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, 2020

OR

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

For the transition period from _____ to _____

Commission file number: **001-34962**

ZOGENIX, INC.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of November 6, 2020 was 55,673,131.

ZOGENIX, INC.

Form 10-Q
For the Quarterly Period Ended September 30, 2020

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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, 2020	December 31, 2019
Assets:		
Current assets:		
Cash and cash equivalents	$ 297,460	$ 62,070
Marketable securities	227,707	189,085
Accounts receivable, net	1,309	—
Inventory	1,010	—
Prepaid expenses and other current assets	12,905	11,084
Acquisition holdback placed in escrow	25,000	25,000
Total current assets	565,391	287,239
Property and equipment, net	9,050	9,424
Operating lease right-of-use assets	8,002	7,774
Intangible asset, net	100,529	102,500
Goodwill	6,234	6,234
Other noncurrent assets	2,840	1,079
Total assets	$ 692,046	$ 414,250
Liabilities and stockholders' equity:		
Current liabilities:		
Accounts payable	$ 7,223	$ 7,979
Accrued and other current liabilities	31,882	30,117
Acquisition holdback liability	24,444	24,444
Deferred revenue, current	4,900	5,927
Current portion of operating lease liabilities	1,654	1,322
Current portion of contingent consideration	22,200	25,600
Total current liabilities	92,303	95,389
Deferred revenue, noncurrent	6,331	7,425
Operating lease liabilities, net of current portion	10,660	10,752
Contingent consideration, net of current portion	32,700	38,200
Convertible senior notes	127,960	—
Deferred tax liability	—	17,425
Total liabilities	269,954	169,191
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000 shares authorized; none issued and outstanding	—	—
Common stock, $0.001 par value; 100,000 shares authorized; and 55,673 and 45,272 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	56	45
Additional paid-in capital	1,676,408	1,360,092
Accumulated deficit	(1,254,670)	(1,115,457)
Accumulated other comprehensive income	298	379
Total stockholders' equity	422,092	245,059
Total liabilities and stockholders' equity	$ 692,046	$ 414,250

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Net product sales	$ 1,520	$ —	$ 1,520	$ —
Collaboration revenue	1,340	630	3,621	1,699
Total revenues	2,860	630	5,141	1,699
Costs and expenses:				
Cost of product sales (excluding amortization of intangible asset)	140	—	140	—
Research and development	34,425	28,372	102,038	79,820
Selling, general and administrative	24,583	15,762	70,332	42,139
Amortization of intangible asset	1,971	—	1,971	—
Acquired in-process research and development and acquisition-related costs	1,500	249,437	4,500	249,437
Change in fair value of contingent consideration	1,800	400	6,100	2,700
Total costs and expenses	64,419	293,971	185,081	374,096
Loss from operations	(61,559)	(293,341)	(179,940)	(372,397)
Other income, net	934	481	20,798	433
Interest income, net	536	2,382	2,504	8,521
Loss before income taxes	(60,089)	(290,478)	(156,638)	(363,443)
Income tax benefit	—	—	(17,425)	—
Net loss	$ (60,089)	$ (290,478)	$ (139,213)	$ (363,443)
Net loss per share, basic and diluted	$ (1.08)	$ (6.75)	$ (2.62)	$ (8.54)
Weighted average number of shares used in the calculation of basic and diluted net loss per common share	55,548	43,029	53,039	42,577

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,	
	2020	2019	2020	2019
Net loss	$ (60,089)	$ (290,478)	$ (139,213)	$ (363,443)
Other comprehensive (loss) income, net of tax:				
Available-for-sale marketable securities:				
Change in unrealized gains related to marketable securities	(249)	18	23	741
Reclassification adjustments for realization of gain on sale of marketable securities included in net loss	(6)	(322)	(6)	(322)
Foreign currency translation adjustments	(69)	—	(98)	—
Total other comprehensive (loss) income	(324)	(304)	(81)	419
Comprehensive loss	$ (60,413)	$ (290,782)	$ (139,294)	$ (363,024)

See accompanying notes to the unaudited condensed consolidated financial statements.

Zogenix, Inc.
Condensed Consolidated Statements of Stockholders' Equity (Unaudited)
(in thousands)

	Nine Months Ended September 30, 2020					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	45,272	$ 45	$ 1,360,092	$ 379	$ (1,115,457)	$ 245,059
Net loss	—	—	—	—	(25,800)	(25,800)
Other comprehensive loss	—	—	—	(167)	—	(167)
Issuance of common stock, net of offering costs	9,798	10	221,698	—	—	221,708
Issuance of common stock under employee equity plans	297	—	3,882	—	—	3,882
Shares repurchased for tax withholdings related to net share settlement of employee equity awards	(26)	—	(569)	—	—	(569)
Stock-based compensation	—	—	6,394	—	—	6,394
Balance at March 31, 2020	55,341	$ 55	$ 1,591,497	$ 212	$ (1,141,257)	$ 450,507
Net loss	—	—	—	—	(53,324)	(53,324)
Other comprehensive income	—	—	—	410	—	410
Issuance of common stock under employee equity plans	153	—	616	—	—	616
Shares repurchased for tax withholdings related to net share settlement of employee equity awards	(49)	—	(1,369)	—	—	(1,369)
Stock-based compensation	—	—	8,303	—	—	8,303
Balance at June 30, 2020	55,445	$ 55	$ 1,599,047	$ 622	$ (1,194,581)	$ 405,143
Net loss	—	—	—	—	(60,089)	(60,089)
Other comprehensive loss	—	—	—	(324)	—	(324)
Issuance of common stock, net of offering costs	202	1	4,865	—	—	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 for tax withholdings related to net share settlement of employee equity awards	(9)	—	(218)	—	—	(218)
Stock-based compensation	—	—	7,141	—	—	7,141
Balance at September 30, 2020	55,673	$ 56	$ 1,676,408	$ 298	$ (1,254,670)	$ 422,092

	Nine Months Ended September 30, 2019					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	42,078	$ 42	$ 1,218,710	$ 3	$ (695,954)	$ 522,801
Net loss	—	—	—	—	(35,202)	(35,202)
Other comprehensive income	—	—	—	370	—	370
Issuance of common stock under employee equity plans	380	—	5,293	—	—	5,293
Shares repurchased for tax withholdings related to net share settlement of employee equity awards	(12)	—	(606)	—	—	(606)
Stock-based compensation	—	—	4,223	—	—	4,223
Balance at March 31, 2019	42,446	$ 42	$ 1,227,620	$ 373	$ (731,156)	$ 496,879
Net loss	—	—	—	—	(37,763)	(37,763)
Other comprehensive income	—	—	—	353	—	353
Issuance of common stock under employee equity plans	52	—	888	—	—	888
Stock-based compensation	—	—	5,358	—	—	5,358
Balance at June 30, 2019	42,498	$ 42	$ 1,233,866	$ 726	$ (768,919)	$ 465,715
Net loss	—	—	—	—	(290,478)	(290,478)
Other comprehensive loss	—	—	—	(304)	—	(304)
Issuance of common stock, net of offering costs	1,595	2	68,122	—	—	68,124
Issuance of common stock under employee equity plans	163	—	2,238	—	—	2,238
Shares repurchased for tax withholdings related to net share settlement of employee equity awards	(5)	—	(138)	—	—	(138)
Stock-based compensation	—	—	5,435	—	—	5,435
Balance at September 30, 2019	44,251	$ 44	$ 1,309,523	$ 422	$ (1,059,397)	$ 250,592

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,	
	2020	2019
Cash flow from operating activities:		
Net loss	$ (139,213)	$ (363,443)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	21,838	15,016
Depreciation and amortization	3,106	910
Deferred income taxes	(17,425)	—
Noncash lease expense	883	—
Net accretion and amortization of investments in marketable securities	(519)	(4,495)
Realized gain on sale of available-for-sale marketable securities	(6)	(322)
Change in fair value of warrant liabilities	(189)	(241)
Acquired in-process research and development expense	4,500	249,437
Change in fair value of contingent consideration	6,100	2,700
Changes in operating assets and liabilities:		
Accounts receivable	(1,309)	—
Inventory	(1,010)	—
Prepaid expenses and other current assets	(3,321)	(18,056)
Other assets	(1,761)	(5,225)
Accounts payable, accrued and other liabilities	541	20,863
Operating lease liability	(975)	12,172
Deferred revenue	(621)	13,801
Net cash used in operating activities	(129,381)	(76,883)
Cash flow from investing activities:		
Cash paid for in-process research and development assets	(4,500)	(175,732)
Purchases of marketable securities	(283,208)	(308,202)
Proceeds from maturities of marketable securities	232,142	364,345
Proceeds from sales of marketable securities	12,987	172,960
Purchases of property and equipment	(657)	(9,584)
Net cash (used in) provided by investing activities	(43,236)	43,787
Cash flow from financing activities:		
Payment of contingent consideration	(15,000)	(10,000)
Proceeds from issuance of common stock under equity incentive plans	4,589	8,399
Taxes paid related to net share settlement of equity awards	(2,157)	(658)
Net proceeds from issuance of convertible senior notes	194,000	—
Proceeds from issuance of common stock, net of issuance costs	226,575	—
Net cash provided by (used in) financing activities	408,007	(2,259)
Net increase (decrease) in cash and cash equivalents	235,390	(35,355)
Cash and cash equivalents, beginning of the period	62,070	68,454
Cash and cash equivalents, end of the period	297,460	33,099

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 (the Company, we, us or our) is a global commercial-stage 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, C-IV has been approved by the U.S. Food and Drug Administration (FDA) and is under review in Europe for the treatment of seizures associated with Dravet syndrome, a rare, severe childhood onset epilepsy. In addition, the company has two late-stage development programs underway: one for Fintepla for the treatment of seizures associated with Lennox-Gastaut syndrome, 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 in one business segment—the research, development and commercialization of pharmaceutical products, and our headquarters are located in Emeryville, California.

Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of Zogenix, Inc. and its wholly-owned subsidiaries. Intercompany accounts and transactions have been eliminated in consolidation. The condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for interim financial reporting. In the opinion of management, the condensed consolidated financial statements reflect all adjustments, which are normal and recurring in nature, necessary for fair financial statement presentation. The results of operations for any interim period are not necessarily indicative of results of operations for any future period. Certain information and footnote disclosures normally included in annual consolidated financial statements prepared in accordance with generally accepted accounting principles in the United States (GAAP) have been condensed or omitted. Accordingly, these unaudited interim condensed consolidated financial statements and accompanying notes should be read in conjunction with the consolidated financial statements and related notes included in our 2019 Annual Report on Form 10-K (2019 Form 10-K), which was filed with the SEC on March 2, 2020.

