UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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 September 30, 2021

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 October 27, 2021 was 55,992,086.

Zogenix, Inc.
Form 10-Q
For the Quarterly Period Ended September 30, 2021

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ZOGENIX, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(In thousands, except par value)

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 106,138	$ 166,916
Marketable securities	236,886	338,193
Accounts receivable, net	9,486	3,824
Inventory	3,502	1,026
Prepaid expenses	13,950	7,279
Other current assets	5,500	4,936
Total current assets	375,462	522,174
Property and equipment, net	7,593	8,724
Operating lease right-of-use assets	6,862	7,748
Intangible asset, net	92,644	98,558
Goodwill	6,234	6,234
Other non-current assets	8,192	7,692
Total assets	$ 496,987	$ 651,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,113	$ 11,945
Accrued and other current liabilities	46,111	54,964
Deferred revenue, current	5,048	5,318
Current portion of operating lease liabilities	1,654	1,688
Current portion of contingent consideration	13,500	8,800
Total current liabilities	78,426	82,715
Deferred revenue, noncurrent	3,436	5,479
Operating lease liabilities, net of current portion	9,055	10,314
Contingent consideration, net of current portion	25,900	33,600
Convertible senior notes	155,871	149,353
Total liabilities	272,688	281,461
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000 shares authorized; none issued and outstanding	—	—
Common stock and additional paid-in capital, $0.001 par value: 200,000 and 100,000 shares authorized and 55,935 and 55,736 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	1,721,694	1,694,580
Accumulated deficit	(1,497,370)	(1,324,840)
Accumulated other comprehensive loss	(25)	(71)
Total stockholders' equity	224,299	369,669
Total liabilities and stockholders' equity	$ 496,987	$ 651,130

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Net product sales	$ 21,398	$ 1,520	$ 51,269	$ 1,520
Collaboration revenue	1,212	1,340	3,813	3,621
Total revenues	22,610	2,860	55,082	5,141
Costs and expenses:				
Cost of product sales (excluding amortization of intangible asset)	1,294	140	3,192	140
Research and development	33,255	34,425	100,868	102,038
Selling, general and administrative	39,559	24,583	104,713	70,332
Intangible asset amortization	1,972	1,971	5,914	1,971
Acquired in-process research and development costs	—	1,500	—	4,500
Change in fair value of contingent consideration	400	1,800	1,500	6,100
Total costs and expenses	76,480	64,419	216,187	185,081
Loss from operations	(53,870)	(61,559)	(161,105)	(179,940)
Other income (expense), net:				
Interest income	85	934	579	2,504
Interest expense	(3,848)	—	(11,373)	—
Other, net	(371)	536	(631)	20,798
Total other (expense) income, net	(4,134)	1,470	(11,425)	23,302
Loss before income taxes	(58,004)	(60,089)	(172,530)	(156,638)
Income tax benefit	—	—	—	(17,425)
Net loss	$ (58,004)	$ (60,089)	$ (172,530)	$ (139,213)
Net loss per share, basic and diluted	$ (1.04)	$ (1.08)	$ (3.09)	$ (2.62)
Weighted average number of shares used in the calculation of basic and diluted net loss per common share	55,905	55,548	55,831	53,039

See accompanying notes to the unaudited condensed consolidated financial statements.

ZOGENIX, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	$ (58,004)	$ (60,089)	$ (172,530)	$ (139,213)
Other comprehensive income (loss):				
Change in net unrealized gains (losses) related to marketable securities	(15)	(255)	(183)	17
Foreign currency translation adjustments	114	(69)	229	(98)
Total other comprehensive (loss) income	99	(324)	46	(81)
Comprehensive loss	$ (57,905)	$ (60,413)	$ (172,484)	$ (139,294)

See accompanying notes to the unaudited condensed consolidated financial statements.

ZOGENIX, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)

(In thousands)

	Shares of Common Stock	Common Stock and Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
Balance at December 31, 2020	55,736	$ 1,694,580	$ (1,324,840)	$ (71)	$ 369,669
Net loss	—	—	(55,630)	—	(55,630)
Other comprehensive income	—	—	—	34	34
Issuance of common stock under employee equity plans	120	6	—	—	6
Shares repurchased to satisfy tax withholding obligation of vesting restricted stock units	(43)	(896)	—	—	(896)
Stock-based compensation	—	8,098	—	—	8,098
Balance at March 31, 2021	55,813	1,701,788	(1,380,470)	(37)	321,281
Net loss	—	—	(58,896)	—	(58,896)
Other comprehensive loss	—	—	—	(87)	(87)
Issuance of common stock under employee equity plans	78	1,036	—	—	1,036
Stock-based compensation	—	9,526	—	—	9,526
Balance at June 30, 2021	55,891	1,712,350	(1,439,366)	(124)	272,860
Net loss	—	—	(58,004)	—	(58,004)
Other comprehensive loss	—	—	—	99	99
Issuance of common stock under employee equity plans	53	295	—	—	295
Shares repurchased to satisfy tax withholding obligation of vesting restricted stock units	(9)	(133)	—	—	(133)
Stock-based compensation	—	9,182	—	—	9,182
Balance at September 30, 2021	55,935	$ 1,721,694	$ (1,497,370)	$ (25)	$ 224,299

See accompanying notes to the unaudited condensed consolidated financial statements.

	Shares of Common Stock	Common Stock and Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
Balance at December 31, 2019	45,272	$ 1,360,137	$ (1,115,457)	$ 379	$ 245,059
Net loss	—	—	(25,800)	—	(25,800)
Other comprehensive loss	—	—	—	(167)	(167)
Issuance of common stock, net of offering costs	9,798	221,708	—	—	221,708
Issuance of common stock under employee equity plans	297	3,882	—	—	3,882
Shares repurchased to satisfy tax withholding obligation of vesting restricted stock units	(26)	(569)	—	—	(569)
Stock-based compensation	—	6,394	—	—	6,394
Balance at March 31, 2020	55,341	1,591,552	(1,141,257)	212	450,507
Net loss	—	—	(53,324)	—	(53,324)
Other comprehensive income	—	—	—	410	410
Issuance of common stock under employee equity plans	153	616	—	—	616
Shares repurchased to satisfy tax withholding obligation of vesting restricted stock units	(49)	(1,369)	—	—	(1,369)
Stock-based compensation	—	8,303	—	—	8,303
Balance at June 30, 2020	55,445	1,599,102	(1,194,581)	622	405,143
Net loss	—	—	(60,089)		(60,089)
Other comprehensive loss	—	—	—	(324)	(324)
Issuance of common stock, net of offering costs	202	4,866	—	—	4,866
Equity component of convertible senior notes	—	65,482	—	—	65,482
Issuance of common stock under employee equity plans	35	91	—	—	91
Shares repurchased to satisfy tax withholding obligation of vesting restricted stock units	(9)	(218)	—	—	(218)
Stock-based compensation	—	7,141	—	—	7,141
Balance at September 30, 2020	55,673	$ 1,676,464	$ (1,254,670)	$ 298	$ 422,092

See accompanying notes to the unaudited condensed consolidated financial statements.

ZOGENIX, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (172,530)	$ (139,213)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	25,776	21,838
Depreciation and amortization	7,092	3,106
Deferred income taxes	—	(17,425)
Amortization of debt discount and issuance costs	6,518	—
Acquired in-process research and development expense	—	4,500
Change in fair value of contingent consideration liability	1,500	6,100
Other non-cash items, net	833	169
Changes in operating assets and liabilities:		
Accounts receivable	(5,662)	(1,309)
Inventory	(1,446)	(1,010)
Prepaid expenses and other current assets	(7,235)	(3,321)
Other non-current assets	(500)	(1,761)
Accounts payable, accrued and other current liabilities	6,585	541
Contingent consideration	(1,500)	—
Operating lease liabilities	(1,293)	(975)
Deferred revenue	(2,313)	(621)
Net cash used in operating activities	(144,175)	(129,381)
Cash flows from investing activities:		
Cash paid for in-process research and development asset	—	(4,500)
Purchases of marketable securities	(317,228)	(283,208)
Proceeds from maturities of marketable securities	404,904	232,142
Proceeds from sale of marketable securities	13,500	12,987
Purchases of property and equipment	(87)	(657)
Net cash (used in) provided by investing activities	101,089	(43,236)
Cash flows from financing activities:		
Payment of contingent consideration	(18,000)	(15,000)
Proceeds from issuance of common stock under equity incentive plans	1,337	4,589
Payments of tax withholding obligation on vesting restricted stock units	(1,029)	(2,157)
Net proceeds from issuance of convertible senior notes	—	194,000
Proceeds from issuance of common stock, net of issuance costs	—	226,575
Net cash (used in) provided by financing activities	(17,692)	408,007
Net (decrease) increase in cash and cash equivalents	(60,778)	235,390
Cash and cash equivalents, beginning of the period	166,916	62,070
Cash and cash equivalents, end of the period	$ 106,138	$ 297,460
Supplemental disclosure of non-cash investing and financing activities:		
Right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 1,156

See accompanying notes to the unaudited condensed consolidated financial statements.

ZOGENIX, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

Note 1 – Organization, Basis of Presentation and Liquidity

Zogenix, Inc., and subsidiaries (also referred to as Zogenix, we, our or us) is a global biopharmaceutical company committed to developing and commercializing therapies with the potential to transform the lives of patients and their families living with rare diseases. Our first rare disease therapy, Fintepla (fenfluramine) oral solution, has been approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of seizures associated with Dravet syndrome, a rare, devastating, severe lifelong epilepsy. Fintepla is also currently under development in Japan. We also have two late-stage development programs underway: one for Fintepla for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), a rare childhood-onset epilepsy, and another for MT1621, an investigational novel substrate enhancement therapy for the treatment of TK2 deficiency, a rare genetic disorder.

We operate as a single operating segment engaged in 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 have been prepared pursuant to generally accepted accounting principles in the United States (GAAP) for interim financial reporting and the rules and regulations of the Securities and Exchange Commission (SEC). The condensed consolidated financial statements do not include all of the information and note disclosures required by GAAP for complete financial statements and should therefore be read in conjunction with the consolidated financial statements and related notes included in our 2020 Annual Report on Form 10-K (2020 Form 10-K), which was filed with the SEC on March 1, 2021. In the opinion of management, these condensed consolidated financial statements reflect all adjustments, which are normal and recurring in nature, necessary for a fair statement of our financial position, results of operations and cash flows for the periods indicated. The results of operations for any interim period are not necessarily indicative of results of operations for any future period.

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.

Liquidity

As of September 30, 2021, our cash, cash equivalents and marketable securities totaled $343.0 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 $1.5 billion as of September 30, 2021. We expect to continue to incur significant operating losses and negative cash flows from operations to support the sales and marketing of Fintepla for Dravet syndrome in the U.S. and Europe, potential commercialization of Fintepla for LGS, as well as continuing to advance our clinical programs. Additionally, we are obligated to pay royalties on sales as well as make future milestone payments that are contingent upon the successful achievement of certain development, regulatory and sales-based milestone events related to Fintepla and MT1621. Historically, we have relied primarily on the proceeds from equity and convertible debt 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, 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 the ongoing COVID-19 pandemic on global economic conditions. Failure to raise sufficient capital when needed could require us 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 – 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* to the consolidated financial statements in our 2020 Form 10-K. There have been no material changes in our significant accounting policies during the nine months ended September 30, 2021.

