UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2020

OR

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

For the transition period from _____ to _____

Commission file number: **001-34962**

ZOGENIX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-5300780**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

5959 Horton Street, Suite 500
Emeryville, California 94608
(Address of Principal Executive Offices and Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**ZGNX**	**The Nasdaq Global Market**

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 April 30, 2020 was 55,340,691.

ZOGENIX, INC.

Form 10-Q
For the Quarterly Period Ended March 31, 2020

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Item 1. Financial Statements

Zogenix, Inc.
Condensed Consolidated Balance Sheets (Unaudited)
(in thousands, except par value)

	March 31, 2020	December 31, 2019
Assets:		
Current assets:		
Cash and cash equivalents	$ 269,975	$ 62,070
Marketable securities	150,218	189,085
Other receivable	19,741	—
Prepaid expenses and other current assets	13,647	11,084
Acquisition holdback placed in escrow	25,000	25,000
Total current assets	478,581	287,239
Property and equipment, net	9,560	9,424
Operating lease right-of-use assets	8,546	7,774
Indefinite-lived intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other noncurrent assets	1,485	1,079
Total assets	$ 606,906	$ 414,250
Liabilities and stockholders' equity:		
Current liabilities:		
Accounts payable	$ 7,887	$ 7,979
Accrued and other current liabilities	25,803	30,117
Acquisition holdback liability	24,444	24,444
Deferred revenue, current	5,696	5,927
Current portion of operating lease liabilities	1,383	1,322
Current portion of contingent consideration	23,600	25,600
Total current liabilities	88,813	95,389
Deferred revenue, noncurrent	6,407	7,425
Operating lease liabilities, net of current portion	11,454	10,752
Contingent consideration, net of current portion	32,300	38,200
Deferred income taxes	17,425	17,425
Total liabilities	156,399	169,191
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; 100,000 shares authorized; and 55,341 and 45,272 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	55	45
Additional paid-in capital	1,591,497	1,360,092
Accumulated deficit	(1,141,257)	(1,115,457)
Accumulated other comprehensive income	212	379
Total stockholders' equity	450,507	245,059
Total liabilities and stockholders' equity	$ 606,906	$ 414,250

See accompanying notes to the unaudited condensed consolidated financial statements.

Zogenix, Inc.

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

	Three Months Ended March 31,	
	2020	**2019**
Collaboration revenue	$ 1,249	$ —
Operating expenses:		
Research and development	33,240	24,352
Selling, general and administrative	21,318	10,918
Acquired in-process research and development expense	1,500	—
Change in fair value of contingent consideration	(7,900)	3,000
Total operating expenses	48,158	38,270
Loss from operations	(46,909)	(38,270)
Other income (expense):		
Interest income	1,088	3,156
Other income (expense), net	20,021	(88)
Total other income	21,109	3,068
Net loss	$ (25,800)	$ (35,202)
Net loss per share, basic and diluted	$ (0.54)	$ (0.83)
Weighted average number of shares used in the calculation of basic and diluted net loss per common share	48,185	42,236

See accompanying notes to the unaudited condensed consolidated financial statements.

Zogenix, Inc.

Condensed Consolidated Statements of Comprehensive Loss (Unaudited)
(in thousands)

	Three Months Ended March 31,	
	2020	2019
Net loss	$ (25,800)	$ (35,202)
Other comprehensive (loss) income, net of tax:		
Change in unrealized (losses) gains related to marketable securities	(172)	370
Foreign currency translation adjustments	5	—
Total other comprehensive (loss) income	(167)	370
Comprehensive loss	$ (25,967)	$ (34,832)

See accompanying notes to the unaudited condensed consolidated financial statements.

Zogenix, Inc.

Condensed Consolidated Statements of Stockholders' Equity (Unaudited)
(in thousands)

	Three Months Ended March 31, 2020					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	45,272	$ 45	$ 1,360,092	$ 379	$ (1,115,457)	$ 245,059
Net loss	—	—	—	—	(25,800)	(25,800)
Other comprehensive loss	—	—	—	(167)	—	(167)
Issuance of common stock, net of offering costs	9,798	10	221,698	—	—	221,708
Issuance of common stock under employee equity plans	297	—	3,882	—	—	3,882
Shares repurchased for tax withholdings related to net share settlement of employee equity awards	(26)	—	(569)	—	—	(569)
Stock-based compensation	—	—	6,394	—	—	6,394
Balance at March 31, 2020	55,341	$ 55	$ 1,591,497	$ 212	$ (1,141,257)	$ 450,507

	Three Months Ended March 31, 2019					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	42,078	$ 42	$ 1,218,710	$ 3	$ (695,954)	$ 522,801
Net loss	—	—	—	—	(35,202)	(35,202)
Other comprehensive income	—	—	—	370	—	370
Issuance of common stock under employee equity plans	380	—	5,293	—	—	5,293
Shares repurchased for tax withholdings related to net share settlement of employee equity awards	(12)	—	(606)	—	—	(606)
Stock-based compensation	—	—	4,223	—	—	4,223
Balance at March 31, 2019	42,446	$ 42	$ 1,227,620	$ 373	$ (731,156)	$ 496,879

See accompanying notes to the unaudited condensed consolidated financial statements.

Zogenix, Inc.

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

	Three Months Ended March 31,	
	2020	**2019**
Cash flow from operating activities:		
Net loss	$ (25,800)	$ (35,202)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	6,394	4,223
Depreciation and amortization	357	191
Noncash lease expense	339	—
Net accretion and amortization of investments in marketable securities	(215)	(1,703)
Change in fair value of warrant liabilities	(162)	303
Acquired in-process research and development expense	1,500	—
Change in fair value of contingent consideration	(7,900)	3,000
Changes in operating assets and liabilities:		
Accounts receivable	—	(15,500)
Other receivable	(19,741)	—
Prepaid expenses, escrow holdback and other current assets	(722)	5,270
Other assets	(405)	(6,580)
Accounts payable, accrued and other liabilities	(4,435)	(7,096)
Operating lease liability	(452)	12,767
Deferred revenue	(1,249)	15,500
Net cash used in operating activities	(52,491)	(24,827)
Cash flows from investing activities:		
Cash paid for in-process research and development asset	(1,500)	—
Purchases of marketable securities	(15,695)	(145,826)
Proceeds from maturities of marketable securities	54,605	171,225
Purchases of property and equipment	(193)	(4,535)
Net cash provided by investing activities	37,217	20,864
Cash flows from financing activities:		
Payment of contingent consideration	—	(10,000)
Proceeds from issuance of common stock under equity incentive plans	2,040	4,379
Taxes paid related to net share settlement of equity awards	(569)	(582)
Proceeds from issuance of common stock, net of issuance costs	221,708	—
Net cash provided by (used in) financing activities	223,179	(6,203)
Net decrease in cash and cash equivalents	207,905	(10,166)
Cash and cash equivalents, beginning of the period	62,070	68,454
Cash and cash equivalents, end of the period	$ 269,975	$ 58,288

See accompanying notes to the unaudited condensed consolidated financial statements.

Note 1 – Organization, Basis of Presentation and Liquidity

Zogenix, Inc. and subsidiaries (the Company, we, us or our) is a global pharmaceutical company committed to developing and commercializing transformative therapies to improve the lives of patients and their families living with rare diseases. We are primarily focused on developing and commercializing two therapeutic product candidates: Fintepla, a low-dose fenfluramine investigational therapy for two pediatric epilepsy disorders, Dravet syndrome and Lennox-Gastaut Syndrome (LGS); and MT1621, an investigational deoxynucleoside substrate enhancement therapy for the treatment of thymidine kinase 2 deficiency (TK2d), an inherited mitochondrial DNA depletion disorder that predominantly affects children and is often fatal.