Liquidity

As of September 30, 2020, our cash, cash equivalents and marketable securities totaled $525.2 million. Excluding gains from two discrete business divestitures, we have incurred significant net losses and negative cash flows from operating activities since inception resulting in an accumulated deficit of $1.3 billion as of September 30, 2020. 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 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. See Note 10 for information related to our recent financing transactions. 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, there is no assurance that such financings could be consummated on acceptable terms or at all. 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 – Summary of Significant Accounting Policies

Use of Estimates

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

Significant Accounting Policies

The significant accounting policies and estimates used in the preparation of the accompanying condensed consolidated financial statements are described in Note 2, *Summary of Significant Accounting Policies* to the consolidated financial

statements in our 2019 Form 10-K. There have been no material changes in our significant accounting policies during the nine months ended September 30, 2020, other than as set forth below.

Revenue Recognition for Net Product Sales

We began to record revenues from product sales to our exclusive specialty distributor, our sole Customer, in the third quarter of 2020, subsequent to the approval of Fintepla by the FDA in June 2020. Prior to the third quarter of 2020, our revenues were derived from our collaboration agreement with Nippon Shinyaku Co., Ltd. (Shinyaku).

We recognize revenue when control of the promised good or service is transferred to the customer, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. We determine revenue recognition through the following steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when collectability of the consideration to which we are entitled in exchange for the goods or services we transfer to the customer is determined to be probable. At contract inception, once the contract is determined to be within the scope of the revenue from contracts with customers accounting standard, we assess whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services until a distinct bundle is identified. We then allocate the transaction price (the amount of consideration we expect to be entitled to from a customer in exchange for the promised goods or services) to each performance obligation and recognize the associated revenue when (or as) each performance obligation is satisfied. Our estimate of the transaction price for each contract includes all variable consideration to which we expect to be entitled. See Note 3 for a detailed discussion of our revenue recognition policy for product sales and our consideration of the transaction price related to variable consideration.

Amounts are recorded as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a significant financing component if the expectation at contract inception is that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less. We expense incremental costs of obtaining a contract, as and when incurred, if the expected amortization period of the asset that we would have recognized is one year or less or the amount is immaterial.

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, 2020, most of the cost of product sales had a zero-cost basis. Prior to receiving FDA approval for Fintepla, we recorded all manufacturing product costs as research and development expense.

Account Receivables, Net

We record accounts receivable, net of certain fees paid to our Customer for distribution services rendered to us that are not distinct from sales of product to that Customer, prompt payment discounts and chargebacks based on contractual terms. As of September 30, 2020, we determined an allowance for credit losses was not recorded based upon our review of contractual payment terms, the short-duration we expect the accounts receivable to be outstanding, the fact each order placed for Fintepla by our Customer is for immediate shipment to their customer, and our assessment of the creditworthiness of our Customer, among other factors. We have standard payment terms that generally require payment within approximately 30 days. Accounts receivable, net excludes receivables from our collaboration agreement with Shinyaku, if any, which are recorded within current assets on our condensed consolidated balance sheets.

We are also subject to credit risk from our accounts receivable related to our product sales. 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.

Concentration of Credit Risk

As is common in the pharmaceutical industry for products treating rare diseases, Fintepla is distributed through an exclusive arrangement with a single specialty distributor, our sole Customer. As a result, our accounts receivable is exposed to concentration of credit risk as 100% of the accounts receivable is due from this Customer.

Inventory

Inventory is recorded at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. Inventory costs include third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process, and indirect overhead costs. We primarily use actual costs to determine the cost basis for our inventory. We periodically review our inventories to identify obsolete, slow moving, excess or otherwise unsaleable items. If obsolete, slow moving, excess or unsaleable items are observed and there are no alternate uses for the inventory, we record a write-down to net realizable value. The determination of net realizable value requires judgment including consideration of many factors, such as estimates of future product demand, product net selling prices, current and future market conditions and potential product obsolescence, among others.

Prior to regulatory approval, we expense costs associated with the manufacture of our product candidates to research and development expense unless we are reasonably certain such costs have future commercial use and net realizable value. Since we consider attaining regulatory approval of a product candidate to be highly uncertain and difficult to predict, we expect only in rare instances will pre-launch inventory be capitalized, if at all.

Finite-Lived Intangible Assets

Purchased finite-lived intangible assets are initially recognized at fair value and subject to amortization over its estimated useful life. Our finite-lived intangible assets are amortized using a method that reflects the pattern in which the economic benefits of the intangible assets are consumed or otherwise used. If that pattern cannot be reliably determined, the intangible assets are amortized using the straight-line method over their estimated useful lives and are tested for impairment along with other long-lived assets. At September 30, 2020, our finite-lived intangible assets consisted of Fintepla product rights (see Note 7).

Long-Lived Assets

Long-lived assets, including right-of-use operating lease assets and our finite-lived intangible asset, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets (group) may not be recoverable. Recoverability of assets is determined by comparing the estimated undiscounted net cash flows of the operations related to the assets (asset group) to their carrying amount. If the carrying value of the assets (asset group) exceeds its undiscounted cash flows, we then compare the fair value of the assets (asset group) to their carrying value to determine the impairment loss. The impairment loss will be allocated to the carrying values of the long-lived assets (asset group), but not below their individual fair values.

If we determine that events and circumstances warrant a revision to the remaining period of amortization, a long-lived asset's remaining useful life shall be changed, and the remaining carrying amount of the long-lived asset shall be depreciated or amortized prospectively over that revised remaining useful life.

Impact of COVID-19 Pandemic

In March 2020, the World Health Organization declared the global novel coronavirus disease (COVID-19) outbreak a pandemic. To date, other than closing our offices, initiating new remote work policies and delaying the initiation of an exploratory Phase 2 basket study by two quarters, our operations have not been significantly impacted by the COVID-19 pandemic. We cannot predict the specific extent, duration, or full impact that the COVID-19 pandemic will have on our financial condition and operations, including ongoing and planned clinical trials, the timelines for receiving feedback or approvals from regulatory authorities, and product launch in the midst of a pandemic.

As of September 30, 2020, the COVID-19 pandemic has not impacted the carrying value of our finite-lived intangible asset, goodwill, long-lived assets and right-of-use assets. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets. If the financial markets and/or the overall economy are impacted for an extended period, our business, results of operations and financial condition may be adversely affected.

Income Taxes

On March 18, 2020, the Families First Coronavirus Response Act (FFCR Act) and on March 27, 2020, The Coronavirus Aid, Relief and Economic Security Act (CARES Act) were signed into law in response to the COVID-19 pandemic. The FFCR Act and CARES Act, includes provisions related to refundable payroll tax credits, deferment of employer side social security payments, retroactively and temporarily (for taxable years beginning before January 1, 2021) suspending the application of the

80%-of-income limitation on the use of net operating losses, which was enacted as part of the Tax Cuts and Jobs Act of 2017. The CARES Act also provides that net operating losses arising in any taxable year beginning after December 31, 2017, and before January 1, 2021 are generally eligible to be carried back up to five years.

On June 29, 2020, Assembly Bill 85 (A.B. 85) was signed into California law. A.B. 85 provides for a three-year suspension of the use of net operating losses for medium and large businesses and a three-year cap on the use of business incentive tax credits to offset no more than $5.0 million of tax per year. A.B. 85 suspends the use of net operating losses for taxable years 2020, 2021 and 2022 for certain taxpayers with taxable income of $1.0 million or more. The carryover period for any net operating losses that are suspended under this provision will be extended. A.B. 85 also requires that business incentive tax credits including carryovers may not reduce the applicable tax by more than $5.0 million for taxable years 2020, 2021 and 2022.

The enactment of the FFCR Act, CARES Act and A.B. 85 did not result in any material adjustments to our income tax provision for the three and nine months ended September 30, 2020 or to our net deferred tax assets as of September 30, 2020. Given our history of losses, we do not expect the provisions of the FFCR Act, CARES Act and A.B. 85 to have a material impact on our annual effective tax rate or condensed consolidated financial statements in 2020; however, we will continue to evaluate the impact of tax legislation and will update our disclosures as additional information and interpretive guidance becomes available.

Recently Adopted Accounting Pronouncements

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

ASU 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. The implied fair value for a reporting unit is determined in the same manner as the amount of goodwill recognized in a business acquisition of the reporting unit. Under the standard, an entity shall recognize an impairment charge for the amount by which the carrying amount of a reporting unit exceeds its fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The standard became effective for us beginning January 1, 2020. The adoption of this standard did not have a material impact on our condensed consolidated financial statements or related disclosures; however, any prospective goodwill impairment losses recognized will be measured in accordance with the updated guidance.

ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* modifies the disclosure requirements in Topic 820 by removing certain disclosure requirements related to the fair value hierarchy, modifying existing disclosure requirements related to measurement uncertainty and adding new disclosure requirements, such as disclosing the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This standard became effective for us beginning January 1, 2020 and the adoption of this standard did not have a material impact on our condensed consolidated financial statements. For the new disclosures regarding our Level 3 fair value measurements, see Note 5, *Fair Value Measurements* to these condensed consolidated financial statements.

ASU 2019-12, *Simplifying the Accounting for Income Taxes (Topic 740*) (ASU 2019-12) removes certain exceptions to the general principles in Topic 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. This ASU is effective for us for all interim and annual periods beginning January 1, 2021, with early adoption permitted. We early adopted ASU 2019-12 beginning January 1, 2020

on a prospective basis. The adoption of this standard did not have a material impact on our condensed consolidated financial statements and related disclosures.

The only aspect of ASU 2019-12 that is currently applicable to us is the removal of the exception related to intraperiod tax allocation. Beginning January 1, 2020, we have applied the general methodology regarding the intraperiod allocation of tax expense for reporting periods where we have a loss from continuing operations by determining the amount of taxes attributable to continuing operations without regard to the tax effect of other items, including changes in unrealized gains related to marketable securities.