Recently Issued Accounting Pronouncements Not Yet Adopted

Account Standard Update (ASU) 2020-06, *Debt — Debt with Conversion and Other Options (subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (subtopic 815-40) (ASU 2020-06)* simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible debt instruments with cash conversion features. Specifically, ASU 2020-06 removes the existing guidance that we currently follow for our convertible senior notes, which requires entities to account for cash conversion features in equity separately from the host contract. These amendments are expected to result in more freestanding financial instruments qualifying for equity classification and, as a result, not accounted for as derivatives, as well as fewer embedded features requiring separate accounting from the host contract. In addition, ASU 2020-06 eliminates the treasury stock method when calculating diluted earnings per share for convertible instruments that can be settled in whole or in part with equity and requires the use of the if-converted method. Early adoption is permitted, but no earlier than the fiscal year beginning after December 15, 2020. The standard can be applied using a full or modified retrospective approach.

ASU 2020-06 will be effective for us as of January 1, 2022. When effective, we expect the accounting for our convertible senior notes as a single unit of account will: i) increase the carrying value of our convertible notes to be closer to its outstanding principal balance, ii) decrease our interest expense over the expected life of the financial instrument, and iii) result in the debt instrument's effective interest rate to be closer to the stated coupon rate. In addition, the use of the more favorable treasury stock method, which allows an entity with a stated policy of settling convertible instruments with a combination of cash and shares to exclude shares issuable upon conversion that it expects to settle with cash when calculating diluted earnings per share, is no longer permitted. Even if we have the intent and ability to settle conversions by paying the conversion value in cash up to the principal amount being converted and any excess in shares, the adoption of ASU 2020-06 will require that we presume such instruments will be settled by issuance of shares (the "if-converted method"). As a result, our diluted earnings per share under ASU 2020-06 may be lower than if we were able to apply the treasury stock method when calculating the dilutive effect of our Notes in earnings per share.

We will adopt the new guidance in the annual period beginning January 1, 2022, on a modified retrospective basis. On the date of adoption, we expect to record a net decrease to additional paid-in capital of approximately $75.3 million to remove the equity component separately recorded for the conversion features associated with the convertible debt instruments and equity component associated with the issuance costs, an increase of approximately $65.6 million in the carrying value of our senior convertible notes to reflect the full principal amount of the Notes outstanding net of issuance costs, and a decrease of approximately $9.7 million to accumulated deficit. These preliminary estimates could change as we continue with our implementation efforts. We do not expect an impact to the our statements of operations or cash flows as the result of the adoption of this ASU.

Note 3 – Product Revenue and Concentration of Credit Risks

Net Product Sales

Fintepla is distributed in the U.S. through an exclusive arrangement with a specialty distributor, who is our customer. The specialty distributor subsequently resells our product through its related specialty pharmacy provider to patients and health care providers. Separately, we have or may enter into payment arrangements with various third-party payers including pharmacy benefit managers, private healthcare insurers and government healthcare programs who provide coverage and reimbursement for our products that have been proscribed to a patient.

We distribute Fintepla in Europe (currently, in Germany and France) through a third-party logistics provider (3PL) for distribution to pharmacies in those countries. The pharmacies are our customers, who subsequently resell our product directly to patients and health care providers.

For the three months ended September 30, 2021, total net product sales for Fintepla were $21.4 million and consisted of U.S. product sales of $18.4 million, with the remainder from sales in Europe. For the nine months ended September 30, 2021, total net product sales for Fintepla were $51.3 million and consisted of U.S. product sales of $45.3 million, with the remainder from sales in Europe. For the three and nine months ended September 30, 2020, total net product sales for Fintepla of $1.5 million were generated in the United States. Fintepla was approved by the FDA in June 2020 and the EMA in December 2020.

We record product revenue at the net sales price (transaction price), which includes estimates of consideration payable to our customers and third-party payers for which reserves are established and that result from government rebates, chargebacks, co-pay assistance, prompt-payment discounts and other allowances that are offered under arrangements between us, our customers, and third-party payers related to the sales of Fintepla.

The following table summarizes the provisions, and credits/payments, for sales-related deductions.

(In thousands)	Rebates	Trade Discounts, Distributor Fees and Other	Total
Balance at December 31, 2020	$ 1,161	$ 129	$ 1,290
Current period provisions	7,134	1,903	9,037
Payments/credits	(4,402)	(1,773)	(6,175)
Balance at September 30, 2021	$ 3,893	$ 259	$ 4,152

We generally invoice our customers and recognize revenue once our performance obligations are satisfied, at which point payment is unconditional. Accordingly, our arrangements with customers did not give rise to contract assets or liabilities during the nine months ended September 30, 2021.

Concentration of Credit Risk and Major Customers

As is common in the pharmaceutical industry for products treating rare diseases, Fintepla is distributed through exclusive arrangements with a specialty distributor in the U.S. and through a 3PL who distributes to pharmacy providers throughout Europe (currently, in Germany and France). As a result, our accounts receivable balance at September 30, 2021 is highly concentrated with our U.S. customer, which accounted for over 80% of the balance and over 80% of net product revenue for the three and nine months ended September 30, 2021. Accounts receivable are stated net of an allowance that reflects our current estimate of credit losses expected to occur over the life of the receivable. Estimates of our allowance for credit losses consider a number of factors including existing contractual payment terms, individual customer circumstances, historical payment patterns of our customers, a review of the local economic environment and its potential impact on expected future customer payment patterns. As of September 30, 2021 and December 31, 2020, we believe that the allowances for doubtful accounts, if any, are adequate based on our analysis of the specific business circumstances and expectations of collection for each of the underlying accounts.

Note 4 – Collaboration Arrangement

Nippon Shinyaku Co., Ltd

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. No development rights or intellectual property licenses were transferred. 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.

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. The collaborative activities under the Shinyaku Agreement prior to regulatory approval are within the scope of the accounting guidance related to collaborative arrangements.

Pursuant to the terms of the agreement, Shinyaku agreed to make aggregate fixed payments of $20.0 million in scheduled installments over a two-year period from the date of the agreement. As of September 30, 2021, all fixed consideration has been received. 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 of which $3.0 million will be due to us upon our submission of an NDA in Japan (J-NDA) to Japan's Pharmaceutical and Medical Devices Agency for Dravet syndrome. At contract inception and through September 30, 2021, the regulatory milestone variable consideration was fully constrained as the achievement of the events tied to these regulatory milestone payments was highly dependent on factors outside our control.

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. 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.

For the three and nine months ended September 30, 2021, collaboration revenue under this arrangement was $1.2 million and $3.8 million, respectively, as compared to the same periods in 2020 of $1.3 million and $3.6 million, respectively. As of September 30, 2021, the deferred revenue balance of $8.5 million was 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 5 – Strategic License Agreements

Universities of Antwerp and Leuven in Belgium (the Universities)

As a result of our 2014 acquisition of Brabant Pharma Limited, we have a collaboration and license agreement with the Universities (the Universities Agreement) that runs through September 2045. Under the terms of the agreement, the Universities granted us an exclusive worldwide license to use the data obtained from a study related to low-dose fenfluramine for the treatment of Dravet syndrome or certain related conditions stemming from infantile epilepsy such as LGS, as well as certain other intellectual property. We are required to pay a mid-single-digit percentage royalty on net sales of products containing low-dose fenfluramine for the treatment of Dravet syndrome or, in the case of a sublicense of products containing low-dose fenfluramine for the treatment of Dravet syndrome, a percentage in the mid-twenties of the sub-licensing revenues.

Subsequent to the execution of the March 2019 Shinyaku Agreement beginning in late 2019, we have been in discussions with the Universities to address the portion of the payments the Universities are entitled to, if any, related to proceeds we received or may receive under the Shinyaku Agreement from Nippon Shinyaku.

In October 2021, we reached an agreement to modify the Universities Agreement and make a one-time payment of $7.0 million related to our previous collaboration activities and consideration received to date under the Shinyaku Agreement. We also agreed to pay the Universities 15% of future regulatory milestone collaboration consideration and sales-based milestone consideration we receive, as well as amending the method of calculating royalties due from sale of Fintepla distributed in Japan.

The payment of $7.0 million has been recorded within accrued and other current liabilities in the condensed consolidated balance sheet at September 30, 2021. For the three and nine months ended September 30, 2021, the $7.0 million was recorded within research and development expense as a cost of our Shinyaku Agreement and as Fintepla has not yet been approved for marketing in Japan.

Tevard Collaboration, Option and License Agreement

In October 2019, we entered into an option agreement with Tevard Biosciences (Tevard), a privately-held company focused on advancing novel gene therapies and other genetic epilepsies. In December 2020, we exercised the option on Tevard's Dravet syndrome program and entered into a collaboration, option and license agreement with Tevard (the Tevard Agreement) and will be responsible for funding preclinical studies and clinical development for this program. The financial terms of the Tevard Agreement included an upfront payment of $5.2 million. In connection with the transaction, we also purchased a convertible promissory note issued by Tevard in the amount of $5.0 million. The note matures in December 2022 and carries interest at 3.5% per year. The note will automatically convert into equity securities issued by Tevard upon the occurrence of an equity financing transaction at a conversion price equal to the price paid per share by other investors of the financing transaction.

For the three and nine months ended September 30, 2021, costs incurred to reimburse Tevard's Dravet syndrome program of $0.8 million and $2.4 million were recorded as research and development expense. For the three and nine months ended September 30, 2020, option maintenance fees of $1.5 million and $4.5 million incurred prior to our opt-in of Tevard's Dravet syndrome program in December 2020 were immediately expensed to acquired in-process research and development costs.

At the inception of the agreement and through September 30, 2021, Tevard is a variable interest entity in which we held variable interests through our licensed Dravet syndrome program and convertible promissory note. We determined that we are not the primary beneficiary of Tevard as we do not have voting control or other forms of power to direct activities that most significantly impact Tevard's economic performance.

At each reporting period, we evaluate the note receivable for current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. As of September 30, 2021, no provision for current expected credit losses was deemed necessary based on the expected timing of an equity financing that would result in the automatic conversion of the note to equity securities of Tevard and their existing cash on hand was sufficient to meet their operating requirements prior to the consummation of a financing transaction.

As of September 30, 2021, we do not have any current legal or contractual obligations to provide financing to Tevard and our maximum exposure to future loss is limited to the $5.0 million note receivable. While we have committed to fund the Dravet syndrome development program for Tevard's early discovery activities, our obligation to fund these efforts is contingent upon continued involvement in the program and/or the lack of any adverse events which could cause the discontinuance of the program. Our exposure to future losses is limited as we have the unilateral right to terminate the agreement with 180 days advanced notice.

Note 6 – 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 September 30, 2021 and December 31, 2020:

	September 30, 2021			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Current assets:				
Cash	$ 29,269	$ —	$ —	$ 29,269
Cash equivalents:				
Money market funds	39,422	—	—	39,422
Commercial paper	35,444	—	—	35,444
Corporate debt securities	2,003	—	—	2,003
Total cash equivalents	76,869	—	—	76,869
Total cash and cash equivalents	106,138	—	—	106,138
Marketable securities:				
U.S. Treasuries	15,510	1	—	15,511
Certificate of deposits	41,874	—	—	41,874
Commercial paper	158,837	—	—	158,837
U.S. Government-sponsored enterprises debt securities	6,200	5	—	6,205
Corporate debt securities	14,459	2	(2)	14,459
Total marketable securities	236,880	8	(2)	236,886
Total cash, cash equivalents and marketable securities	$ 343,018	$ 8	$ (2)	$ 343,024

(In thousands)	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Current assets:				
Cash	$ 23,887	$ —	$ —	$ 23,887
Cash equivalents:				
Money market funds	80,986	—	—	80,986
Commercial paper	61,043	—	—	61,043
Certificate of deposits	1,000	—	—	1,000
Total cash equivalents	143,029	—	—	143,029
Total cash and cash equivalents	166,916	—	—	166,916
Marketable securities:				
U.S. Treasuries	43,050	1	(1)	43,050
Commercial paper	210,986	—	—	210,986
Certificate of deposits	44,480	—	—	44,480
U.S. Government-sponsored enterprises debt securities	6,200	17	—	6,217
Corporate debt securities	33,288	172	—	33,460
Total marketable securities	338,004	190	(1)	338,193
Total cash, cash equivalents and marketable securities	$ 504,920	$ 190	$ (1)	$ 505,109

As of September 30, 2021, all marketable securities held have maturity dates within one year or less. 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. As of September 30, 2021, the aggregate difference between the amortized cost and fair value of each security in an unrealized loss position was de minimis. Since any provision for expected credit losses for a security held is limited to the amount the fair value is less than its amortized cost, no allowance for expected credit loss was deemed necessary at September 30, 2021.