We operate in one business segment—the research, development and commercialization of pharmaceutical products and our 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 (SEC) for interim financial reporting. In the opinion of management, the condensed consolidated financial statements reflect all adjustments, which are normal and recurring in nature, necessary for fair financial statement presentation. The results of operations for any interim period are not necessarily indicative of results of operations for any future period. Certain information and footnote disclosures normally included in annual consolidated financial statements prepared in accordance with generally accepted accounting principles in the United States (GAAP) have been condensed or omitted. Accordingly, these unaudited interim condensed consolidated financial statements and accompanying notes should be read in conjunction with the consolidated financial statements and related notes included in our 2019 Annual Report on Form 10-K (2019 Form 10-K), which was filed with the SEC on March 2, 2020.

Certain prior period amounts within the accompanying unaudited condensed consolidated financial statements have been reclassified to conform to current period presentation. These reclassifications did not affect our financial position, net loss, comprehensive loss, or cash flows as of and for the periods presented.

Future Funding Requirements

As of March 31, 2020, our cash, cash equivalents and marketable securities totaled $420.2 million. Excluding gains from two discrete business divestitures, we have incurred significant net losses and negative cash flows from operating activities since inception resulting in an accumulated deficit of $1.1 billion as of March 31, 2020. We expect to continue to incur significant operating losses and negative cash flows from operations as we continue to advance our product candidates through development and commercialization. Additionally, we are obligated to make future milestone payments that are contingent upon the successful achievement of certain regulatory and sales-based milestone events related to Fintepla and certain regulatory milestone events related to MT1621. Historically, we have relied primarily on the proceeds from equity offerings to finance our operations. Until such time, if ever, we can generate a sufficient amount of revenue to finance our cash requirements, we may need to continue to rely on additional financing to achieve our business objectives. However, if such financing is not available at adequate levels when needed, we may be required to significantly delay, scale back or discontinue one or more of our product development programs or commercialization efforts or other aspects of our business plans, and our operating results and financial condition would be adversely affected.

Note 2 – Summary of Significant Accounting Policies

Use of Estimates

The preparation of our condensed consolidated financial statements requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis we evaluate our estimates, judgments and methodologies. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenues and expenses. Actual results may differ from those estimates.

Significant Accounting Policies

The significant accounting policies and estimates used in the preparation of the accompanying condensed consolidated financial statements are described in Note 2, *Summary of Significant Accounting Policies* of notes to the consolidated financial statements in our 2019 Form 10-K. There have been no material changes in our significant accounting policies during the three months ended March 31, 2020 other than the recently adopted accounting pronouncements set forth below.

Impact of COVID-19 Pandemic

In March 2020, the World Health Organization declared the global novel coronavirus disease (COVID-19) outbreak a pandemic. To date, our operations have not been significantly impacted by the COVID-19 outbreak. However, we cannot predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on our financial condition and operations, including ongoing and planned clinical trials, the timelines for receiving feedback or approvals from regulatory authorities, and a potential product launch in the midst of a pandemic.

Management is monitoring the potential impact of the COVID-19 pandemic, if any, on the carrying value of our indefinite-lived in-process research and development (IPR&D) intangible asset, goodwill, long-lived assets and right-of-use assets. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets. If the financial markets and/or the overall economy are impacted for an extended period, our business, results of operations and financial condition may be adversely affected.

Income Taxes

On March 27, 2020, The Coronavirus Aid, Relief and Economic Security Act (CARES Act) was signed into law which lifts certain limitations originally imposed by the Tax Cuts and Jobs Act of 2017 (Tax Act). The CARES Act, among other provisions, retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of net operating losses, which was enacted as part of the Tax Act. It also provides that net operating losses arising in any taxable year beginning after December 31, 2017, and before January 1, 2021 are generally eligible to be carried back up to five years. The enactment of the CARES Act did not result in any material adjustments to our income tax provision for the three months ended March 31, 2020 or to our net deferred tax assets as of March 31, 2020. Given our history of losses, we do not expect the provisions of the CARES Act to have a material impact on our annual effective tax rate or condensed consolidated financial statements in 2020; however, we will continue to evaluate the impact of tax legislation and will update our disclosures as additional information and interpretive guidance becomes available.

Recently Adopted Accounting Pronouncements

Accounting Standards Update (ASU) 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* revises the measurement of credit losses for most financial instruments measured at amortized cost, including trade receivables, from an incurred loss methodology to an expected loss methodology which results in earlier recognition of credit losses. Under the incurred loss model, a loss is not recognized until it is probable that the loss-causing event has already occurred. The standard introduces a forward-looking expected credit loss model that requires an estimate of the expected credit losses over the life of the instrument by considering all relevant information including historical experience, current conditions, and reasonable and supportable forecasts that affect collectability. In addition, the standard also modifies the impairment model for available-for-sale debt securities, which are measured at fair value, by eliminating the consideration for the length of time fair value has been less than amortized cost when assessing credit loss for a debt security and provides for reversals of credit losses through income upon credit improvement. The standard became effective for us beginning January 1, 2020. Based on the composition of our investment portfolio, which reflects our primary investment objective of capital

preservation, the adoption of this standard did not have a material impact on our condensed consolidated financial statements or related 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. The implied fair value for a reporting unit is determined in the same manner as the amount of goodwill recognized in a business acquisition of the reporting unit. Under the standard, an entity shall 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 standard became effective for us beginning January 1, 2020. The adoption of this standard did not have a material impact on our condensed consolidated financial statements or related disclosures; however, any prospective goodwill impairment losses recognized will be measured in accordance with the updated guidance.

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 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 range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This standard became effective for us beginning January 1, 2020 and the adoption of this standard did not have a material impact on our condensed consolidated financial statements. For the new disclosures regarding our Level 3 fair value measurements, see Note 5, *Fair Value Measurements* to these condensed consolidated financial statements.

ASU 2019-12, *Simplifying the Accounting for Income Taxes (Topic 740*) removes certain exceptions to the general principles in Topic 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. This ASU is effective for us for all interim and annual periods beginning January 1, 2021, with early adoption permitted. We early adopted ASU 2019-12 beginning January 1, 2020 on a prospective basis. The adoption of this standard did not have a material impact on our condensed consolidated financial statements and related disclosures.

The only aspect of ASU 2019-12 that is currently applicable to us is the removal of the exception related to intraperiod tax allocation. Beginning in 2020, we will apply the general methodology regarding the intraperiod allocation of tax expense. After the adoption of ASU 2019-12, in periods where we have a loss from continuing operations, we will determine the amount of taxes attributable to continuing operations without regard to the tax effect of other items, including changes in unrealized gains related to marketable securities.

Recent Accounting Pronouncements

We have reviewed recently issued accounting pronouncements and concluded they are either not applicable to our business or no material effect is expected on our condensed consolidated financial statements as a result of future adoption.

