UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

[Mark One]

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

For the Quarterly Period Ended September 30, 2021

OR

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

Commission File No. 001-33057

CATALYST PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**76-0837053**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
355 Alhambra Circle Suite 801 Coral Gables, Florida	**33134**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (305) 420-3200

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

Title of Each Class	Ticker Symbol	Name of Exchange on Which Registered
Common Stock, par value $0.001 per share	**CPRX**	**NASDAQ Capital Market**

Indicate by checkmark 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 report(s), 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 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 definitions of "accelerated filer", "large 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 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 ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date 103,117,579 shares of common stock, $0.001 par value per share, were outstanding as of November 5, 2021.

CATALYST PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

CATALYST PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	September 30, 2021 (unaudited)	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 154,836	$ 130,237
Short-term investments	19,956	10,041
Accounts receivable, net	6,625	5,987
Inventory	6,950	4,651
Prepaid expenses and other current assets	4,428	8,328
Total current assets	192,795	159,244
Operating lease right-of-use asset	3,093	—
Property and equipment, net	951	130
Deferred tax assets	26,400	32,971
Deposits	9	9
Total assets	$ 223,248	$ 192,354
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,752	$ 4,256
Accrued expenses and other liabilities	17,862	18,500
Total current liabilities	20,614	22,756
Operating lease liability, net of current portion	3,973	—
Total liabilities	24,587	22,756
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized: none issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized; 103,153,459 shares and 103,781,641 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	103	104
Additional paid-in capital	231,165	223,168
Accumulated deficit	(32,544)	(53,705)
Accumulated other comprehensive income (loss)	(63)	31
Total stockholders' equity	198,661	169,598
Total liabilities and stockholders' equity	$ 223,248	$ 192,354

The accompanying notes are an integral part of these consolidated financial statements.

CATALYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (unaudited)
(in thousands, except share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Product revenue, net	$ 35,890	$ 29,167	$ 99,731	$ 87,908
License and other revenue	64	150	2,793	150
Total revenues	35,954	29,317	102,524	88,058
Operating costs and expenses:				
Cost of sales	5,310	3,879	14,536	12,170
Research and development	4,487	3,749	11,944	12,322
Selling, general and administrative	12,153	9,985	36,401	30,881
Total operating costs and expenses	21,950	17,613	62,881	55,373
Operating income	14,004	11,704	39,643	32,685
Other income, net	68	33	211	481
Net income before income taxes	14,072	11,737	39,854	33,166
Income tax provision (benefit)	3,743	(31,603)	9,681	(30,380)
Net income	$ 10,329	$ 43,340	$ 30,173	$ 63,546
Net income per share:				
Basic	$ 0.10	$ 0.42	$ 0.29	$ 0.61
Diluted	$ 0.10	$ 0.41	$ 0.28	$ 0.60
Weighted average shares outstanding:				
Basic	103,196,550	103,535,431	103,470,762	103,452,025
Diluted	107,843,196	106,316,241	107,476,175	106,386,617
Net income	$ 10,329	$ 43,340	$ 30,173	$ 63,546
Other comprehensive income:				
Unrealized gain (loss) on available-for-sale securities	(26)	(5)	(94)	(16)
Comprehensive income	$ 10,303	$ 43,335	$ 30,079	$ 63,530

The accompanying notes are an integral part of these consolidated financial statements.

CATALYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (unaudited)
For the three and nine months ended September 30, 2021
(in thousands)

	Preferred Stock	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total
		Shares	Amount				
Balance at December 31, 2020	$ —	103,782	$ 104	$223,168	$ (53,705)	$ 31	$169,598
Issuance of stock options for services	—	—	—	1,442	—	—	1,442
Exercise of stock options for common stock	—	90	—	188	—	—	188
Amortization of restricted stock for services	—	—	—	129	—	—	129
Repurchase of common stock	—	(67)	—	—	(293)	—	(293)
Other comprehensive gain (loss)	—	—	—	—	—	(76)	(76)
Net income	—	—	—	—	7,663	—	7,663
Balance at March 31, 2021	—	103,805	104	224,927	(46,335)	(45)	178,651
Issuance of stock options for services	—	—	—	1,388	—	—	1,388
Exercise of stock options for common stock	—	83	—	271	—	—	271
Amortization of restricted stock for services	—	—	—	130	—	—	130
Repurchase of common stock	—	(733)	(1)	—	(3,667)	—	(3,668)
Issuance of common stock upon vesting of restricted stock units, net	—	7	—	(17)	—	—	(17)
Other comprehensive gain (loss)	—	—	—	—	—	8	8
Net income	—	—	—	—	12,181	—	12,181
Balance at June 30, 2021	—	103,162	103	226,699	(37,821)	(37)	188,944
Issuance of stock options for services	—	—	—	1,380	—	—	1,380
Exercise of stock options for common stock	—	941	1	2,954	—	—	2,955
Amortization of restricted stock for services	—	—	—	132	—	—	132
Repurchase of common stock	—	(950)	(1)	—	(5,052)	—	(5,053)
Other comprehensive gain (loss)	—	—	—	—	—	(26)	(26)
Net income	—	—	—	—	10,329	—	10,329
Balance at September 30, 2021	$ —	103,153	$ 103	$231,165	$ (32,544)	$ (63)	$198,661

The accompanying notes are an integral part of these consolidated financial statements.

CATALYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (unaudited)
For the three and nine months ended September 30, 2020
(in thousands)

	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total
Balance at December 31, 2019	$ —	103,397	$ 103	$216,206	$ (128,689)	$ 10	$ 87,630
Issuance of stock options for services	—	—	—	1,384	—	—	1,384
Exercise of stock options for common stock	—	12	—	26	—	—	26
Amortization of restricted stock for services	—	—	—	136	—	—	136
Other comprehensive gain (loss)	—	—	—	—	—	74	74
Net income	—	—	—	—	10,426	—	10,426
Balance at March 31, 2020	—	103,409	103	217,752	(118,263)	84	99,676
Issuance of stock options for services	—	—	—	1,627	—	—	1,627
Exercise of stock options for common stock	—	13	—	36	—	—	36
Amortization of restricted stock for services	—	—	—	167	—	—	167
Other comprehensive gain (loss)	—	—	—	—	—	(85)	(85)
Net income	—	—	—	—	9,780	—	9,780
Balance at June 30, 2020	—	103,422	103	219,582	(108,483)	(1)	111,201
Issuance of stock options for services	—	—	—	1,346	—	—	1,346
Exercise of stock options for common stock	—	215	—	631	—	—	631
Amortization of restricted stock for services	—	—	—	132	—	—	132
Issuance of common stock upon vesting of restricted stock units, net	—	11	—	(17)	—	—	(17)
Other comprehensive gain (loss)	—	—	—	—	—	(5)	(5)
Net income	—	—	—	—	43,340	—	43,340
Balance at September 30, 2020	$ —	103,648	$ 103	$221,674	$ (65,143)	$ (6)	$156,628

The accompanying notes are an integral part of these consolidated financial statements.

CATALYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)
(in thousands)

	For the Nine Months Ended September 30,	
	2021	2020
Operating Activities:		
Net income	$ 30,173	$ 63,546
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation	159	73
Stock-based compensation	4,601	4,792
Deferred taxes	6,571	(31,347)
Change in accrued interest and accretion of discount on investments	(9)	(12)
Reduction in the carrying amount of right-of-use asset	216	781
(Increase) decrease in:		
Accounts receivable, net	(638)	4,665
Inventory	(2,299)	(2,791)
Prepaid expenses and other current assets and deposits	3,900	(1,263)
Increase (decrease) in:		
Accounts payable	(1,504)	(2,112)
Accrued expenses and other liabilities	(916)	(3,570)
Operating lease liability	942	(833)
Net cash provided by (used in) operating activities	41,196	31,929
Investing Activities:		
Purchases of property and equipment	(980)	(11)
Purchases of investments	(10,000)	(10,000)
Proceeds from maturities and sales of investments	—	5,000
Net cash provided by (used in) investing activities	(10,980)	(5,011)
Financing Activities:		
Payment of employee withholding tax related to stock-based compensation	(17)	(17)
Proceeds from exercise of stock options	3,414	693
Repurchase of common stock	(9,014)	—
Net cash provided by (used in) financing activities	(5,617)	676
Net increase (decrease) in cash and cash equivalents	24,599	27,594
Cash and cash equivalents—beginning of period	130,237	89,512
Cash and cash equivalents—end of period	$ 154,836	$ 117,106
Supplemental disclosures of cash flow information:		
Cash paid for income taxes	$ 1,438	$ 2,195
Non-cash investing and financing activities:		
Unrealized gain (loss) on available-for-sale securities	$ (94)	$ (16)
Operating lease liabilities arising from obtaining right-of-use assets	$ 3,309	$ —

The accompanying notes are an integral part of these consolidated financial statements.

CATALYST PHARMACEUTICALS, INC.
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of Business.

Catalyst Pharmaceuticals, Inc. and subsidiary (collectively, the "Company") is a commercial-stage patient-centric biopharmaceutical company focused on in-licensing, developing and commercializing novel high-quality medicines for patients living with rare diseases.

On November 28, 2018, the U.S. Food and Drug Administration, or FDA, granted approval of Firdapse® for the treatment of adults with Lambert-Eaton Myasthenic Syndrome ("LEMS") (ages 17 and above). On January 15, 2019, the Company launched its first product, Firdapse®, in the United States for the treatment of adults with LEMS.

On August 6, 2020, the Company announced that Canada's national healthcare regulatory agency, Health Canada, has approved Firdapse® for the treatment of adult patients in Canada with LEMS. On October 28, 2020, the Company launched Firdapse® in Canada for the treatment of patients with LEMS through a license and supply agreement with KYE Pharmaceuticals.

Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets, raising capital, and selling its product. The Company incurred operating losses in each period from inception until the second quarter of 2019, when it started reporting net income. The Company has been able to fund its cash needs to date through offerings of its securities and revenues from sales of its product. See Note 13 (Stockholders' Equity).

Capital Resources

While there can be no assurance, based on currently available information, the Company estimates that it has sufficient resources to support its planned operations for at least the next 12 months from the issuance date of this Form 10-Q.

The Company may raise funds in the future through public or private equity offerings, debt financings, corporate collaborations, governmental research grants or other means. The Company may also seek to raise new capital to fund additional drug development efforts, even if it has sufficient funds for its planned operations. Any sale by the Company of additional equity or convertible debt securities could result in dilution to the Company's current stockholders. There can be no assurance that any required additional funding will be available to the Company at all or available on terms acceptable to the Company. Further, to the extent that the Company raises additional funds through collaborative arrangements, it may be necessary to relinquish some rights to the Company's drug candidates or grant sublicenses on terms that are not favorable to the Company. If the Company is not able to secure additional funding when and if needed, the Company may have to delay, reduce the scope of, or eliminate one or more research and development programs, which could have an adverse effect on the Company's business.

Risks and Uncertainties

There are numerous aspects of the coronavirus (COVID-19) pandemic that have adversely affected the Company's business since the beginning of the pandemic. The Company closely monitors the impact of the pandemic on all aspects of its business and takes steps, wherever possible, to lessen those impacts. However, the Company is unable to predict the impact that the coronavirus pandemic will have on its business in future periods.

2. Basis of Presentation and Significant Accounting Policies.

a. INTERIM FINANCIAL STATEMENTS. The accompanying unaudited interim consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP), and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for reporting of interim financial information. Pursuant to such rules and regulations, certain information and note disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been omitted. The consolidated balance sheet as of December 31, 2020 included in this Form 10-Q was derived from the audited financial statements and does not include all disclosures required by U.S. GAAP.

In the opinion of management, the accompanying unaudited interim consolidated financial statements of the Company contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly the financial position of the Company as of the dates and for the periods presented. Accordingly, these consolidated statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2020 included in the 2020 Annual Report on Form 10-K filed by the Company with the SEC. The results of operations for the nine months ended September 30, 2021 are not necessarily indicative of the results to be expected for any future period or for the full 2021 fiscal year.

2. Basis of Presentation and Significant Accounting Policies (continued).

b. **PRINCIPLES OF CONSOLIDATION**. The consolidated financial statements include the Company's accounts and those of its wholly owned subsidiary, Catalyst Pharmaceuticals Ireland, Ltd. ("Catalyst Ireland"). All intercompany accounts and transactions have been eliminated in consolidation. Catalyst Ireland was organized in 2017.

c. **USE OF ESTIMATES.** The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

d. **CASH AND CASH EQUIVALENTS.** The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents consist mainly of money market funds and U.S. Treasuries. The Company has substantially all of its cash and cash equivalents deposited with one financial institution. These amounts exceed federally insured limits.

e. **INVESTMENTS**. The Company invests in high credit-quality instruments in order to obtain higher yields on its cash available for investments. At September 30, 2021 and December 31, 2020, investments consisted of short-term bond funds and U.S. Treasuries. Such investments are not insured by the Federal Deposit Insurance Corporation.