See Note 7 for further information regarding the fair value of our financial instruments.

Note 7 – 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.

The following tables summarize assets and liabilities recognized or at fair value on a recurring basis as of September 30, 2021 and December 31, 2020:

(In thousands)	September 30, 2021 Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 39,422	$ —	$ —	$ 39,422
Commercial paper	—	35,444	—	35,444
Corporate debt securities	—	2,003	—	$ 2,003
Marketable securities:				
U.S. Treasuries	—	15,511	—	15,511
Certificate of deposits	—	41,874	—	41,874
Commercial paper	—	158,837	—	158,837
U.S. Government-sponsored enterprises debt securities	—	6,205	—	6,205
Corporate debt securities	—	14,459	—	14,459
Total[(1)]	$ 39,422	$ 274,333	$ —	$ 313,755
Liabilities:				
Contingent consideration	$ —	$ —	$ 39,400	$ 39,400

(In thousands)	December 31, 2020 Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 80,986	$ —	$ —	$ 80,986
Commercial paper	—	61,043	—	61,043
Certificate of deposits	—	1,000	—	1,000
Marketable securities:				
U.S. Treasuries	—	43,050		43,050
Commercial paper	—	210,986		210,986
Certificate of deposits	—	44,480		44,480
U.S. Government-sponsored enterprises debt securities	—	6,217		6,217
Corporate debt securities	—	33,460	—	33,460
Total[(1)]	$ 80,986	$ 400,236	$ —	$ 481,222
Liabilities:				
Contingent consideration	$ —	$ —	$ 42,400	$ 42,400

(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

As of September 30, 2021, our contingent consideration liability consisted of sales-based milestones for Fintepla, which resulted from our 2014 acquisition of Brabant. The maximum amount of future contingent consideration (undiscounted) that we could be required to pay was $40.5 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 and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Balance at beginning of period	$ 39,000	$ 53,100	$ 42,400	$ 63,800
Change in fair value	400	1,800	1,500	6,100
Settlements	—	—	(4,500)	(15,000)
Balance at end of period	$ 39,400	$ 54,900	$ 39,400	$ 54,900

For the three and nine months ended September 30, 2021, the increases to the estimated fair value of the contingent consideration liability primarily reflects the interest component of contingent consideration related to the passage of time.

The following table summarizes the significant unobservable inputs used in the fair value measurement of our contingent consideration liability as of September 30, 2021.

Fair Value as of September 30, 2021 (in thousands)	Valuation Technique	Unobservable Input	Range	Weighted Average[1]
		Discount rate	0.0% — 2.0%	1.0%
$39,400	Discounted cash flow	Probability of payment	100%	100%
		Projected year of payment	2022 — 2023	2022

(1) Unobservable inputs were weighted by the relative fair value of each sales-based milestone payment.

Fair Value Disclosures

Some of our financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate fair value due to their short-term nature. Such financial assets and financial liabilities include accounts receivable, promissory note receivable, certain other current assets, accounts payable and accrued liabilities.

Convertible Senior Notes

As of September 30, 2021 and December 31, 2020, the estimated fair value of our convertible senior notes due 2027 was approximately $227.0 million and $260.5 million, respectively, and was determined based on a binomial lattice model with Level 2 inputs. When determining the estimated fair value of the Notes, we utilize a binomial lattice model which incorporates the terms and conditions of our convertible senior notes and market-based risk measurements that are indirectly observable, such as credit risk. The lattice model produces an estimated fair value based on changes in the price of the underlying common stock price over successive periods of time. An estimated yield based on comparable non-convertible debt instruments in the market is used to discount the cash flows.

Note 8 – Intangible Asset

Our intangible asset consists of worldwide development, commercialization and related intellectual property rights including patents and licenses for Fintepla, our first rare disease therapy approved for marketing in the U.S. and Europe.

The following table provides details of the carrying amount of our finite-lived intangible asset:

(In thousands)	September 30, 2021	December 31, 2020
Finite-lived intangible asset	$ 102,500	$ 102,500
Accumulated amortization	(9,856)	(3,942)
Total intangible asset, net	$ 92,644	$ 98,558

As of September 30, 2021 and December 31, 2020, the carrying value of the intangible asset will be amortized over its estimated remaining useful life of 11.8 years and 12.5 years, respectively. At September 30, 2021, the estimated amortization expense for each of the five succeeding years was approximately $7.9 million per year.

Note 9 – Balance Sheet Details

Inventory

The following table provides details of our inventory balance:

(In thousands)	September 30, 2021	December 31, 2020
Raw materials	$ 1,011	$ 391
Work in process	1,299	243
Finished goods	1,192	392
Total	$ 3,502	$ 1,026

Accrued and Other Current Liabilities

The following table provides details of accrued and other current liabilities:

(In thousands)	September 30, 2021	December 31, 2020
Accrued clinical trial expenses	$ 13,272	$ 16,477
Accrued compensation	12,243	10,917
Accrued milestone payment	—	15,000
Other accrued liabilities	20,596	12,570
Total	$ 46,111	$ 54,964

Note 10 – Convertible Senior Notes

In September and October 2020, we issued $230.0 million aggregate principal amount of 2.75% convertible senior notes due 2027 (the Notes) and realized net proceeds of $222.5 million. The Notes are governed by an indenture (Indenture), dated as of September 28, 2020, between Zogenix and U.S. Bank National Association, as trustee. Under the Indenture, the Notes are senior, unsecured obligations of Zogenix, are equal in right of payment with its future senior, unsecured indebtedness of Zogenix, and structurally subordinated to all indebtedness and liabilities of its subsidiaries. Interest is payable semi-annually in arrears on April 1 and October 1 of each year, beginning on April 1, 2021 at a rate of 2.75% per year. The Notes mature on October 1, 2027, unless earlier repurchased, redeemed or converted. The Indenture contains customary terms and covenants and may become due and payable upon the occurrence of an event of default, but does not contain any financial covenants. As of September 30, 2021, we were in compliance with all covenants under the Indenture.

The Notes are convertible, subject to certain conditions described below, into shares of our common stock at an initial conversion rate of 41.1794 shares per $1,000 principal amount of the Notes, which represents an initial conversion price of approximately $24.28 per share, subject to adjustments upon the occurrence of certain events. Certain corporate events described in the Indenture may increase the conversion rate for holders who elect to convert their Notes upon the occurrence of certain corporate events. We also may choose to repurchase outstanding Notes through open-market transactions, including through a Rule 10b5-1 trading plan to facilitate open-market repurchases, or otherwise, from time to time.

Holders may convert the Notes in multiples of $1,000 principal amount at any time prior to October 1, 2027, but only in the following circumstances:

- during any calendar quarter ending after December 31, 2020, if our closing stock price exceeds 130% of the conversion price on each of at least 20 trading days of the last 30 consecutive trading days of the immediately preceding calendar quarter;
- during the five consecutive business day period after any 10 consecutive trading day period in which the Notes' trading price is less than 98% of the product of our closing stock price times the conversion rate; or
- the occurrence of certain corporate events, such as a change of control, merger, default or liquidation.

In addition, holders may also convert their Notes at their option at any time beginning on July 1, 2027 until the close of business on the second scheduled trading day immediately before the maturity date for the Notes, without regard to the foregoing circumstances.

Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination thereof at our election.

We may not redeem the Notes prior to October 7, 2024. On or after October 7, 2024, the Notes are redeemable for cash, in whole or in part (subject to minimum redemption amounts), at our option at any time, and from time to time, before the 40th scheduled trading day immediately before October 1, 2027, at a cash redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest, if any, but only if our closing stock price exceeds 130% of the conversion price on (1) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date we send the related redemption notice; and (2) the trading day immediately before the date we send such notice. In addition, calling any Note for redemption will constitute a make-whole fundamental change (as defined in the Indenture) with respect to that Note, in which case the conversion rate applicable to the conversion of that Note will be increased in certain circumstances if it is converted after it is called for redemption.

In accounting for the issuance of the Notes, we separated the Notes between a liability component and an equity component utilizing applicable accounting guidance for convertible instruments that may be settled with a combination of cash and shares, at our election. This resulted in the recognition of $152.1 million as the liability component of the Notes. The carrying amount of the equity component of approximately $77.9 million, representing the conversion option, was determined by deducting the fair value of the liability component from the principal amount of the Notes. The difference between the principal amount of the Notes and the liability component (the debt discount) is amortized to interest expense using the effective interest method over the expected term of the Notes. The equity component of the Notes is included in additional paid-in capital in the condensed consolidated balance sheets. In accounting for debt issuance costs, we allocated the total amount incurred of $7.5 million to the liability and equity components using the same proportions as the principal amount of the Notes. Debt issuance costs attributable to the liability component of $4.9 million were recorded as debt discount and are being amortized to interest expense over the expected term of the Notes. Debt issuance costs attributable to the equity component of approximately $2.6 million were netted with the equity component within our condensed consolidated stockholders' equity.

The equity component balance of $75.3 million, net of allocated issuance costs, is not remeasured as long as the conversion option of the Notes continues to meet the conditions for equity classification. As of September 30, 2021, there have been no changes to the net carrying value of the equity component balance since the date of issuance of the Notes.

The following table provides additional details on the carrying amounts of the Notes:

(in thousands)	September 30, 2021	December 31, 2020
Liability component:		
Principal amount of Notes	$ 230,000	$ 230,000
Less: unamortized debt discount and issuance costs	(74,129)	(80,647)
Net carrying amount of Notes	$ 155,871	$ 149,353
Equity component — net carrying amount	$ 75,333	$ 75,333

For the three and nine months ended September 30, 2021, total interest expense recognized related to the Notes consists of the following:

(in thousands)	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2021
Contractual coupon interest	1,581	4,777
Amortization of debt discount and issuance costs	2,238	6,518
Total interest expense	$ 3,819	$ 11,295

For the three and nine months ended September 30, 2021, the effective interest rate on the liability component of the Notes was 9.9%, which remained unchanged from the date of issuance. The unamortized debt discount and issuance costs of $74.1 million as of September 30, 2021 will be amortized over the estimated remaining term of approximately 6.0 years. Interest expense related to the Notes was not material for the same periods in 2020.

During the third quarter of 2021, the closing price of our common stock did not exceed 130% of the applicable conversion price of the Notes on at least 20 of the last 30 consecutive trading days of the quarter; furthermore, no other conditions allowing holders of the Notes to convert were met as of September 30, 2021. Therefore, the Notes are not convertible for the fourth quarter of 2021 and are classified as long-term debt. Should the closing price conditions be met in a future quarter, the Notes will be convertible at the holders' option during the immediately following quarter. Based on the closing price of our common stock of $15.19 per share on September 30, 2021, the if-converted value of the Notes was less than the outstanding principal balance.

Note 11 – Common Stock and Stock-Based Compensation

Increase in Authorized Shares of Common Stock

In May 2021, our stockholders approved an amendment to our Fifth Amended and Restated Certificate of Incorporation to increase the total number of authorized shares of our common stock from 100,000,000 to 200,000,000 shares. The increase in the authorized common shares was effected pursuant to a Certificate of Amendment of our Fifth Amended and Restated Certificate of Incorporation filed with the State of Delaware on May 28, 2021 and was effective as of such date.