Recently Issued Accounting Pronouncements Not Yet Adopted

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), or ASU 2020-06, reduces the number of accounting models in ASC 470-20 that require separate accounting for embedded conversion features, which we followed in accounting for the issuance of our convertible senior notes (see Note 9). ASU 2020-06 will be effective for SEC-reporting entities for fiscal years beginning after December 15, 2021 (or, in the case of smaller reporting companies, December 15, 2023), including interim periods within those fiscal years. However, early adoption is permitted in certain circumstances for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. When effective, we expect the elimination of the requirement to separately account for the conversion feature into its equity component by recording amounts as debt discount related to our senior convertible notes will result in a decrease to our interest expense over the expected life of the financial instrument. In addition, interest expense is expected to be closer to the stated coupon rate of the convertible senior notes.

As we intend to settle conversions by paying the conversion value in cash up to the principal amount being converted and any excess in shares, we expect to be eligible to use the treasury stock method to reflect the shares underlying the notes in our diluted earnings per share. Under this method, if the conversion value of the notes exceeds their principal amount for a reporting period, then we will calculate our diluted earnings per share assuming that all the notes were converted and that we issued shares of our common stock to settle the excess. However, if reflecting the notes in diluted earnings per share in this manner is anti-dilutive, or if the conversion value of the notes does not exceed their principal amount for a reporting period, then the shares underlying the notes will not be reflected in our diluted earnings per share. Upon adoption of ASU 2020-06, we also expect to lose the ability to use the treasury stock method, which would cause our diluted earnings per share to decline. For example, ASU 2020-06 eliminates the treasury stock method for convertible instruments that can be settled in whole or in part with equity and instead require application of the "if-converted" method. Under that method, diluted earnings per share would generally be calculated assuming that all the notes were converted solely into shares of common stock at the beginning of the reporting period, unless the result would be anti-dilutive. The application of the if-converted method could reduce our reported diluted earnings per share.

Note 3 – Revenues

Net Product Sales

We distribute Fintepla in the United States through an arrangement with a single specialty distributor. Our Customer subsequently resells our product through its related specialty pharmacy provider to patients and health care providers. Separately, we 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 product provided to a patient.

Revenue from product sales is recorded at the net sales price (transaction price), which includes estimates of consideration payable to our Customer 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 Customer, and third-party payers related to the sales of Fintepla. These reserves are classified as either reductions of accounts receivable (if the amounts are payable to our Customer) or as refund liabilities within current liabilities (if the amounts are payable to a party other than our Customer). Amounts billed or invoiced are included in accounts receivable, net on our condensed consolidated balance sheet. We did not have any contract assets (unbilled receivables) at September 30, 2020, as we generally invoice our Customer before or at the time of revenue recognition. We did not have any contract liabilities at September 30, 2020, as we did not receive payments in advance of fulfilling our performance obligations to our Customer.

We recognize product revenues when our Customer obtains control of our product, which occurs at a point in time and is typically upon delivery to our Customer or, in the case of products that are subject to consignment agreements, when our Customer takes title of the product from our consigned inventory location for shipment directly to a patient or healthcare provider. In the event the variable consideration is constrained, we include an amount to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur in a future reporting period. Depending on the type of variable consideration, we use either the most likely method or expected value method to estimate variable

consideration related to Fintepla product sales. We do not have any material constraints on our variable consideration included within the transaction price for Fintepla product sales. The actual amount of consideration ultimately received may differ from our estimates. If actual results in the future vary from estimates, the estimates will be adjusted, which will affect our revenue from net product sales in the period that such variances become known. Each unit of Fintepla that is ordered by our Customer represents a separate performance obligation that is completed when our Customer obtains control of our product. We record product revenues, net of variable consideration, any applicable constraint, and consideration payable to parties other than our Customer at that point in time. We record shipping and handling costs within cost of product sales on our condensed consolidated statements of operations. We classify payments to our Customer or its affiliates for certain services, to the extent that the services we received are distinct from the sale of our product, as selling, general and administrative expenses on our condensed consolidated statements of operations. We have elected to exclude taxes collected from our customers (we currently have one) and remitted to governmental authorities from the measurement of the transaction price.

We sell Fintepla to our Customer at wholesale acquisition cost, and calculate product revenue from Fintepla sales, net of variable consideration and consideration payable to parties other than our Customer. Variable consideration and consideration payable to parties other than our Customer consists of estimates related to the following categories:

Trade Discounts and Allowances: We provide our Customer with discounts for prompt payment and we also pay fees to our Customer for distribution services rendered that are not distinct from product sales. We expect our Customer to earn these discounts and fees, and accordingly we deduct these discounts and fees in full from our gross product revenue and accounts receivable at the time we recognize the related revenue.

Government Rebates: Fintepla is eligible for purchase by, or qualifies for reimbursement from, Medicaid and other government programs that are eligible for rebates on the price they pay for Fintepla. To determine the appropriate amount to reserve for these rebates, we identify the government-funded health insurer of patients who receive Fintepla as sold by our Customer through its related specialty pharmacy, apply the applicable government discount to these sales, and estimate the portion of total rebates that we anticipate will be claimed.

Other Rebates and Chargebacks: We may contract with various third-party payers for coverage and reimbursement of Fintepla. We estimate the rebates and chargebacks that we expect to be obligated to provide to such third-party payers based upon the terms of the applicable arrangement or negotiations with such third-party payers and our visibility regarding the payer mix.

Patient Assistance Program: We provide financial assistance to eligible patients whose insurance policies have high deductibles or co-payments and deduct our estimate of the amount of such assistance from gross product revenue.

Product Returns: We do not provide contractual return rights to our Customer, except in instances where the product is damaged or defective, which we expect to be rare.

During the three and nine months ended September 30, 2020, we recorded net product sales of $1.5 million, which consisted of commercial sales of Fintepla in the United States.

Collaboration Revenue

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

Shinyaku has agreed to support development and regulatory approval of Fintepla in Japan by actively participating in the design of non-clinical, clinical and manufacturing requirements needed for regulatory submission, actively planning and participating in product labeling decisions and discussions with the Japanese Ministry of Health, Labor and Welfare (MHLW) and obtained distribution exclusivity through the payment of an initial fixed consideration. Pursuant to the terms of the agreement, Shinyaku agreed to make aggregate fixed payments of $20.0 million to us in scheduled installments. As of

September 30, 2020, we have received $17.0 million with the remaining balance due within the next year. We will be actively running the clinical trials, performing manufacturing validation activities, preparing regulatory filings and holding discussions with MHLW, and negotiating pricing. We and Shinyaku have agreed to proportionally share the Japan specific development costs that may arise outside of the initial development plan and any post-approval clinical study costs in Japan. In addition, we can earn up to $66.0 million from Shinyaku for the achievement of certain regulatory milestones for the treatment of Dravet syndrome and LGS. If regulatory approval of Fintepla is received in Japan, we have agreed to supply Shinyaku with Fintepla upon receipt of purchase orders at our actual manufacturing cost plus a fixed transfer price mark-up, a fixed percentage of Shinyaku's net sales of Fintepla in Japan for such fiscal year, and a net price mark-up based on a percent of the applicable aggregate sales of Fintepla by Shinyaku for such fiscal year. The net price mark-up percentage increases with Shinyaku’s sales of Fintepla annual net sales in Japan and ranges between mid-twenties and is capped at a low thirties of the aggregate annual net sales for an applicable fiscal year. In addition, we can earn up to an additional $42.5 million tied to the achievement of certain net sales milestones by Shinyaku through the term of the agreement, which generally expires in 2045.

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

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

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

The initial collaboration consideration consisted solely of the fixed consideration payments of $20.0 million and was allocated on a relative standalone selling price basis to the two identified development programs akin to performance obligations related to collaborative activities for development and regulatory approval efforts for Dravet syndrome and LGS. Analogizing to the revenue from contracts with customers variable consideration guidance, all potential regulatory milestone payment consideration will be included in the collaboration consideration if and when it is probable that a significant reversal in the amount of cumulative collaboration consideration recognized will not occur when the uncertainty associated with the variable collaboration consideration is subsequently resolved. At contract inception and through September 30, 2020, this consideration was fully constrained as the achievement of the events tied to these regulatory milestone payments was highly dependent on factors outside our control.

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

For the three and nine months ended September 30, 2020, we recognized collaboration revenue of $1.3 million and $3.6 million, respectively. As of September 30, 2020, the deferred revenue balance of $11.2 million included a $1.5 million installment receivable recorded within other current assets related to the $20.0 million fixed consideration under the arrangement. We classified deferred revenue as either current or net of current portion in the accompanying condensed consolidated balance sheets based on the period over which the collaboration revenue is expected to be recognized. We expect to recognize collaboration revenue related to these collaborative activities through the end of 2023.

Note 4 – Cash, Cash Equivalents and Marketable Securities

The following tables summarize the amortized cost and the estimated fair value of our cash, cash equivalents and marketable securities as of September 30, 2020 and December 31, 2019 (in thousands):

	September 30, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Current assets:				
Cash	$ 219,469	$ —	$ —	$ 219,469
Cash equivalents:				
U.S. Treasuries	13,799	—	—	13,799
Money market funds	39,536	—	—	39,536
Certificate of deposits	3,008	—	—	3,008
Commercial paper	21,648	—	—	21,648
Total cash and cash equivalents	297,460	—	—	297,460
Marketable securities:				
U.S. Treasuries	27,894	2	—	27,896
Commercial paper	101,951	—	—	101,951
U.S. Government-sponsored enterprises debt securities	6,200	19	—	6,219
Corporate debt securities	49,980	377	—	50,357
Certificate of deposits	41,284	—	—	41,284
Total marketable securities	227,309	398	—	227,707
Total cash, cash equivalents and marketable securities	$ 524,769	$ 398	$ —	$ 525,167

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

The following table summarizes the cost and fair value of marketable securities based on stated effective maturities as of September 30, 2020 (in thousands):

	Amortized Cost	Fair Value
Due within one year	$ 216,609	$ 216,962
Due between one and two years	10,700	10,745
Total	$ 227,309	$ 227,707

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, 2020, no assessment of expected credit losses was necessary as we did not have any individual security in an unrealized loss position.

Accrued interest receivable on available-for-sale marketable securities are recorded within “Prepaid expenses and other current assets” on our condensed consolidated balance sheets and was $0.6 million and $0.6 million at September 30, 2020 and December 31, 2019, respectively.