Note 3 – Collaborative Arrangement

In March 2019, we entered into an agreement (Shinyaku Agreement) with Nippon Shinyaku Co., Ltd. (Shinyaku) for the exclusive distribution of Fintepla in Japan for the treatment of Dravet syndrome and LGS. As part of the Shinyaku Agreement, we are responsible for completing the global clinical development and all regulatory approval activities for Fintepla to support the submission of new drug applications in Japan for Dravet syndrome and LGS. Upon regulatory approval of Fintepla in Japan, Shinyaku will act as our exclusive distributor for Fintepla and will be responsible for the commercialization activities including the promotion, marketing, sale and distribution of Fintepla in Japan. Upon regulatory approval of Fintepla in Japan, Shinyaku will also act as our exclusive distributor for commercial shipment and distribution of Fintepla in Japan. If we pursue global development of Fintepla for indications other than Dravet syndrome or LGS, Shinyaku has the option to participate in the development for such indications in Japan, subject to cost sharing requirements pursuant to the agreement. Activities under the Shinyaku Agreement will be governed by a joint steering committee (JSC) consisting of three representatives from each party to the agreement. All decisions of the JSC are to be made by a unanimous vote with tie-breaking rights provided to each party for certain matters related to development, regulatory approval and commercialization select distribution activities of Fintepla in that territory.

Shinyaku has agreed to support development and regulatory approval of Fintepla in Japan by actively participating in the design of non-clinical, clinical and manufacturing requirements needed for regulatory submission, actively planning and participating in product labeling decisions and discussions with the Japanese Ministry of Health, Labor and Welfare (MHLW) and obtained distribution exclusivity through the payment of an initial fixed consideration. Pursuant to the terms of the agreement, Shinyaku agreed to make aggregate fixed payments of $20.0 million to us in scheduled installments. As of March 31, 2020, we have received $17.0 million with the remaining balance due within the next year. We will be actively running the clinical trials, performing manufacturing validation activities, preparing regulatory filings and holding discussions with MHLW, and negotiating pricing. We and Shinyaku have agreed to proportionally share the Japan specific development costs that may arise outside of the initial development plan and any post-approval clinical study costs in Japan. In addition, we can earn up to $66.0 million from Shinyaku for the achievement of certain regulatory milestones for the treatment of Dravet syndrome and LGS. If regulatory approval of Fintepla is received in Japan, we have agreed to supply Shinyaku with Fintepla upon receipt of purchase orders at our actual manufacturing cost plus a fixed transfer price mark-up, a fixed percentage of Shinyaku's net sales of Fintepla in Japan for such fiscal year, and a net price mark-up based on a percent of the applicable aggregate sales of Fintepla by Shinyaku for such fiscal year. The net price mark-up percentage increases with Shinyaku’s sales of Fintepla annual net sales in Japan and ranges between mid-twenties and is capped at a low thirties of the aggregate annual net sales for an applicable fiscal year. In addition, we can earn up to an additional $42.5 million tied to the achievement of certain net sales milestones by Shinyaku through the term of the agreement, which generally expires in 2045.

The collaborative activities under the Shinyaku Agreement prior to regulatory approval are within the scope of the accounting guidance related to collaborative arrangements as both parties are active participants and are exposed to significant risks and rewards dependent on the success of commercializing Fintepla in Japan. Since Shinyaku is not a customer as it does not obtain an output of our development and regulatory approval activities for Fintepla as they were not provided a license to our intellectual property or the ability to manufacture the product, and we do not consider performing development and regulatory approval services to be a part of our ongoing activities. Shinyaku will only become a customer and subject to revenue from contracts from customers accounting guidance after regulatory approval of Fintepla in Japan occurs and Shinyaku places purchase orders with us. To date, Shinyaku has not provided us with any purchase orders and thus no revenue has been recognized for the supply of Fintepla.

We considered the revenue from contracts with customers guidance by analogy in determining the unit of account, and the recognition and measurement of such unit of account for collaborative activities under the Shinyaku Agreement and concluded that there are two development programs akin to performance obligations related to collaborative activities for development and regulatory approval efforts for Dravet and LGS. We are the principal as it relates to the collaborative development and regulatory approval activities primarily because we are responsible for the acceptability of the results of the work of the third-party vendors that are used to assist us in performing such activities. Therefore, such collaboration revenue is presented on a gross basis in our condensed consolidated statements of operations apart from research and development expenses incurred.

Since Shinyaku was not provided a license to our intellectual property or the ability to manufacture Fintepla, Shinyaku will only become a customer, and payments made under the Shinyaku Agreement will only be subject to the accounting guidance related to revenue from contracts from customers, after regulatory approval of Fintepla in Japan occurs and Shinyaku places purchase orders with us.

The initial collaboration consideration consisted solely of the fixed consideration payments of $20.0 million and was allocated on a relative standalone selling price basis to the two identified development programs akin to performance obligations related to collaborative activities for development and regulatory approval efforts for Dravet syndrome and LGS. Analogizing to the revenue from contracts with customers variable consideration guidance, all potential regulatory milestone payment consideration will be included in the collaboration consideration if and when it is probable that a significant reversal in the amount of cumulative collaboration consideration recognized will not occur when the uncertainty associated with the variable collaboration consideration is subsequently resolved. At contract inception and through March 31, 2020, this consideration was fully constrained as the achievement of the events tied to these regulatory milestone payments was highly dependent on factors outside our control.

Collaboration revenue is being recognized over time as the collaborative activities related to each development program are rendered. We determined an input method is a reasonable representative depiction of the performance of the collaborative activities under the Shinyaku Agreement. The method of measuring progress towards completion incorporates actual internal and external costs incurred, relative to total internal and external costs expected to be incurred over an estimated period to satisfy the collaborative activities. The period over which total costs are estimated reflects our estimate of the period over which it will perform the collaborative activities for each development program. Changes in estimates of total internal and external costs expected to be incurred are recognized in the period of change as a cumulative catch-up adjustment to collaboration revenue.

For the three months ended March 31, 2020, we recognized collaboration revenue of $1.2 million. As of March 31, 2020, $12.1 million related to this agreement was recorded as deferred revenue, which is classified as either current or net of current portion in the accompanying condensed consolidated balance sheets based on the period over which the collaboration revenue is expected to be recognized. We expect to recognize collaboration revenue related to these collaborative activities through the end of 2023.

Note 4 – Cash, Cash Equivalents and Marketable Securities

The following tables summarize the amortized cost and the estimated fair value of our cash, cash equivalents and marketable securities as of March 31, 2020 and December 31, 2019 (in thousands):

	March 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Current assets:				
Cash	$ 11,271	$ —	$ —	$ 11,271
Cash equivalents:				
Money market funds	224,070	—	—	224,070
Commercial paper	34,634	—	—	34,634
Total cash and cash equivalents	269,975	—	—	269,975
Marketable securities:				
Commercial paper	39,528	—	—	39,528
Corporate debt securities	70,543	273	(66)	70,750
Certificate of deposits	39,940	—	—	39,940
Total marketable securities	150,011	273	(66)	150,218
Total cash, cash equivalents and marketable securities	$ 419,986	$ 273	$ (66)	$ 420,193

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Current assets:				
Cash	$ 43,058	$ —	$ —	$ 43,058
Cash equivalents:				
Money market funds	11,527	—	—	11,527
Commercial paper	7,485	—	—	7,485
Total cash and cash equivalents	62,070	—	—	62,070
Marketable securities:				
Commercial paper	73,366	—	—	73,366
Corporate debt securities	74,038	381	(2)	74,417
Certificate of deposits	41,302	—	—	41,302
Total marketable securities	188,706	381	(2)	189,085
Total cash, cash equivalents and marketable securities	$ 250,776	$ 381	$ (2)	$ 251,155

The following table summarizes the cost and fair value of marketable securities based on stated effective maturities as of March 31, 2020 (in thousands):

	Amortized Cost	Fair Value
Due within one year	$ 127,968	$ 128,147
Due between one and two years	22,043	22,071
Total	$ 150,011	$ 150,218

We regularly review our available-for-sale marketable securities in an unrealized loss position and evaluate the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. For all marketable securities that have been in a continuous loss position as of March 31, 2020, we have the ability and intent to hold until maturity or recovery. We determined the gross unrealized losses were caused by market fluctuations. There have been no specific facts or circumstances that have arisen to indicate that there has been any significant deterioration in the creditworthiness of the issuers of these securities. As such, we determined no allowance for credit losses was deemed necessary.