2010 Equity Incentive Award Plan

Under our 2010 Equity Incentive Award Plan, as amended and restated effective May 22, 2019 (the Prior 2010 Plan), the aggregate number of shares with respect to which awards may be granted was 11,500,000 shares. The various types of awards that may be granted include stock options, stock appreciation rights, restricted stock units, restricted stock and other stock-based awards, any of which may be performance-based.

In May 2021, our board of directors adopted, and our stockholders approved, an amendment and restatement of the Prior 2010 Plan. The 2010 Equity Incentive Award Plan, as amended and restated effective May 27, 2021 (the 2010 Plan), increased the aggregate number of shares authorized for issuance under the plan from 11,500,000 to 16,000,000 shares, and an extension of the expiration date of the Prior 2010 Plan from March 2029 to May 2031.

2021 Employment Inducement Equity Incentive Award Plan

In May 2021, our board of directors approved the adoption of the Zogenix, Inc. 2021 Employment Inducement Equity Incentive Award Plan (2021 Inducement Plan), pursuant to which we reserved 1,000,000 shares of our common stock (subject to customary adjustments in the event of a change in capital structure). The 2021 Inducement Plan provides for the grant of non-statutory stock options, restricted stock units and other incentive awards and was adopted without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules.

The terms and conditions of the 2021 Inducement Plan are substantially similar to our 2010 Plan, but with such other terms and conditions intended to comply with the Nasdaq inducement award rules. In accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules, the only persons eligible to receive grants of equity awards under the 2021 Inducement Plan are individuals who were not previously a Zogenix employee or director, or following a bona fide period of non-employment, as an inducement material to such persons entering into employment with us.

Stock Options

The following is a summary of stock option activity for the nine months ended September 30, 2021 (in thousands, except per share data):

	Shares	Weighted-Average Exercise Price per Share
Outstanding at December 31, 2020	5,311	$ 29.12
Granted	1,625	18.21
Exercised	(50)	9.77
Canceled	(330)	28.73
Outstanding at September 30, 2021	6,556	$ 26.58

Restricted Stock Units

Time-based restricted stock units (RSUs) and performance-based restricted stock units (PSUs) will be settled with our common stock on a one-to-one basis upon vesting. The following is a summary of our stock award activity for the nine months ended September 30, 2021 (in thousands, except per share data):

	RSUs	PSUs	Total
Outstanding at December 31, 2020	393	—	393
Granted[(1)]	533	494	1,027
Vested	(144)	—	(144)
Canceled	(47)	(36)	(83)
Outstanding at September 30, 2021	735	458	1,193
(1) Weighted-average grant date fair value	$ 18.11	$ 19.53	$ 18.79

For the nine months ended September 30, 2021, we granted approximately 494,000 PSUs to employees and executive officers. The PSUs are subject to vesting based on various performance conditions including achievement of certain regulatory milestones, net product revenue targets and the number of patients on reimbursed therapy, subject to continued service by the employee. Compensation expense related to equity-based awards with performance conditions and terms that provide for a graded vesting schedule is recognized over the requisite service period on a straight-line basis for each separately vesting tranche of the award, and is based on the expected satisfaction of the performance conditions at each reporting date. For performance conditions associated with regulatory milestones, we determined the outcome is not probable of being achieved unless and until the occurrence of the event. As a result, compensation expense will only be recognized, at a point in time, when regulatory approval occurs. We expect stock-based compensation will fluctuate from period to period based on the timing of achievement of regulatory milestones and such fluctuations may be material. For performance conditions associated with the net product revenue and the number of patients receiving reimbursed therapy, we determined the outcome is probable of being achieved and stock-based compensation expense is recognized commencing at the grant date over the implicit service period.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2021	2020	2021	2020
Research and development	$ 2,905	$ 2,865	$ 10,729	$ 9,082
Selling, general and administrative	5,247	4,276	15,047	12,756
Total	$ 8,152	$ 7,141	$ 25,776	$ 21,838

Stock-based compensation of $1.0 million was capitalized into inventory for the three and nine months ended September 30, 2021.

The following table summarizes stock-based compensation expense by award type included in our condensed consolidated statements of operations:

(In thousands)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Time-based stock options and RSUs	$ 6,962	$ 5,507	23,171	19,923
Performance-based stock units	1,066	1,441	2,120	1,441
Employee stock purchase plan (ESPP)	124	193	485	474
Total	$ 8,152	$ 7,141	$ 25,776	$ 21,838

Shares reserved and available for future issuance under all employee equity plans as of September 30, 2021 and December 31, 2020 were approximately 7.1 million shares and 3.9 million shares, respectively.

Note 12 – 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, warrants to purchase common stock and rights under the Notes.

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 September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Numerator:				
Net loss	$ (58,004)	$ (60,089)	$ (172,530)	$ (139,213)
Denominator:				
Shares used in per share calculation	55,905	55,548	55,831	53,039
Net loss per share, basic and diluted	$ (1.04)	$ (1.08)	$ (3.09)	$ (2.62)

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 September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Shares subject to outstanding stock options	6,534	5,149	6,118	4,848
Shares subject to outstanding restricted stock units	1,173	422	1,032	487
Shares subject to outstanding warrants to purchase common stock	6	28	21	28
Shares issuable upon conversion of Notes	9,430	269	9,430	90
Total	17,143	5,868	16,601	5,453

Note 13 - Income Taxes

We record a tax provision or benefit for interim periods using an estimated annual effective tax rate. This rate is applied to the current year-to-date pre-tax income or loss to determine the income tax provision or benefit allocated to the interim period. The income tax effects of unusual or infrequent items including a change in the valuation allowance as a result of a change in judgment about the realizability of the related deferred tax asset are excluded from the estimated annual effective tax rate and are required to be discretely recognized in the interim period they occur.

For the three and nine months ended September 30, 2021 and the three months ended September 30, 2020, there was no provision for income taxes as we incurred pretax losses and maintained a full valuation allowance against our net deferred tax assets for these periods. For the nine months ended September 30, 2020, our income tax benefit consisted of a discrete income tax adjustment related to the completion of our in-process research program upon approval of Fintepla for marketing by the FDA. Until June 2020, our net deferred tax liability was related to book and tax basis differences for our indefinite-lived Fintepla IPR&D intangible asset that was acquired through the October 2014 acquisition of Brabant Pharma Limited. Previously, this deferred tax liability was not considered to be a source of income for purposes of establishing our deferred tax asset valuation allowance due to the uncertainty associated with the timing of reversals for this temporary tax difference. Upon FDA approval of Fintepla in June 2020, the indefinite-lived asset was reclassified to a finite-lived intangible asset and was subject to amortization over its estimated useful life. Because the detail scheduling of the timing of reversal for this temporary tax difference became available, the deferred tax liability associated with this finite-lived intangible asset was considered to be a source of income when assessing the realizability of our deferred tax assets. We therefore recorded a $17.4 million income tax benefit for the nine months ended September 30, 2020 with a corresponding reduction to our valuation allowance on our deferred tax assets. The income tax benefit included the effects of foreign exchange differences on remeasurement of the deferred tax liability. An immaterial portion of the adjustment for foreign exchange differences was related to prior periods.

Note 14 – 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 can make an election (i) 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, or (ii) 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.

In December 2019, we elected to surrender net operating losses by submitting claims to receive cash payments of $9.9 million and $9.8 million related to our 2017 and 2018 tax years, respectively. Upon approval of our submitted claims by the U.K. tax authorities in the first quarter of 2020, we recorded income of $19.7 million as a component of other income on the condensed consolidated statement of operations. For our 2019 tax year, we have not amended our tax return by surrendering some of our losses for a tax credit cash rebate claim or elect to receive an enhanced U.K. tax deduction on our eligible R&D activities. Under the U.K.'s tax legislation, any claims must be submitted within two years from the end of a tax year. We have not yet filed our U.K. tax return for the 2020 tax year.

Note 15 – Litigation

On July 21, 2021, we received a letter dated July 20, 2021, notifying us that Apotex Inc. and Apotex Corp. (collectively, "Apotex") submitted to FDA an abbreviated new drug application ("ANDA") for a generic version of 2.2 mg base/ml Fintepla (fenfluramine hydrochloride) that included "Paragraph IV" certifications (pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)) with respect to two of our patents covering Fintepla, U.S. Patent Nos. 10,603,290, expiration date August 2, 2037; and 10,452,815, expiration date June 29, 2038. These patents are listed in FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, for Fintepla. The letter included a statement setting forth the basis for Apotex's opinion that these patents are invalid and/or will not be infringed by the manufacture, use or sale of Apotex's fenfluramine hydrochloride oral solution, 2.2 mg base/ml product. On August 30, 2021, we filed a complaint against Apotex Inc. and Apotex Corp. for infringement based on these Paragraph IV certifications. On October 13, 2021, we received a letter dated October 12, 2021 notifying us that Apotex had amended its ANDA and submitted additional Paragraph IV certifications with respect to two additional Orange Book-listed patents covering Fintepla, U.S. Patent Nos. 10,950,331, expiration date September 28, 2035; and 10,947,183, expiration date December 20, 2036. The letter included a statement setting forth the basis for Apotex's opinion that these two additional patents are also invalid and/or will not be infringed by the manufacture, use or sale of Apotex's fenfluramine hydrochloride oral solution, 2.2 mg base/ml product. On October 28, 2021, we filed a second complaint against Apotex Inc. and Apotex Corp. for infringement based on these additional paragraph IV certifications.

On August 31, 2021, we received a letter dated August 27, 2021 notifying us that Lupin Limited ("Lupin") submitted to FDA an abbreviated new drug application ("ANDA") for a generic version of 2.2 mg base/ml Fintepla

(fenfluramine hydrochloride) that contains “Paragraph IV” certifications (pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)) with respect to seven of our patents covering Fintepla, U.S. Patent Nos. 9,549,909, expiration date May 3, 2033; 9,603,814, expiration date May 3, 2033; 9,603,815, expiration date May 3, 2033; 9,610,260, expiration date May 3, 2033; 10,478,441, expiration date May 3, 2033; 10,478,442, expiration date May 3, 2033; and 10,947,183, expiration date December 20, 2036 (collectively, "the Asserted Patents"). These patents are listed in FDA’s list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, for Fintepla. The letter included a statement setting forth the basis for Apotex’s opinion that these patents are invalid and/or will not be infringed by the manufacture, use or sale of Lupin’s fenfluramine hydrochloride oral solution, 2.2 mg base/ml product. On October 6, 2021, we filed a complaint against Lupin for infringement based on the Paragraph IV certifications.

Fintepla has Orphan Drug exclusivity, which prevents FDA from approving an ANDA referencing Fintepla until June 25, 2027. We intend to vigorously enforce our intellectual property rights relating to Fintepla. We cannot predict the ultimate outcome of these actions, and we may spend significant resources enforcing and defending these patents. If we are unsuccessful, some or all of our claims in the patents may be narrowed or invalidated and the patent protection for our products could be shortened, allowing for the sale of generic versions of these products earlier than their patent expiration, which could have a significant negative effect on our revenues and results of operations.

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:

- our ability to commercialize Fintepla;
- the progress and timing of clinical trials of 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), the European Medicines Agency (EMA) 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, 2020 and the related Management's Discussion and Analysis of

Financial Condition and Results of Operations, both of which are contained in our 2020 Annual Report on Form 10-K, which was filed with the SEC on March 1, 2021 (2020 Form 10-K).