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

Note 5 – Fair Value Measurements

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

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

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

The following tables summarize assets and liabilities recognized or disclosed at fair value on a recurring basis as of September 30, 2020 and December 31, 2019 (in thousands):

	September 30, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
U.S. Treasuries	$ —	$ 13,799	$ —	$ 13,799
Money market funds	39,536	—	—	39,536
Certificate of deposits	—	3,008	—	3,008
Commercial paper	—	21,648	—	21,648
Marketable securities:				
U.S. Treasuries	—	27,896	—	27,896
Commercial paper	—	101,951	—	101,951
U.S. Government-sponsored enterprises debt securities	—	6,219	—	6,219
Corporate debt securities	—	50,357	—	50,357
Certificate of deposits	—	41,284	—	41,284
Total assets[1]	$ 39,536	$ 266,162	$ —	$ 305,698
Liabilities:				
Common stock warrant liabilities	$ —	$ —	$ 9	$ 9
Contingent consideration liabilities	—	—	54,900	54,900
Total liabilities	$ —	$ —	$ 54,909	$ 54,909

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

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

Contingent Consideration Liability

Pursuant to the terms of the Brabant purchase agreement in 2014 in which we acquired worldwide development and commercialization rights to Fintepla, we are obligated to make future milestone payments that are contingent upon the successful achievement of certain regulatory and sales-based milestone events related to Fintepla. As of September 30, 2020, the potential amount of future payments that we may be required to make is between zero, if none of the remaining milestones are achieved, to a maximum of $60.0 million.

The following table provides a reconciliation of our contingent consideration liability measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Balance at beginning of period	$ 53,100	$ 70,500	$ 63,800	$ 78,200
Change in fair value	1,800	400	6,100	2,700
Settlements	—	—	(15,000)	(10,000)
Balance at end of period	$ 54,900	$ 70,900	$ 54,900	$ 70,900

For the nine months ended September 30, 2020, the $6.1 million increase to the estimated fair value of our contingent consideration liability was primarily due to updated assumptions used regarding the probability of success for achieving certain regulatory and sales-based milestone events in light of FDA approval of Fintepla in June 2020. The change in fair value for the three and nine months ended September 30, 2019 and the three months ended September 30, 2020 was attributable to immaterial adjustments to certain assumptions and estimates used in the remeasurement to fair value and changes in the discount rate used as a result of market interest rate changes.

The following table summarizes the significant unobservable inputs used in the fair value measurement of our contingent consideration liabilities as of September 30, 2020.

Fair Value as of September 30, 2020 (in thousands)	Valuation Technique	Unobservable Input	Range	Weighted Average[1]
$54,900	Discounted cash flow	Discount rate	3.6% — 10.1%	5.5%
		Probability of payment	0% — 94.3%	94.3%
		Projected year of payment	2021 — 2030	2022

(1) Unobservable inputs were weighted by the relative fair value of the contingent consideration liability.

The weighted average discount rate was calculated based on the relative fair value of our contingent consideration obligations. Significant increases or decreases in projected revenues, probabilities of payment, discount rates or the time until payment is made would have resulted in a significantly lower or higher fair value measurement as of September 30, 2020.

Convertible Senior Notes

As of September 30, 2020, the estimated fair value of our Convertible Senior Notes was approximately $199.7 million and was determined based on a binomial lattice model with Level 2 inputs.

Note 6 – Balance Sheet Details

Inventory

The following table provides details of our inventory balance (in thousands):

	September 30, 2020
Raw materials	$ 391
Work in process	531
Finished goods	88
Total	$ 1,010

As of September 30, 2020, our inventory balance reflects the cost of post-approval manufacturing activities related to our product. During the three and nine months ended September 30, 2020, most of the cost of product sales had a zero-cost basis. Prior to receiving FDA approval for Fintepla, we recorded all manufacturing product costs as research and development expense. As of September 30, 2020, no write-downs of inventory were deemed necessary.

Accrued and Other Current Liabilities

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

	September 30, 2020	December 31, 2019
Accrued clinical trial expenses	$ 13,088	$ 18,666
Accrued compensation	8,668	7,179
Other accrued liabilities	10,117	4,074
Common stock warrant liabilities	9	198
Total accrued and other current liabilities	$ 31,882	$ 30,117

Note 7 – Intangible Assets

The following table provides details of the carrying amount of our intangible assets (in thousands):

	September 30, 2020	December 31, 2019
Finite-lived intangible assets	$ 102,500	$ —
Accumulated amortization	(1,971)	—
Indefinite-lived in-process research and development (IPR&D) intangible assets	—	102,500
Total intangible assets, net	$ 100,529	$ 102,500

Our intangible assets consist of worldwide development, commercialization and related intellectual property rights including patents and licenses for our product, Fintepla (fenfluramine; formerly referred to as ZX008), which at the time of our acquisition in October 2014 and as of December 31, 2019, was classified as an indefinite-lived IPR&D asset. Upon FDA approval of Fintepla in June 2020, this indefinite-lived asset was reclassified to a finite-lived intangible asset subject to amortization.

In July 2020, we commercially launched Fintepla and commenced amortization of this asset on a straight-line basis over its estimated useful life. Due to the inherent subjectivity of forecasting the timing in which the cash flows may be generated from this intangible asset over a long-term time horizon, we concluded the pattern of economic benefit cannot be reliably determined. As such, we elected to use the straight-line method of amortization for this intangible asset.

In estimating the useful life of the finite-lived Fintepla intangible asset, we considered the estimated period over which the asset will contribute directly or indirectly to our future cash flows, the strength of issued or licensed patents and related period of intellectual property protection, the availability of competitor products treating similar indications and the impact of patent expiry on the sustainability of future operating cash flows of the asset. Based on these factors, we estimated the useful life of the finite-lived intangible asset to be 13 years.

As of September 30, 2020, the estimated future amortization of intangible assets for the next five years and thereafter is as follows (in thousands):

	Estimated Amortization Expense
2020 (remaining 3 months)	$ 1,971
2021	7,885
2022	7,885
2023	7,885
2024	7,885
Thereafter	67,018
Total	$ 100,529

Note 8 – Leases

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

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

	Nine Months Ended September 30,	
	2020	2019
Lease costs		
Operating lease cost	$ 1,510	$ 1,505
Short-term lease cost	346	690
Sublease income	(115)	(435)
Total	$ 1,741	$ 1,760

Cash paid for amounts included in the measurement of lease liabilities for the nine months ended September 30, 2020 and 2019 was $1.6 million and $1.2 million, respectively. The amounts were included in net cash used in operating activities in our condensed consolidated statements of cash flows. Right-of-use assets obtained in exchange for new operating lease liabilities were $1.2 million for the nine months ended September 30, 2020.

Maturities of operating lease liabilities as of September 30, 2020 and December 31, 2019 were as follows (in thousands):

	September 30, 2020	December 31, 2019
2020 (remaining 3 months and 12 months, respectively)	$ 589	$ 1,986
2021	2,305	1,957
2022	2,243	1,894
2023	2,300	1,951
2024	2,311	2,010
Thereafter	5,101	5,101
Total lease payments	14,849	14,899
Less imputed interest	(2,535)	(2,825)
Total operating lease liabilities	$ 12,314	$ 12,074

	September 30, 2020	December 31, 2019
Current portion of operating lease liabilities	$ 1,654	$ 1,322
Operating lease liabilities, net of current portion	10,660	10,752
Total lease liabilities	$ 12,314	$ 12,074

As of September 30, 2020, the weighted-average remaining lease term was 6.3 years and the weighted-average discount rate, weighted based on the remaining balance of lease payments, was 6.2%.

Note 9 – Convertible Senior Notes

On September 28, 2020, we issued $200.0 million aggregate principal amount of 2.75% convertible senior Notes due 2027 (Initial Notes) to certain initial purchasers for resale to qualified institutional buyers in a private offering exempt from registration under the Securities Act of 1933. In connection with the offering, we granted the initial purchasers an option to purchase up to an additional $30.0 million in principal amount of notes (Option Notes), which was exercised in full on October 5, 2020. Total proceeds realized, net of issuance costs, from the sale of the Initial Notes and Option Notes (collectively, the Convertible Senior Notes, or the Notes) were approximately $222.5 million, of which $194.0 million were received upon closing of the Initial Notes in September 2020. 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. The principal amount of the Notes was issued at par value and the Notes accrue interest at a rate of 2.75% per year, payable semi-annually in arrears on April 1 and October 1 of each year, beginning on April 1, 2021. The Notes mature on October 1, 2027, unless earlier converted by the holders or redeemed or repurchased by us in accordance with their terms prior to such date. The Indenture contains customary terms and covenants, including certain events of default upon which the Notes may be due and payable immediately, but does not contain any financial covenants.

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 also may 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.

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 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 $200.0 million Initial Notes, we performed an assessment of all embedded features of the debt instrument to determine if (i) such features should be bifurcated and separately accounted for, and (ii) if bifurcation requirements are met, whether such features should be classified and accounted for as equity or liability instruments. If the embedded feature meets the requirements to be bifurcated and accounted for as a liability, the fair value of the embedded feature is measured initially, included as a liability on the condensed consolidated balance sheets and re-measured to fair value at each reporting period.

We determined the embedded conversion feature in the Initial Notes is not required to be separately accounted for as a derivative liability instrument because it is considered to be indexed to our common stock. However, since the Initial Notes may be settled with a combination of cash and shares, at our election, we are required to separate the Initial Notes into debt and equity components. The value assigned to the debt component is the estimated fair value, as of the issuance date, of a similar debt instrument issued by us without the conversion feature. The difference between the full principal amount of the Initial Notes and this estimated fair value was recorded as a debt discount on the Notes, with a corresponding offset to additional paid-in capital (the equity component). In addition, the underlying debt issuance costs of associated with the Initial Notes were allocated to the debt and equity components in proportion to the allocation of the full principal amount to those components. The Option Notes that settled in October 2020 will be accounted for similarly.

The debt component of the Initial Notes was estimated to have a fair value of $132.3 million based on the contractual cash flows discounted at our estimated non-convertible debt borrowing rate of 9.7%. Our determination of an appropriate discount rate was based on a yield curve derived from recent publicly traded bond offerings with a similar term for companies with similar credit ratings to us (Level 2 inputs). After the allocation of underlying debt issuance costs of $6.6 million to the debt and equity components, $65.5 million was attributable to additional-paid-in capital within stockholders' equity and the corresponding offset was recorded as unamortized debt discount and issuance costs and included within the carrying amount of the Notes. The debt discount and issuance costs will be amortized as interest expense over the expected term of the Initial Notes of seven years using the effective interest method. The effective interest rate on the $200.0 million Initial Notes was 9.9%. The equity component is not remeasured as long as it continues to meet the conditions for equity classification.