Accrued interest receivable is recorded in “Prepaid expenses and other current assets” on our condensed consolidated balance sheets and was $0.7 million and $0.6 million as of March 31, 2020 and December 31, 2019, respectively.

See Note 5 for further information regarding the fair value of our financial instruments.

Note 5 – Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. A three-level valuation hierarchy has been established under GAAP for disclosure of fair value measurements. The valuation hierarchy is based on the transparency of inputs to the valuation of an asset or liability as of the measurement date. The three levels are defined 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.

Our financial instruments consist primarily of cash and cash equivalents, marketable securities, other current assets, accounts payable and accrued liabilities, contingent consideration liabilities and our outstanding common stock warrant liabilities. Certain cash equivalents, marketable securities, contingent consideration liabilities and common stock warrant liabilities are reported at their respective fair values on our condensed consolidated balance sheets. The remaining financial instruments are carried at cost which approximates their respective fair values because of the short-term nature of these financial instruments. See Note 4 for further information regarding the amortized cost of our financial assets.

The following tables summarize assets and liabilities recognized or disclosed at fair value on a recurring basis as of March 31, 2020 and December 31, 2019 (in thousands):

	March 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Commercial paper	$ —	$ 34,634	$ —	$ 34,634
Money market funds	224,070		—	224,070
Marketable securities:				
Commercial paper	—	39,528	—	39,528
Corporate debt securities	—	70,750	—	70,750
Certificate of deposits	—	39,940	—	39,940
Total assets (1)	$ 224,070	$ 184,852	$ —	$ 408,922
Liabilities:				
Common stock warrant liabilities	$ —	$ —	$ 36	$ 36
Contingent consideration liabilities	—	—	55,900	55,900
Total liabilities	$ —	$ —	$ 55,936	$ 55,936

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 11,527	$ —	$ —	$ 11,527
Commercial paper	—	7,485	—	$ 7,485
Marketable securities:				
Commercial paper	—	73,366	—	73,366
Corporate debt securities	—	74,417	—	74,417
Certificate of deposits	—	41,302	—	41,302
Total assets (1)	$ 11,527	$ 196,570	$ —	$ 208,097
Liabilities:				
Common stock warrant liabilities	$ —	$ —	$ 198	$ 198
Contingent consideration liabilities	—	—	63,800	63,800
Total liabilities	$ —	$ —	$ 63,998	$ 63,998

(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.

Contingent Consideration Liability

Pursuant to the terms of the Brabant purchase agreement in 2014 in which we acquired worldwide development and commercialization rights to Fintepla, we are obligated to make future milestone payments that are contingent upon the successful achievement of certain regulatory and sales-based

milestone events related to Fintepla. The potential amount of future payments that we may be required to make is between zero, if none of the remaining milestones are achieved, to a maximum of $75.0 million.

The following table provides a reconciliation of our contingent consideration liability measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the three months ended March 31, 2020 and 2019 (in thousands):

	Three Months Ended March 31,	
	2020	2019
Balance at beginning of period	$ 63,800	$ 78,200
Change in fair value	(7,900)	3,000
Settlements	—	(10,000)
Balance at end of period	$ 55,900	$ 71,200

The decrease in fair value of our contingent consideration for the three months ended March 31, 2020 was primarily due to changes to our probability-weighted estimates for achieving regulatory/commercial milestones and the use of a higher discount rate to reflect an increase in credit-adjusted interest rates. The increase in fair value of our contingent consideration for the three months ended March 31, 2019 was primarily due to the inclusion of sales in Japan in our forecast associated with the execution of the Shinyaku Agreement, which accelerated the estimated timing of when certain sales milestones will be reached, and a market driven decrease in the discount rate.

The following table summarizes the significant unobservable inputs used in the fair value measurement of our contingent consideration liabilities as of March 31, 2020.

Fair Value as of March 31, 2020 (in thousands)	Valuation Technique	Unobservable Input	Range	Weighted Average (1)
		Discount rate	6.5% — 14.8%	9.8%
$55,900	Discounted cash flow	Probability of payment	0% — 85.1%	85.1%
		Projected year of payment	2020 — 2030	2022

(1) Unobservable inputs were weighted by the relative fair value of the contingent consideration liability. For projected year of payment, the amount represents the median of the inputs and is not a weighted average.

The weighted average discount rate was calculated based on the relative fair value of our contingent consideration obligations. Significant increases or decreases in projected revenues, probabilities of payment, discount rates or the time until payment is made would have resulted in a significantly lower or higher fair value measurement as of March 31, 2020.

Note 6 – Accrued and Other Current Liabilities

The following table provides details of accrued and other current liabilities (in thousands):

	March 31, 2020	December 31, 2019
Accrued clinical trial expenses	$ 14,215	$ 18,666
Accrued compensation	4,930	7,179
Other accrued liabilities	6,622	4,074
Common stock warrant liabilities	36	198
Total accrued and other current liabilities	$ 25,803	$ 30,117

Note 7 – Leases

We have operating leases consisting of office space for our Emeryville, California headquarters and for our various subsidiaries. In March 2020, our operating lease for our former headquarters in San Diego, California and the co-terminus sublease arrangement with our sublessee expired in accordance with the terms of the leases. In February 2020, we entered into a lease for office space in Maidenhead, United Kingdom, for a five-year term with aggregate lease payments of approximately $1.5 million. Operating lease assets represent our right to use an underlying asset for the lease term. Operating lease liabilities represent the present value of lease payments over the lease term, discounted using an estimate of our secured incremental borrowing rate.

The components of lease costs, which were included in our condensed consolidated statements of operations, were as follows (in thousands):

	Three Months Ended March 31,	
	2020	2019
Lease costs		
Operating lease cost	$ 567	$ 499
Short-term lease cost (1)	157	328
Sublease income	(115)	(145)
Total	$ 609	$ 682

(1) Short-term lease cost included $0.2 million related to a short-term lease that expired in March 2019.

Cash paid for amounts included in the measurement of lease liabilities for the three months ended March 31, 2020 and 2019 was $0.6 million and $0.3 million, respectively. The amounts were included in net cash used in operating activities in our condensed consolidated statements of cash flows. Right-of-use assets obtained in exchange for new operating lease liabilities were $1.2 million for the three months ended March 31, 2020.

Maturities of operating lease liabilities as of March 31, 2020 and December 31, 2019 were as follows (in thousands):

	March 31, 2020	December 31, 2019
2020 (remaining 9 months and 12 months, respectively)	$ 1,533	$ 1,986
2021	2,292	1,957
2022	2,230	1,894
2023	2,287	1,951
2024	2,300	2,010
Thereafter	5,103	5,101
Total lease payments	15,745	14,899
Less imputed interest	(2,908)	(2,825)
Total operating lease liabilities	$ 12,837	$ 12,074

	March 31, 2020	December 31, 2019
Current portion of operating lease liabilities	$ 1,383	$ 1,322
Operating lease liabilities, net of current portion	11,454	10,752
Total lease liabilities	$ 12,837	$ 12,074

As of March 31, 2020, the weighted average remaining lease term was 6.8 years and the weighted average discount rate, weighted based on the remaining balance of lease payments, was 6.2%.