Overview

We are a global biopharmaceutical company committed to developing and commercializing therapies with the potential to transform the lives of patients and their families living with rare diseases. Our first rare disease therapy, Fintepla (fenfluramine) oral solution has been approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of seizures associated with Dravet syndrome, a rare, severe lifelong epilepsy. We have three additional late-stage development programs underway: Fintepla for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) and for the treatment of seizures associated with CDKL5 syndrome (CDD), two other rare, difficult-to-treat epilepsies, and MT1621, an investigational therapy for the treatment of TK2 deficiency (TK2d), a rare genetic disease.

Fintepla for Patients with Rare Epilepsy Disorders

Dravet Syndrome

On June 25, 2020, the FDA granted approval of Fintepla for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older. During the third quarter of 2020, we commercially launched Fintepla through a restricted distribution program, called the Fintepla Risk Evaluation and Mitigation Strategy (REMS) Program. On December 18, 2020, the EMA granted marketing authorization for Fintepla for the treatment of seizures associated with Dravet syndrome as an add-on therapy to other anti-epileptic medicines for patients two years of age and older. Fintepla is available in Europe under a controlled access program requested by the EMA to prevent off-label use for weight management and to confirm that prescribing physicians have been informed of the need for periodic cardiac monitoring in patients taking Fintepla. We launched Fintepla for sale in Germany and France in 2021 and expect to expand into other European markets thereafter. The approval for marketing of Fintepla in the U.S. and Europe was based on positive safety and efficacy results from two randomized, international, multi-center, placebo-controlled Phase 3 trials (Study 1 and Study 2), as well as data from an interim analysis of a long-term, open-label extension study in 330 Dravet syndrome patients treated up to three years.

In September 2020, we reported positive top-line results from our third Phase 3 trial (Study 3) of Fintepla for the treatment of seizures associated with Dravet syndrome. Study 3 corroborates the substantial impact of Fintepla on convulsive seizure reduction in patients with Dravet syndrome as previously demonstrated in Studies 1 and 2. Study 3 expands the countries where Fintepla has been evaluated to include Japan. In March 2019, we entered into an exclusive distribution agreement (Shinyaku Agreement) with Nippon Shinyaku Co., Ltd. (Shinyaku) for the potential commercialization of Fintepla in Japan. We retained responsibility for clinical development programs for Fintepla, including completion of an additional Phase 3 trial (Study 3) to expand the countries to include Japan, amongst others, where Fintepla for the treatment of Dravet syndrome has been evaluated. We expect to include Study 3 as the pivotal study in our targeted submission of a Japanese New Drug Application (J-NDA) to Japan's Pharmaceuticals and Medical Devices Agency (PMDA) in the fourth quarter of 2021.

Lennox-Gastaut Syndrome

In February 2020, we reported positive top-line results from our Phase 3 multicenter, global LGS trial (Study 1601), a double-blind, placebo-controlled study to assess the safety, tolerability and efficacy of Fintepla when added to a patient's current anti-epileptic regimen. Study 1601 included a total of 263 patients between the ages of 2 and 35 years whose seizures were uncontrolled while on one or more anti-epileptic drugs. The trial 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 and demonstrated statistically significant improvements versus placebo in key secondary efficacy measures, including proportion of patients with a clinically meaningful reduction in drop seizure frequency.

In September 2021, we submitted a supplemental New Drug Application (sNDA) for Fintepla for the treatment of seizures associated with LGS to the FDA and plan to submit a Marketing Authorization Application (MAA) with European Medicines Agency (EMA) in the fourth quarter of 2021.

Other Potential Indications

In addition to Dravet syndrome and LGS, we are evaluating the treatment potential of Fintepla in other serious, treatment-resistant epileptic syndromes, including CDD, an infantile-onset genetic seizure disorder. New data presented from an investigator-initiated study in CDD at the American Epilepsy Society Annual Meeting in December 2020 suggests potential of Fintepla for the treatment of seizures associated with CDD. We are on track to initiate a global Phase 3 study of Fintepla for the treatment of CDD in the fourth quarter of 2021.

MT1621 for Patients with TK2 Deficiency

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 disease that primarily affects infants and children and for which there are currently no approved therapies.

In April 2020, we held an End-of-Phase 2 meeting with the FDA and in June 2020, we met with the FDA to discuss chemistry, manufacturing, and controls (CMC) for MT1621. In the meetings, the FDA outlined the additional clinical and non-clinical information needed for an NDA submission. In July 2021, we had a Type B Meeting with the FDA where the FDA confirmed the adequacy of the proposed data packages for an NDA submission due to the rare and serious nature of TK2d and the unmet medical need.

Based on this feedback, we are targeting an NDA submission to the FDA for TK2d in the second half of 2022. In addition, we are conducting a Phase 1 pharmacokinetic (PK) study in renal impairment, as recommended by the FDA, to provide dosing recommendations in the setting of impaired renal function and include the results in the NDA submission. The FDA also concurred with our proposed CMC plan for the prospective NDA submission.

Preclinical Pipeline

Tevard Gene Therapy Collaboration for Genetic Epilepsies

In December 2020, we entered into a collaboration with Tevard Biosciences, Inc. (Tevard) for the research, development and commercialization of gene therapies for the treatment of Dravet syndrome and other epilepsy disorders. The collaboration is at the research and discovery stage and will leverage Tevard’s novel t-RNA-based technology to treat genetic disorders not amenable to traditional types of gene therapies, such as Dravet Syndrome.

Business Update Regarding the COVID-19 Pandemic

We have taken an active role in managing the ongoing pandemic's impact on our employees, patients and our business. In response to mandates and/or recommendations from federal, state, local and other governmental authorities in our international locations, as well as decisions we have made to protect the health and safety of our employees, we have temporarily implemented a nearly-all remote work environment for our office employees. Our top priority in this process continues to be the health and safety of our employees.

We commenced the commercial launch of Fintepla in the United States in July 2020 and in Germany and France in 2021. During the pandemic, our specialized sales force has primarily relied on virtual engagement with physicians and healthcare providers in conducting educational and promotional activities for Fintepla as well as to support patient care, which may impact our ability to market Fintepla. In addition, Fintepla is being launched through our Fintepla REMS program in the U.S. and a controlled access program in Europe, with each program requiring patients to obtain echocardiograms during an outbreak of a pandemic.

To date, we have not experienced any significant interruptions in our ability to supply Fintepla for commercial use in Dravet syndrome or clinical trials for LGS, or MT1621 to our patients currently enrolled in our clinical trials. The evolving COVID-19 pandemic could directly or indirectly impact the pace of patient enrollment after the initiation of our planned Phase 3 study of Fintepla in CDD in the fourth quarter of 2021 as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices except for a health emergency. We currently do not anticipate any interruptions in supply. 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 the duration and spread of the pandemic, the availability of vaccines and vaccination rates, the implementation or recurrence of shelter in place or similar orders and 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

The preparation of our unaudited condensed consolidated financial statements in accordance with GAAP requires that we 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. Our critical accounting policies are discussed in Part II, Item 7,

“Management's Discussion and Analysis of Financial Condition and Results of Operations” section of our 2020 Form 10-K. There have been no material changes during the nine months ended September 30, 2021 to the critical accounting policies previously disclosed in that report.

Recent Accounting Pronouncements

For information with respect to recent accounting pronouncements that are of significance or potential significance to us, see Note 2, *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 and Nine Months Ended September 30, 2021 and 2020

The following table summarizes our total revenues for the periods indicated:

Revenues

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2021**	**2020**	**Change**	**2021**	**2020**	**Change**
Net product sales	$ 21,398	$ 1,520	$ 19,878	$ 51,269	$ 1,520	$ 49,749
Collaboration revenue	1,212	1,340	(128)	3,813	3,621	192
Total revenues	$ 22,610	$ 2,860	$ 19,750	$ 55,082	$ 5,141	$ 49,941

Net Product Sales

For the three months ended September 30, 2021, total net product sales for Fintepla were $21.4 million and consisted of U.S. product sales of $18.4 million, with the remainder from sales in Europe (currently, Germany and France). For the nine months ended September 30, 2021, total net product sales for Fintepla were $51.3 million and consisted of U.S. product sales of $45.3 million, with the remainder from sales in Europe (currently, Germany and France). For the three and nine months ended September 30, 2020, total net product sales for Fintepla of $1.5 million were generated in the United States. Fintepla was approved by the FDA in June 2020 and the EMA in December 2020. The year-over-year increases in net product sales was attributable to the growth in the number of patients initiating Fintepla for Dravet syndrome therapy across all regions as well as a price increase we instituted in the U.S. during the second quarter of 2021. Our gross-to-net deductions increased for the three and nine months ended September 30, 2021 as compared to the same periods in 2020. The increases were primarily attributable to increases in volume of purchases eligible for government mandated discounts and rebates as well as changes in the discount percentage impacted by our price increase.

Collaboration Revenue

Collaboration revenue was flat for the three and nine months ended September 30, 2021 as compared to the same periods in 2020 as we conducted an additional Phase 3 trial (Study 3) to expand the countries where Fintepla has been evaluated to include Japan in fulfillment of our performance obligations under the collaboration arrangement. We anticipate Study 3 will be the pivotal study included in our targeted submission of a J-NDA to Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) in the fourth quarter of 2021.

Cost of Product Sales (Excluding Amortization of Intangible Asset)

Cost of product sales (excluding amortization of intangible asset) includes the cost of producing and distributing inventories that are related to product revenues during the respective period (including salary-related and stock-based compensation expenses for employees involved with production and distribution, freight and indirect overhead costs) and third-party royalties payable on our net product revenues. Cost of product sales may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances.

During the three and nine months ended September 30, 2021, cost of product sales primarily consisted of royalties payable on net product sales of Fintepla under a license agreement and labeling and packaging costs. Substantially all the cost of product sold during the three and nine months ended September 30, 2021 had a zero-cost basis. Prior to receiving FDA approval for Fintepla, we recorded all manufacturing product costs as research

and development expense. We expect our inventory with zero-cost basis will be depleted by the end of 2021 and expect cost of product sales to increase as a percentage of net sales in future periods as we produce and then sell inventory that reflects the full cost of manufacturing.

Research and Development Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2021**	**2020**	**Change**	**2021**	**2020**	**Change**
Research and development	$ 33,255	$ 34,425	$ (1,170)	$ 100,868	$ 102,038	$ (1,170)

Research and development (R&D) 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; costs incurred under our collaboration agreement with Nippon Shinyaku to develop Fintepla in Japan; 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 R&D 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 R&D expenses for each of our key development programs. We have not tracked internal costs on a program-by-program basis because our R&D employees and infrastructure resources are utilized across our product candidate development programs.

The table below sets forth components of our R&D expenses for the periods presented.

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2021**	**2020**	**Change**	**2021**	**2020**	**Change**
Fintepla for Dravet syndrome[(1)]	$ 10,679	$ 8,442	$ 2,237	$ 22,699	$ 23,396	$ (697)
Fintepla for LGS	4,892	11,223	(6,331)	19,906	26,925	(7,019)
MT1621	6,457	2,200	4,257	18,821	8,284	10,537
Tevard gene-therapy program for Dravet syndrome	786	—	786	2,358	—	2,358
Other[(2)]	64	305	(241)	219	1,748	(1,529)
Total external costs	22,878	22,170	708	64,003	60,353	3,650
Internal costs	10,377	12,255	(1,878)	36,865	41,685	(4,820)
Total	$ 33,255	$ 34,425	$ (1,170)	$ 100,868	$ 102,038	$ (1,170)

(1) Includes a $7.0 million accrual recorded in the three and nine months ended September 30, 2021 related to an agreement to modify our existing collaboration and license agreement with the Universities described below.
(2) Other external costs include early-phase exploratory research programs.