The short-term bond funds and U.S. Treasuries held at September 30, 2021 are classified as available-for-sale securities. The short-term bond funds are classified as current assets, which reflects management's intention to use the proceeds from the sale of these investments to fund the Company's operations, as necessary. The Company classifies U.S. Treasuries with stated maturities of greater than three months and less than one year in short-term investments. U.S. Treasuries with stated maturities greater than one year are classified as non-current investments in the Company's consolidated balance sheets. There are no non-current investments as of September 30, 2021 and December 31, 2020.

The Company records available-for-sale securities at fair value with unrealized gains and losses reported in accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses are included in other income, net and are derived using the specific identification method for determining the cost of securities sold. Interest income is recognized when earned and is included in other income, net in the consolidated statements of operations and comprehensive income. The Company recognizes a charge when the declines in the fair value below the amortized cost basis of its available-for-sale securities are judged to be as a result of a credit loss. The Company considers various factors in determining whether to recognize an allowance for credit losses including whether the Company intends to sell the security or whether it is more likely than not that the Company would be required to sell the security before recovery of the amortized cost basis. If the unrealized loss of an available-for-sale debt security is determined to be a result of a credit loss the Company would recognize an allowance and the corresponding credit loss would be included in the consolidated statements of operations and comprehensive income. The Company has not recorded an allowance for credit loss on its available-for-sale securities. See Note 3 (Investments).

f. **ACCOUNTS RECEIVABLE, NET.** Accounts receivable is recorded net of customer allowance for distribution fees, trade discounts, prompt payment discounts, chargebacks and expected credit losses. Allowances for distribution fees, trade discounts, prompt payment discounts and chargebacks are based on contractual terms. The Company estimates the allowance for expected credit loss based on existing contractual payment terms, actual payment patterns of its customer and individual customer circumstances. At September 30, 2021 and December 31, 2020, the Company determined that an allowance for expected credit losses was not required. No accounts were written off during the periods presented.

g. **INVENTORY.** Inventories are stated at the lower of cost or net realizable value. Inventories consist of raw materials, work-in-process and finished goods. Costs to be capitalized as inventories primarily include third party manufacturing costs and other overhead costs. Cost is determined using a standard cost method, which approximates actual cost, and assumes a first-in, first out (FIFO) flow of goods. The Company began capitalizing inventories post FDA approval of Firdapse® on November 28, 2018 as the related costs were expected to be recoverable through the commercialization of the product. Costs incurred prior to the FDA approval of Firdapse® were recorded as research and development expenses in prior years' consolidated statements of operations and comprehensive income. If information becomes available that suggests that inventories may not be realizable, the Company may be required to expense a portion or all of the previously capitalized inventories. As of September 30, 2021 inventory consisted of raw materials, work-in process and finished goods. As of December 31, 2020, inventory consisted mainly of work-in-process and finished goods.

Products that have been approved by the FDA or other regulatory authorities, such as Firdapse®, are also used in clinical programs to assess the safety and efficacy of the products for usage in treating diseases that have not been approved by the FDA or other regulatory authorities. The form of Firdapse® utilized for both commercial and clinical programs is identical and, as a result, the inventory has an "alternative future use" as defined in authoritative guidance. Raw materials associated with clinical development programs are included in inventory and charged to research and development expense when the product enters the research and development process and no longer can be used for commercial purposes and, therefore, does not have an "alternative future use".

2. Basis of Presentation and Significant Accounting Policies (continued).

The Company evaluates for potential excess inventory by analyzing current and future product demand relative to the remaining product shelf life. The Company builds demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance, and patient usage.

h. **PREPAID EXPENSES AND OTHER CURRENT ASSETS.** Prepaid expenses and other current assets consist primarily of prepaid manufacturing, prepaid tax, prepaid insurance, prepaid subscription fees, prepaid research fees, prepaid commercialization expenses, amounts due from collaborative and license arrangements and prepaid conference and travel expenses. Prepaid research fees consist of advances for the Company's product development activities, including contracts for pre-clinical studies, clinical trials and studies, regulatory affairs and consulting. Prepaid manufacturing consists of advances for the Company's drug manufacturing activities. Such advances are recorded as expense as the related goods are received or the related services are performed.

i. **FAIR VALUE OF FINANCIAL INSTRUMENTS.** The Company's financial instruments consist of cash and cash equivalents, investments, accounts receivable, accounts payable and accrued expenses and other liabilities. At September 30, 2021 and December 31, 2020, the fair value of these instruments approximated their carrying value.

j. **FAIR VALUE MEASUREMENTS.** Current Financial Accounting Standards Board (FASB) fair value guidance emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, current FASB guidance establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions that it believes market participants would use in pricing assets or liabilities (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability, which are typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

	Fair Value Measurements at Reporting Date Using (in thousands)			
	Balances as of September 30, 2021	Quoted Prices in Active Markets for Identical Assets/ Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents:				
Money market funds	$ 38,925	$ 38,925	$ —	$ —
U.S. Treasuries	$ 104,995	$ 104,995	$ —	$ —
Short-term investments:				
Short-term bond funds	$ 19,956	$ 19,956	$ —	$ —

	Balances as of December 31, 2020	Quoted Prices in Active Markets for Identical Assets/ Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents:				
Money market funds	$ 15,674	$ 15,674	$ —	$ —
U.S. Treasuries	$ 104,994	$ —	$ 104,994	$ —
Short-term investments:				
Short-term bond funds	$ 10,041	$ 10,041	$ —	$ —

2. Basis of Presentation and Significant Accounting Policies (continued).

k. OPERATING LEASES. The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use (ROU) assets, other current liabilities, and operating lease liabilities on its consolidated balance sheets. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As the Company's lease does not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. The Company's lease term includes options to extend or terminate the lease, however, these options are not considered in the lease term as the Company is not reasonably certain that it will exercise these options. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. The Company has a lease agreement with lease and non-lease components, which are accounted for separately.

l. SHARE REPURCHASES. In March 2021, the Company's Board of Directors approved a share repurchase program that authorizes the repurchase of up to $40 million of the Company's common stock.

The Company accounts for share repurchases by charging the excess of the repurchase price over the repurchased common stock's par value entirely to accumulated deficit. All repurchased shares are retired and become authorized but unissued shares. The Company accrues for the shares purchased under the share repurchase plan based on the trade date. The Company may terminate or modify its share repurchase program at any time.

m. REVENUE RECOGNITION.

Product Revenues:

The Company recognizes revenue when its customer obtains title of the promised goods, in an amount that reflects the consideration to which the Company expects to be entitled in exchange for these goods. The Company had no contracts with customers until the FDA approved Firdapse® in November 2018. Subsequent to receiving FDA approval, the Company entered into an arrangement with one distributor (the "Customer"), which is the exclusive distributor of Firdapse® in the United States. The Customer subsequently resells Firdapse® to a small group of exclusive specialty pharmacies ("SPs") whose dispensing activities for patients with specific payors may result in government-mandated or privately negotiated rebate obligations for the Company with respect to the purchase of Firdapse®.

To determine revenue recognition for arrangements that are within the scope of Accounting Standards Codification ("ASC") Topic 606 – Revenue from Contracts with Customers ("Topic 606"), the Company performs the following five 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) the entity satisfies a performance obligation. The Company only applies the five-step model to arrangements that meet the definition of a contract under Topic 606, including when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for product revenue, see Product Revenue, Net below.

The Company also may generate revenues from payments received under collaborative and license agreements. Collaborative and license agreement payments may include nonrefundable fees at the inception of the agreements, contingent payments for specific achievements designated in the agreements, and/or net profit-sharing payments on sales of products resulting from the collaborative and license arrangements. For a complete discussion of accounting for collaborative and licensing arrangements, see Revenues from Collaboration and Licensing Arrangements below.

Product Revenue, Net: The Company sells Firdapse® to the Customer (its exclusive distributor) who subsequently resells Firdapse® to both a small group of SPs who have exclusive contracts with the Company to distribute the Company's products to patients and potentially to medical centers or hospitals on an emergency basis. In addition to the distribution agreement with its Customer, the Company enters into arrangements with health care providers and payors that provide for government-mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's products.

2. Basis of Presentation and Significant Accounting Policies (continued).

The Company recognizes revenue on product sales when the Customer obtains control of the Company's product, which occurs at a point in time (upon delivery or upon dispense to patient). Product revenue is recorded net of applicable reserves for variable consideration, including discounts and allowances. The Company's payment terms range between 15 and 30 days.

Shipping and handling costs for product shipments occur prior to the customer obtaining control of the goods and are recorded in cost of sales.

If taxes should be collected from the Customer relating to product sales and remitted to governmental authorities, they will be excluded from revenue. The Company expenses incremental costs of obtaining a contract when incurred, if the expected amortization period of the asset that the Company would have recognized is one year or less. However, no such costs were incurred during the three and nine months ended September 30, 2021 and 2020.

During the three and nine months ended September 30, 2021 and 2020, principally all of the Company's sales of Firdapse® in the United States were to its Customer.

Reserves for Variable Consideration: Revenue from product sales is recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, prompt payment discounts, product returns, provider chargebacks and discounts, government rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its Customer, payors, and other indirect customers relating to the Company's sale of its products. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified as reductions of accounts receivable (if the amount is payable to the Customer) or a current liability (if the amount is payable to a party other than a Customer).

These estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in Topic 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted Customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplates application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of September 30, 2021 and, therefore, the transaction price was not reduced further during the three and nine months ended September 30, 2021 and 2020. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances: The Company provides its Customer with a discount that is explicitly stated in its contract and is recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, the Company receives sales order management, transactional data and distribution services from the Customer. To the extent the services received are distinct from the sale of Firdapse® to the Customer, these payments are classified in selling, general and administrative expenses in the Company's consolidated statement of operations and comprehensive income. However, if the Company has determined such services received to date are not distinct from the Company's sale of products to the Customer, these payments have been recorded as a reduction of revenue within the consolidated statement of operations and comprehensive income through September 30, 2021 and September 30, 2020, as well as a reduction to accounts receivable, net on the consolidated balance sheets.

Prompt Payment Discounts: The Company provides its Customer with prompt payment discounts which may result in adjustments to the price that is invoiced for the product transferred, in the case that payments are made within a defined period. The prompt payment discount reserve is based on actual invoice sales and contractual discount rates. Reserves for prompt payment discounts are included in accounts receivable, net on the consolidated balance sheets.

2. Basis of Presentation and Significant Accounting Policies (continued).

Funded Co-pay Assistance Program: The Company contracts with a third-party to manage the co-pay assistance program intended to provide financial assistance to qualified commercially-insured patients. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with Firdapse® that has been recognized as revenue, but remains in the distribution channel at the end of each reporting period. These payments are considered payable to the third-party vendor and the related reserve is recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities in the consolidated balance sheets.

Product Returns: Consistent with industry practice, the Company offers the SPs and its distributor limited product return rights for damaged and expiring product, provided it is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company estimates the amount of its product sales that may be returned by its Customer and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return liabilities using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. These payments are considered payable to the third-party vendor and the related reserve is recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities in the consolidated balance sheets. The Company has an insignificant amount of returns to date and believes that returns of its products will continue to be minimal.

Provider Chargebacks and Discounts: Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to the Customer, who directly purchases the product from the Company. The Customer charges the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue, net and accounts receivable, net. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by the Customer, and the Company generally issues credits for such amounts within a few weeks of the Customer's notification to the Company of the resale. Reserves for chargebacks consist primarily of chargebacks that the Customer has claimed, but for which the Company has not yet issued a credit.

Government Rebates: The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability, which is included in accrued expenses and other current liabilities on the consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Bridge and Patient Assistance Programs: The Company provides Firdapse® free of charge to uninsured patients who satisfy pre-established criteria for either the Bridge Program or the Patient Assistance Program. Patients who meet the Bridge Program eligibility criteria and are transitioning from investigational product while they are waiting for a coverage determination, or later, for patients whose access is threatened by the complications arising from a change of insurer may receive a temporary supply of free Firdapse® while the Company is determining the patient's third-party insurance, prescription drug benefit or other third-party coverage for Firdapse®. The Patient Assistance Program provides Firdapse® free of charge for longer periods of time for those who are uninsured or functionally uninsured with respect to Firdapse® because they are unable to obtain coverage from their payor despite having health insurance, to the extent allowed by applicable law. The Company does not recognize any revenue related to these free products and the associated costs are classified in selling, general and administrative expenses in the Company's consolidated statements of operations and comprehensive income.

Revenues from Collaboration and Licensing Arrangements:

The Company analyzes license and collaboration arrangements pursuant to FASB ASC Topic 808, Collaborative Arrangement Guidance and Consideration, ("Topic 808") to assess whether such arrangements, or transactions between arrangement participants, involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities or are more akin to a vendor-customer relationship. In making this evaluation, the Company considers whether the activities of the collaboration are considered to be distinct and deemed to be within the scope of the collaborative arrangement guidance or if they are more reflective of a vendor-customer relationship and, therefore, within the scope of Topic 606. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement.

2. Basis of Presentation and Significant Accounting Policies (continued).

For elements of collaboration arrangements that are not accounted for pursuant to guidance in Topic 606, an appropriate recognition method is determined and applied consistently, generally by analogy to the revenue from contracts with customers guidance.