Note 8 – Stockholders' Equity and Stock-Based Compensation

Sale of Common Stock

In March 2020, we completed an underwritten public offering of 9,798,000 shares of our common stock at an offering price of $23.50 per share, including 1,278,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares. Net proceeds realized from the offering amounted to approximately $221.7 million, after deducting commissions and other offering expenses.

Equity Incentive Plans

We have issued stock-based awards from various equity incentive and stock purchase plans, as more fully described in Note 12, *Stock-Based Compensation* to the consolidated financial statements in our 2019 Form 10-K.

Stock Options

The following is a summary of stock option activity for the three months ended March 31, 2020 (in thousands, except per share data):

	Shares	Weighted-Average Exercise Price per Share
Outstanding at December 31, 2019	4,253	$ 29.59
Granted	841	30.11
Exercised	(230)	16.87
Canceled	(65)	37.07
Outstanding at March 31, 2020	4,799	$ 30.19

Restricted Stock Units

The following is a summary of restricted stock unit activity for the three months ended March 31, 2020 (in thousands, except per share data):

	Shares	Weighted- Average Fair Value per Share at Grant Date
Outstanding at December 31, 2019	439	$ 36.97
Granted	216	27.36
Vested	(66)	48.41
Canceled	(8)	37.56
Outstanding at March 31, 2020	581	$ 32.11

Stock-Based Compensation Expense Allocation

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 March 31,	
	2020	2019
Research and development	$ 2,729	$ 1,435
Selling, general and administrative	3,665	2,788
Total	$ 6,394	$ 4,223

Note 9 – Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding for the period. Diluted net loss per share is calculated by dividing net loss 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. Our 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 per share is as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2020	2019
Numerator:		
Net loss	$ (25,800)	$ (35,202)
Denominator:		
Shares used in per share calculation	48,185	42,236
Net loss per share, basic and diluted	$ (0.54)	$ (0.83)

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

	Three Months Ended March 31,	
	2020	2019
Shares subject to outstanding stock options	4,450	3,716
Shares subject to outstanding restricted stock units	485	295
Shares subject to outstanding warrants to purchase common stock	28	28
Total	4,963	4,039

Note 10 – United Kingdom (U.K.) Research and Development (R&D) Tax Relief Scheme

We conduct extensive research and development activities that benefit from U.K.'s small and medium-sized enterprises (SMEs) R&D tax relief scheme. Under this tax relief scheme, a SME has an option to receive an enhanced U.K. tax deduction on its eligible R&D activities or, when an SME entity is in a net operating loss position, can elect to surrender net operating losses that arise from its eligible R&D activities in exchange for a cash payment from the U.K. tax authorities. As the tax incentives may be received without regard to an entity's actual tax liability, they are not subject to accounting for income taxes. Amounts recognized by us for cash payment claims under the SME R&D tax relief scheme are recorded as a component of other income after an election for tax relief has been made by submitting a claim for a discrete tax year and collectability is deemed probable and reasonably assured.

As of December 31, 2019, we submitted claims as an SME for a total amount of $19.7 million, consisting of tax credit cash rebates of $9.9 million and $9.8 million for our 2017 and 2018 tax years, respectively. In April 2020, we received correspondence from the U.K. tax authorities informing us the claim has been approved. As a result, the amount of the claim was recorded as other receivable on the condensed consolidated balance sheet at March 31, 2020 and recognized as a component of other income on the condensed consolidated statement of operations for the three months ended March 31, 2020. For our 2019 tax year, we have not yet decided whether to seek tax relief by surrendering some of our losses for a tax credit cash rebate claim or electing to receive enhanced U.K. tax deductions on our eligible research and development activities. Under the U.K's tax legislation, there is a two-year window after the end of a tax year to seek relief under this tax relief scheme.

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 our product candidates Fintepla and MT1621;
- the safety and efficacy of our product candidates;
- the impact of COVID-19 pandemic;
- 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 regards to the demonstration of the safety and efficacy of our product candidates and adequacy of the manufacturing processes related to our product candidates to the satisfaction of the FDA and such other regulatory agencies;
- our ability to obtain, maintain and successfully enforce adequate patent and other intellectual property or regulatory exclusivity protection of our product candidates and the ability to operate our business without infringing the intellectual property rights of others;
- the goals of our development activities and estimates of the potential markets for our product candidates, and our ability to compete within those markets;
- our ability to obtain and maintain adequate levels of coverage and reimbursement from third-party payors for any of our product candidates that may be approved for sale, the extent of such coverage and reimbursement and the willingness of third-party payors to pay for our products versus less expensive therapies;
- the impact of healthcare reform laws; and
- projected cash needs and our expected future revenues, operations and expenditures.

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

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

Fintepla® 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., a Delaware corporation, and 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, 2019 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our 2019 Annual Report on Form 10-K, which was filed with the SEC on March 2, 2020 (2019 Form 10-K).

Overview

We are a global pharmaceutical company committed to developing and commercializing transformative therapies to improve the lives of patients and their families living with rare diseases. We are primarily focused on developing and commercializing two therapeutic product candidates: Fintepla, a low-dose fenfluramine investigational therapy for two pediatric epilepsy disorders, Dravet syndrome and Lennox-Gastaut syndrome (LGS); and MT1621, an investigational deoxynucleoside substrate enhancement therapy for the treatment of thymidine kinase 2 deficiency (TK2d), an inherited mitochondrial DNA depletion disorder.

Fintepla for Patients with Rare Epilepsy Disorders

We own and control worldwide development and commercialization rights to Fintepla, our lead product candidate, for which we have submitted a new drug application (NDA) to the United States Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) seeking approval to market and sell the product for the treatment of seizures associated with Dravet syndrome, a rare and devastating pediatric epilepsy disorder. In March 2019, we entered into an exclusive distribution agreement with Nippon Shinyaku Co., Ltd. to support the sales and distribution of the product in Japan, if approved.

Dravet Syndrome

In February 2019, following the completion of Study 1 and Study 1504, our two global pivotal Phase 3 clinical trials of Fintepla, we completed our rolling submission of an NDA with the FDA and submitted a MAA to the EMA for Fintepla for the treatment of seizures associated with Dravet syndrome. In March 2019, the EMA accepted the MAA and initiated its review and we currently anticipate a decision on the MAA in the fourth quarter of 2020. In April 2019, we received a Refusal to File (RTF) letter from the FDA regarding our NDA for Fintepla for the treatment of seizures associated with Dravet syndrome. In September 2019, following a Type A meeting with the FDA in May 2019 to review the issues identified in the RTF letter, we resubmitted the NDA and in November 2019, the FDA accepted the NDA for filing. The FDA granted priority review for the NDA for Fintepla, which established a target action date of six months from the date of receipt, with an assigned Prescription Drug User Fee Act, (PDUFA) date of March 25, 2020. As part of their review, the FDA requested additional information from us including, but not limited to, additional data to conduct additional efficacy analyses from our two pivotal studies in Dravet syndrome. On February 27, 2020, we announced that the FDA extended the PDUFA target action date to June 25, 2020, which provides the FDA additional time to review the NDA.