In October 2014, we acquired worldwide development and commercialization rights to Fintepla from the acquisition of Brabant and have since incurred significant expenditures related to conducting clinical trials of Fintepla.

R&D expenses related to Fintepla for Dravet syndrome for the three and nine months ended 2021 was driven by a $7.0 million of costs associated with our collaboration agreement with the Universities, the licensor of our Fintepla rights, and past collaboration activities and related consideration received to date under the Shinyaku Agreement. In addition, R&D expenses included costs incurred to conduct a Phase 3 clinical trial to support a targeted J-NDA submission to Japan's PDMA in the fourth quarter of 2021.

R&D expenses related to Fintepla for LGS decreased by $6.3 million and $7.0 million for the three and nine months ended 2021 compared to the same periods in 2020 due to a reduction in development activities. In September 2021, we submitted a sNDA for Fintepla for the treatment of seizures associated with LGS to the FDA and plan to submit a MAA with the EMA in the fourth quarter of 2021.

R&D expenses related to MT1621 increased by $4.3 million and $10.5 million for the three and nine months ended September 30, 2021 compared to the same periods in 2020. The increase was attributable to our continued advancement of the MT1621 development program, including work related to chemistry, manufacturing, and controls process requirements. We expect availability of all required data by the end of the first quarter of 2022 to support a targeted NDA submission to the FDA for TK2 deficiency in the second half of 2022.

Our internal costs for the three and nine months ended 2021 decreased by $1.9 million and $4.8 million compared to the same periods in 2020. We expect R&D expenses related to Fintepla for Dravet syndrome to decrease as Fintepla for Dravet syndrome was approved for marketing by the FDA and EMA in June 2020 and December 2020, respectively.

Selling, General and Administrative Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2021**	**2020**	**Change**	**2021**	**2020**	**Change**
Selling, general and administrative	$ 39,559	$ 24,583	$ 14,976	$ 104,713	$ 70,332	$ 34,381

Selling, general and administrative expenses consist primarily of salaries and related costs for our personnel, including stock-based compensation, market research expenses for our product and product candidates that are in development and marketing expenses to support our commercial launch efforts, executive, finance, accounting, business development and internal support functions, facility-related costs and consulting fees, in each case not otherwise included in R&D expenses.

Selling, general and administrative expenses increased by $15.0 million and $34.4 million for the three and nine months ended September 30, 2021 compared to the same periods in 2020 and were primarily attributable to increases in personnel-related costs as we build out our specialized and focused commercial teams in support of our Fintepla product launches in the U.S. and Europe, the inclusion of personnel-related costs of our medical affairs function that no longer qualified as research and development expenses and headcount additions in general and administrative to support our anticipated growth. In addition, commercial spending related to market research, strategic and logistic planning for our product launch also contributed to the increase. The remainder of the increase was attributable to higher insurance premium costs and an increase in utilization of professional services, as well as infrastructure and facilities-related costs.

Amortization of Intangible Asset

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2021**	**2020**	**Change**	**2021**	**2020**	**Change**
Amortization of intangible asset	$ 1,972	$ 1,971	$ 1	$ 5,914	$ 1,971	$ 3,943

Our intangible asset consists of worldwide development, commercialization and related intellectual property rights including patents and licenses for our product, Fintepla, which we began to amortize after receipt of FDA approval over its estimated useful life of 13 years on a straight-line basis.

Acquired In-Process Research and Development (IPR&D) Costs

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	**2021**	**2020**	**Change**	**2021**	**2020**	**Change**
Acquired IPR&D costs	$ —	$ 1,500	$ (1,500)	$ —	$ 4,500	$ (4,500)

For the three and nine months ended September 30, 2020, acquired IPR&D costs consisted of option maintenance fees for the right to license a preclinical development program to identify and develop potential next-generation gene therapies for Dravet syndrome from Tevard. We exercised the option to opt-in this program by entering into a collaboration, option and license agreement with Tevard in December 2020. For the three and nine months ended September 30, 2021, costs incurred to reimburse Tevard's Dravet syndrome program of $0.8 million and $2.4 million were recorded as research and development expense.

Change in Fair Value of Contingent Consideration

(in thousands)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Change in fair value of contingent consideration	$ 400	$ 1,800	$ 1,500	$ 6,100

The contingent consideration liability relates to sales-based 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 and timing of achievement of various sales-based milestones, the applicable risk-free adjusted discount rate based on the estimated timing of when a sales milestone will be achieved, and our nonperformance risk. Any change in the fair value is recorded as contingent consideration (income) expense.

For the three and nine months ended September 30, 2021, the increases to the estimated fair value of our contingent consideration liability as compared to the same period in 2020 reflects the interest component of contingent consideration related to the passage of time.

Other Income (Expense)

(in thousands)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Other income (expense):				
Interest income	85	934	579	2,504
Interest expense	(3,848)	—	(11,373)	—
Other income, net	(371)	536	(631)	20,798
Total	$ (4,134)	$ 1,470	$ (11,425)	$ 23,302

For the three and nine months ended September 30, 2021, other expense of $4.1 million and $11.4 million consisted primarily of interest expense related to the Notes, which were issued in September and October 2020. For the nine months ended September 30, 2020, other income included a $19.7 million claim submitted under UK's R&D Tax Relief Scheme for eligible R&D expenditures incurred in tax years 2017 and 2018.

Income Taxes

For the three and nine months ended September 30, 2021 and the three months ended September 30, 2020, there was no provision for income taxes as we incurred pretax losses and maintained a full valuation allowance against our net deferred tax assets for these periods. For the nine months ended September 30, 2020, our income tax benefit consisted of a discrete income tax adjustment related to the completion of our in-process research program upon approval of Fintepla for marketing by the FDA. Until June 2020, our net deferred tax liability was related to book and tax basis differences for our indefinite-lived Fintepla IPR&D intangible asset that was acquired through the October 2014 acquisition of Brabant Pharma Limited. Previously, this deferred tax liability was not considered to be a source of income for purposes of establishing our deferred tax asset valuation allowance due to the uncertainty associated with the timing of reversals for this temporary tax difference. Upon FDA approval of Fintepla in June 2020, the indefinite-lived asset was reclassified to a finite-lived intangible asset and was subject to amortization over its estimated useful life. Because the detail scheduling of the timing of reversal for this temporary tax difference became available, the deferred tax liability associated with this finite-lived intangible asset was considered to be a source of income when assessing the realizability of our deferred tax assets. We therefore recorded a $17.4 million income tax benefit for the nine months ended September 30, 2020 with a corresponding reduction to our valuation allowance on our deferred tax assets. The income tax benefit included the effects of foreign exchange differences on remeasurement of the deferred tax liability. An immaterial portion of the adjustment for foreign exchange differences was related to prior periods.

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. As of September 30, 2021, our accumulated deficit was $1.5

billion. We expect to continue to incur significant operating losses and negative cash flows from operations to support the marketing and commercialization of Fintepla for Dravet syndrome as well as continuing to advance our clinical programs. 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. We recently launched Fintepla in the U.S. and Europe and generate revenue from product sales. We also generate collaboration revenue from our collaborative arrangement with Nippon Shinyaku Co., Ltd. We expect to continue to incur significant operating losses and negative cash flows from operations as we begin to commercialize Fintepla and advance our product candidates through development in the short-term. Historically, we have relied primarily on the proceeds from equity and convertible debt offerings to finance our operations.

We are party to an at-the-market sales agreement (ATM Sales Agreement) with Cantor Fitzgerald & Co. (Cantor), pursuant to which Cantor has agreed to act as sales agent in connection with the issuance and sale of up to $200.0 million in gross aggregate proceeds of our common stock from time to time pursuant to the ATM Sales Agreement and our automatic “shelf” registration statement on Form S-3 registering the offering filed in June 2020. For the nine months ended September 30, 2021, there were no sales of common stock under the ATM Sales Agreement and as of September 30, 2021, we have remaining capacity to sell up to approximately $195.0 million of common stock under the ATM Sales Agreement.

In September and October 2020, we issued $230.0 million aggregate principal amount of 2.75% convertible senior Notes due 2027 (Notes) and realized net proceeds of $222.5 million. The Notes are governed by an indenture (Indenture), dated as of September 28, 2020, between Zogenix and U.S. Bank National Association, as trustee. Under the Indenture, the Notes are senior, unsecured obligations of Zogenix, are equal in right of payment with its future senior, unsecured indebtedness of Zogenix, and structurally subordinated to all indebtedness and liabilities of its subsidiaries. Interest is payable semi-annually in arrears on April 1 and October 1 of each year, beginning on April 1, 2021 at a rate of 2.75% per year. The Notes mature on October 1, 2027, unless earlier repurchased, redeemed or converted. The Indenture contains customary terms and covenants and may become due and payable upon the occurrence of an event of default, but does not contain any financial covenants. As of September 30, 2021, we were in compliance with all covenants under the Indenture.

The Notes are convertible, subject to certain conditions described below, into shares of our common stock at an initial conversion rate of 41.1794 shares per $1,000 principal amount of the Notes, which represents an initial conversion price of approximately $24.28 per share, subject to adjustments upon the occurrence of certain events. Certain corporate events described in the Indenture may increase the conversion rate for holders who elect to convert their Notes in connection with such corporate event should they occur. We may also choose to repurchase outstanding Notes through open-market transactions, including through Rule 10b5-1 trading plan to facilitate open-market repurchases, or otherwise, from time to time.

Holders may convert the Notes in multiples of $1,000 principal amount at any time prior to October 1, 2027, but only in the following circumstances:

- during any calendar quarter ending after December 31, 2020, if our closing stock price exceeds 130% of the conversion price on each of at least 20 trading days of the last 30 consecutive trading days of the immediately preceding calendar quarter;
- during the five consecutive business day period after any 10 consecutive trading day period in which the Notes’ trading price is less than 98% of the product of our closing stock price times the conversion rate; or
- the occurrence of certain corporate events, such as a change of control, merger, default or liquidation.

During the third quarter of 2021, the closing price of our common stock did not exceed 130% of the applicable conversion price of the Notes on at least 20 of the last 30 consecutive trading days of the quarter. Furthermore, no other conditions allowing holders of the Notes to convert have been met as of September 30, 2021. Therefore, the Notes are not convertible for the fourth quarter of 2021. If the closing price conditions are met in a future quarter, the Notes will be convertible at the holders’ option during the immediately following quarter.

As of September 30, 2021, our cash, cash equivalents and marketable securities totaled $343.0 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:

- our ability to generate sales of Fintepla for the treatment of seizures associated with Dravet syndrome;

- the costs of establishing or outsourcing sales, marketing and distribution capabilities for Fintepla for the treatment of Dravet syndrome and, should we elect to do so, for any of our other product candidates;
- 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 Fintepla and any other 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, 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, our commercialization efforts, 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):

	Nine Months Ended September 30,	
	2021	2020
Cash and cash equivalents, beginning of the period	$ 166,916	$ 62,070
Net cash used in operating activities	(144,175)	(129,381)
Net cash provided by (used in) investing activities	101,089	(43,236)
Net cash (used in) provided by financing activities	(17,692)	408,007
Net (decrease) increase in cash and cash equivalents	(60,778)	235,390
Cash and cash equivalents, end of the period	$ 106,138	$ 297,460

Operating Activities

For the nine months ended September 30, 2021, net cash used in operating activities of $144.2 million was primarily attributable to a net loss of $172.5 million and net changes in operating assets and liabilities of $13.4 million, partially offset by an aggregate of $41.7 million of non-cash charges. Non-cash items included stock-based compensation expense of $25.8 million, amortization of debt discount and issuance costs of $6.5 million related to our convertible senior notes and intangible asset amortization of $5.9 million. Net changes in operating assets and liabilities totaled an outflow of $13.4 million principally due to the timing of vendor payments and increases in accounts receivable and inventory as a result of growth in Fintepla product sales.