Pursuant to Topic 606, for arrangements or transactions between arrangement participants determined to be within the scope of the contracts with customers guidance, the Company performs the following steps to determine the appropriate amount of revenue to be recognized as the Company fulfills its obligations: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company evaluates the performance obligations promised in the contract that are based on goods and services that will be transferred to the customer and determines whether those obligations are both (i) capable of being distinct and (ii) distinct in the context of the contract. Goods or services that meet these criteria are considered distinct performance obligations. The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration.

The agreements provide for milestone payments upon achievement of development and regulatory events. The Company accounts for milestone payments as variable consideration in accordance with Topic 606. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of potential transaction price and the likelihood that the transaction price will be received. The Company utilizes either the most likely amount method or expected value method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration that is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and, if so, these options are considered performance obligations.

Revenue is recognized when, or as, the Company satisfies a performance obligation by transferring a promised good or service to a customer. An asset is transferred when, or as, the customer obtains control of that asset.

After contract inception, the transaction price is reassessed at every period end and updated for changes such as resolution of uncertain events. Any change in the overall transaction price is allocated to the performance obligations based on the same methodology used at contract inception.

The Company recognizes sales-based royalties or net profit-sharing when the later of (a) the subsequent sale occurs, or (b) the performance obligation to which the sales-based royalty or net profit-sharing has been allocated has been satisfied.

Payments to and from the collaborator are presented in the statement of operations based on the nature of the Company's business operations, the nature of the arrangement, including the contractual terms, and the nature of the payments.

Refer to Note 9 (Collaboration and Licensing Arrangements), for further discussion on the Company's collaborative and licensing arrangements.

n. **RESEARCH AND DEVELOPMENT.** Costs incurred in connection with research and development activities are expensed as incurred. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform research related services for the Company.

o. **STOCK-BASED COMPENSATION.** The Company recognizes expense in the consolidated statements of operations for the fair value of all stock-based payments to employees, directors and consultants, including grants of stock options and other share-based awards. For stock options, the Company uses the Black-Scholes option valuation model, the single-option award approach, and the straight-line attribution method. Using this approach, compensation cost is amortized on a straight-line basis over the vesting period of each respective stock option, generally one to three years. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur.

2. Basis of Presentation and Significant Accounting Policies (continued).

p. CONCENTRATION OF RISK. The financial instruments that potentially subject the Company to concentration of credit risk are cash equivalents (i.e., money market funds), investments and accounts receivable, net. The Company places its cash and cash equivalents with high-credit quality financial institutions. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in these accounts.

The Company sells its product in the United States through an exclusive distributor (its Customer) to SPs. Therefore, its distributor and SPs account for principally all of its trade receivables and net product revenues. The creditworthiness of its Customer is continuously monitored, and the Company has internal policies regarding customer credit limits. The Company estimates an allowance for expected credit loss primarily based on the credit worthiness of its Customer, historical payment patterns, aging of receivable balances and general economic conditions.

The Company currently has a single product with limited commercial sales experience, which makes it difficult to evaluate its current business, predict its future prospects and forecast financial performance and growth. The Company has invested a significant portion of its efforts and financial resources in the development and commercialization of the lead product, Firdapse®, and expects Firdapse® to constitute virtually all of product revenue for the foreseeable future. The Company's success depends on its ability to effectively commercialize Firdapse®.

The Company relies exclusively on third parties to formulate and manufacture Firdapse® and its drug candidates. The commercialization of Firdapse® and any other drug candidates, if approved, could be stopped, delayed or made less profitable if those third parties fail to provide sufficient quantities of product or fail to do so at acceptable quality levels or prices. The Company does not intend to establish its own manufacturing facilities. The Company is using the same third-party contractors to manufacture, supply, store and distribute drug supplies for clinical trials and for the commercialization of Firdapse®. If the Company is unable to continue its relationships with one or more of these third-party contractors, it could experience delays in the development or commercialization efforts as it locates and qualifies new manufacturers. The Company intends to rely on one or more third-party contractors to manufacture the commercial supply of its drugs.

q. ROYALTIES. Royalties incurred in connection with the Company's license agreement, as disclosed in Note 11 (Agreements), are expensed to cost of sales as revenue from product sales is recognized.

r. INCOME TAXES. The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. The Company is subject to income taxes in the U.S. federal jurisdiction and various state jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. The Company is not subject to U.S. federal, state and local tax examinations by tax authorities for years before 2017. If the Company were to subsequently record an unrecognized tax benefit, associated penalties and tax related interest expense would be reported as a component of income tax expense.

s. COMPREHENSIVE INCOME. U.S. GAAP requires that all components of comprehensive income be reported in the financial statements in the period in which they are recognized. Comprehensive income is net income, plus certain other items that are recorded directly into stockholders' equity. The Company's comprehensive income is shown on the consolidated statements of operations and comprehensive income for the three and nine months ended September 30, 2021 and 2020, and is comprised of net unrealized gains (losses) on the Company's available-for-sale securities.

t. NET INCOME PER COMMON SHARE. Basic net income per share is computed by dividing net income for the period by the weighted average number of common shares outstanding during the period. With regard to common stock subject to vesting requirements, the calculation includes only the vested portion of such stock and units.

Diluted net income per common share is computed by dividing net income by the weighted average number of common shares outstanding, increased by the assumed conversion of other potentially dilutive securities during the period.

2. Basis of Presentation and Significant Accounting Policies (continued).

The following table reconciles basic and diluted weighted average common shares:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Basic weighted average common shares outstanding	103,196,550	103,535,431	103,470,762	103,452,025
Effect of dilutive securities	4,646,646	2,780,810	4,005,413	2,934,592
Diluted weighted average common shares outstanding	107,843,196	106,316,241	107,476,175	106,386,617

Outstanding common stock equivalents totaling approximately 2.6 million and 5.3 million, were excluded from the calculation of diluted net income per common share for the three and nine months ended September 30, 2021 as their effect would be anti-dilutive. For the three and nine months ended September 30, 2020, approximately 5.4 million and 4.8 million shares of common stock equivalents were excluded from the calculation of diluted net income per common share as their effect would be anti-dilutive.

u. **RECLASSIFICATIONS.** Certain prior year amounts in the consolidated financial statements have been reclassified to conform to the current year presentation.

v. **RECENTLY ISSUED ACCOUNTING STANDARDS.** In December 2019, the FASB issued ASU 2019-12, *Income Taxes: Simplifying the Accounting for Income Taxes*, a new standard intended to simplify the accounting for income taxes by eliminating certain exceptions related to the approach for intra-period 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 standard 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. The standard was effective for annual periods beginning after December 15, 2020 and interim periods within, with early adoption permitted. Adoption of the standard required certain changes to be made prospectively, with some changes to be made retrospectively. The Company adopted the new standard on January 1, 2021. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

3. Investments.

Available-for-sale investments by security type were as follows (in thousands):

	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses	Amortized Cost
At September 30, 2021:				
U.S. Treasuries – Cash equivalents	$104,995	$ —	$ —	$104,995
Short-term bond funds	19,956	—	(63)	20,019
Total	$124,951	$ —	$ (63)	$125,014
At December 31, 2020:				
U.S. Treasuries – Cash equivalents	$104,994	$ 2	$ —	$104,992
Short-term bond funds	10,041	29	—	10,012
Total	$115,035	$ 31	$ —	$115,004

There were no realized gains or losses from available-for-sale securities for the three or nine months ended September 30, 2021 or 2020.

3. Investments (continued).

The estimated fair values of available-for-sale securities at September 30, 2021, by contractual maturity, are summarized as follows (in thousands):

	September 30, 2021
Due in one year or less	$ 124,951

4. Inventory, net.

Inventory, net consists of the following (in thousands):

	September 30, 2021	December 31, 2020
Raw materials	$ 1,112	$ —
Work-in-process	4,847	3,555
Finished goods	991	1,096
Total inventory, net	$ 6,950	$ 4,651

5. Prepaid Expenses and Other Current Assets.

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Prepaid manufacturing costs	$ 2,233	$ 3,328
Prepaid tax	13	1,368
Prepaid insurance	231	1,285
Prepaid subscription fees	689	729
Prepaid research fees	523	453
Prepaid commercialization expenses	90	199
Due from collaborative and licensing arrangements	197	437
Prepaid conference and travel expenses	224	83
Other	228	446
Total prepaid expenses and other current assets	$ 4,428	$ 8,328

6. Operating Lease.

The Company has an operating lease agreement for its corporate office. The lease includes an option to extend the lease for up to 5 years and options to terminate the lease within 6 and 7.6 years. There are no obligations under finance leases.

The Company entered into an agreement in May 2020 that amended its lease for its office facilities. Under the amended lease, the Company's leased space increased from approximately 7,800 square feet of space to approximately 10,700 square feet of space. The amended lease commenced in March 2021 when construction of the asset was completed and space became available for use. Consequently, the Company recorded the effects of the amended lease during Q1 2021.

6. Operating Lease (continued).

The components of lease expense were as follows (in thousands):

	For the three months ended September 30, 2021	For the nine months ended September 30, 2021
Operating lease cost	$ 108	$ 272

Supplemental cash flow information related to leases was as follows:

	September 30, 2021
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows	$ 29
Right-of-use assets obtained in exchange for lease obligations:	
Operating leases	$ 58

Supplemental balance sheet information related to leases was as follows:

Operating lease right-of-use assets	$ 3,093
Other current liabilities	$ 278
Operating lease liabilities, net of current portion	3,973
Total operating lease liabilities	$ 4,251

Remaining lease term	9.6 years
Discount rate	4.51%

Remaining payments of lease liabilities as of September 30, 2021 were as follows (in thousands):

2021 (remaining three months)	$ 80
2022	492
2023	506
2024	522
2025	537
Thereafter	3,150
Total lease payments	5,287
Less: imputed interest	(1,036)
Total	$ 4,251

Rent expense was approximately $0.1 million and $0.3 million for the three and nine months ended September 30, 2021, respectively, and $0.1 million and $0.3 million for the three and nine months ended September 30, 2020, respectively.

7. Property and Equipment, net.

Property and equipment, net consists of the following (in thousands):

	September 30, 2021	December 31, 2020
Computer equipment	$ 51	$ 51
Furniture and equipment	203	242
Leasehold improvements	939	177
Less: Accumulated depreciation	(242)	(340)
Total property and equipment, net	$ 951	$ 130

8. Accrued Expenses and Other Liabilities.

Accrued expenses and other liabilities consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Accrued preclinical and clinical trial expenses	$ 487	$ 585
Accrued professional fees	1,978	1,884
Accrued compensation and benefits	2,647	3,991
Accrued license fees	9,105	10,373
Accrued purchases	1,483	258
Accrued contributions	—	310
Operating lease liability	278	29
Accrued variable consideration	1,439	964
Accrued income tax	335	—
Other	110	106
Current accrued expenses and other liabilities	17,862	18,500
Lease liability—non-current	3,973	—
Non-current accrued expenses and other liabilities	3,973	—
Total accrued expenses and other liabilities	$ 21,835	$ 18,500

9. Collaboration and Licensing Arrangements.

Endo

In December 2018, the Company entered into a collaboration and license agreement (Collaboration) with Endo, for the further development and commercialization of generic Sabril® (vigabatrin) tablets through Endo's U.S. Generic Pharmaceuticals segment, doing business as Par Pharmaceutical. Under the Collaboration, Endo assumes all development, manufacturing, clinical, regulatory, sales and marketing costs under the collaboration, while the Company is responsible for exercising commercially reasonable efforts to develop, or cause the development of, a final finished, stable dosage form of generic Sabril® tablets.

Under the terms of the Collaboration, the Company has received an up-front payment, and will receive a milestone payment, and a sharing of defined net profits upon commercialization from Endo consisting of a mid-double digit percent of net sales of generic Sabril®. The Company has also agreed to a sharing of certain development expenses. Unless terminated earlier in accordance with its terms, the collaboration continues in effect until the date that is ten years following the commercial launch of the product.

The Company evaluated the license agreement with Endo to determine whether it is a collaborative arrangement for purposes of Topic 808. As the Company shares in the significant risks and rewards, the Company has concluded that this is a collaborative arrangement. As developing a final finished dosage form of a generic product in exchange for consideration is not an output of the Company's ongoing activities, Endo does not represent a contract with a customer. However, Topic 808 does not provide guidance on the recognition of consideration exchanged or accounting for the obligations that may arise between the parties. The Company concluded that ASC Topic 730, *Research and Development*, should be applied by analogy to payments between the parties during the development activities and Topic 606 for the milestone payment and sharing of defined net profits upon commercialization.

The collaborative agreement included a nonrefundable upfront license fee that was recognized upon receipt following execution of the collaborative arrangement for vigabatrin tablets.

The collaborative agreement provides for a $2.0 million milestone payment on the commercial launch of the product by Par. As of September 30, 2021 and 2020, no milestone payments have been earned.

There were no revenues from this collaborative arrangement for the three or nine months ended September 30, 2021 or 2020. Total expenses incurred, net, in connection with the collaborative agreement for the three and nine months ended September 30, 2021 were approximately $0 and $45,000, respectively. Total expenses incurred, net, in connection with the collaborative agreement for three and nine months ended September 30, 2020 were approximately $0 and $4,200, respectively. These expenses have been included in research and development expenses in the accompanying consolidated statements of operations and comprehensive income.