The following table provides information on our Convertible Senior Notes balance as of September 30, 2020 (in thousands):

	September 30, 2020
Principal amount of Convertible Senior Notes	$ 200,000
Less: Unamortized debt discount and issuance costs	(72,040)
Net carrying amount	$ 127,960

For the three and nine months ended September 30, 2020, interest expense for the Initial Notes was not material. For the same periods in 2019, we had no interest expense as we had no borrowings..

Note 10 – Stockholders' Equity and Stock-Based Compensation

Sale of Common Stock

Underwritten Public Offerings

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

At-the-Market Offerings

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 on June 12, 2020. In August and September 2020, we sold 202,503 shares of common stock and realized net proceeds of approximately $4.9 million, after deducting commissions and other offering costs, pursuant to the ATM Sales Agreement. As of September 30, 2020, approximately $195.0 million remains available under the ATM Sales Agreement.

Equity Incentive Plans

We have issued stock-based awards from various equity incentive and stock purchase plans, as more fully described in Note 12, *Stock-Based Compensation* to the consolidated financial statements in our 2019 Form 10-K. In June 2020, our shareholders approved an amendment and restatement of our 2010 Employee Stock Purchase Plan (the Restated ESPP). Effective May 29, 2020, the plan was amended to increase the aggregate number of shares authorized for issuance from 375,000 to 875,000 shares and to eliminate the annual evergreen feature, which automatically added 31,250 shares to the aggregate shares authorized for issuance on January 1 of each year under the plan. In addition, the expiration date of the Restated ESPP was modified from October 2020 to the date that all shares authorized have been issued. As of September 30, 2020, there were 524,962 shares of common stock available for future purchases under the Restated ESPP.

Stock Options

The following is a summary of stock option activity for the nine months ended September 30, 2019 (in thousands, except per share data):

	Shares	Weighted-Average Exercise Price per Share
Outstanding at December 31, 2019	4,253	$ 29.59
Granted	1,396	28.83
Exercised	(239)	16.64
Canceled	(230)	39.02
Outstanding at September 30, 2020	5,180	$ 29.57

Restricted Stock Units

The following is a summary of restricted stock unit activity for the nine months ended September 30, 2019 (in thousands, except per share data):

	Shares	Weighted-Average Fair Value per Share at Grant Date
Outstanding at December 31, 2019	439	$ 36.97
Granted	218	27.34
Vested	(220)	26.39
Canceled	(42)	38.79
Outstanding at September 30, 2020	395	$ 37.61

In June 2020, approximately 128,000 shares of performance-based restricted stock units (PSU's) granted in March 2017 vested upon satisfaction of both a service-period condition and a performance condition, the latter of which was satisfied following the FDA's approval of Fintepla in June 2020. As of September 30, 2020, all outstanding restricted stock units were subject to time-based vesting.

Stock-Based Compensation Expense Allocation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 2,865	$ 2,012	$ 9,082	$ 5,521
Selling, general and administrative	4,276	3,423	12,756	9,495
Compensation expense related to acquired IPR&D	—	4,927	—	4,927
Total	$ 7,141	$ 10,362	$ 21,838	$ 19,943

Stock-based compensation expense for the nine months ended September 30, 2020 included $1.4 million of compensation expense related to the vesting of PSUs.

Note 11 – 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 our Senior Convertible 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,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Numerator:				
Net loss	$ (60,089)	$ (290,478)	$ (139,213)	$ (363,443)
Denominator:				
Shares used in per share calculation	55,548	43,029	53,039	42,577
Net loss per share, basic and diluted	$ (1.08)	$ (6.75)	$ (2.62)	$ (8.54)

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,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Shares subject to outstanding stock options	5,149	4,172	4,848	4,040
Shares subject to outstanding restricted stock units	422	402	487	371
Shares subject to outstanding warrants to purchase common stock	28	28	28	28
Shares issuable upon conversion of Convertible Senior Notes	269	—	90	—
Total	5,868	4,602	5,453	4,439

Note 12 - Income Taxes

Income tax benefit during interim periods is based on applying an estimated annual effective income tax rate to year-to-date income, plus any significant unusual or infrequently occurring items, which are recorded in the interim period. The income tax benefit for the nine months ended September 30, 2020 differs from the U.S. federal statutory rate of 21.0% primarily due to effect of change in the valuation allowance against our deferred tax assets, which resulted in an income tax benefit.

As of December 31, 2019, 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 the reversal of 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 of 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 as of September 30, 2020. 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 deferred tax assets. The income tax benefit recognized for the nine months ended September 30, 2020 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. As of September 30, 2020, given our recurring net operating losses, we maintained a full valuation allowance against our net deferred tax assets.

Note 13 – 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. In May 2020, we received the cash payment for our submitted claims. For our 2019 tax year, we have not yet decided whether to seek tax relief by surrendering some of our losses for a tax credit cash rebate claim or electing to receive enhanced U.K. tax deductions on our eligible research and development activities. Under the U.K.'s tax legislation, there is a two-year window after the end of a tax year to seek relief under this tax relief scheme.

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

Forward-Looking Statements

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

- our ability to commercialize Fintepla for the treatment of seizures associated with Dravet syndrome;
- the progress and timing of clinical trials of our product candidates Fintepla outside the United States and to treat patients with Lennox-Gastaut Syndrome (LGS) 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, 2019 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our 2019 Annual Report on Form 10-K, which was filed with the SEC on March 2, 2020 (2019 Form 10-K).

Overview

We are a global commercial-stage 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, C-IV has been approved by the FDA and is under review in Europe for the treatment of seizures associated with Dravet syndrome, a rare, severe childhood onset epilepsy. In addition, the company has two late-stage development programs underway: one for Fintepla for the treatment of seizures associated with Lennox-Gastaut syndrome, 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.

Fintepla for Patients with Rare Epilepsy Disorders

Dravet Syndrome

United States. In June 2020, we received FDA approval of Fintepla (fenfluramine) oral solution, CIV for the treatment of seizures associated with Dravet syndrome in patients two years of age and older. The FDA's approval of Fintepla in Dravet syndrome was based on data from two randomized, double-blinded, placebo-controlled Phase 3 clinical trials, published in *The Lancet* (Volume 394, Issue 10216, P2243-2254, December 21, 2019) and *JAMA Neurology* (2020 Mar; 77(3): 300–308), and safety data from an open-label extension trial in which many patients received Fintepla for up to three years. When added to existing treatment regimens, Fintepla significantly reduced the monthly convulsive seizure frequency compared to placebo in study patients whose seizures were not adequately controlled on one or more antiepileptic drugs. In addition, most study patients responded to treatment with Fintepla within three to four weeks and effects remained consistent over the treatment period.

In July 2020, we launched Fintepla in the U.S. market under a Risk Evaluation and Mitigation Strategy (REMS) program called the Zogenix REMS. This program is designed to ensure that Fintepla will only be made available for prescription and distribution by specially certified providers, and that patients receive proper cardiac monitoring. All REMS requirements, such as scheduling echocardiograms, are coordinated through a program called Zogenix Central, which serves as a logistical hub, through which patient care and information is managed.

Fintepla is marketed in the United States through our own specialty sales force and commercial team and distributed through our specialty pharmacy partner that specializes in the dispensing of medications for complex or chronic conditions which require a high level of patient education and ongoing management.

Europe. Our submission to the EMA of a Marketing Authorization Application (MAA) for Fintepla in Dravet syndrome has been under review since its acceptance in March 2019. In October 2020, we announced that the Committee for Medicinal Products for Human Use (CHMP), a part of the EMA, adopted a positive opinion recommending the marketing authorization of Fintepla for the treatment of seizures associated with Dravet syndrome. We anticipate a decision on our MAA from the European Commission in the fourth quarter of 2020.

Japan. In September 2020, we reported positive top-line results from our third Phase 3 study (Study 3) of Fintepla (fenfluramine) oral solution for the treatment of seizures associated with Dravet syndrome. The study corroborates the substantial impact of Fintepla on convulsive seizure reduction previously demonstrated in two earlier Phase 3 trials (Studies 1 and 2) in patients with this severe, rare and often debilitating form of infant-onset epilepsy. It also expands the countries where Fintepla has been evaluated to include Japan. We anticipate Study 3 will be the pivotal study included in our planned submission of a new drug application (J-NDA) in that country, expected to occur in 2021.

Lennox-Gastaut Syndrome

Fintepla is also under late-stage development for the treatment of seizures associated with LGS, another rare and devastating form of childhood-onset epilepsy. In November 2017, we announced the initiation of Study 1601, our double-blind, placebo-controlled, multicenter global Phase 3 clinical trial of Fintepla as an adjunctive treatment for seizures in patients with LGS. In February 2020, we announced positive top-line results from Study 1601, which met its primary objective of demonstrating that Fintepla at a dose of 0.7 mg/kg/day was superior to placebo in reducing the frequency of drop seizures, based on the change between baseline and the titration and maintenance treatment period (p=0.0012). The same dose of Fintepla (0.7 mg/kg/day) also demonstrated improvements versus placebo in key secondary efficacy measures, including a significant reduction in the proportion of patients with a clinically meaningful reduction (≥50%) in drop seizure frequency (p=0.0150). A decrease in the frequency of drop seizures between baseline and the treatment period was observed for a lower dose of Fintepla (0.2 mg/kg/day) compared to placebo, but this change did not reach statistical significance (p=0.0915). In Study 1601, Fintepla was generally well-tolerated, with the adverse events consistent with those observed in our two prior Phase 3 studies in Dravet syndrome. The most common adverse events (≥10%) in the Fintepla-treated groups were decreased appetite, somnolence, fatigue, vomiting, diarrhea, seizure and pyrexia. The incidence of serious treatment emergent adverse

events was 11.5% (n=10) in the 0.7 mg/kg/day group, 4.5% (n=4) in the 0.2 mg/kg/day group, and 4.6% (n=4) in the placebo group. Patients who completed the double-blind phase of Study 1601 and were eligible could enter a 12-month open label extension study to evaluate the long-term safety, tolerability and effectiveness of Fintepla. We are working to gather the additional data required to support a supplemental New Drug Application (sNDA), including two-year carcinogenicity data from our non-clinical study in rats and additional safety data from our ongoing open label extension study. Based on our clinical development plan and written feedback received from the FDA in September 2020, we expect to submit the sNDA in the second quarter of 2021.