For the nine months ended September 30, 2020, net cash used in operating activities of $129.4 million was primarily attributable to a net loss of $139.2 million and net changes in operating assets and liabilities of $8.5 million, offset by an aggregate of $18.3 million of non-cash charges, net. Non-cash items included stock-based compensation expense of $21.8 million, fair value adjustments related to contingent consideration liability of $6.1 million, an IPR&D charge of $4.5 million and an income tax benefit of $17.4 million. Cash used in operating activities included R&D expenses 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. This cash outflow was partially offset by cash received of $19.7 million for a cash rebate claim submitted under 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.

Investing Activities

For the nine months ended September 30, 2021, net cash provided by in investing activities of $101.1 million was primarily attributable to maturities of available-for-sale marketable securities.

For the nine months ended September 30, 2020, net cash used in investing activities of $43.2 million was primarily attributable to net purchases of available-for-sale marketable securities.

Financing Activities

For the nine months ended September 30, 2021, net cash used in financing activities of $17.7 million was attributable to payments of contingent consideration for regulatory and sales-based milestones related to Fintepla, partially offset by net proceeds received from the issuance of common stock pursuant to our equity incentive plans.

For the nine months ended September 30, 2020, net cash provided by financing activities of $408.0 million primarily consisted of net proceeds realized from the issuance of our common stock in a public offering, the issuance of convertible debt and proceeds from the sale of common stock under our "at-the-market" program, as well as net proceeds received related to our equity incentive program. In July 2020, we made a $15.0 million milestone payment pursuant to our purchase agreement of Brabant in 2014 upon FDA approval of Fintepla.

Contractual Obligations

There were no material changes outside the ordinary course of our business during the nine months ended September 30, 2021 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 2020 Form 10-K.

Off-Balance Sheet Arrangements

As of September 30, 2021, 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 2020 Form 10-K. Our exposures to market risk have not changed materially since December 31, 2020.

Item 4. Controls and Procedures

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

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

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded

that our disclosure controls and procedures were effective as of September 30, 2021 at the reasonable assurance level.

Changes in Disclosure Controls and Procedures

There were no changes in our internal control over financial reporting during the nine months ended September 30, 2021 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

Apotex ANDA Litigation

On July 21, 2021, we received a letter dated July 20, 2021, notifying us that Apotex Inc. and Apotex Corp. (collectively, “Apotex”) submitted to FDA an abbreviated new drug application (“ANDA”) for a generic version of 2.2 mg base/ml Fintepla (fenfluramine hydrochloride) that included "Paragraph IV" certifications (pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)) with respect to two of our patents covering Fintepla, U.S. Patent Nos. 10,603,290, expiration date August 2, 2037; and 10,452,815, expiration date June 29, 2038. These patents are listed in FDA’s list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, for Fintepla. The letter included a statement setting forth the basis for Apotex’s opinion that these patents are invalid and/or will not be infringed by the manufacture, use or sale of Apotex’s fenfluramine hydrochloride oral solution, 2.2 mg base/ml product. On August 30, 2021, we filed a complaint against Apotex Inc. and Apotex Corp. for infringement based on these Paragraph IV certifications. On October 13, 2021, we received a letter dated October 12, 2021 notifying us that Apotex had amended its ANDA and submitted additional Paragraph IV certifications with respect to two additional Orange Book-listed patents covering Fintepla, U.S. Patent Nos. 10,950,331, expiration date September 28, 2035; and 10,947,183, expiration date December 20, 2036. The letter included a statement setting forth the basis for Apotex’s opinion that these two additional patents are also invalid and/or will not be infringed by the manufacture, use or sale of Apotex’s fenfluramine hydrochloride oral solution, 2.2 mg base/ml product. On October 28, 2021, we filed a second complaint against Apotex Inc. and Apotex Corp. for infringement based on these additional paragraph IV certifications. Fintepla has Orphan Drug exclusivity, which prevents FDA from approving an ANDA referencing Fintepla until June 25, 2027. We cannot predict the ultimate outcome of these actions, and we may spend significant resources enforcing and defending these patents. If we are unsuccessful, some or all of our claims in the patents may be narrowed or invalidated and the patent protection for our products could be shortened, allowing for the sale of generic versions of these products earlier than their patent expiration, which could have a significant negative effect on our revenues and results of operations.

Lupin ANDA Litigation

On August 31, 2021, we received a letter dated August 27, 2021, notifying us that Lupin Limited (“Lupin”) submitted to FDA an abbreviated new drug application (“ANDA”) for a generic version of 2.2 mg base/ml Fintepla (fenfluramine hydrochloride) that included "Paragraph IV" certifications (pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)) with respect to seven of our patents covering Fintepla, U.S. Patent Nos. 9,549,909, expiration date May 3, 2033; 9,603,814, expiration date May 3, 2033; 9,603,815, expiration date May 3, 2033; 9,610,260, expiration date May 3, 2033; 10,478,441, expiration date May 3, 2033; 10,478,442, expiration date May 3, 2033; and 10,947,183, expiration date December 20, 2036 (collectively, the “Asserted Patents”). These patents are listed in FDA’s list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, for Fintepla. The letter included a statement setting forth the basis for Apotex’s opinion that these patents are invalid and/or will not be infringed by the manufacture, use or sale of Lupin’s fenfluramine hydrochloride oral solution, 2.2 mg base/ml product. On October 6, 2021, we filed a complaint against Lupin for infringement based on the Paragraph IV certifications. Fintepla has Orphan Drug exclusivity, which prevents FDA from approving an ANDA referencing Fintepla until June 25, 2027. We cannot predict the ultimate outcome of these actions, and we may spend significant resources enforcing and defending these patents. If we are unsuccessful, some or all of our claims in the patents may be narrowed or invalidated and the patent protection for our products could be shortened, allowing for the sale of generic versions of these products earlier than their patent expiration, which could have a significant negative effect on our revenues and results of operations.

Item 1A. Risk Factors

Risks Related to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success depends in large part on obtaining and maintaining patent, trademark and trade secret protection of our commercial products and pipeline product candidates, their respective components, formulations, methods of manufacture and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to prevent unauthorized third parties from making, using, selling, offering

to sell and/or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents and/or trade secrets that cover these activities. For example, we received two letters from Apotex on July 21, 2021 and October 12, 2021, respectively, indicating that it has submitted to FDA an Abbreviated New Drug Application (ANDA) seeking approval to manufacture and sell a generic version of 2.2 mg base/ml Fintepla prior to the expiration of certain Orange Book-listed patents protecting Fintepla. In addition, we received a letter from Lupin on August 31, 2021, indicating that it has submitted to the FDA an ANDA seeking approval to manufacture and sell a generic version of 2.2 mg base/ml Fintepla prior to the expiration of certain Orange Book-listed patents protecting Fintepla. In an ANDA, the applicant must certify for each listed patent that (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the new product. A certification that the generic product will not infringe the already approved product's listed patent and/or that such patent is invalid is known as a Paragraph IV certification (pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). The Apotex ANDA contains Paragraph IV certifications with respect to four of our patents covering Fintepla, U.S. Patent Nos. 10,603,290, expiration date August 2, 2037; 10,452,815, expiration date October 22, 2039; 10,950,331, expiration date September 28, 2035; and 10,947,183, expiration date December 20, 2036. The Lupin ANDA contains Paragraph IV certifications with respect to seven of our patents covering Fintepla, U.S. Patent Nos. 9,549,909, expiration date May 3, 2033; 9,603,814, expiration date May 3, 2033; 9,603,815, expiration date May 3, 2033; 9,610,260, expiration date May 3, 2033; 10,478,441, expiration date May 3, 2033; 10,478,442, expiration date May 3, 2033; and 10,947,183, expiration date December 20, 2036. While we have initiated patent infringement lawsuits against Apotex and Lupin and intend to vigorously defend and enforce our intellectual property rights protecting Fintepla, we can offer no assurance that our efforts will be successful in which case our business may be materially and adversely affected.

We in-licensed certain data from a continuing, long-term, open-label study in 15 Dravet syndrome patients, as well as certain intellectual property related to fenfluramine for the treatment of Dravet syndrome from the Universities of Antwerp and Leuven in Belgium (the Universities).

Prior to receiving rights to four U.S. patents in 2017, we did not own or control any issued patents covering Fintepla or its use. There is no guarantee that any of our pending patent applications will issue as patents. The composition of matter patents covering the active pharmaceutical ingredient (API) in Fintepla have expired and therefore are not subject to patent protection. With respect to our MT1621 product candidate, we have certain patent rights that we obtained through our acquisition of Modis. In September 2016, Modis entered into a license agreement (the Columbia Agreement), with Columbia, under which Modis was granted an exclusive worldwide license and sublicense to certain intellectual property rights owned or controlled by Columbia to develop and commercialize MT1621 and certain backup compounds for any application or purpose. These licensed patent rights include patents owned by Columbia and patents jointly owned by Columbia and Vall d'Hebron Research Institute (VHIR). VHIR delegated to Columbia the rights to enter into the Columbia Agreement on VHIR's behalf. The patent family jointly owned by Columbia and VHIR is directed to the use of MT1621 to treat TK2d and includes a granted U.S. patent and a granted European patent application, pending applications in Australia, Brazil, Canada, China, Hong Kong, Israel, India, Japan, Korea, Mexico and Russia, as well as continuation applications in the United States and Europe. There are no patents covering the APIs in MT1621.

The initial patent applications covering MT1621 and methods of treatment using Fintepla were licensed by us and not written by our attorneys. Neither we nor our licensors had control over the drafting and initial prosecution of these applications. Further, the patent prosecution counsel previously handling the Fintepla and MT1621 matters might not have given the same attention to the drafting and prosecution to these applications as we would have if we had been the owners and originators of the applications and had control over the drafting and prosecution. In addition, the former patent prosecution counsel handling these matters may not have been completely familiar with U.S. patent law or the patent law in various countries, possibly resulting in inadequate disclosures, improperly claiming inventions and/or filing of applications at times which do not meet appropriate priority requirements. The named inventors on the pending patent applications and others involved in the protection of the intellectual property related to Fintepla and MT1621 did not and may still not have sufficient knowledge relating to preferred procedures and the legal requirements related to the protection of intellectual property. They published papers which adversely affected our licensed rights, particularly in jurisdictions without a grace period for inventors' own disclosures. Although they have been advised with respect to procedures going forward, we cannot directly control their actions. All of these factors and others could result in the inability to obtain the issuance of additional patent applications in the United States or elsewhere in the world. Even if additional patents issue, such issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts.

The patent positions of pharmaceutical, biopharmaceutical and medical device companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States. There have been recent changes regarding how patent laws are interpreted, and both the U.S. Patent and Trademark Office (USPTO), and Congress have recently made significant changes to the patent system. There have been three U.S. Supreme Court decisions that now show a trend of the Supreme Court which is distinctly negative regarding patents. The trend of these decisions along with resulting changes in patentability requirements being implemented by the USPTO could make it increasingly difficult for us to obtain and maintain patents on our products. We cannot accurately predict future changes in the interpretation of patent laws or changes to patent laws which might be enacted into law. Those changes may materially affect our patents, our ability to obtain patents and/or the patents and patent applications of our collaborators and licensors. The patent situation in these fields outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license or third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are the same or similar to the pharmaceutical compounds used in our product candidates but that are not covered by the claims of our patents or our in-licensed patents;
- the API in Fintepla may soon become, commercially available in generic drug products, and no patent protection will be available without regard to formulation or method of use;
- the APIs in MT1621 are well-known and available commercially from many sources, and no patent protection claiming the APIs as a composition of matter will be available;
- we or our licensors, as the case may be, may not be able to detect infringement against our patents or in-licensed patents, which may be especially difficult for process of manufacturing or formulation patents;
- we or our licensors, as the case may be, might not have been the first to make the inventions covered by our owned or in-licensed issued patents or pending patent applications;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that our owned or in-licensed U.S. patents are not eligible for listing in the Orange-Book;
- it is possible that there are dominating patents to Fintepla and MT1621 of which we are not aware;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our system or products or our system of product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, or may be narrowed in scope, be held invalid or unenforceable as a result of legal administrative challenges by third parties;
- we may not develop additional proprietary technologies for which we can obtain patent protection; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and we have limited control

over the protection of trade secrets used by our licensors, collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, state laws in the United States vary, and their courts as well as courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully penetrate our target markets could be severely compromised.