9. Collaboration and Licensing Arrangements (continued).

KYE Pharmaceuticals

In August 2020, the Company entered into a collaboration and license agreement with KYE Pharmaceuticals Inc (KYE), for the commercialization of Firdapse® in Canada.

Under the agreement, Catalyst granted KYE an exclusive license to commercialize and market Firdapse® in Canada. KYE assumes all selling and marketing costs under the collaboration, while the Company is responsible for supply of Firdapse® based on the collaboration partner's purchase orders.

Under the terms of the agreement, the Company will receive an up-front payment, received payment upon transfer of Marketing Authorization and delivery of commercial product, received payment for supply of Firdapse®, will receive milestone payments, and a sharing of defined net profits upon commercialization from KYE consisting of a mid-double-digit percent of net sales of Firdapse®. The Company has also agreed to a sharing of certain development expenses. Unless terminated earlier in accordance with its terms, the collaboration continues in effect until the date that is ten years following the commercial launch of the product in Canada.

Although this agreement is in form identified as a collaborative agreement, the Company has concluded for accounting purposes that it represents a contract with a customer. This is because the Company grants to KYE a license and provides supply of Firdapse® in exchange for consideration, which are outputs of the Company's ongoing activities. Accordingly, the Company has concluded that this collaborative arrangement will be accounted for pursuant to Topic 606.

The collaborative agreement included a nonrefundable upfront license fee that was recognized upon transfer of the license based on a determination that the right is provided as the intellectual property exists at the point in time in which the license is granted.

Under the arrangement, the Company will receive profit-sharing reports within nine days after quarter end from the collaborator. Revenue from sales of collaboration products by the Company's collaborator will be recognized in the quarter in which the sales occurred.

Revenues from the arrangement with KYE for the three or nine months ended September 30, 2021 were not material. Revenue is included in product revenue, net and license and other revenue in the accompanying consolidated statements of operations and comprehensive income. Expenses incurred, net have been included in selling, general and administrative expenses in the accompanying consolidated statements of operations and comprehensive income.

DyDo Pharma, Inc.

On June 28, 2021, the Company entered into a license agreement with DyDo Pharma, Inc. (DyDo), for the development and commercialization of Firdapse® in Japan.

Under the agreement, DyDo has joint rights to develop Firdapse®, and exclusive rights to commercialize the product, in Japan. DyDo is responsible for funding all clinical, regulatory, marketing and commercialization activities in Japan, while the Company is responsible for clinical and commercial supply based on purchase orders, as well as providing support to DyDo in its efforts to obtain regulatory approval for the product from the Japanese regulatory authorities.

Under the terms of the agreement, the Company has earned an up-front payment and may earn further development and sales milestones for Firdapse®, as well as revenue on product supplied to DyDo.

The Company has concluded that this license agreement will be accounted for pursuant to Topic 606. The agreement included a nonrefundable upfront license fee that was recognized upon the effective date of the agreement as the intellectual property exists at the point in time in which the right to the license is granted. The Company determined the granting of the right to the license is distinct from the supply of Firdapse® and represents a separate performance obligation in the agreement.

Additionally, the agreement includes sales-based milestones in which the license is deemed to be the predominant item to which these milestones relate. Revenue will be recognized when the later of (a) the subsequent sale occurs, or (b) the performance obligation to which the sales-based royalty has been allocated has been satisfied. Variable consideration related to regulatory milestones is fully constrained and only recognized when the uncertainty is subsequently resolved. For clinical and commercial supply of the product, the Company will recognize revenue when the Customer obtains control of the Company's product, which will occur at a point in time which is generally at time of shipment.

9. Collaboration and Licensing Arrangements (continued).

Revenue from the arrangement with DyDo for the three and nine months ended September 30, 2021 was approximately $0 and $2.7 million, respectively, relating to the nonrefundable upfront license fee and is included in license and other revenue in the accompanying consolidated statements of operations and comprehensive income. As of September 30, 2021, no milestone payments have been earned and there has been no clinical or commercial supply of Firdapse®.

10. Commitments and Contingencies.

In May 2019, the FDA approved a New Drug Application (NDA) for Jacobus Pharmaceuticals for Ruzurgi®, their version of amifampridine (3,4-DAP), for the treatment of pediatric LEMS patients (ages 6 to under 17). The Company believes that Jacobus is offering Ruzurgi® at a lower price than the Company is offering Firdapse®. While the NDA for Ruzurgi® only covers pediatric patients, the Company believes that Ruzurgi® is being prescribed off-label to adult LEMS patients. If Jacobus is able to successfully continue to sell Ruzurgi® off-label to adult LEMS patients, it could have a material adverse effect on the Company's business, financial condition and results of operations.

The Company believes that the FDA's approval of Ruzurgi® violated its statutory rights and was in multiple other respects arbitrary, capricious and contrary to law. As a result, in June 2019 the Company filed suit against the FDA and several related parties challenging this approval and related drug labeling, and Jacobus intervened in the case. The Company's complaint, which was filed in the federal district court for the Southern District of Florida, alleged that the FDA's approval of Ruzurgi® violated multiple provisions of FDA regulations regarding labeling, resulting in misbranding in violation of the Federal Food, Drug, and Cosmetic Act (FDCA); violated its statutory rights to Orphan Drug Exclusivity and New Chemical Entity Exclusivity under the FDCA; and was in multiple other respects arbitrary, capricious, and contrary to law, in violation of the Administrative Procedure Act. Among other remedies, the suit sought an order vacating the FDA's approval of Ruzurgi®.

On July 30, 2020, the Magistrate Judge considering the Company's lawsuit against the FDA filed a Report and Recommendation in which she recommended to the District Judge handling the case that she grant the FDA's and Jacobus' motions for summary judgment and deny the Company's motion for summary judgment. On September 29, 2020, the District Judge adopted the Report and Recommendation of the Magistrate Judge, granted the FDA's and Jacobus's motions for summary judgment, and dismissed the Company's case. The Company appealed the District Court's decision to the Eleventh Circuit Court of Appeals. The case was fully briefed, and oral argument was held in March 2021.

On September 30, 2021, a three-judge panel of judges on the Eleventh Circuit Court of Appeals issued a unanimous decision overturning the District Court's decision. The court adopted the Company's argument that the FDA's approval of Ruzurgi® violated the Company's rights to Orphan Drug Exclusivity and remanded the case to the District Court with orders to enter summary judgment in the Company's favor. This decision reverses the FDA's approval of Ruzurgi®. The Company is presently waiting to see if the FDA or Jacobus will seek rehearing of the case from the full Eleventh Circuit Court of Appeals or appeal the appellate court's decision to the Supreme Court. Until the appeal period ends, it is likely that Ruzurgi® will continue to be available on the market.

On August 10, 2020, Health Canada issued a Notice of Compliance (NOC) to Medunik for Ruzurgi® for the treatment of LEMS. The Company has since initiated a legal proceeding in Canada seeking judicial review of Health Canada's decision to issue the NOC for Ruzurgi® as incorrect and unreasonable under Canadian law. Data protection, per Health Canada regulations, is supposed to prevent Health Canada from issuing a NOC to a drug that directly or indirectly references an innovative drug's data, for eight years from the date of the innovative drug's approval. The Ruzurgi® Product Monograph clearly references pivotal nonclinical carcinogenicity and reproductive toxicity data for amifampridine phosphate developed by the Company. As such, the Company believes that its data was relied upon to establish the nonclinical safety profile of Ruzurgi® needed to meet the standards of the Canadian Food and Drugs Act.

On June 3, 2021, the Company announced a positive decision in this proceeding that quashed the NOC previously issued for Ruzurgi® and remanded the matter to the Minister of Health to redetermine its decision to grant marketing authorization to Ruzurgi® in spite of Firdapse®'s data protection rights. However, on June 28, 2021, the Company announced that Health Canada had re-issued a NOC for Ruzurgi®, once again allowing the product to be marketed in Canada for patients with LEMS. As a result, in early July 2021, the Company, along with its partner KYE, filed a second suit against Health Canada to overturn their most recent decision. There can be no assurance of the result of this proceeding.

Additionally, from time to time the Company may become involved in legal proceedings arising in the ordinary course of business. Except as set forth above, the Company believes that there is no other litigation pending at this time that could have, individually or in the aggregate, a material adverse effect on its results of operations, financial condition or cash flows.

11. Agreements.

a. **LICENSE AGREEMENT FOR FIRDAPSE®.** On October 26, 2012, the Company entered into a license agreement with BioMarin Pharmaceutical, Inc. (BioMarin) for the North American rights to Firdapse®. Under the license agreement, the Company pays: (i) royalties to the licensor for seven years from the first commercial sale of Firdapse® equal to 7% of net sales (as defined in the license agreement) in North America for any calendar year for sales up to $100 million, and 10% of net sales in North America in any calendar year in excess of $100 million; and (ii) royalties to the third-party licensor of the rights sublicensed to the Company for seven years from the first commercial sale of Firdapse® equal to 7% of net sales (as defined in the license agreement between BioMarin and the third-party licensor) in any calendar year for the duration of any regulatory exclusivity within a territory and 3.5% for territories in any calendar year in territories without regulatory exclusivity.

On May 29, 2019, the Company and BioMarin entered into an amendment to the Company's license agreement for Firdapse®. Under the amendment, the Company has expanded its commercial territory for Firdapse®, which originally was comprised of North America, to include Japan. Additionally, the Company has an option to further expand its territory under the license agreement to include most of Asia, as well as Central and South America, upon the achievement of certain milestones in Japan. Under the amendment, the Company will pay royalties on net sales in Japan of a similar percentage to the royalties that the Company is currently paying under its original license agreement for North America.

In January 2020, the Company was advised that BioMarin has transferred certain rights under the license agreement to SERB S.A.

b. **AGREEMENTS FOR DRUG MANUFACTURING, DEVELOPMENT, PRECLINICAL AND CLINICAL STUDIES.** The Company has entered into agreements with contract manufacturers for the manufacture of commercial drug and drug and study placebo for the Company's trials and studies, with contract research organizations (CRO) to conduct and monitor the Company's trials and studies and with various entities for laboratories and other testing related to the Company's trials and studies. The contractual terms of the agreements vary, but most require certain advances as well as payments based on the achievement of milestones. Further, these agreements are cancellable at any time, but obligate the Company to reimburse the providers for any time or costs incurred through the date of termination.

12. Income Taxes.

The Company's effective income tax rate was 24.3% and 2.8% for the nine months ended September 30, 2021 and 2020, respectively. The difference in the effective rates between periods is driven by the release of the Company's valuation allowance against deferred taxes in the third quarter of 2020. Differences in the effective tax and the statutory federal income tax rate of 21% are driven by state income taxes and anticipated annual permanent differences and offset by the orphan drug credit claimed.

The Company had no uncertain tax positions as of September 30, 2021 and December 31, 2020.

13. Stockholders' Equity.

Preferred Stock

The Company has 5,000,000 shares of authorized preferred stock, $0.001 par value per share, at September 30, 2021 and December 31, 2020. No shares of preferred stock were outstanding at September 30, 2021 and December 31, 2020.

Common Stock

The Company has 200,000,000 shares of authorized common stock, par value $0.001 per share. At September 30, 2021 and December 31, 2020, 103,153,459 and 103,781,641 shares, respectively, of common stock were issued and outstanding. Each holder of common stock is entitled to one vote of each share of common stock held of record on all matters on which stockholders generally are entitled to vote.

Share Repurchases

In March 2021, the Company's Board of Directors approved a share repurchase program that authorizes the repurchase of up to $40 million of the Company's common stock, pursuant to a repurchase plan under Rule 10b-18 of the Securities Act. The share repurchase program commenced on March 22, 2021 and, during the three and nine months ended September 30, 2021, 949,746 and 1,749,746 shares were repurchased for an aggregate purchase price of approximately $5.1 million ($5.32 average price per share) and $9.0 million ($5.15 average price per share), respectively.

13. Stockholders' Equity (continued).

2020 Shelf Registration Statement

On July 23, 2020, the Company filed a shelf registration statement with the SEC to sell up to $200 million of common stock, preferred stock, warrants to purchase common stock, debt securities and units consisting of one or more of such securities (the "2020 Shelf Registration Statement"). The 2020 Shelf Registration Statement (file no. 333-240052) was declared effective by the SEC on July 31, 2020. As of the date of this report, no offerings have been completed under the Company's 2020 Shelf Registration Statement.

14. Stock Compensation.

For the three and nine months ended September 30, 2021 and 2020, the Company recorded stock-based compensation expense as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Research and development	$ 428	$ 399	$1,193	$1,239
Selling, general and administrative	1,084	1,079	3,408	3,553
Total stock-based compensation	$ 1,512	$ 1,478	$4,601	$4,792

Stock Options

As of September 30, 2021, there were outstanding stock options to purchase 13,162,504 shares of common stock, of which stock options to purchase 7,956,962 shares of common stock were exercisable as of September 30, 2021.