Other Potential Indications

In addition to Dravet syndrome and LGS, we are evaluating Fintepla in other rare epileptic syndromes and diseases. We believe that the unique mechanism of action of Fintepla has the potential to treat other epileptic encephalopathies where there is a significant unmet medical need. We delayed the initiation (originally planned for the second quarter of 2020) of our exploratory Phase 2 study (the "basket study"), which is a study designed to understand the characteristics of rare epilepsy disorders other than Dravet syndrome and LGS in separate cohorts and evaluate whether Fintepla is safe and effective versus placebo in these patient populations and we now anticipate to commence initiation of the basket study in early 2021.

MT1621 for Patients with TK2 Deficiency

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

In April 2020, we held an End-of-Phase 2 meeting with the FDA and 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. Based on the feedback, we expect availability of all required data by end of 2021 to support an NDA submission, which we are targeting for first half of 2022. Also, in the meeting, the FDA requested we include additional information on treated patients who did not participate in the Modis-sponsored portion of the RETRO study in order to have a complete survival analysis for the NDA. This additional information will be collected in a non-interventional medical chart-review study. In addition, we plan to conduct a Phase 1 pharmacokinetic (PK) study in renal impairment which was 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.

Business Update Regarding the COVID-19 Pandemic

The current COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, patients and their families and caregivers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, and restricting business functions outside of one's home. In response, we closed our offices for all but the most essential activities and have implemented a policy allowing all employees to work from across all locations, following the guidelines or directives issued by federal, state and local government agencies in the U.S. as well as the U.K. government.

In July 2020, we commenced the commercial launch of Fintepla in the United States. Our commercialization efforts will need to navigate through the operational restrictions imposed on our sales force from quarantines, travel restrictions and bans and other governmental and healthcare restrictions related to COVID-19. As a result of these restrictions, our sales force has not been able to conduct in-person interactions with physicians and healthcare providers in many cases and have been restricted to primarily conducting educational and promotional activities for Fintepla virtually, which may impact our ability to market Fintepla. In addition, Fintepla is being launched through REMS program requiring patients to visit sites of care for an echocardiogram during this pandemic. To date, we have been able to continue to supply Fintepla and MT1621 to our patients currently enrolled in our clinical trials and do not currently anticipate any interruptions in supply. While the pandemic had limited impact on our ongoing clinical trials that were already underway in sites across the globe prior to the onset of the pandemic, we had to delay the initiation of our basket study that was originally planned to commence in the second quarter of 2020 to early 2021 as a result of COVID-19 precautions. Any delays in the completion of our clinical trials and any disruption in our supply chain could have a material adverse effect on our business, results of operations and financial condition. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets.

Critical Accounting Policies and Estimates

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

We consider an accounting estimate to be critical if: (1) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (2) changes in the estimate that are reasonably likely to occur from period to period, or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. Our critical accounting policies and estimates are described in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of our 2019 Form 10-K. There were no material changes to our critical accounting policies during the nine months ended September 30, 2020, as compared to the critical accounting policies and estimates disclosed in our 2019 Form 10-K, except as described below.

Revenue Recognition for Net Product Sales

We recognize revenue when control of the promised good or service is transferred to the customer, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. We determine revenue recognition through the following steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when collectability of the consideration to which we are entitled in exchange for the goods or services we transfer to the customer is determined to be probable. At contract inception, once the contract is determined to be within the scope of the revenue from contracts with customers accounting standard, we assess whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services until a distinct bundle is identified. We then allocate the transaction price (the amount of consideration we expect to be entitled to from a customer in exchange for the promised goods or services) to each performance obligation and recognize the associated revenue when (or as) each performance obligation is satisfied. Our estimate of the transaction price for each contract includes all variable consideration to which we expect to be entitled.

We distribute Fintepla in the United States through an arrangement with a single specialty distributor. Our Customer subsequently resells our product through its related specialty pharmacy provider to patients and health care providers. Separately, we 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 product provided to a patient.

Revenue from product sales is recorded at the net sales price (transaction price), which includes estimates of consideration payable to our Customer 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 Customer, and third-party payers related to the sales of Fintepla. These reserves are classified as either reductions of accounts receivable (if the amounts are payable to our Customer) or as refund liabilities within current liabilities (if the amounts are payable to a party other than our Customer). Amounts billed or invoiced are included in accounts receivable, net on our condensed consolidated balance sheet. We did not have any contract assets (unbilled receivables) at September 30, 2020, as we generally invoice our Customer before or at the time of revenue recognition. We did not have any contract liabilities at September 30, 2020, as we did not receive payments in advance of fulfilling our performance obligations to our Customer.

We recognize product revenues when our Customer obtains control of our product, which occurs at a point in time and is typically upon delivery to our Customer or, in the case of products that are subject to consignment agreements, when our Customer takes title of the product from our consigned inventory location for shipment directly to a patient or healthcare provider. In the event the variable consideration is constrained, we include an amount to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur in a future reporting period. Depending on the type of variable consideration, we use either the most likely method or expected value method to estimate variable consideration related to Fintepla product sales. We do not have any material constraints on our variable consideration included within the transaction price for Fintepla product sales. The actual amount of consideration ultimately received may differ from our estimates. If actual results in the future vary from estimates, the estimates will be adjusted, which will affect our revenue from net product sales in the period that such variances become known. Each unit of Fintepla that is ordered by our Customer represents a separate performance obligation that is completed when our Customer obtains control of our product. We record product revenues, net of variable consideration, any applicable constraint, and consideration payable to parties other than our Customer at that point in time. We record shipping and handling costs within cost of product sales on our condensed consolidated statements of operations. We classify payments to our Customer or its affiliates for certain services, to the extent that the services we received are distinct from the sale of our product, as selling, general and administrative expenses on our condensed consolidated statements of operations. We have elected to exclude taxes collected from our customers (we currently have one) and remitted to governmental authorities from the measurement of the transaction price.

We sell Fintepla to our Customer at wholesale acquisition cost, and calculate product revenue from Fintepla sales, net of variable consideration and consideration payable to parties other than our Customer. Variable consideration and consideration payable to parties other than our Customer consists of estimates related to the following categories:

Trade Discounts and Allowances: We provide our Customer with discounts for prompt payment and we also pay fees to our Customer for distribution services rendered that are not distinct from product sales. We expect our Customer to earn these discounts and fees, and accordingly we deduct these discounts and fees in full from our gross product revenue and accounts receivable at the time we recognize the related revenue.

Government Rebates: Fintepla is eligible for purchase by, or qualifies for reimbursement from, Medicaid and other government programs that are eligible for rebates on the price they pay for Fintepla. To determine the appropriate amount to reserve for these rebates, we identify the government-funded health insurer of patients who receive Fintepla as sold by our Customer through its related specialty pharmacy, apply the applicable government discount to these sales, and estimate the portion of total rebates that we anticipate will be claimed.

Other Rebates and Chargebacks: We may contract with various third-party payers for coverage and reimbursement of Fintepla. We estimate the rebates and chargebacks that we expect to be obligated to provide to such third-party payers based upon the terms of the applicable arrangement or negotiations with such third-party payers and our visibility regarding the payer mix.

Patient Assistance Program: We provide financial assistance to eligible patients whose insurance policies have high deductibles or co-payments and deduct our estimate of the amount of such assistance from gross product revenue.

Product Returns: We do not provide contractual return rights to our Customer, except in instances where the product is damaged or defective, which we expect to be rare.

During the three and nine months ended September 30, 2020, we recorded net product sales of $1.5 million, which consisted of commercial sales of Fintepla in the United States.

Convertible Senior Notes

In accounting for the issuance of the $200.0 million Initial Notes, we performed an assessment of all embedded features of the debt instrument to determine if (i) such features should be bifurcated and separately accounted for, and (ii) if bifurcation requirements are met, whether such features should be classified and accounted for as equity or liability instruments. If the embedded feature meets the requirements to be bifurcated and accounted for as a liability, the fair value of the embedded

feature is measured initially, included as a liability on the condensed consolidated balance sheets and re-measured to fair value at each reporting period.

We determined the embedded conversion feature in the Initial Notes is not required to be separately accounted for as a derivative liability instrument because it is considered to be indexed to our common stock. However, since the Initial Notes may be settled with a combination of cash and shares, at our election, we are required to separate the Initial Notes into debt and equity components. The value assigned to the debt component is the estimated fair value, as of the issuance date, of a similar debt instrument issued by us without the conversion feature. The difference between the full principal amount of the Initial Notes and this estimated fair value was recorded as a debt discount on the Notes, with a corresponding offset to additional paid-in capital (the equity component). In addition, the underlying debt issuance costs of associated with the Initial Notes were allocated to the debt and equity components in proportion to the allocation of the full principal amount to those components. The Option Notes that settled in October 2020 will be accounted for similarly.

The debt component of the Initial Notes was estimated to have a fair value of $132.3 million based on the contractual cash flows discounted at our estimated non-convertible debt borrowing rate of 9.7%. Our determination of an appropriate discount rate was based on a yield curve derived from recent publicly traded bond offerings with a similar term for companies with similar credit ratings to us (Level 2 inputs). After the allocation of underlying debt issuance costs of $6.6 million to the debt and equity components, $65.5 million was attributable to additional-paid-in capital within stockholders' equity and the corresponding offset was recorded as unamortized debt discount and issuance costs and included within the carrying amount of the Notes. The debt discount and issuance costs will be amortized as interest expense over the expected term of the Initial Notes of seven years using the effective interest method. The effective interest rate on the $200.0 million Initial Notes was 9.9%. The equity component is not remeasured as long as it continues to meet the conditions for equity classification.

Finite-Lived Intangible Assets

Purchased finite-lived intangible assets are initially recognized at fair value and subject to amortization over its estimated useful life. Finite-lived intangible assets are amortized using the method that best reflects how their economic benefits are utilized or, if a pattern of economic benefits cannot be reliably determined, on a straight-line basis over their estimated useful lives. Due to the inherent subjectivity of forecasting the timing in which the cash flows may be generated from our Fintepla intangible asset over a long-term time horizon, we concluded the pattern of economic benefit could not be reliably determined. We have therefore elected to use the straight-line method of amortization for this intangible asset.