If any of our owned or in-licensed patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology and products.

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

A list of exhibits filed with this report or incorporated herein by reference is found in the Exhibit Index below.

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit	
3.1	Fifth Amended and Restated Certificate of Incorporation of the Registrant	S-1/A	333-169210	October 27, 2010	3.5	
3.2	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant	10-Q	001-34962	November 8, 2012	3.2	
3.3	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant	10-Q	001-34962	August 10, 2015	3.3	
3.4	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant	10-Q	001-34962	August 6, 2019	3.4	
3.5	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-34962	June 2, 2021	3.1	
3.6	Amended and Restated Bylaws	S-1/A	333-169210	October 27, 2010	3.7	
4.1	Form of the Registrant's Common Stock Certificate	S-1/A	333-169210	November 4, 2010	4.1	
4.2	Indenture, dated as of September 28, 2020, between Zogenix, Inc. and U.S. Bank National Association, as trustee	8-K	001-34962	September 28, 2020	4.1	
4.3	Form of Global Note representing the 2.75% Convertible Senior Notes due 2027 (included as Exhibit A to the Indenture)	8-K	001-34962	September 28, 2020	4.1	
10.1†	Amendment to Employment Agreement, dated July 2, 2018 by and between the Registrant and Ashish Sagrolikar					X
10.2†	Second Amendment to Employment Agreement, dated July 2, 2018 by and between the Registrant and Ashish Sagrolikar					X
10.3†	Third Amendment to Employment Agreement, dated July 2, 2018 by and between the Registrant and Ashish Sagrolikar					X
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)					X
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)					X
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)					X
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)					X
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.					X
104*	Inline XBRL for the cover page of this Quarterly Report on Form 10-Q, included in the Exhibit 101 Inline XBRL Document Set.					X

† Management compensatory plan or arrangement.

* 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: November 5, 2021

By: /s/ Stephen J. Farr
Stephen J. Farr
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2021

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

Exhibit 10.1

AMENDMENT TO EMPLOYMENT AGREEMENT

This AMENDMENT TO EMPLOYMENT AGREEMENT (this "Amendment") is made and entered into effective as of December 19, 2019, by and between ZOGENIX, INC. (the "Company") and ASHISH SAGROLIKAR ("Executive").

RECITALS

WHEREAS, Executive and the Company previously entered into that certain Employment Agreement effective July 2, 2018 (the "Agreement"), pursuant to which Executive currently is employed by the Company; and

WHEREAS, the Company and Executive wish to enter into this Amendment to modify certain terms of the Agreement.

NOW, THEREFORE, in consideration of the mutual promises and covenants and the respective undertakings of the Company and Executive set forth below, the Company and Executive agree as follows:

AGREEMENT

1. Amendment to Section 2(h)(i). The first sentence of Section 2(h)(i) of the Agreement is hereby amended to read as follows:

> The Company expects Executive to relocate his principal place of residence from Cary, North Carolina to the San Francisco Bay Area on or before December 31, 2020.

2. Amendment to Section 2(h)(ii). The fifth sentence of Section 2(h)(ii) of the Agreement is hereby amended to read as follows:

> If Executive voluntarily terminates his employment without Good Reason prior to the first anniversary of the date the Relocation Reimbursement is paid to Executive, Executive shall repay to the Company a pro rata portion of the Relocation Reimbursement and any Tax Gross-Up based on the number of days elapsed in the one-year period ending on the first anniversary of the date the Relocation Reimbursement is paid to Executive.

3. Amendment to Section 2(h)(iii). Section 2(h)(iii) of the Agreement is hereby amended to read as follows:

> In addition to the foregoing, during the period commencing on the Effective Date and ending on the earlier of (A) the date Executive relocates his primary residence to the San Francisco Bay Area or (B) December 31, 2020, the Company will pay for or reimburse Executive for temporary housing in the San Francisco Bay Area, subject to the Company's prior approval of Executive's temporary housing arrangements.

4. Status of Agreement. Except to the limited extent expressly amended hereby, the Agreement and its terms and conditions remain in full force and effect and unchanged by this Amendment. Capitalized terms used herein but not defined herein shall have the meanings ascribed such terms in the Agreement.

5. Duplicate Counterparts; Facsimile. This Amendment may be executed in duplicate counterparts, each of which shall be deemed an original; provided, however, such counterparts shall together constitute only one agreement. Facsimile signatures or signatures sent via electronic mail shall be as effective as original signatures.

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the date(s) set forth below.

ZOGENIX, INC.

Dated: [redacted]

By: /s/Stephen J. Farr, Ph.D.

Name: Stephen J. Farr, Ph.D.

Title: Chief Executive Officer

EXECUTIVE

Dated: [redacted]

/s/ Ashish Sagrolikar

Ashish Sagrolikar

SECOND AMENDMENT TO EMPLOYMENT AGREEMENT

This SECOND AMENDMENT TO EMPLOYMENT AGREEMENT (this "Amendment") is made and entered into effective as of January 1, 2021, by and between Zogenix, Inc. (the "Company") and Ashish Sagrolikar ("Executive").

RECITALS

WHEREAS, Executive and the Company previously entered into that certain Employment Agreement effective July 2, 2018, as amended by that certain Amendment to Employment Agreement effective December 19, 2019 (together, the "Agreement"), pursuant to which Executive currently is employed by the Company; and

WHEREAS, the Company and Executive wish to enter into this Amendment to modify certain terms of the Agreement.

NOW, THEREFORE, in consideration of the mutual promises and covenants and the respective undertakings of the Company and Executive set forth below, the Company and Executive agree as follows:

AGREEMENT

1. Amendment to Section 2(h)(i). The first sentence of Section 2(h)(i) of the Agreement is hereby amended to read as follows:

> The Company expects Executive to relocate his principal place of residence from Cary, North Carolina to the San Francisco Bay Area on or before December 31, 2021 (the date of such relocation, the "***Relocation Date***").

2. Amendment to Section 2(h)(ii). The fifth sentence of Section 2(h)(ii) of the Agreement is hereby amended to read as follows:

> If Executive voluntarily terminates his employment without Good Reason prior to the first anniversary of the Relocation Date, Executive shall repay to the Company a pro rata portion of the Relocation Reimbursement and any Tax Gross-Up based on the number of days elapsed in the one-year period ending on the first anniversary of the Relocation Date.

3. Amendment to Section 2(h)(iii). Section 2(h)(iii) of the Agreement is hereby amended to read as follows:

> In addition to the foregoing, during the period commencing on the Effective Date and ending on the earlier of (A) the date Executive relocates his primary residence to the San Francisco Bay Area or (B) December 31, 2021, the Company will pay for or reimburse Executive for temporary housing in the San Francisco Bay Area, subject to the Company's prior approval of Executive's temporary housing arrangements.

4. Governing Law; Status of Agreement. This Amendment is to be governed by and construed in accordance with the laws of the State of California applicable to contracts made and to be performed wholly within such State, and without regard to the conflicts of laws principles thereof. Except to the limited extent expressly amended hereby, the Agreement and its terms and conditions remain in full force and effect and unchanged by this Amendment. Capitalized terms used herein but not defined herein shall have the meanings ascribed such terms in the Agreement.

5. Duplicate Counterparts; Facsimile. This Amendment may be executed in duplicate counterparts, each of which shall be deemed an original; provided, however, such counterparts shall together constitute only one agreement. Facsimile signatures or signatures sent via electronic mail shall be as effective as original signatures.

(Signature Page Follows)

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the date(s) set forth below.

ZOGENIX, INC.

Dated: [redacted]

By: /s/Stephen J. Farr, Ph.D.

Name: Stephen J. Farr, Ph.D.

Title: Chief Executive Officer

EXECUTIVE

Dated: [redacted]

/s/ Ashish Sagrolikar

Ashish Sagrolikar

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Exhibit 10.3

THIRD AMENDMENT TO EMPLOYMENT AGREEMENT

This THIRD AMENDMENT TO EMPLOYMENT AGREEMENT (this "Amendment") is made and entered into effective as of August 5, 2021, by and between Zogenix, Inc. (the "Company") and Ashish Sagrolikar ("Executive").

RECITALS

WHEREAS, Executive and the Company previously entered into that certain Employment Agreement effective July 2, 2018, as amended by that certain Amendment to Employment Agreement effective December 19, 2019 and that certain Amendment to Employment Agreement effective January 1, 2021 (collectively, the "Agreement"), pursuant to which Executive currently is employed by the Company; and

WHEREAS, the Company and Executive wish to enter into this Amendment to modify certain terms of the Agreement.

NOW, THEREFORE, in consideration of the mutual promises and covenants and the respective undertakings of the Company and Executive set forth below, the Company and Executive agree as follows:

AGREEMENT

1. Amendment to Section 2(h)(i). The first sentence of Section 1(a) of the Agreement is hereby amended to read as follows:

Effective August 5, 2021, Executive shall serve as Executive Vice President and Chief Operating Officer.

2. Amendment to Section 2(a). The first sentence of Section 2(a) of the Agreement is hereby amended to read as follows:

Effective August 5, 2021, the Company shall pay to Executive a base salary of $490,000.00 per year, payable in accordance with the Company's usual pay practices (and in any event no less frequently than monthly).

3. Amendment to Section 2(b). The second sentence of Section 2(b) of the Agreement is hereby amended to read as follows:

Commencing in 2021, Executive's target bonus under the Company's annual bonus plan shall be fifty percent (50%) of Executive's base salary.

4. Governing Law; Status of Agreement. This Amendment is to be governed by and construed in accordance with the laws of the State of California applicable to contracts made and to be performed wholly within such State, and without regard to the conflicts of laws principles thereof. Except to the limited extent expressly amended hereby, the Agreement and its terms and

conditions remain in full force and effect and unchanged by this Amendment. Capitalized terms used herein but not defined herein shall have the meanings ascribed such terms in the Agreement.

4. Duplicate Counterparts; Facsimile. This Amendment may be executed in duplicate counterparts, each of which shall be deemed an original; provided, however, such counterparts shall together constitute only one agreement. Facsimile signatures or signatures sent via electronic mail shall be as effective as original signatures.

(Signature Page Follows)

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the date(s) set forth below.

ZOGENIX, INC.

Dated: May 3, 2021

By: /s/Stephen J. Farr, Ph.D.

Name: Stephen J. Farr, Ph.D.

Title: Chief Executive Officer

EXECUTIVE

Dated: April 21, 2021

/s/ Ashish Sagrolikar

Ashish Sagrolikar

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.

Date: November 5, 2021

By: /s/ Stephen J. Farr
Stephen J. Farr
President and Chief Executive Officer
(Principal Executive Officer)

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.

Date: November 5, 2021

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

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 September 30, 2021, 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: November 5, 2021

By: /s/ Stephen J. Farr
Stephen J. Farr
President and Chief Executive Officer
(Principal 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 September 30, 2021, 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: November 5, 2021

By: /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.