During the three and nine months ended September 30, 2021, the Company granted seven-year term options to purchase an aggregate of 400,000 and 1,030,000 shares, respectively, of the Company's common stock to employees. The Company recorded stock-based compensation related to stock options totaling $1.4 million and $4.2 million, respectively, during the three and nine months ended September 30, 2021.

During the three and nine months ended September 30, 2020, the Company granted seven-year term options to purchase an aggregate of 10,000 and 1,005,000 shares, respectively, of the Company's common stock to employees. The Company recorded stock-based compensation related to stock options totaling $1.3 million and $4.4 million, respectively, during the three and nine months ended September 30, 2020.

During the three and nine months ended September 30, 2021, options to purchase 941,164 shares and 1,114,494 shares, respectively, of the Company's common stock were exercised, with proceeds of $3.0 million and $3.4 million respectively, to the Company.

During the three and nine months ended September 30, 2020, options to purchase 215,097 shares and 240,096 shares, respectively, of the Company's common stock were exercised, with proceeds of $0.6 million and $0.7 million respectively, to the Company.

As of September 30, 2021, there was approximately $8 million of unrecognized compensation expense related to non-vested stock option awards granted under the 2014 and 2018 Stock Incentive Plans. The cost is expected to be recognized over a weighted average period of approximately 2.15 years.

Restricted Stock Units

There were no grants of restricted stock units to employees or directors during the three or nine months ended September 30, 2021. The Company granted zero and 30,000 restricted stock units during the three and nine months ended September 30, 2020, respectively. During the three and nine months ended September 30, 2021, the Company recorded non-cash stock-based compensation expense related to restricted stock units totaling $0.1 million and $0.4 million, respectively. During the three and nine months ended September 30, 2020, the Company recorded non-cash stock-based compensation expense related to restricted stock units totaling $0.1 million and $0.4 million, respectively.

As of September 30, 2021, there was approximately $0.6 million of unrecognized compensation expense related to non-vested restricted stock units granted under the 2018 Stock Incentive Plan. The cost is expected to be recognized over a weighted average period of approximately 1.24 years.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Introduction

Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is intended to provide an understanding of our financial condition, changes in financial condition and results of operations. The discussion and analysis is organized as follows:

- *Overview.* This section provides a general description of our business and information about our business that we believe is important in understanding our financial condition and results of operations.
- *Basis of Presentation.* This section provides information about key accounting estimates and policies that we followed in preparing our consolidated financial statements for the third quarter of fiscal 2021.
- *Critical Accounting Policies and Estimates.* This section discusses those accounting policies that are both considered important to our financial condition and results of operations, and require significant judgment and estimates on the part of management in their application. All of our significant accounting policies, including the critical accounting policies, are also summarized in the notes to our interim consolidated financial statements that are included in this report.
- *Results of Operations.* This section provides an analysis of our results of operations for the three and nine months ended September 30, 2021 as compared to the three and nine month periods ended September 30, 2020.
- *Liquidity and Capital Resources.* This section provides an analysis of our cash flows, capital resources, off-balance sheet arrangements and our outstanding commitments, if any.
- *Caution Concerning Forward-Looking Statements.* This section discusses how certain forward-looking statements made throughout this MD&A and in other sections of this report are based on management's present expectations about future events and are inherently susceptible to uncertainty and changes in circumstance.

OVERVIEW

We are a commercial-stage patient centric biopharmaceutical company focused on in-licensing, developing and commercializing novel high-quality medicines for patients living with rare diseases. We are currently focusing our efforts on products that treat diseases in the neuromuscular and neurological space, but in early 2021 our Board of Directors approved an expansion in our company's strategic focus to include potentially acquiring or in-licensing innovative technology platforms and earlier stage programs in other rare disease therapeutic categories outside of neuromuscular diseases. To accomplish these new priorities, we are planning to invest more heavily in research and development, including acquiring earlier stage opportunities and innovative technology. We believe that this strategic expansion will better position our company to build out a broader more diversified portfolio of drug candidates that we believe will add greater value to our company over the near and long-term. However, there can be no assurance that whatever product candidates or technology platforms we acquire, if any, will be successfully developed.

We are currently exploring several potential opportunities to acquire companies with drug products in development or to in-license drug products in development. However, no definitive agreements have been entered into to date. Further, during the third quarter, we hired Dr. Preethi Sundaram as our Chief Product Development Officer. In that position, Dr. Sundaram will lead the strategy and direct the development of programs from early-stage R&D assets through late-stage clinical programs that will be focusing on developing therapies to treat rare diseases.

We are dedicated to making a meaningful impact on the lives of those suffering from rare diseases, and we believe in putting patients first in everything we do.

Impact of the COVID-19 pandemic on our business

The COVID-19 pandemic has resulted, and is expected to continue to result, in economic disruption and has adversely affected and will likely continue to adversely affect our business. We are actively monitoring the situation and are taking those actions that may be required by federal, state or local authorities or that we determine are in the best interests of our patients, investigators, employees and stockholders.

In March 2020, in response to worsening conditions in the pandemic, we implemented a number of safety related initiatives among our employees, including a travel ban and a work from home policy for all employees. This included our customer-facing employees, who began working remotely and utilizing telephone and web-based technologies to provide support to patients and their healthcare providers. As the situation has developed, we have revised and relaxed these restrictions at various times, including returning to in-person work. However, we continue to monitor the changing nature of the pandemic to assess whether additional or renewed restrictions are warranted – either across the company or on a local basis – and will implement them as necessary.

We believe that because many healthcare providers have delayed seeing new patients because of the pandemic, there has been a delay in the diagnosis of new LEMS patients and their initiating therapy, which has slowed our efforts to locate new patients who could benefit from our therapy. However, we believe that as more healthcare providers resume seeing new patients on a regular basis, the impact of this aspect of the COVID-19 pandemic on our business will lessen.

One area where we have not been impacted by the pandemic is in our supply chain. To date, we have seen no material disruptions in the production of Firdapse® and, based upon current estimates, we have sufficient inventory to meet current and foreseeable patient needs for at least the next 12 months.

Firdapse®

On November 28, 2018, we received approval from the FDA for Firdapse® Tablets, 10 mg for the treatment of adult LEMS patients (ages 17 and above). In January 2019, we launched Firdapse® in the United States. We sell our product through a field force experienced in neurologic, central nervous system or rare disease products consisting at this time of approximately 30 field personnel, including sales (Regional Account Managers), patient assistance and insurance navigation support (Patient Access Liaisons), and payor reimbursement (National Account Managers). We also have a field-based force of five medical science liaisons who are helping educate the medical communities and patients about LEMS and about our ongoing clinical trial activities evaluating Firdapse® for other ultra-orphan, neuromuscular diseases.

Further, we have contracted with an experienced inside sales agency that works to generate leads through telemarketing to targeted physicians. This inside sales agency allows our sales efforts to not only reach the neuromuscular specialists who regularly treat LEMS patients, but also the roughly 9,000 neurology and neuromuscular healthcare providers that may be treating an adult LEMS patient who can benefit from Firdapse®. Additionally, we recently began non-personal promotion to oncologists that may treat adult LEMS patients. We also are continuing to make available at no-cost a LEMS voltage gated calcium channel (VGCC) antibody testing program for use by physicians who suspect that one of their patients may have LEMS and wish to reach a definitive diagnosis.

Finally, we are continuing to expand our digital and social media activities in order to introduce our product and services to potential patients and their healthcare providers. We also work with several rare disease advocacy organizations (including Global Genes, the National Organization for Rare Disorders (NORD), and the Myasthenia Gravis Foundation of America) to help increase awareness and level of support for patients living with LEMS and to provide education for the physicians who treat these rare diseases and the patients they treat.

We are supporting the distribution of Firdapse® through Catalyst Pathways®, our personalized treatment support program. Catalyst Pathways® is a single source for personalized treatment support, education and guidance through the challenging dosing and titration regimen to an effective therapeutic dose. It also includes distributing the drug through a very small group of exclusive specialty pharmacies (primarily AnovoRx), which is consistent with the way that most pharmaceutical products for ultra-orphan diseases are distributed and dispensed to patients. We believe that by using specialty pharmacies in this way, the difficult task of navigating the health care system is far better for the patient needing treatment for their rare disease and the health care community in general.

In order to help adult LEMS patients afford their medication, we, like other pharmaceutical companies which are marketing drugs for ultra-orphan conditions, have developed an array of financial assistance programs that are available to reduce patient co-pays and deductibles to a nominal affordable amount. For eligible patients with commercial coverage, a co-pay assistance program designed to keep out-of-pocket costs to not more than $10.00 per month (currently $0.00 per month) available for all LEMS patients prescribed Firdapse®. We are also donating, and committing to continue to donate, money to qualified, independent charitable foundations dedicated to providing assistance to any U.S. LEMS patients in financial need. Subject to compliance with regulatory requirements, our goal is that no LEMS patient is ever denied access to their medication for financial reasons.

In May 2019, the FDA approved a New Drug Application (NDA) for Ruzurgi®, another version of amifampridine (3,4-DAP), for the treatment of pediatric LEMS patients (ages 6 to under 17). While the NDA for Ruzurgi® only covers pediatric patients, we believe that Ruzurgi® is regularly being prescribed off-label to adult LEMS patients. We also believed that the FDA's approval of Ruzurgi® violated our statutory rights and was in multiple other respects arbitrary, capricious and contrary to law. As a result, in June 2019 we filed suit against the FDA and several related parties challenging this approval and related drug labeling, and Jacobus Pharmaceuticals (Jacobus) intervened in our case. Our complaint, which was filed in the federal district court for the Southern District of Florida, alleged that the FDA's approval of Ruzurgi® violated multiple provisions of FDA regulations regarding labeling, resulting in misbranding in violation of the Federal Food, Drug, and Cosmetic Act (FDCA); violated our statutory rights to Orphan Drug Exclusivity and New Chemical Entity Exclusivity under the FDCA; and was in multiple other respects arbitrary, capricious, and contrary to law, in violation of the Administrative Procedure Act. Among other remedies, the suit sought an order setting aside the FDA's approval of Ruzurgi®.

On July 30, 2020, the Magistrate Judge considering our lawsuit against the FDA filed a Report and Recommendation in which she recommended to the District Judge handling the case that she grant the FDA's and Jacobus' motions for summary judgment and deny our motion for summary judgment. On September 29, 2020, the District Judge adopted the Report and Recommendation of the Magistrate Judge, granted the FDA's and Jacobus' motions for summary judgment, and dismissed our case. We appealed the District Court's decision to the Eleventh Circuit Court of Appeals. The case was fully briefed, and oral argument was held in March 2021.

On September 30, 2021, a three-judge panel of judges on the Eleventh Circuit Court of Appeals issued a unanimous decision overturning the District Court's decision. The court adopted our argument that the FDA's approval of Ruzurgi® violated our rights to Orphan Drug Exclusivity and remanded the case to the District Court with orders to enter summary judgment in our favor. This decision reverses the FDA's approval of Ruzurgi®. We are presently waiting to see if the FDA or Jacobus will seek rehearing of the case from the full Eleventh Circuit Court of Appeals or appeal the appellate court's decision to the Supreme Court. Until the appeal period ends it is likely that Ruzurgi® will continue to be available on the market.

In light of the Eleventh Circuit decision, we are actively working with parents and physicians of pediatric LEMS patients to make sure that such patients will be able to obtain Firdapse®. In addition, we intend to file an application with the FDA seeking approval for use of Firdapse® by pediatric LEMS patients, though any effort to obtain such authorization will take some time and is not guaranteed. For the larger number of adult LEMS patients who have been receiving Ruzurgi® off-label, we are already working with prescribers to be in a position to transition such patients to Firdapse®.

We are currently developing a long-acting formulation of amifampridine phosphate. A number of candidate formulations have been prepared, and three of the most promising formulations were evaluated in a pharmacokinetic (PK) study completed during the fourth quarter of 2020. The results of this first PK study are being used to inform the design and refinement of future product formulations and additional PK work to be conducted. We have also completed an advisory board meeting with both patients and doctors in order to establish the optimum target characteristics of the long-acting formulation of amifampridine phosphate that are desired by the LEMS patient community and treating physicians. There can be no assurance that we will be able to successfully develop a long-acting formulation of amifampridine phosphate, that any such formulation will be approved by the FDA for marketing, or that any such formulation will be commercially viable.

On August 10, 2020, we announced the top-line results from our Phase 3 clinical trial (MSK-002) evaluating Firdapse® for the treatment of adults with MuSK-MG. Unfortunately, the MSK-002 trial did not achieve statistical significance on its primary endpoint or its secondary endpoint. Following our receipt of these results, we analyzed the data and proposed a plan to FDA to perform an additional study evaluating Firdapse® for MuSK-MG. In response, the FDA provided written comments that were unfavorable towards our proposed revised study design and further questioned the ability of the initial MuSK-MG pilot study to be supportive. These remarks make it unlikely that a single study similar design to MSK-002 would be sufficient for potential approval of the MuSK-MG indication. We also held an appropriate expert panel to discuss options and review the likelihood of success for a MuSK-MG indication for Firdapse®. Based upon the input of FDA and advisors that was received, we have concluded that the use of Firdapse® as a first line therapy for MuSK-MG is unlikely and therefore we have decided not to continue to pursue this indication.

