.1 million. Our cash equivalents and marketable securities include money market funds and certificate of deposits, securities issued by the U.S. government and its agencies, corporate debt securities and commercial paper meeting the criteria of our investment policy, which prioritizes the preservation of capital. These investments are subject to general credit, liquidity, market and interest rate risks, instability in the global financial markets, or other factors. As a result, the value or liquidity of our investments could decline and result in a material impairment, which could have a material adverse effect on our financial results and the availability of cash to fund our operations.

### **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**

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. As previously disclosed, the U.S. Securities and Exchange Commission, or SEC, had an ongoing investigation to determine whether Clovis violated federal securities laws in connection with its regulatory update announced in November 2015 that the FDA had requested additional clinical data on the efficacy and safety of a product under development by Clovis. On September 18, 2018, the SEC announced that it had reached an agreement with Clovis and certain of its executive officers, including Mr. Mast, to settle this matter on negligence based charges. Pursuant to the settlement, without admitting or denying the SEC’s allegations, Mr. Mast paid a civil penalty and disgorgement and agreed to a standard injunction against future violations of those provisions of the federal securities laws. The settlement agreement does not allege that Clovis or any of its current or former officers, including Mr. Mast, engaged in any intentional fraud or misconduct and it does not preclude Mr. Mast from continuing to serve as a director or officer of a public company.

27

---

**Item 6. Exhibits**  
**EXHIBIT INDEX**

<u>Exhibit Number</u>	<u>Description</u>
3.1(1)	<u>Fifth Amended and Restated Certificate of Incorporation of the Registrant</u>
3.2(4)	<u>Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant</u>
3.3(5)	<u>Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant</u>
3.4(1)	<u>Amended and Restated Bylaws of the Registrant</u>
4.1(2)	<u>Form of the Registrant's Common Stock Certificate</u>
4.5(3)	<u>Warrant dated July 18, 2011 issued by the Registrant to Healthcare Royalty Partners (formerly Cowen Healthcare Royalty Partners II, L.P.)</u>

- 10.1† Employment Agreement dated July 2, 2018, by and between the Registrant and Ashish Sagrolikar
- 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

32.2\* of 2002 (18  
U.S.C. §1350,  
as adopted)  
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.INS XBRL Instance  
Document - the  
instance  
document does  
not appear in  
the Interactive  
Data File  
because its  
XBRL tags are  
embedded  
within the  
Inline XBRL  
document.

101.SCH XBRL  
Taxonomy  
Extension  
Schema  
Document.

101.CAL XBRL  
Taxonomy  
Extension  
Calculation  
Linkbase  
Document.

101.DEF XBRL  
Taxonomy  
Extension  
Definition  
Linkbase  
Document.

101.LAB

XBRL  
Taxonomy  
Extension  
Label Linkbase  
Document.

101.PRE  
XBRL  
Taxonomy  
Extension  
Presentation  
Linkbase  
Document.

1. Filed with Amendment No. 2 to the Registrant's Registration Statement on Form S-1 on October 27, 2010.
2. Filed with Amendment No. 3 to the Registrant's Registration Statement on Form S-1 on November 4, 2010.
3. Filed with the Registrant's Quarterly Report on Form 10-Q on August 12, 2011.
4. Filed with the Registrant's Quarterly Report on Form 10-Q on November 8, 2012.
5. Filed with the Registrant's Quarterly Report on Form 10-Q on August 10, 2015.

† Indicates management contract or compensatory plan.

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

**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: November 8, 2018 By: /s/ Stephen J. Farr  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: November 8, 2018 By: /s/ Michael P. Smith  
Executive Vice President, Chief Financial Officer, Treasurer and Secretary  
(Principal Financial and Accounting Officer)