The estimate of the useful life of our Fintepla intangible asset involves management judgment. In determining the estimated useful life, we considered the estimated period over which the asset will contribute directly or indirectly to our future cash flows, the strength of issued patents and related period of intellectual property protection, the availability of competitor products treating similar indications and the impact of patent expiry on the sustainability of future operating cash flows of the asset.

Recent Accounting Pronouncements

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

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2020 and 2019

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

Revenues

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	2020	2019	Change	2020	2019	Change
Net product sales	$ 1,520	$ —	$ 1,520	$ 1,520	$ —	$ 1,520
Collaboration revenue	1,340	630	710	3,621	1,699	1,922
Total revenues	$ 2,860	$ 630	$ 2,230	$ 5,141	$ 1,699	$ 3,442

We began to record product revenue in the third quarter of 2020 following the approval of Fintepla by the FDA on June 25, 2020 and its subsequent commercial launch in the United States. Prior to the third quarter of 2020, our revenues were generated entirely through a collaboration agreement with Shinyaku entered into in March 2019.

Net Product Sales

During the three and nine months ended September 30, 2020, we recognized net product sales of $1.5 million related to sales of Fintepla in the United States following commercial launch in July 2020.

Collaboration Revenue

Collaboration revenue increased by $0.7 million and $1.9 million during the three and nine months ended September 30, 2020, respectively as compared to the same periods in 2019, as we conducted Study 3 in fulfillment of our performance obligations under the arrangement. We anticipate Study 3 will be the pivotal study included in our planned submission of a new drug application (J-NDA) in that country, expected to occur in 2021.

As recognition of our collaboration revenue is based on costs incurred to date relative to total estimated costs at completion when measuring progress combined with the uncertainty of when the events underlying various milestones are resolved, we expect our collaboration revenue will fluctuate from period to period. As of September 30, 2020, we recorded a $1.5 million installment receivable within other current assets related to the $20.0 million fixed consideration under the arrangement with a corresponding increase to deferred revenue. As of September 30, 2020, we have received $17.0 million of the fixed consideration.

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, 2020, cost of sales primarily consisted of royalties payable on net sales of Fintepla under a license agreement and labeling and packaging costs. Most of the cost of product sold during the three and nine months ended September 30, 2020 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 cost of sales for Fintepla 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)	2020	2019	Change	2020	2019	Change
Research and development	$ 34,425	$ 28,372	$ 6,053	$ 102,038	$ 79,820	$ 22,218

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; 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)	2020	2019	Change	2020	2019	Change
Fintepla for Dravet syndrome	$ 8,442	$ 10,153	$ (1,711)	$ 23,396	$ 30,819	$ (7,423)
Fintepla for LGS	11,223	6,843	4,380	26,925	19,514	7,411
MT1621	2,200	620	1,580	8,284	620	7,664
Other[(1)]	305	702	(397)	1,748	1,194	554
Total external costs	22,170	18,318	3,852	60,353	52,147	8,206
Internal costs	12,255	10,054	2,201	41,685	27,673	14,012
Total	$ 34,425	$ 28,372	$ 6,053	$ 102,038	$ 79,820	$ 22,218

(1) 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 decreased by $1.7 million and $7.4 million for the three and nine months ended September 30, 2020, respectively, compared to the same periods in 2019 primarily due to wind-down of clinical activities related to our Phase 3 trials Study 1 and Study 1504, partially offset by costs incurred to conduct a Phase 3 clinical trial (Study 3) to support registration of Fintepla in Japan. R&D expenses related to Fintepla for LGS increased by $4.4 million and $7.4 million in the same year-over-year periods reflecting the progression and expansion of our clinical trial activities within Study 1601. R&D expenses related to MT1621 increased by $1.6 million and $7.7 million in the same year-over-year periods as we continue to advance the MT1621 development program, including work related to chemistry, manufacturing, and controls process requirements. Internal costs for research and development activities increased by $2.2 million and $14.0 million for the three and nine months ended September 30, 2020, respectively, compared to the same periods in 2019 primarily driven by personnel-related expenses from increased headcount.

Selling, General and Administrative Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	2020	2019	Change	2020	2019	Change
Selling, general and administrative	$ 24,583	$ 15,762	$ 8,821	$ 70,332	$ 42,139	$ 28,193

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 research and development expenses.

Selling, general and administrative expense increased by $8.8 million and $28.2 million for the three and nine months ended September 30, 2020, respectively, compared to the same periods in 2019. The increases were primarily attributable to increased personnel-related costs as a result of headcount additions in preparation for commercialization and launch of Fintepla for Dravet syndrome, which commenced in July 2020, and headcount additions in general and administrative functions as well as staffing newly created foreign subsidiaries in Europe.

Amortization of Intangible Asset

Our intangible asset consist 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 the useful life of 13 years on a straight-line basis.

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in thousands)	2020	2019	Change	2020	2019	Change
Acquired IPR&D and acquisition-related costs	$ 1,500	$ 249,437	$ (247,937)	$ 4,500	$ 249,437	$ (244,937)

For the three and nine months ended September 30, 2020, we incurred $1.5 million and $4.5 million, respectively, in aggregate monthly option maintenance fees for the right to license an IPR&D asset. The underlying program subject to our option maintenance fees had not yet reached technological feasibility and had no alternative future use which resulted in a write-off to acquired IPR&D expense.

For the three and nine months ended September 30, 2019, acquired IPR&D expense primarily relates to our asset acquisition of Modis, which included one IPR&D project, MT1621.

Change in Fair Value of Contingent Consideration

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2020	2019	2020	2019
Change in fair value of contingent consideration	$ 1,800	$ 400	$ 6,100	$ 2,700

The contingent consideration liability relates to milestone payments under an existing agreement in connection with our prior acquisition of Fintepla. At each reporting period, the estimated fair value of the liability is determined by applying the income approach which utilizes variable inputs, such as the probability of success for achieving regulatory and sales-based milestones, anticipated future cash flows, risk-free adjusted discount rates, and nonperformance risk. Any change in the fair value is recorded as contingent consideration (income) expense.

For the nine months ended September 30, 2020, the $6.1 million increase to the estimated fair value of our contingent consideration liability was primarily due to updated assumptions used regarding the probability of success for achieving certain regulatory and sales-based milestone events in light of FDA approval of Fintepla in June 2020. The change in fair value for the three and nine months ended September 30, 2019 and the three months ended September 30, 2020 was attributable to immaterial adjustments to certain assumptions and estimates used in the remeasurement of fair value and changes in the discount rate used as a result of market interest rate changes.

Other Income

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2020	2019	2020	2019
Other income:				
Other income, net	934	481	20,798	433
Interest income, net	536	2,382	2,504	8,521
Total	$ 1,470	$ 2,863	$ 23,302	$ 8,954

The increase in other income, net for the nine months ended September 30, 2020 compared to the same period in 2019 was primarily due to amounts recorded to other income of $19.7 million for a cash rebate claim submitted under the U.K.'s small and medium-sized enterprise and research and development tax relief scheme for qualifying expenditures incurred in tax years 2017 and 2018. For our 2019 tax year, we have not yet decided whether to seek tax relief by surrendering some of our losses for a tax credit cash rebate claim or electing to receive enhanced U.K. tax deductions on our eligible research and development activities. Under the U.K.'s tax legislation, there is a two-year window after the end of a tax year to seek relief under this tax relief scheme.

The decrease in interest income for the three and nine months ended September 30, 2020 compared to the same periods in 2019 was attributable to lower average cash and investment balances as we funded our acquisition of Modis in September 2019 with cash on hand.

Income Tax Benefit

For the nine months ended September 30, 2020, we recorded a tax benefit of $17.4 million resulting from our determination that the deferred tax liability associated with the IPR&D intangible asset acquired in connection with our acquisition of Brabant in 2014 can be considered as a source of income when assessing the realizability of our deferred tax assets as of September 30, 2020. This change in estimate was based on the approval of Fintepla by the FDA in June 2020.

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, 2020, our accumulated deficit was $1.3 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. In June 2020, we received FDA approval in the United States for Fintepla. As a result, we began to generate net revenues from product sales during the third quarter of 2020. Prior to our Fintepla launch, our revenues were derived solely from a collaboration agreement related to development and commercialization activities for Fintepla in Japan. To date, we have relied primarily on the proceeds from equity and convertible debt offerings to finance our operations.

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

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 on June 12, 2020. In August and September of 2020, we sold 202,503 shares of common stock and realized net proceeds of approximately $4.9 million, after deducting commissions and other offering costs, pursuant to the ATM Sales Agreement. As of September 30, 2020, approximately $195.0 million remains available under the ATM Sales Agreement.

On September 28, 2020, we issued $200.0 million aggregate principal amount of 2.75% convertible senior Notes due 2027 (Initial Notes) to certain initial purchasers for resale to qualified institutional buyers in a private offering exempt from registration under the Securities Act of 1933. In connection with the offering, we granted the initial purchasers an option to purchase up to an additional $30.0 million in principal amount of notes (Option Notes), which was exercised in full on October 5, 2020. Total proceeds realized, net of issuance costs, from the sale of the Initial Notes and Option Notes (collectively, the Convertible Senior Notes, or the Notes) were approximately $222.5 million, of which $194.0 million was received upon closing of the Initial Notes in September 2020. 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. The principal amount of the Notes was issued at par value and the Notes accrue interest at a rate of 2.75% per year, payable semi-annually in arrears on April 1 and October 1 of each year, beginning on April 1, 2021. The Notes mature on October 1, 2027, unless earlier converted by the holders or redeemed or repurchased by us in accordance with their terms prior to such date. The Indenture contains customary terms and covenants, including certain events of default upon which the Notes may be due and payable immediately, but does not contain any financial covenants.

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.

As of September 30, 2020, our cash, cash equivalents and marketable securities totaled $525.2 million. We believe our existing capital resources are sufficient to meet our projected operating requirements for at least the next 12 months. Our principal uses of cash are research and development expenses, selling, general and administrative expenses and other working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- 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,	
	2020	2019
Cash and cash equivalents, beginning of the period	$ 62,070	$ 68,454
Net cash used in operating activities	(129,381)	(76,883)
Net cash (used in) provided by investing activities	(43,236)	43,787
Net cash provided by (used in) financing activities	408,007	(2,259)
Net increase (decrease) in cash and cash equivalents	235,390	(35,355)
Cash and cash equivalents, end of the period	$ 297,460	$ 33,099

Operating Activities

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.