We previously announced our intent to conduct a proof-of-concept study evaluating Firdapse® as a treatment for Hereditary Neuropathy with Liability to Pressure Palsies (HNPP). The scientific basis for considering this indication is that leakage of neuron potassium channels is observed in HNPP. Since Firdapse® is a potassium channel blocker, it may mitigate the pathological effects of the potassium channel leakage in HNPP patients. The FDA requested that a new, patient centric endpoint be researched and used for our proposed study, without assurance that such endpoint would be acceptable for approval. Based upon the uncertainty of such an endpoint, we have decided not to conduct this as a company sponsored study. We continue to offer the opportunity for an interested investigator to conduct this study as an investigator-initiated study.

There can be no assurance that any future clinical trials of Firdapse® that we undertake will be successful. Further, there can be no assurance that we will ever be granted the right to commercialize Firdapse® for any additional indications.

Our NDS filing for Firdapse® for the symptomatic treatment of LEMS was approved by Health Canada on July 31, 2020. In August 2020, we entered into a license agreement with KYE Pharmaceuticals (KYE), pursuant to which we licensed the Canadian rights for Firdapse® for the treatment of LEMS to KYE. Pursuant to the license agreement, KYE was obligated to pay us an up-front payment based on approval, a milestone upon attainment of marketing authorization and product supply, milestones based on achievements of sales and regulatory milestones, and a sharing of defined net sales following commercialization.

On August 10, 2020, Health Canada issued a Notice of Compliance (NOC) to Medunik for Ruzurgi® for the treatment of LEMS. We initiated a legal proceeding in Canada seeking judicial review of Health Canada's decision to issue the NOC for Ruzurgi® as incorrect and unreasonable under Canadian law. Data protection, per Health Canada regulations, is supposed to prevent Health Canada from issuing a NOC to a drug that directly or indirectly references an innovative drug's data, for eight years from the date of the innovative drug's approval. The Ruzurgi® Product Monograph clearly references pivotal nonclinical carcinogenicity and reproductive toxicity data for amifampridine phosphate developed by us. As such, we believe that our data was relied upon to establish the nonclinical safety profile of Ruzurgi® needed to meet the standards of the Canadian Food and Drugs Act.

On June 3, 2021, we announced a positive decision in this proceeding that quashed the NOC previously issued for Ruzurgi® and remanded the matter to the Minister of Health to redetermine its decision to grant marketing authorization to Ruzurgi® in spite of Firdapse®'s data protection rights. However, on June 28, 2021, we announced that Health Canada had re-issued an NOC for Ruzurgi®, once again allowing the product to be marketed in Canada for patients with LEMS. As a result, in early July 2021, we, along with our partner KYE, filed a second suit against Health Canada to overturn their most recent decision, which suit is currently ongoing. There can be no assurance as to the outcome of this proceeding.

In May 2019, we entered into an amendment to our license agreement for Firdapse®. Under the amendment, we expanded our commercial territory for Firdapse®, which originally was comprised of North America, to include Japan. Additionally, we have an option to further expand our territory under the license agreement to include most of Asia, as well as Central and South America, upon the achievement of certain milestones in Japan. Under the amendment, we will pay royalties on net sales in Japan of a similar percentage to the royalties that we are currently paying under our original license agreement for North America.

We have reached an agreement with Japanese regulatory authorities as to the scope of the clinical trial that we will be required to undertake in Japan before we will be permitted to submit an application to the Japanese regulatory authorities to seek to commercialize Firdapse® for the treatment of LEMS in Japan. We also have been granted orphan drug designation in Japan for Firdapse® for the symptomatic treatment of LEMS. There can be no assurance that we will successfully obtain the right to commercialize Firdapse® in Japan.

On June 28, 2021, we entered into a license agreement with DyDo Pharma, Inc. (DyDo), pursuant to which we sub-licensed to DyDo the Japanese rights for Firdapse® for the treatment of LEMS. Under the terms of the Agreement, DyDo will have joint rights to develop Firdapse®, and exclusive rights to commercialize the product, in Japan. DyDo will be responsible for funding all clinical, regulatory, marketing and commercialization activities in Japan. We will be responsible for clinical and commercial supply, as well as providing support to DyDo in its efforts to obtain regulatory approval for the product from the Japanese regulatory authorities. Subject to the satisfaction of terms and conditions as set forth in the Agreement, we have earned an upfront payment and are eligible to receive further development and sales milestones for Firdapse®, as well as revenue on product supplied to DyDo.

All of our patent rights for Firdapse® are derived from our license agreement. In August 2020, the United States Patent and Trademark Office (USPTO) allowed Patent No. 10,793,893 (the '893 patent) to our licensor and thereby to us, and the patent issued on October 6, 2020. The patent is directed to the use of suitable doses of amifampridine to treat patients, regardless of the therapeutic indication, that are slow metabolizers of amifampridine. Any drug product containing amifampridine with a label that states the patented dosing regimens and doses in the Dosing and Administration section prior to April 7, 2034, the expiration date of the patent, could possibly infringe this patent. Generic drug product labels would necessarily have to do this, and we intend to take all appropriate actions to protect our intellectual property.

In April 2021, the USPTO also allowed Patent No. 11,060,128 (the '128 patent) to our licensor and thereby to us, and this second patent issued on July 13, 2021. The patent is directed to the use of suitable doses of amifampridine to treat patients suffering with LEMS that are slow metabolizers of amifampridine. Any drug product containing amifampridine with a label for the treatment of LEMS, that states the patented dosing regimens and doses in the Dosing and Administration section of a product label, including generic drug product labels, could possibly infringe this patent prior to this patent's expiration date.

We are also pursuing additional patent applications for Firdapse® in an effort to further protect our drug product. There can be no assurance that any additional patents will be issued which provide additional intellectual property protection for our drug product.

In that regard, in October 2020, we filed lawsuits against Jacobus and the specialty pharmacy marketing Ruzurgi®, PantherRx Rare LLC (PantherRx), for infringement of the '893 patent. The suits have now been consolidated in a single action in the U.S. District Court for New Jersey. In August 2021, the lawsuits were amended to include alleged infringement of the '128 patent. The lawsuits arise from Jacobus' and PantherRx's sales and marketing of Ruzurgi® (amifampridine) Tablets, 10 mg. The lawsuits allege that the Ruzurgi® product infringes the '893 patent and the '128 patent when administered in accordance with its product labeling. The lawsuit seeks damages and injunctive relief to prevent further marketing of Ruzurgi® in violation of our patent rights. The lawsuit is in the discovery stage and there can be no assurance as to the results of these proceedings.

There can be no assurance that we do not or will not infringe on patents held by third parties or that third parties in the future will not claim that we have infringed on their patents. In the event that our products or technologies infringe or violate the patent or other proprietary rights of third parties, there is a possibility we may be prevented from pursuing product development, manufacturing or commercialization of our products that utilize such technologies until the underlying patent dispute is resolved. For example, there may be patents or patent applications held by others that contain claims that our products or operations might be determined to infringe or that may be broader than we believe them to be. Given the complexities and uncertainties of patent laws, there can be no assurance as to the impact that future patent claims against us may have on our business, financial condition, results of operations, or prospects.

Generic Sabril®

In December 2018, we entered into a definitive agreement with Endo International plc's subsidiary, Endo Ventures Limited ("Endo"), for the further development and commercialization of generic Sabril® tablets through Endo's United States Generic Pharmaceuticals segment, Par Pharmaceutical. If and when the product is launched, we will be entitled to receive a milestone payment of $2.0 million on the commercial launch of the product. Further, we will receive a sharing of defined net profits upon commercialization and we are obligated to share the costs of certain development expenses. There can be no assurance that our collaboration with Endo for the development of generic Sabril® (vigabatrin) tablets will be successful and that if an abbreviated new drug application (ANDA) is approved for vigabatrin tablets in the future, that it will be profitable to us.

Capital Resources

At September 30, 2021, we had cash and investments of approximately $174.8 million and no funded debt. Based on our current financial condition and forecasts of available cash, we believe that we have sufficient funds to support our operations for at least the next 12 months from the date of this Form 10-Q. There can be no assurance that we will continue to be successful in commercializing Firdapse® or will continue to be profitable and cash flow positive. Further, there can be no assurance that if we need additional funding in the future, whether such funding will be available to us. See "Liquidity and Capital Resources" below for further information on our liquidity and cash flow.

Basis of Presentation

Revenues.

During the fiscal quarter ended September 30, 2021, we continued to generate revenues from product sales of Firdapse® in the U.S. We expect these revenues to fluctuate in future periods based on our sales of Firdapse®. We received approval from Health Canada on July 31, 2020, for Firdapse® for the symptomatic treatment of LEMS in adults and as of December 31, 2020, we had launched Firdapse® in Canada. For the three and nine months ended September 30, 2021 and 2020, revenues generated under our collaborative agreement with KYE Pharmaceuticals were immaterial. We expect our revenues from the KYE collaborative agreement to fluctuate in future periods based on our collaborator's ability to sell Firdapse® in Canada.

For the three and nine months ended September 30, 2021, we did not generate revenues under our collaborative agreement with Endo. We expect our revenues from the Endo collaborative agreement to fluctuate in future periods based on our collaborator's ability to meet various regulatory milestones set forth in such agreement.

For the three and nine months ended September 30, 2021, we earned approximately $0 and $2.7 million, respectively, in revenue under our licensing agreement with DyDo. We expect our revenues from the DyDo license agreement to fluctuate in future periods based on DyDo's ability to meet various regulatory milestones set forth in such agreement.

Cost of Sales.

Cost of sales consists of third-party manufacturing costs, freight, royalties, and indirect overhead costs associated with sales of Firdapse®. Cost of sales may also include period costs related to certain inventory manufacturing services, inventory adjustments charges, unabsorbed manufacturing and overhead costs, and manufacturing variances.

Research and Development Expenses.

Our research and development expenses consist of costs incurred for company-sponsored research and development activities, as well as support for selected investigator-sponsored research. The major components of research and development costs include preclinical study costs, clinical manufacturing costs, clinical study and trial expenses, insurance coverage for clinical trials, consulting, and other third-party costs, salaries and employee benefits, stock-based compensation expense, supplies and materials, and allocations of various overhead costs related to our product development efforts. To date, all of our research and development resources have been devoted to the development of Firdapse®, CPP-109 (our version of vigabatrin), and formerly CPP-115, and we currently expect that our future development costs will be attributable principally to the continued development of Firdapse®. However, as noted in the Overview above, we are prepared to invest in future research and development, including earlier stage opportunities and innovative technology.

Our cost accruals for clinical studies and trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical study and trial sites and clinical research organizations (CROs). In the normal course of our business we contract with third parties to perform various clinical study and trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events or milestones, the successful enrollment of patients, the allocation of responsibilities among the parties to the agreement, and the completion of portions of the clinical study or trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our consolidated financial statements to the actual services received and efforts expended. As such, expense accruals related to preclinical and clinical studies or trials are recognized based on our estimate of the degree of completion of the event or events specified in the specific study or trial contract. We monitor service provider activities to the extent possible; however, if we underestimate activity levels associated with various studies or trials at a given point in time, we could be required to record significant additional research and development expenses in future periods. Preclinical and clinical study and trial activities require significant up-front expenditures. We anticipate paying significant portions of a study or trial's cost before they begin and incurring additional expenditures as the study or trial progresses and reaches certain milestones.

Selling, General and Administrative Expenses.

We incur substantial commercialization expenses relating to our commercialization of Firdapse® including expenses relating to sales, marketing, patient services and patient advocacy.

Our general and administrative expenses consist primarily of salaries and personnel expenses for accounting, corporate, compliance, and administrative functions. Other costs include administrative facility costs, regulatory fees, insurance, and professional fees for legal including litigation cost, information technology, accounting, and consulting services.

Stock-Based Compensation.

We recognize expense for the fair value of all stock-based awards to employees, directors, and consultants in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP). For stock options, we use the Black-Scholes option valuation model in calculating the fair value of the awards.

Income Taxes.

Our effective income tax rate is the ratio of income tax expense (benefit) over our income before income taxes.

Recently Issued Accounting Standards.

For discussion of recently issued accounting standards, please see Note 2, "Basis of Presentation and Significant Accounting Policies," in the interim consolidated financial statements included in this report.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make judgments, estimates, and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenues and expenses during the reporting periods. For a full discussion of our accounting policies, please refer to Note 2 on the Financial Statements included in our 2020 Annual Report on Form 10-K that we filed with the SEC on March 15, 2021. Our most critical accounting policies and estimates include: accounting for revenue recognition, leases, preclinical study and clinical trial expenses, stock-based compensation and valuation allowance for deferred tax assets. We continually evaluate our judgments, estimates and assumptions. We base our estimates on the terms of underlying agreements, our expected course of development, historical experience and other factors that we believe are reasonable based on the circumstances, the results of which form our management's basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates. There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations* included in our 2020 Annual Report on Form 10-K.

Results of Operations

Revenues.

For the three and nine months ended September 30, 2021, we recognized approximately $35.9 million and $99.7 million, respectively, in net revenue from product sales from Firdapse® compared to approximately $29.2 million and $87.9 million, respectively, for the three and nine months ended September 30, 2020. We recognized approximately $0.1 million and $2.8 million for the three and nine months ended September 30, 2021, respectively, in license and other revenue compared to approximately $0.2 million for the three and nine months ended September 30, 2020.