Lennox-Gastaut Syndrome

Fintepla is also under late-stage development for the treatment of seizures associated with LGS, another rare and devastating form of childhood-onset epilepsy. In November 2017, we announced the initiation of Study 1601, our double-blind, placebo-controlled, multicenter global Phase 3 clinical trial of Fintepla as an adjunctive treatment for seizures in patients with LGS. In February 2020, we announced positive top-line results from Study 1601, which met its primary objective of demonstrating that Fintepla at a dose of 0.7 mg/kg/day was superior to placebo in reducing the frequency of drop seizures, based on the change between baseline and the titration and maintenance treatment period ($p=0.0012$). The same dose of Fintepla (0.7 mg/kg/day) also demonstrated improvements versus placebo in key secondary efficacy measures, including a significant reduction in the proportion of patients with a clinically meaningful reduction (≥50%) in drop seizure frequency ($p=0.0150$). A decrease in the frequency of drop seizures between baseline and the treatment period was observed for a lower dose of Fintepla (0.2 mg/kg/day) compared to placebo, but this change did not reach statistical significance ($p=0.0915$). In Study 1601, Fintepla was generally well-tolerated, with the adverse events consistent with those observed in our two prior Phase 3 studies in Dravet syndrome. The most common adverse events (≥10%) in the Fintepla-treated groups were decreased appetite, somnolence, fatigue, vomiting, diarrhea, seizure and pyrexia. The incidence of serious treatment emergent adverse events was 11.5% (n=10) in the 0.7 mg/kg/day group, 4.5% (n=4) in the 0.2 mg/kg/day group, and 4.6% (n=4) in the placebo group. Patients who completed the double-blind phase of Study 1601 and were eligible could enter a 12-month open label extension study to evaluate the long-term safety, tolerability and effectiveness of Fintepla. We are now focused on finalizing the studies and data required to support a supplemental NDA (sNDA) and intend to meet with the FDA in the second half of 2020 to discuss an sNDA planned submission.

Other Potential Indications

In addition to Dravet syndrome and LGS, we are evaluating Fintepla in other rare epileptic syndromes and diseases, including an ongoing investigator-initiated study being conducted in Sunflower Syndrome. Sunflower Syndrome is a rare, drug-resistant epileptic disorder with photo-induced seizures characterized by episodes of hand-waving while looking towards bright light, as well as absence and generalized tonic-clonic seizures.

The investigator-initiated open-label, Phase 2 study evaluated the efficacy and tolerability of Fintepla as an adjunctive antiepileptic treatment for patients with Sunflower Syndrome. On April 22, 2020, we held a conference call with investors to

discuss investigator-reported interim data of this study. Following a four-week baseline period, during which patients observed a baseline median convulsive seizure frequency (MCSF) of 121 seizures per day (range 11-240), patients received 0.2 mg/kg/day Fintepla which was added to their current treatment regimen, and were dose titrated over a two month period to determine maximum tolerability (maximum dose of 26 mg/day), with an overall treatment period of three months (2 month titration period, one month full dose). Of the ten patients enrolled in the trial, nine patients completed the trial. Following treatment with Fintepla, MCSF was reduced by 84% compared to the pre-treatment baseline ($p < 0.001$). Fintepla was generally well-tolerated and the most common adverse events were minor loss of appetite and fatigue (n=2).

MT1621 for Patients with TK2 Deficiency

In September 2019, we acquired all the outstanding equity interests of Modis Therapeutics, Inc. (Modis), a privately-held biopharmaceutical company based in Oakland, California. Modis holds an exclusive worldwide license from Columbia University in New York City to certain intellectual property rights owned or controlled by Columbia University to develop and commercialize MT1621. MT1621 is an investigational deoxynucleoside-combination substrate enhancement therapy in development for the treatment of TK2d, a rare, debilitating, and often fatal genetic mitochondrial DNA depletion disorder that primarily affects infants and children and for which there are currently no approved therapies. Modis previously completed the RETRO study, a potentially pivotal Phase 2 global retrospective study of MT1621 in 38 pediatric and adult patients with TK2d (median age of disease onset, 2.5 years) treated at eight clinical sites in the United States, Spain and Israel. Subjects received MT1621 for a median of 71 weeks (range 92 days – 7 years). In October 2019, we announced positive top-line results from the RETRO study in which 94.7% of treated patients had either improved (68%) or stabilized (26%) overall responses in major functional domains. A survival analysis using a time-dependent Cox regression model showed that the difference in probability of survival between treated patients and untreated natural history control patients was statistically significant ($p<0.0006$). Among clinical responders, a subset demonstrated profound responses, in some cases reacquiring previously lost motor milestones such as ambulation, respiratory function and feeding. Safety data from RETRO indicated that MT1621 was generally well-tolerated. Most reported adverse events were considered not related to study drug (199 of 292), with mild or moderate diarrhea being the most common treatment-related adverse event (AE), occurring in 63% of patients. Serious AEs (SAEs) were reported in 14 subjects (37%). The majority of SAEs were deemed related to TK2d; two patients experienced three adverse events related to study drug alone (kidney stone, kidney stone removal, diarrhea). Two adult-onset patients stopped treatment due to asymptomatic increases in aminotransferase liver enzymes (no increase in bilirubin levels), which resolved upon discontinuation of treatment. In April 2020, we held an End of Phase 2 meeting with the FDA and are scheduled to meet with the FDA in June 2020 to receive feedback with respect to chemistry, manufacturing, and controls (CMC). In addition, we plan to seek feedback from regulatory authorities in Europe during the third quarter of 2020 to determine the path forward to a potential submission of an MAA.

Business Update Regarding COVID-19

The current COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, patients and their families and caregivers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of “stay-at-home” orders, and restricting business functions outside of one’s home. In response, we have implemented a work from home policy for all employees across all facilities, following the guidelines or directives issued by federal, state and local government agencies in the U.S. as well as the U.K. government. To date, we have been able to continue to supply Fintepla and MT1621 to our patients currently enrolled in our clinical trials and do not currently anticipate any interruptions in supply. While we are currently continuing the clinical trials we have underway in sites across the globe, we expect that COVID-19 precautions may directly or indirectly impact the timeline for some of our clinical trials. For example, due to the challenges of enrolling new patients posed by the COVID-19 pandemic, we have paused the initiation of our exploratory Phase 2 study (the “basket study”), which is a study designed to understand the characteristics of rare epilepsy disorders other than Dravet syndrome and LGS in separate cohorts and evaluate whether Fintepla is safe and effective versus placebo in these patient populations. Any delays in the completion of our clinical trials and any disruption in our supply chain could have a material adverse effect on our business, results of operations and financial condition. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets.

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 consider an accounting estimate to be critical if: (1) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (2) changes in the estimate that are reasonably likely to occur from period to period, or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. Our critical accounting policies and estimates are described in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of our 2019 Form 10-K. There were no material changes to our critical accounting policies during the three months ended March 31, 2020, as compared to the critical accounting policies and estimates disclosed in our 2019 Form 10-K.

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*, to the condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Results of Operations

Comparison of Three Months Ended March 31, 2020 and 2019

Collaboration Revenue

	Three Months Ended March 31,		
(in thousands)	2020	2019	Change
Collaboration revenue	$ 1,249	$ —	$ 1,249

We currently do not have an approved product for sale. Collaboration revenue increased from prior periods as a result of our Shinyaku Agreement entered into in March 2019 and related performance of such collaboration activities under the agreement. We may also be entitled to receive additional milestone payments pursuant to the Shinyaku Agreement upon the occurrence of specific events. As the recognition of this collaboration revenue is based on costs incurred to date relative to total estimated costs at completion when measuring progress and the uncertainty of when the events underlying various milestones are resolved, we expect our collaboration revenue will fluctuate from period to period.

Research and Development Expenses

	Three Months Ended March 31,		
(in thousands)	2020	2019	Change
Research and development	$ 33,240	$ 24,352	$ 8,888

Research and development expenses consist of expenses incurred in developing, testing and seeking marketing approval of our product candidates, including: 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; pre-launch inventory, personnel related expenses, such as salaries, benefits, travel and other related expenses, including stock-based compensation; and facility, maintenance, depreciation and other related expenses.