For the nine months ended September 30, 2019, net cash used in operating activities of $76.9 million was primarily attributable to R&D expenses related to clinical trials and manufacturing process development for Fintepla and general and administrative costs to support our R&D activities, offset by upfront payments received of $15.5 million in connection with the Shinyaku Agreement entered into in March 2019 and the receipt of $3.1 million in tenant improvement allowance related to our headquarters.

Investing Activities

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.

For the nine months ended September 30, 2019, net cash provided by investing activities of $43.8 million was attributable to net sales/maturities of our available-for-sale marketable securities of $229.1 million, of which approximately $175.7 million was used to fund the cash portion of the upfront payment for the asset acquisition of Modis. In addition, we incurred capital expenditures of $9.6 million primarily related to the build-out of our headquarters, which we began to occupy in early March 2019.

Financing Activities

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.

For the nine months ended September 30, 2019, net cash used in financing activities of $2.3 million consisted of a $10.0 million payment of contingent consideration related to a prior acquisition and cash used to remit withholding taxes of $0.6 million related to the vesting of restricted stock units that were net share-settled by us to cover the required withholding tax. These cash outflows were offset by $8.4 million of proceeds from common stock issuances pursuant to our equity incentive plans.

Contractual Obligations

The following table describes our contractual cash obligations and commitments as of September 30, 2020:

	Payments due by period						
	Total	**2020**	**2021**	**2022**	**2023**	**2024**	**Thereafter**
	(In Thousands)						
Principal on Convertible Senior Notes due 2027[(1)]	$ 200,000	$ —	$ —	$ —	$ —	$ —	$ 200,000
Coupon interest on Convertible Senior Notes[(1)]	38,530	—	5,530	5,500	5,500	5,500	16,500
Operating lease obligations	14,849	589	2,305	2,243	2,300	2,311	5,101
Total	$ 253,379	$ 589	$ 7,835	$ 7,743	$ 7,800	$ 7,811	$ 221,601

(1) Assumes the notes are not converted or redeemed prior to the maturity date.

We enter into contracts in the normal course of business with CROs for preclinical studies and clinical trials and CMOs for the manufacture of drug materials. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be cancelled, we would only be obligated for costs of products or services that have been incurred by the vendor prior the effective date of cancellation, plus applicable cancellation fees.

In connection with our acquisition of Fintepla and Modis, we may be required to make certain regulatory and sales-based milestone payments. We cannot, at this time, determine when or if the related milestones will be achieved or whether the events triggering the commencement of payment obligations will occur. Therefore, such payments were not included in the table above.

Off-Balance Sheet Arrangements

As of September 30, 2020, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

As of September 30, 2020, we had an outstanding balance of $200.0 million aggregate principal amount of convertible senior notes that mature in 2027, which has a fixed interest rate of 2.75% per year. We carry these instruments at face value, less unamortized discounts and issuance costs, on our accompanying condensed consolidated balance sheets. Since these instruments bear interest at fixed rates, we have no financial statement risk associated with changes in interest rates. However, the fair value of these instruments fluctuates as interest rate changes and, in the case of our convertible senior notes, when the market price of our common stock fluctuates.

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, 2020 at the reasonable assurance level.

Changes in Disclosure Controls and Procedures

There were no changes in our internal control over financial reporting during the nine months ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

See discussion of legal proceedings set forth under Part II, Item 1. Legal Proceedings in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, filed with the SEC on May 6, 2020, which is incorporated by reference into this Part II. Item 1, as well as the discussion in Part I, Item 3. Legal Proceedings in our 2019 Form 10-K.

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

Item 1A. Risk Factors

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

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

The current COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, patients, communities and business operations, as well as the U.S. and global economy and financial markets. International and U.S. governmental authorities in impacted regions are taking actions to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, and restricting business functions outside of one's home. In response, we closed our offices for all but the most essential activities and have implemented a policy allowing all employees to work from across all locations, following the guidelines or directives issued by federal, state and local government agencies in the U.S. as well as the U.K. government. To date, we have been able to continue to supply Fintepla and MT1621 to our patients currently enrolled in our clinical trials and do not currently anticipate any interruptions in clinical or commercial supply. In addition, while we are continuing the clinical trials we have underway in sites across the globe, we expect that COVID-19 precautions may directly or indirectly impact the timeline for some of our clinical trials. For example, due to the challenges of enrolling new patients posed by the COVID-19 pandemic, we delayed the initiation of our exploratory Phase 2 basket study originally planned for the second quarter of 2020 until early 2021. The basket study is designed to understand the characteristics of rare epilepsy disorders other than Dravet syndrome and LGS in separate cohorts and evaluate whether Fintepla is safe and effective versus placebo in these patient populations. As the COVID-19 pandemic continues to spread around the globe, we may experience disruptions that could severely impact our business, clinical trials and manufacturing and supply chains, including:

- interruption or delays in the operations of the FDA, EMA or other regulatory authorities, which may impact review and approval timelines of our NDA and MAA for Fintepla for the treatment of seizures associated with Dravet syndrome;
- further delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, including interruption of commercial supply;
- delays or inability of us or our independent registered public accounting firm to count and/or observe the counts of our physical inventories;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials and interruption in global shipping that may affect the transport of clinical trial materials;
- limitations on employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;

- delays in receiving feedback or approvals from the FDA, EMA or other regulatory authorities with respect to future clinical trials or regulatory submissions, including for MT1621;
- changes in local regulations as part of a response to COVID-19 which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- refusal of the FDA or EMA to accept data from clinical trials in affected geographies; and
- difficulties launching or commercializing products, including due to reduced access to doctors as a result of social distancing protocols.

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

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

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

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

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

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our obligations under the Convertible Senior Notes.

In September 2020, we issued $200.0 million aggregate principal amount of our Convertible Senior Notes in a private offering exempt from registration under the Securities Act of 1933. In connection with the offering, we granted the initial purchasers an option to purchase up to an additional $30.0 million in principal amount of Convertible Senior Notes, which was exercised in full in October 2020. We may also incur additional indebtedness to meet future financing needs. Our indebtedness

could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which reduces the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the Convertible Senior Notes; and
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, including the Convertible Senior Notes, and our cash needs may increase in the future. In addition, any future indebtedness that we may incur may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full.

We depend on a sole specialty distributor, our Customer, for distribution of Fintepla in the United States, and the failure of this specialty distributor to distribute Fintepla effectively would adversely affect sales of Fintepla.

We rely on our sole Customer, a specialty distributor for the distribution of Fintepla in the United States. Our Customer subsequently resells our product through its related specialty pharmacy provider to patients and health care providers. A specialty pharmacy is a pharmacy that specializes in the dispensing, and a specialty distributor is a distributor that specializes in the distribution, of medications for complex or chronic conditions, which often require a high level of patient education, physician administration and ongoing management. The use of a specialty distributor who distributes Fintepla through its related specialty pharmacy provider to patients and health care providers involves certain risks, including, but not limited to, risks that our Customer will:

- not provide us accurate or timely information regarding their inventories, the number of patients who are using our product or complaints about our product;
- reduce or discontinue their efforts to sell or support or otherwise not effectively sell or support our product;
- not devote the resources necessary to sell our products in the volumes and within the time frames that we expect;
- engage in unlawful or inappropriate business practices that result in legal or regulatory enforcement activity which could result in liability to us or damage the goodwill within the Dravet syndrome community associated with Fintepla;
- be unable to satisfy financial obligations to us or others.

In the event that our Customer does not fulfill its contractual obligations to us or refuses to or fails to adequately perform distribution of Fintepla to patients and healthcare providers, or the agreements are terminated without adequate notice, shipments of Fintepla, and associated revenues, would be adversely affected.

Further, if our Customer becomes subject to bankruptcy, is unable to pay us for our products or is acquired by a company that wants to terminate the relationship with us, or if we otherwise lose our relationship with our Customer, our revenue, results of operations and cash flows would be adversely affected. Even if we are able to replace our Customer with a different specialty distributor/customer, we cannot predict with certainty that such transition would not result in a decline in our revenue, results of operations and cash flows.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

[Item 6. Exhibits]

EXHIBIT INDEX

Exhibit Number	Exhibit Description
3.1[(1)]	Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.2[(2)]	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.3[(3)]	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.4[(4)]	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.5[(1)]	Fifth Amended and Restated Certificate of Incorporation of the Registrant
4.1[(5)]	Form of the Registrant's Common Stock Certificate
4.2[(6)]	Warrant dated July 18, 2011 issued by the Registrant to Healthcare Royalty Partners (formerly Cowen Healthcare Royalty Partners II, L.P.)
4.3[(7)]	Indenture, dated as of September 28, 2020, between Zogenix, Inc. and U.S. Bank National Association, as trustee
4.4[(7)]	Form of Global Note representing the 2.75% Convertible Senior Notes due 2027 (included as Exhibit A to Exhibit 4.3)
10.1[(8)]†	Employment Agreement dated April 20, 2020, by and between the Registrant and Shawnte M. Mitchell
10.2[(7)]†	Zogenix, Inc. Employee Stock Purchase Plan Stock Purchase Plan
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
32.1**	Certification of Chief Executive Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
32.2**	Certification of Chief Financial Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
101*	Inline XBRL Document Set for the condensed consolidated financial statements and accompanying notes in Part I, Item 1, "Financial Statements" of this Quarterly Report on Form 10-Q.
104*	Inline XBRL for the cover page of this Quarterly Report on Form 10-Q, included in the Exhibit 101 Inline XBRL Document Set.

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

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

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

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

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

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

(7) Incorporated by reference to the Registrant's Current Report on Form 8-K filed on September 28, 2020.

(8) Incorporated by reference to Appendix A of the Registrant's Definitive Proxy Statement on Schedule 14A filed on April 17, 2020.

† Indicates management contract or compensatory plan.

* Filed herewith.

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

SIGNATURES

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

ZOGENIX, INC.

Date: November 9, 2020

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

Date: November 9, 2020

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

Exhibit 31.1

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

I, Stephen J. Farr, certify that:

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

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

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

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

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

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

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

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

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

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

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

/s/ Stephen J. Farr

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

Date: November 9, 2020

Exhibit 31.2

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

I, Michael P. Smith, certify that:

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

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

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

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

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

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

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

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

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

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

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

/s/ Michael P. Smith

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

Date: November 9, 2020

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Zogenix, Inc. (the "Company") for the period ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen J. Farr, as Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Date: November 9, 2020

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

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Zogenix, Inc. (the "Company") for the period ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael P. Smith, as Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Date: November 9, 2020

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

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