Cost of Sales.

Cost of sales was approximately $5.3 million and $14.5 million for the three and nine months ended September 30, 2021 compared to approximately $3.9 million and $12.2 million for the three and nine months ended September 30, 2020. Cost of sales consists principally of royalty payments, which are based on net revenue as defined in the applicable license agreement.

Research and Development Expenses.

Research and development expenses for the three months ended September 30, 2021 and 2020 were approximately $4.5 million and $3.7 million, respectively, and represented approximately 20% and 21% of total operating costs and expenses for the three months ended September 30, 2021 and 2020, respectively. Research and development expenses for the three months ended September 30, 2021 and 2020 were as follows (in thousands):

	Three months ended September 30,		Change	
	2021	2020	$	%
Research and development expenses	$ 4,059	$ 3,350	709	21.2%
Employee stock-based compensation	428	399	29	7.3%
Total research and development expenses	$ 4,487	$ 3,749	738	19.7%

Research and development expenses for the nine months ended September 30, 2021 and 2020 were approximately $11.9 million and $12.3 million, respectively, and represented approximately 19% and 22% of total operating costs and expenses for the nine months ended September 30, 2021 and 2020, respectively. Research and development expenses for the nine months ended September 30, 2021 and 2020 were as follows (in thousands):

	Nine months ended September 30,		Change	
	2021	2020	$	%
Research and development expenses	$10,751	$11,083	(332)	(3.0)%
Employee stock-based compensation	1,193	1,239	(46)	(3.7)%
Total research and development expenses	$11,944	$12,322	(378)	(3.1)%

Research and development expenses stayed relatively consistent for the three and nine month periods ended September 30, 2021 when compared to the same periods in 2020. For the three and nine months ended September 30, 2020, research and development expenses included costs relating to our MuSK-MG clinical trial and our SMA type 3 proof-of-concept trial, both of which were completed in the second half of 2020. For the three and nine months ended September 30, 2021, research and development expenses included costs relating to winding down of the sites for both the MuSK-MG clinical trial and SMA type 3 proof-of-concept trial. Research and development costs in both the 2020 and 2021 periods also included expenses relating to medical and regulatory affairs, our expanded access programs, and our efforts to develop a long-acting formulation of amifampridine phosphate.

We expect that research and development expenses will continue to be substantial in 2021 and beyond as we continue our Expanded Access Program and take steps to continue the development of a long-acting formulation of amifampridine phosphate. Research and development expenses will also increase in future periods if we successfully execute on our strategic initiative to acquire or in-license innovative technology platforms and/or earlier stage programs in other therapeutic categories outside of neuromuscular diseases.

Selling, General and Administrative Expenses.

Selling, general and administrative expenses for the three months ended September 30, 2021 and 2020 were approximately $12.2 million and $10.0 million, respectively, and represented 55% and 57% of total operating costs and expenses for the three months ended September 30, 2021 and 2020, respectively. Selling, general and administrative expenses for the three months ended September 30, 2021 and 2020 were as follows (in thousands):

	Three months ended September 30,		Change	
	2021	2020	$	%
Selling	$ 6,521	$5,578	943	16.9%
General and administrative	4,548	3,328	1,220	36.7%
Employee stock-based compensation	1,084	1,079	5	0.5%
Total selling, general and administrative expenses	$12,153	$9,985	2,168	21.7%

Selling, general and administrative expenses for the nine months ended September 30, 2021 and 2020 were approximately $36.4 million and $30.9 million, respectively, and represented 58% and 56% of total operating costs and expenses for the nine months ended September 30, 2021 and 2020, respectively. Selling, general and administrative expenses for the nine months ended September 30, 2021 and 2020 were as follows (in thousands):

	Nine months ended September 30,		Change	
	2021	2020	$	%
Selling	$18,177	$17,004	1,173	6.9%
General and administrative	14,816	10,324	4,492	43.5%
Employee stock-based compensation	3,408	3,553	(145)	(4.1)%
Total selling, general and administrative expenses	$36,401	$30,881	5,520	17.9%

For the three and nine months ended September 30, 2021, selling, general and administrative expenses increased approximately $2.2 million and $5.5 million, respectively, when compared to the same periods in 2020. The increase for the three and nine months ended September 30, 2021 was primarily attributable to the timing of our commitments to make contributions to 501(c)(3) organizations supporting LEMS patients of approximately $0.5 million and $2.0 million, respectively, and increases in legal fees of approximately $1.0 million and $2.0 million, respectively. The increase for the nine months ended September 30, 2021 was also due to increased costs due to the expansion of our operations and headcount required to support our ongoing efforts to commercialize Firdapse®.

We expect that selling, general and administrative expenses will continue to be substantial in future periods as we continue our efforts to increase our revenues from Firdapse® and take steps to expand our business.

Stock-Based Compensation.

Total stock-based compensation for the three and nine months ended September 30, 2021 were $1.5 million and $4.6 million, respectively, and for the three and nine months ended September 30, 2020 were $1.5 million and $4.8 million, respectively. In the first nine months of 2021, grants were principally for stock options relating to 2020 year-end bonus awards and grants to new employees. In the first nine months of 2020, grants were principally of stock options relating to 2019 year-end bonus awards and grants to new employees.

Other Income, Net.

We reported other income, net in all periods relating to our investment of our cash and cash equivalents and investments. The increase in other income, net for the three months ended September 30, 2021 when compared to the same period in 2020 is primarily due to the timing of the purchases of the short-term bond funds. The decrease in other income, net for the nine months ended September 30, 2021 when compared to the same period in 2020 is primarily due to lower yields on investments, despite higher invested balances. Other income, net, consists primarily of interest and dividend income.

Income Taxes.

Our effective income tax rate was 24.3% and 2.8% for the nine months ended September 30, 2021 and 2020, respectively. The difference in the effective rates between periods is driven by the release of the valuation allowance against deferred taxes in the third quarter of 2020. Differences in the effective tax and the statutory federal income tax rate of 21% are driven by state income taxes and anticipated annual permanent differences, and offset by the orphan drug credit claimed.

We had no uncertain tax positions as of September 30, 2021 and December 31, 2020.

Net Income.

Our net income was approximately $10.3 million and $30.2 million, respectively, for the three and nine months ended September 30, 2021 ($0.10 and $0.29, respectively, per basic and $0.10 and $0.28, respectively, per diluted share) as compared to net income of approximately $43.3 million and $63.5 million, respectively, for the three and nine months ended September 30, 2020 ($0.42 and $0.61, respectively, per basic and $0.41 and $0.60, respectively, per diluted share).

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through multiple public and private offering of our securities and, since January 2019, from revenues from sales of Firdapse®. At September 30, 2021, we had cash and cash equivalents and investments aggregating approximately $174.8 million and working capital of approximately $172.2 million. At December 31, 2020, we had cash and cash equivalents and investments aggregating $140.3 million and working capital of $136.5 million. At September 30, 2021, substantially all of our cash and cash equivalents was deposited with one financial institution, and such balances were in excess of federally insured limits. Further, as of such date, substantially all such funds were invested in money market accounts, short-term interest-bearing obligations and U.S. Treasuries.

We incurred operating losses through the quarter ended March 31, 2019 and reported net income for the first time during the three and six month periods ended June 30, 2019. We expect to continue to spend substantial dollars on our current and future drug development programs.

Based on forecasts of available cash, we believe that we have sufficient resources to support our currently anticipated operations for at least the next 12 months from the date of this report. There can be no assurance that we will remain profitable or that we will be able to obtain any additional funding that we may require in the future.

In the future, we may require additional working capital to support our operations depending on our future success with Firdapse® sales and whether our results continue to be profitable and cash flow positive. There can be no assurance as to the amount of any such funding that will be required for these purposes or whether any such funding will be available to us when it is required.

In that regard, our future funding requirements will depend on many factors, including:

- the extent to which we seek to acquire or in-license additional drug development candidates;
- the scope, rate of progress and cost of our clinical trials and other product development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and delays in product development as a result of any changes in regulatory oversight applicable to our products;
- the level of revenues that we report from sales of Firdapse®;
- the effect of competition and market developments; and
- the cost of filing and potentially prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We may raise additional funds if required in the future through public or private equity offerings, debt financings, corporate collaborations or other means. We also may seek governmental grants for a portion of the required funding for our clinical trials and preclinical trials. We may further seek to raise capital to fund additional product development efforts or product acquisitions, even if we have sufficient funds for our planned operations. Any sale by us of additional equity or convertible debt securities could result in dilution to our stockholders. There can be no assurance that any such required additional funding will be available to us at all or available on terms acceptable to us. Further, to the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our technologies or grant sublicenses on terms that are not favorable to us. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs, which could have an adverse effect on our business.

On July 23, 2020, we filed a shelf registration statement with the SEC to sell up to $200 million of common stock, preferred stock, warrants to purchase common stock, debt securities and units consisting of one or more of such securities (the "2020 Shelf Registration Statement"). The 2020 Shelf Registration Statement (file no. 333-240052) was declared effective by the SEC on July 31, 2020. As of the date of this report, no offerings have been completed under the 2020 Shelf Registration Statement.

Cash Flows.

Net cash provided by operating activities was $41.2 million and $31.9 million, respectively, for the nine-month periods ended September 30, 2021 and 2020. During the nine months ended September 30, 2021 net cash provided by operating activities was primarily attributable to our net income of $30.2 million, decreases of $3.9 million in prepaid expenses and other current and non-current assets, increases of $0.9 million in lease liability, $6.6 million in deferred taxes and of $4.9 million of non-cash expenses. This was partially offset by increases of $0.6 million in accounts receivable, $2.3 million in inventory and decreases of $1.5 million in accounts payable and $0.9 million in accrued expenses and other liabilities. During the nine months ended September 30, 2020 net cash provided by operating activities was primarily attributable to our net income of $63.5 million, a decrease of $4.7 million in accounts receivable, net and $5.6 million in non-cash expenses. This was partially offset by increases of $2.8 million in inventory, $1.3 million in prepaid expenses and other current assets and deposits and decreases of $31.3 million in deferred taxes, $2.1 million in accounts payable, $3.6 million in accrued expenses and other liabilities and $0.8 in operating lease liability.

Net cash used in investing activities was $11.0 million, for the nine-month period ended September 30, 2021, consisting primarily of purchases of investments. Net cash used in investing activities was $5.0 million for the nine-month period ended September 30, 2020, consisting mostly of purchases of short-term investments, partially offset by proceeds from maturities of investments.

Net cash used in financing activities during the nine-month period ended September 30, 2021 was $5.6 million and consisted primarily of the repurchase of common stock, partially offset by proceeds from the exercise of stock options. Net cash provided by financing activities during the nine-month period ended September 30, 2020 was $0.7 million, consisting primarily of proceeds from the exercise of options to purchase common stock.

Contractual Obligations and Arrangements.

We have entered into the following contractual arrangements:

- *Payments under our license agreement*. We have agreed to pay the following royalties under our license agreement:
  - Royalties to our licensor for seven years from the first commercial sale of Firdapse® equal to 7% of net sales (as defined in the License Agreement) in North America for any calendar year for sales up to $100 million, and 10% of net sales in North America in any calendar year in excess of $100 million; and
  - Royalties to the third-party licensor of the rights sublicensed to us from the first commercial sale of Firdapse® equal to 7% of net sales (as defined in the License Agreement between BioMarin and the third-party licensor) in any calendar year for the duration of regulatory exclusivity within a territory and 3.5% for territories in any calendar year in territories without regulatory exclusivity.

  For the three and nine months ended September 30, 2021, we recognized an aggregate of approximately $4.9 million and $13.3 million, respectively, of royalties, which is included in cost of sales in the accompanying consolidated statement of operations and comprehensive income.
- *Employment agreements*. We have entered into an employment agreement with our Chief Executive Officer that requires us to make base salary payments of approximately $630,000 in 2021. The agreement expires in November 2022.
- *Purchase commitment.* We have entered into a purchase commitment with our contract manufacturing organization for approximately $500,000 per year. The agreement expires in December 2023.
- *Lease for office space*. We operate our business in leased office space in Coral Gables, Florida. We entered into an agreement in May 2020 that amended our lease for the office facilities. Under the amended lease, our leased space increased from approximately 7,800 square feet of space to approximately 10,700 square feet of space. We moved into the new space on March 1, 2021 when the space became available for use. We expect to pay annual rent of approximately $0.5 million.

Off-Balance Sheet Arrangements.

We currently have no debt or finance leases. We have an operating lease for our office facilities. We do not have any off-balance sheet arrangements as such term is defined in rules promulgated by the SEC.

Caution Concerning Forward-Looking Statements

This Current Report on Form 10-Q contains "forward-looking statements", as that term is defined in the Private Securities Litigation Reform Act of 1995. These include statements regarding our expectations, beliefs, plans or objectives for future operations and anticipated results of operations. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, "believes", "anticipates", "proposes", "plans", "expects", "intends", "may", and other similar expressions are intended to identify forward-looking statements. Such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or other achievements to be materially different from any future results, performances or achievements expressed or implied by such forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in the section entitled "Item 1A – Risk Factors" in our 2020 Annual Report on Form 10-K.