For each of our research and development programs, we incur both external and internal costs. External costs include clinical and non-clinical activities performed by CROs, lab services, purchases of product candidate materials and manufacturing development costs. We track external research and development expenses for each of our key development programs. We have not tracked internal costs on a program-by-program basis because our research and development employees and infrastructure resources are utilized across our product candidate development programs.

The table below sets forth components of our research and development expenses for the periods presented.

(in thousands)	Three Months Ended March 31, 2020	2019	Change
Fintepla for Dravet syndrome	$ 7,311	$ 9,620	$ (2,309)
Fintepla for LGS	7,943	6,003	1,940
MT1621	1,652	—	1,652
Other (1)	797	466	331
Total external costs	17,703	16,089	1,614
Internal costs	15,537	8,263	7,274
Total	$ 33,240	$ 24,352	$ 8,888

(1) Other external costs include early-phase exploratory research programs.

In October 2014, we acquired worldwide development and commercialization rights to Fintepla through an acquisition of a business and have since incurred significant expenditures related to conducting clinical trials of Fintepla. Research and development expenses related to Fintepla for Dravet syndrome decreased by $2.3 million for the three months ended March 31, 2020 compared to the same period in 2019 primarily due to wind-down of clinical activities related to our Phase 3 trials Study 1501 and Study 1504. Research and development spend related to Fintepla for LGS increased by $1.9 million in the same year-over-year period reflecting the progression and expansion of our clinical trial activities within Study 1601. External costs increased by $1.7 million due to our spend on the MT1621 development program, which we acquired through our acquisition of Modis in September 2019. Internal costs for research and development activities increased by $7.3 million for the three months ended March 31, 2020 compared to the same period in 2019 primarily driven by additions to headcount, including, in part, former Modis employees who continued their employment with us.

Selling, General and Administrative Expenses

(in thousands)	Three Months Ended March 31, 2020	2019	Change
Selling	$ 10,352	$ 3,915	$ 6,437
General and administrative	10,966	7,003	3,963
Total selling, general and administrative	$ 21,318	$ 10,918	$ 10,400

Selling expense consists primarily of salaries and benefits of sales and marketing personnel 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 $6.4 million for the three months ended March 31, 2020 compared to the same period in 2019 and was primarily attributable to increased personnel-related costs as a result of headcount additions in preparation for the potential approval and commercialization of Fintepla for Dravet syndrome.

General and administrative expense increased by $4.0 million for the three months ended March 31, 2020 compared to the same period in 2019 and was primarily attributable to increased personnel-related costs, including stock-based compensation and professional services.

Acquired In-Process Research and Development Expense

Acquired in-process research and development (IPR&D) expense consists of a transaction accounted for as an IPR&D asset acquisition. For the three months ended March 31, 2020, we incurred $1.5 million in aggregate monthly option maintenance fees for the right to license an IPR&D asset.

Change in Fair Value of Contingent Consideration

(in thousands)	Three Months Ended March 31, 2020	2019
Change in fair value of contingent consideration	$ (7,900)	$ 3,000

The contingent consideration liability relates to milestone payments under an existing agreement in connection with our prior acquisition of Fintepla. 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.

The decrease in fair value of our contingent consideration for the three months ended March 31, 2020 was primarily due to changes to our probability-weighted estimates for achieving regulatory/commercial milestones and the use of a higher discount rate to reflect an increase in credit-adjusted interest rates. The increase in fair value of our contingent consideration for the three months ended March 31, 2019 was primarily due to the inclusion of sales in Japan in our forecast associated with the execution of the Shinyaku Agreement, which accelerated the estimated timing of when certain sales milestones will be reached, and a market driven decrease in the discount rate.

Other Income (Expense)

(in thousands)	Three Months Ended March 31, 2020	2019
Other income (expense):		
Interest income	$ 1,088	$ 3,156
Other income, net	20,021	(88)
Total other income	$ 21,109	$ 3,068

The decrease in interest income for the three months ended March 31, 2020 compared to the same period in 2019 was attributable to lower average cash and investment balances as we funded our acquisition of Modis in September 2019 with cash on hand.

The increase in other income, net for the three months ended March 31, 2020 compared to the same period in 2019 was primarily due to $19.7 million of other income recognized for a cash rebate claim submitted under the U.K.'s small and medium-sized enterprise and research and development tax relief scheme for qualifying expenditures incurred in tax years 2017 and 2018. For our 2019 tax year, we have not yet decided whether to seek tax relief by surrendering some of our losses for a tax credit cash rebate claim or electing to receive enhanced U.K. tax deductions on our eligible research and development activities. Under the U.K's tax legislation, there is a two-year window after the end of a tax year to seek relief under this tax relief scheme.

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 $1.1 billion at March 31, 2020. 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, we are obligated to make future milestone payments that are contingent upon the successful achievement of certain substantive development, regulatory and sales-based milestone events related to Fintepla and MT1621. As of March 31, 2020, we derive collaboration revenue from our Shinyaku Agreement related to development and commercialization activities for Fintepla in Japan. 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 our product candidates. To date, we have relied primarily on the proceeds from equity offerings to finance our operations.

In March 2020, we completed an underwritten public offering of 9,798,000 shares of our common stock at an offering price of $23.50 per share, including 1,278,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares. Net proceeds realized from the offering amounted to approximately $221.7 million, after deducting commissions and other offering expenses. As of March 31, 2020, our cash, cash equivalents and marketable securities totaled $420.2 million. We believe our existing capital resources are sufficient to meet our projected operating requirements for at least the next 12 months.

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 Fintepla, MT1621 and our other product candidates and any other product candidates that we may develop, in-license or acquire;
- the timing of regulatory approval of our product candidates and the commercial success of any approved products;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with Fintepla, MT1621 and any of our other product candidates;
- the timing and amounts of the milestone or other payments we must make related to Fintepla and MT1621;
- 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;
- the effect of competing technological and market developments; and
- any delays and cost increases that result from the COVID-19 pandemic.

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, and this risk could be exacerbated by the impact of COVID-19 on global economic conditions. 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 our 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):

	Three Months Ended March 31,	
	2020	2019
Cash and cash equivalents, beginning of the period	$ 62,070	$ 68,454
Net cash used in operating activities	(52,491)	(24,827)
Net cash provided by investing activities	37,217	20,864
Net cash provided by (used in) financing activities	223,179	(6,203)
Net decrease in cash and cash equivalents	207,905	(10,166)
Cash and cash equivalents, end of the period	$ 269,975	$ 58,288

Operating Activities

For the three months ended March 31, 2020, net cash used in operating activities of $52.5 million was primarily attributable to research and development spend related to ongoing open-label clinical trials for Fintepla and manufacturing process development for Fintepla and MT1621, commercial preparedness and planning expenses including additions in headcount to build out our sales force of key account managers and general and administrative costs to support our business objectives.

For the three months ended March 31, 2019, net cash used in operating activities of $24.8 million was primarily attributable to a net loss of $35.2 million, plus the net effect of non-cash items of $6.0 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 $4.4 million.

Investing Activities

For the three months ended March 31, 2020, net cash provided by investing activities of $37.2 million was attributable to the net purchase and maturities of our available-for-sale marketable securities of $38.9 million.

For the three months ended March 31, 2019, net cash provided by investing activities of $20.9 million was attributable to maturities of marketable securities. These cash inflows were offset by purchases of marketable securities and property and equipment, the majority of which was attributable to the build-out of our headquarters, which we began to occupy in early March 2019.