The continued successful commercialization of Firdapse® and the development of additional indications for Firdapse® is highly uncertain. Factors that will affect our success include the uncertainty of:

- The impact of the COVID-19 pandemic on our business or on the economy generally;
- Whether we will be able to continue to successfully market Firdapse® while maintaining full compliance with applicable federal and state laws, rules and regulations;
- Whether our estimates of the size of the market for Firdapse® for the treatment of Lambert-Eaton Myasthenic Syndrome ("LEMS") will turn out to be accurate;
- Whether we will be able to locate LEMS patients who are undiagnosed or are misdiagnosed with other diseases;
- Whether patients will discontinue from the use of our drug at rates that are higher than historically experienced or are higher than we project;
- Whether the daily dose taken by patients changes over time and affects our results of operations;
- Whether Firdapse® patients can be successfully titrated to stable therapy;
- Whether we can continue to market Firdapse® on a profitable and cash flow positive basis;
- Whether any revenue guidance that we provide to the public market will turn out to be accurate;
- Whether payors will reimburse for our product at the price that we charge for the product;
- The ability of our third-party suppliers and contract manufacturers to maintain compliance with current Good Manufacturing Practices (cGMP);
- The ability of our distributor and the specialty pharmacies that distribute our product to maintain compliance with applicable law;
- Our ability to maintain compliance with applicable rules relating to our patient assistance programs and our contributions to 501(c)(3) organizations that support LEMS patients;
- The scope of our intellectual property and the outcome of any future challenges or opposition to our intellectual property, and, conversely, whether any third-party intellectual property presents unanticipated obstacles for Firdapse®;
- Whether our lawsuits against Jacobus and the specialty pharmacy distributing its product for patent infringement will be successful;
- Whether the decision of the Eleventh Circuit on our case against the FDA will be overturned;
- Whether we can continue to compete successfully if Ruzurgi® continues to be on the market and prescribed for off-label use by adult LEMS patients;
- Whether, if Ruzurgi® remains on the market at the lower price, payors will require that patients try off-label Ruzurgi® first before they approve Firdapse® as a treatment for adult LEMS patients;
- The impact on Firdapse® of adverse changes in potential reimbursement and coverage policies from government and private payors such as Medicare, Medicaid, insurance companies, health maintenance organizations and other plan administrators, or the impact of pricing pressures enacted by industry organization, the federal government or the government of any state, including as a result of increased scrutiny over pharmaceutical pricing or otherwise;
- The impact on our business and results of operations of public statements by politicians and a vocal group of LEMS patients and doctors who object to our pricing of Firdapse®;
- Changes in the healthcare industry and the effect of political pressure from and actions by President Biden, Congress and/or medical professionals seeking to reduce prescription drug costs;
- The state of the economy generally and its impact on our business;
- Changes to the healthcare industry occasioned by any changes in laws relating to the pricing of drug products, or changes in the healthcare industry generally;

- The scope, rate of progress and expense of our clinical trials and studies, pre-clinical studies, proof-of-concept studies, and our other drug development activities, and whether our trials and studies will be successful;
- Our ability to complete any clinical trials and studies that we may undertake on a timely basis and within the budgets we establish for such trials and studies;
- Whether COVID-19 will further affect the timing and costs of our currently ongoing and contemplated clinical trials;
- Whether Firdapse® will ever be approved for the treatment of any neuromuscular disease other than LEMS;
- Whether Firdapse® can be successfully commercialized in Canada on a profitable basis;
- Whether our suit to overturn the approval of Ruzurgi® in Canada will be successful;
- The impact on sales of Firdapse® in the United States if an amifampridine product is purchased in Canada for use in the United States;
- Whether we will be able to successfully complete the clinical trial in Japan that will be required to seek approval to commercialize Firdapse® in Japan;
- Whether we will be able to obtain approval to commercialize Firdapse® in Japan;
- Whether we can successfully develop, obtain approval of and successfully market a long-acting version of amifampridine phosphate;
- Whether our efforts to grow our business beyond Firdapse® through acquisitions of companies or in-licensing of product opportunities will be successful;
- Whether we will have sufficient capital to finance any such acquisitions;
- Whether our version of generic vigabatrin tablets will ever be approved by the FDA;
- Even if our version of vigabatrin tablets is approved for commercialization, whether Endo Ventures/Par Pharmaceutical (our collaborator in this venture) will be successful in marketing the product; and
- Whether we will earn milestone payments on the first commercial sale of vigabatrin tablets and royalties on sales of generic vigabatrin tablets.

Our current plans and objectives are based on assumptions relating to the continued commercialization of Firdapse® and the development of additional indications for Firdapse®. Although we believe that our assumptions are reasonable, any of our assumptions could prove inaccurate. In light of the significant uncertainties inherent in the forward-looking statements we have made herein, which reflect our views only as of the date of this report, you should not place undue reliance upon such statements. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Market risk represents the risk of changes in the value of market risk-sensitive instruments caused by fluctuations in interest rates, foreign exchange rates and commodity prices. Changes in these factors could cause fluctuations in our results of operations and cash flows.

Our exposure to interest rate risk is currently confined to our cash and short-term investments that are from time to time invested in highly liquid money market funds, U.S. Treasuries and short-term bond funds. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. We do not use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations.

ITEM 4. CONTROLS AND PROCEDURES

a. We have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of September 30, 2021, our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act, was recorded, processed, summarized or reported within the time periods specified in the rules and regulations of the SEC, and include controls and procedures designed to ensure that information required to be disclosed by us in such reports was accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

b. During the three months ended September 30, 2021, there were no changes in our internal controls or in other factors that could have a material effect, or are reasonably likely to have a material effect, on our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Ruzurgi®

We believe that the FDA's approval of Ruzurgi® violated our statutory rights and was in multiple other respects arbitrary, capricious and contrary to law. As a result, in June 2019 we filed suit against the FDA and several related parties challenging this approval and related drug labeling, and Jacobus intervened in the litigation. Our complaint, which was filed in the federal district court for the Southern District of Florida, alleged that the FDA's approval of Ruzurgi® violated multiple provisions of FDA regulations regarding labeling, resulting in misbranding in violation of the Federal Food, Drug, and Cosmetic Act (FDCA); violated our statutory rights to Orphan Drug Exclusivity and New Chemical Entity Exclusivity under the FDCA; and was in multiple other respects arbitrary, capricious, and contrary to law, in violation of the Administrative Procedure Act. Among other remedies, the suit sought an order setting aside the FDA's approval of Ruzurgi®.

On July 30, 2020, the Magistrate Judge considering our lawsuit against the FDA filed a Report and Recommendation in which she recommended to the District Judge handling the case that she grant the FDA's and Jacobus' motions for summary judgment and deny our motion for summary judgment. On September 29, 2020, the District Judge adopted the Report and Recommendation of the Magistrate Judge, granted the FDA's and Jacobus' motions for summary judgment, and dismissed our case. We appealed the District Court's decision to the Eleventh Circuit Court of Appeals. The case was fully briefed, and oral argument was held in March 2021.

On September 30, 2021, a three-judge panel of judges on the Eleventh Circuit Court of Appeals issued a unanimous decision overturning the District Court's decision. The court adopted our argument that the FDA's approval of Ruzurgi® violated our rights to Orphan Drug Exclusivity and remanded the case to the District Court with orders to enter summary judgment in our favor. This decision reverses the FDA's approval of Ruzurgi®. We are presently waiting to see if the FDA or Jacobus will seek rehearing of the case from the full Eleventh Circuit Court of Appeals or appeal the appellate court's decision to the Supreme Court. Until the appeal period ends, it is likely that Ruzurgi® will continue to be available on the market.

On August 10, 2020, Health Canada issued a Notice of Compliance (NOC) to Medunik for Ruzurgi® for the treatment of LEMS. We have since initiated a legal proceeding in Canada seeking judicial review of Health Canada's decision to issue the NOC for Ruzurgi® as incorrect and unreasonable under Canadian law. Data protection, per Health Canada regulations, is supposed to prevent Health Canada from issuing a NOC to a drug that directly or indirectly references an innovative drug's data, for eight years from the date of the innovative drug's approval. The Ruzurgi® Product Monograph clearly references pivotal nonclinical carcinogenicity and reproductive toxicity data for amifampridine phosphate developed by us. As such, we believe that our data was relied upon to establish the nonclinical safety profile of Ruzurgi® needed to meet the standards of the Canadian Food and Drugs Act.

On June 3, 2021, we announced a positive decision in this proceeding that quashed the NOC previously issued for Ruzurgi® and remanded the matter to the Minister of Health to redetermine its decision to grant marketing authorization to Ruzurgi® in spite of Firdapse®'s data protection rights. However, on June 28, 2021, we announced that Health Canada had re-issued an NOC for Ruzurgi®, once again allowing the product to be marketed in Canada for patients with LEMS. As a result, in early July 2021, we, along with our partner KYE, filed a second suit against Health Canada to overturn their most recent decision, which suit is currently ongoing. There can be no assurance as to the outcome of this proceeding.

Patent Litigation

All of our patent rights for Firdapse® are derived from our license agreement. In August 2020, the United States Patent and Trademark Office (USPTO) allowed U.S. Patent No. 10,793,893 (the '893 patent) to our licensor and thereby to us, and the patent issued on October 6, 2020. A second patent was issued in April 2021 (Patent No. 11,060,128). Both patents are directed to the use of suitable doses of amifampridine to treat patients, regardless of the therapeutic indication, that are slow metabolizers of amifampridine.

On October 19, 2020, we filed a lawsuit in the U.S. District Court for New Jersey against Jacobus and a lawsuit in the U.S. District Court for the Western District of Pennsylvania against the specialty pharmacy marketing Ruzurgi®, PantherRx Rare LLC (PantherRx), for infringement of the '893 Patent. The suits have since been combined in the U.S. District Court for New Jersey. We further amended our suit in August 2021 to add alleged infringement of our second patent to this suit. The lawsuit arises from Jacobus' and PantherRx's sales and marketing of Ruzurgi® (amifampridine) Tablets, 10 mg. The lawsuit alleges that the Ruzurgi® product infringes our patent when administered in accordance with its product labeling. The lawsuit seeks damages and injunctive relief to prevent further marketing of Ruzurgi® in violation of our patent rights.

This lawsuit is in the discovery stage and there can be no assurance as to the results of this proceeding.

Other Litigation

From time to time we may become involved in legal proceedings arising in the ordinary course of business. Other than as set forth above, we believe that there is no litigation pending at this time that could have, individually or in the aggregate, a material adverse effect on our results of operations, financial condition or cash flows.

ITEM 1A. RISK FACTORS

There are many factors that affect our business, our financial condition, and the results of our operations. In addition to the information set forth in this quarterly report, you should carefully read and consider "Item 1A. Risk Factors" in Part I, and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, of our 2020 Annual Report on Form 10-K filed with the SEC, which contain a description of significant factors that might cause our actual results of operations in future periods to differ materially from those currently expected or desired.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Issuer Purchases of Equity Securities

In March 2021, the Company's Board of Directors approved a share repurchase program that authorizes the repurchase of up to $40 million of the Company's common stock, pursuant to a repurchase plan under Rule 10b-18 of the Securities Act. The share repurchase program commenced on March 22, 2021.

Period	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Program	Dollar Value of Shares that May Yet Be Purchased *(in thousands)*
July 1, 2021 – July 31, 2021	199,746	$ 5.48	199,746	$ 34,946
August 1, 2021 – August 31, 2021	197,287	$ 5.47	197,287	$ 33,867
September 1, 2021 – September 30, 2021	552,713	$ 5.21	552,713	$ 30,987

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable

ITEM 5. OTHER INFORMATION

None

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ITEM 6. EXHIBITS

31.1	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURES

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

Catalyst Pharmaceuticals, Inc.

By: /s/ Alicia Grande
Alicia Grande
Vice President, Treasurer and Chief Financial Officer

Date: November 9, 2021

Exhibit 31.1

Certification of Principal Executive Officer

I, Patrick J. McEnany, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Catalyst Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly 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 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 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 15(d)-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 subsidiary, 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 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 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 registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 9, 2021

/s/ Patrick J. McEnany
Patrick J. McEnany
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer

I, Alicia Grande, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Catalyst Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly 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 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 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 15(d)-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 subsidiary, 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 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 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 registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 9, 2021

/s/ Alicia Grande
Alicia Grande
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

Certification Required by 18 U.S.C. Section 1350
(as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002)

I, Patrick J. McEnany as Principal Executive Officer of Catalyst Pharmaceuticals, Inc. (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 accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2021 (the "Report"), filed with the U.S. Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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, 2021

/s/ Patrick J. McEnany
Patrick J. McEnany
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

Certification Required by 18 U.S.C. Section 1350
(as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002)

I, Alicia Grande as Principal Financial Officer of Catalyst Pharmaceuticals, Inc. (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 accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2021 (the "Report"), filed with the U.S. Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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, 2021

/s/ Alicia Grande
Alicia Grande
Chief Financial Officer
(Principal Financial Officer)