Financing Activities

For the three months ended March 31, 2020, net cash provided by financing activities of $223.2 million primarily consisted of net proceeds realized from the issuance of 9,798,000 million shares of our common stock in a public offering and $1.5 million in net proceeds received from the issuance of common stock pursuant to our equity incentive plans.

For the three months ended March 31, 2019, net cash used in financing activities of $6.2 million consisted of a $10.0 million payment of contingent consideration related to a prior acquisition and cash used to remit withholding taxes of $0.6 million related to the vesting of restricted stock units that were net share-settled by us to cover the required withholding tax. These cash outflows were offset by $4.4 million of proceeds from common stock issuances pursuant to our equity incentive plans.

Contractual Obligations

There were no material changes outside the ordinary course of our business during the three months ended March 31, 2020 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 2019 Form 10-K.

Off-Balance Sheet Arrangements

As of March 31, 2020, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

For quantitative and qualitative disclosures about market risk, see Item 7A, *Quantitative and Qualitative Disclosures About Market Risk*, of our 2019 Form 10-K. Our exposures to market risk have not changed materially since December 31, 2019.

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 March 31, 2020 at the reasonable assurance level.

Changes in Disclosure Controls and Procedures

There were no changes in our internal control over financial reporting during the three months ended March 31, 2020 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

On April 12, 2019, a plaintiff stockholder filed a class action lawsuit against us and certain of our executive officers alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act in the United States District Court for the Northern District of California captioned *Lake v. Zogenix*, Case No. 3:19-cv-01975-RS. The plaintiff sought to represent a class of investors who purchased our stock between February 6, 2019 and April 8, 2019, and alleged that certain statements made during this period regarding the prospects for our NDA for Fintepla were false or misleading. On October 4, 2019, we filed a motion to dismiss the complaint in the action. On January 27, 2020, the court entered an order dismissing the complaint without prejudice. Rather than amend the complaint, the plaintiffs opted to voluntarily dismiss their claims. A final judgment in favor of Zogenix and our executive officers was filed on February 13, 2020.

On January 17, 2020, a plaintiff stockholder filed a shareholder derivative lawsuit against our directors and officers alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act, breach of fiduciary duties, unjust enrichment, and waste of corporate assets, in the United States District Court for the Northern District of California captioned *Lui v. Farr*, Case No. 3:20-cv-00390. The plaintiff alleged that certain statements regarding the prospects for our NDA for Fintepla were false or misleading, and that we failed to maintain adequate internal controls in connection with its FDA submission process. Following dismissal of the *Lake v. Zogenix* securities class action, the plaintiff stockholder opted to voluntarily dismiss his suit. On April 2, 2020, the Court entered an order dismissing the action without prejudice pursuant to the parties' stipulation.

We 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 our business, results of operations, financial position or cash flows.

Item 1A. Risk Factors

There have been no material changes in our risk factors from those disclosed in Part I, Item 1A of our 2019 Form 10-K, other than as set forth below.

Our business is subject to risks arising from epidemic diseases, such as the recent COVID-19 pandemic.

The current COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, patients, communities and business operations, as well as the U.S. and global economy and financial markets. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, and restricting business functions outside of one's home. In response, we have implemented a work from home policy for all employees across all facilities, following the guidelines or directives issued by federal, state and local government agencies in the U.S. as well as the U.K. government. To date, we have been able to continue to supply Fintepla and MT1621 to our patients currently enrolled in our clinical trials and do not currently anticipate any interruptions in supply. In addition, while we are continuing the clinical trials we have underway in sites across the globe, we expect that COVID-19 precautions may directly or indirectly impact the timeline for some of our clinical trials. For example, due to the challenges of enrolling new patients posed by the COVID-19 pandemic, we have paused the initiation of our exploratory Phase 2 basket study, which is designed to understand the characteristics of rare epilepsy disorders other than Dravet syndrome and Lennox-Gastaut syndrome in separate cohorts and evaluate whether Fintepla is safe and effective versus placebo in these patient populations. As the COVID-19 pandemic continues to spread around the globe, we may experience disruptions that could severely impact our business, clinical trials and manufacturing and supply chains, including:

- interruption or delays in the operations of the FDA, EMA or other regulatory authorities, which may impact review and approval timelines of our NDA and MAA for Fintepla for the treatment of seizures associated with Dravet syndrome;
- further delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;

- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, including interruption of supply if Fintepla is approved for marketing;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials and interruption in global shipping that may affect the transport of clinical trial materials;
- limitations on employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving feedback or approvals from the FDA, EMA or other regulatory authorities with respect to future clinical trials or regulatory submissions, including for MT1621;
- changes in local regulations as part of a response to COVID-19 which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- refusal of the FDA or EMA to accept data from clinical trials in affected geographies; and
- difficulties launching or commercializing products, including due to reduced access to doctors as a result of social distancing protocols.

In addition, the spread of COVID-19 has had and may continue to severely impact the trading price of shares of our common stock and could further severely impact our ability to raise additional capital on a timely basis or at all.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 may impact our business, including our clinical trials, manufacturing and supply chains and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this section and in the “Risk Factors” section of our 2019 Form 10-K.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA’s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA’s ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory

submissions, including FDA's ability to make a decision by the June 25, 2020 PDUFA target action date, which could have a material adverse effect on our business.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Exhibit Description
3.1[(1)]	Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.2[(2)]	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.3[(3)]	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.4[(4)]	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.5[(1)]	Fifth Amended and Restated Certificate of Incorporation of the Registrant
4.1[(5)]	Form of the Registrant's Common Stock Certificate
4.2[(6)]	Warrant dated July 18, 2011 issued by the Registrant to Healthcare Royalty Partners (formerly Cowen Healthcare Royalty Partners II, L.P.)
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
32.1**	Certification of Chief Executive Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
32.2**	Certification of Chief Financial Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
101*	Inline XBRL Document Set for the condensed consolidated financial statements and accompanying notes in Part I, Item 1, "Financial Statements" of this Quarterly Report on Form 10-Q.
104*	Inline XBRL for the cover page of this Quarterly Report on Form 10-Q, included in the Exhibit 101 Inline XBRL Document Set.

(1) Incorporated by reference to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 filed on October 27, 2010.

(2) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed on November 8, 2012.

(3) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed on August 10, 2015.

(4) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed on August 6, 2019.

(5) Incorporated by reference to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 filed on November 4, 2010.

(6) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed on August 12, 2011.

† Indicates management contract or compensatory plan.

* Filed herewith.

** 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 herewith.

SIGNATURES

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

ZOGENIX, INC.

Date: May 5, 2020

By: /s/ Stephen J. Farr

President and Chief Executive Officer

(Principal Executive Officer)

Date: May 5, 2020

By: /s/ Michael P. Smith

Executive Vice President, Chief Financial Officer and Treasurer

(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stephen J. Farr, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Zogenix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Stephen J. Farr

Stephen J. Farr
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 5, 2020

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael P. Smith, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Zogenix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Michael P. Smith

Michael P. Smith
Executive Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer)

Date: May 5, 2020

Exhibit 32.1

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Quarterly Report on Form 10-Q of Zogenix, Inc. (the "Company") for the period ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen J. Farr, as Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 5, 2020

/s/ Stephen J. Farr
Stephen J. Farr
President and Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Quarterly Report on Form 10-Q of Zogenix, Inc. (the "Company") for the period ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael P. Smith, as Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 5, 2020

/s/ Michael P. Smith
Michael P. Smith
Executive Vice President, Chief Financial Officer and Treasurer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.